PATENT GRANTED

Patent write-up

FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

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THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A DEVICE FOR PHYSICALLY RESTRAING MOVEMENT"

APPLICANT

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to a medical device. More particularly, the present invention relates to a device which can physically restrain the movement of a patient who is non-cooperative.

BACKGROUND OF THE INVENTION

In medical field, the restraints are often used to help ensure patient and staff safety for example physical restraint, mechanical restraint, chemical restraint, psychological restraint. Out of this the more suitable restraint in medical science is physical restraint. The physical restraint has many uses for instance physically restraining a patient during surgical procedures is utilized to place the patient in a proper surgical position, and to avoid sudden involuntary movements during surgery. Restraining devices are also used in psychological facilities to help restrict patients from injuring themselves or the others. It can be also used to control difficult or unpredictable patients during transport. In short physical restraints are used for patients who are assessed to be in extreme danger of injury to themselves and others.

Mechanical appliances, material or equipment attached to the patient's body that he/she cannot easily remove themselves, restricting movement or normal access to one's body. There are a Restraint standards, Regulations and policies (Hospital Restraint Policies, Dr. Richard Griffiths and Dr. Nicholas Love, Imperial College Healthcare, AAGBI Position Statement, September 2013) to be followed, as the use of Restraint has been found to be sometimes unnecessary or many a times used inappropriately and often found to be the cause of injury or even death. The guidelines are restraints are medical appliances used as a last resort, when alternatives have been failed to prevent harm from violent or non violent behavior; It is also mandatory to provide a safe environment for the patient, who is in restraint; Patients and families must be provided with information on restraint to allow for an informed decision; Patient should be monitored every 15 minutes, Patient

restraint management flow chart sheet should be maintained every two hours, Physician is responsible for writing and reviewing the restraint order, Nurse is responsible for assessment and documentation, New order is required after 24 hours, Modify the environment, provide companionship and supervision; Give attention to patient's hydration, nutrition, elimination and range of motion; Keep record of patient's vital signs; Regular checks should be carried out that the restraint appliance does not restrict the circulation; Restraints are not to be used for discipline or staff convenience; Restraints should be applied by the trained staff.

The prior art US5546962 disclose a device for restraining movement without completely prohibiting movement is disclosed. Two coupling devices connected by a extensible material form the physical restraint device. One of the coupling devices may be coupled to a patient while the other may be coupled to a fixed object. The length and extensibility of the extensible material connecting the coupling devices determines the amount of movement allowed between the user and the fixed object. A variety of lengths and strengths of the extensible material may be used and interchanged. Because of the flexibility and extensibility of the material, the physical restraint device may also be used as an exerciser for the person being restrained. A recessed pin locking device is located within each coupling device. Access to each pin locking device is through a hole located in the coupling device. An object such as a pen or a pin must be inserted into the hole in order to release the locking device. When the locking device is released, the coupling device is opened so that it can be connected to or disconnected from the user or fixed object. Because the lock is recessed, access is quick and easy for the person applying the restraint, but is unavailable to the person being restrained. This device might work like handcuff and is difficult to prevent the movement of violent patients (like alcoholic, psychotic or the patients who consume poison) as the device of US'692' is restricted to specific movement only. Further, as the metal is used as a component US'962', this device would not suitable for performing certain important medical procedure such as MRI or CT scan.

Another disclosure US4414969 relates to wrist restraint which is a device especially for restraining the movements of the limb of a patient during a medical procedure is disclosed. The device includes a generally long rectangular flexible member which encircles the limb. The outside surface of this member is a Velcro loop pile. A strap having a Velcro hook fiber surface is attached at one of its ends to the encircling member. The strap is wrapped around the encircling member in the direction toward the end closest to which the strap is attached such that the Velcro hook fiber surface of the strap is brought into contact and locking engagement with the Velcro pile surface of the encircling member. The strap is routed through a small ring attached to the outside surface of the encircling member and proceeds to a support structure to which it is releasably attached by fastening means located at or near said end. Because of the locking engagement of the Velcro surfaces of the encircling member and the strap and the small size of the ring, the encircling member cannot be substantially tightened by a pulling force exerted on or by the encircled limb in a direction away from the support structure. As the patient's movement as concerned, US'969' is limited to particular part only, moreover the prior art is silent how the device is applicable to the violent patients.

Accordingly, there is a need to provide a solution for physically restraining the movement of a patient.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a medical device for physically restraining the movement of a patient.

It is another objective of the invention is to provide a device for physically restraining the movement of a patient who is non-cooperative.

It is another objective of the invention is to provide a novel polymer based physical restraint device.

It is yet another objective of the invention is to provide a device to ensure the immediate physical safety of the patients, staff members and others in emergency situation.

It is yet another objective of the invention is to provide a device to conduct certain procedures smoothly for instance inserting/securing important tubes, intravenous line etc.

It is yet another objective of the invention is to provide a device to prevent disoriented/alcoholic patient from self-extubation, oxygen cannulae, Ryle's tube, drains, naso-tracheal tube, urinary catheter etc.

It is yet another objective of the invention is to provide a physical restraint device with minimum discomfort.

It is yet another objective of the invention is to provide a device which does not cause ulcers or trauma to the wrist, ankles and skin.

It is further objective of the invention is to provide a device which can be used to prevent the movement of the patients who have undergo MRI or CT scan.

SUMMARY OF THE INVENTION

There is provided A device for physically restraining movement of a patient comprising

first strap and second strap; the second trap being placed within the first strap;

plurality of buckles having a slide release mechanism; the said buckle being made up of polypropylene derivative;

a padding unit being made of the sheet which consists of polyethylene vinyl acetate;

wherein the first strap being made up a polymer selected from a combination of polyamide: polystyrene: polyacrylamide;
wherein polyamide: polystyrene: polyacrylamide is 1.0:0.7:0.5 by weight.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates schematically a physical restraint device in accordance with present invention;

Figure 2 illustrates schematically an outer view of the device in accordance with the present invention;

Figure 3 illustrates schematically a top view (closed manner) of the device in accordance with present invention;

Figure 4 illustrates a flow chart of working of the device in accordance with the present invention;

Figure 5 is an image of working of the device in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to Figure 1 (inside view) and Figure 2 (outside view), the present invention provides a novel polymer based physical restraint device, the said device consists of:

i) first strap (1);

ii) second strap (2);

iii) plastic buckles (3,4); &

iv) padding unit (5)

i) First strap (denoting as symbol “1” in Figure 1):

The first strap (1) which could be considered as a base, used to fix with the cot/bed framework. The strap according to present invention is made up of a polymer which is selected from a group consisting of polyamide (nylon), polystyrene, polyacryl amide and the combination thereof. The ratio of the polymers polyamide, polystyrene and polyacrylamide as used in present invention is 0.5:0.5:0.5 to 1:1:1 by weight. All the polymers are commonly available in market. The suitable method known in the art is referred for making the strap.

The length of the first strap according to present invention is 38inch, while the width is 1.5inch. The thickness of the strap is 0.07inch.

ii) second strap (denoting as symbol “2” in Figure 1);

A second strap (2) is placed in between the first strap which is used as a support for first strap. The second strap according to present invention is made up of rexin and the suitable process known in art is used to prepare the second strap.

The length of the second strap according to present invention is 38inch and while the width is 0.05-1.5inch.

iii) plastic buckles (denoting as symbol “3,4” in Figure 1);

According to present invention, there are 3 buckles (3,4) having male (3)-female (4) system for ease of locking and un-locking. The buckles also have a

sliding release mechanism. The buckle according to present invention is made up of high density polypropylene which is also commonly available in market. The size of the buckle according to present invention is 1.5inch.

iv) padding unit (denoting as symbol “5” in Figure 1):

The padding unit (5) is used as cushioning purpose for the device, is made up of polyethylene-vinyl-acetate sheet, which is secured at patient’s wrist or ankles or both. The length of the padding unit according to present invention is 7inch, while the width is 2inch. The thickness of the padding unit is 2mm. Polyethylene-vinyl-acetate as used in the invention is commonly available in market.

As shown in Figure 3, present inventor illustrates the top view (close) of the physical restraint device.

The working of the device to establish the advantageous effect of the present invention is demonstrated in Figure 4 and 5. The studies were performed at **Krishna Institute of Medical Sciences and Krishna Hospital, Karad** and10 patients is selected from each group as follows:

Cooperative: 10 NOS

Alcoholic: 10 NOS

Psychotic: 10 NOS } NON-COOPERATIVE

Poison consuming: 10 NOS

As shown in the flow chart (Figure 4), a patient who is sleeping on the bed and the device whose one end is secured to wrist and ankle of the patient (Figure 5) and another end is fixed to a bed framework. A system is attached to the bed framework so that it can be worked as an alarm when the patient gets detached from the device.

First strap of the physical restraint device is having the following ratio:

1) Polyamide: Polystyrene: Polyacrylamide = 0.5:0.5:0.5 by weight
2) Polyamide: Polystyrene: Polyacrylamide = 0.5:0.7:1.0 by weight
3) Polyamide: Polystyrene: Polyacrylamide = 1.0:0.7:0.5 by weight

The efficacy of the device is evaluated by the alarm system as above i.e. the alarm is ON if the patient gets unlocked any time after securing the device.

Table 1: Efficacy of physical restraint device (in hours)

Sr. No.	Patients			
	Co-operative	Alcoholic	Psychotic	Poison consuming
Polyamide: Polystyrene: Polyacrylamide = 0.5:0.5:0.5	Alarm on after 5 hour	Alarm on after 1 hour	Alarm on after 0.5 hour	Alarm on after 1 hour
Polyamide: Polystyrene: Polyacrylamide = 0.5:0.7:1.0	Alarm on after 5.5 hour	Alarm on after 1.2 hour	Alarm on after 0.5 hour	Alarm on after 1.1 hour
Polyamide: Polystyrene: Polyacrylamide = 1.0:0.7:0.5	Alarm on after 10 hour	Alarm on after 6 hour	Alarm on after 5 hour	Alarm on after 6.5 hour

Table 1 shows the superior effect of the first strap which is made up of Polyamide: Polystyrene: Polyacrylamide = 1.0:0.7:0.5. Accordingly the present device is not a mere admixture.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

We Claim,

1. A device for physically restraining movement comprising

   first strap (1) and second strap (2); the second trap being placed within the first strap;

   plurality of buckles (3,4) having a slide release mechanism; the said buckle being made up of polypropylene derivative;

   a padding unit (5) being made of the sheet which consists of polyethylene vinyl acetate;

   wherein the first strap being made up a polymer selected from a combination of polyamide, polystyrene and polyacrylamide;
   wherein polyamide: polystyrene: polyacrylamide is 1.0:0.7:0.5 by weight.

2. The device as claimed in claim 1, wherein length of the first strap is 38inch.

3. The device as claimed in claim 1, wherein width of the first strap is 1.5inch.

4. The device as claimed in claim 1, wherein thickness of the first strap is 0.07inch.

5. The device as claimed in claim 1, wherein length of the second strap is 38inch.

6. The device as claimed in claim 1, wherein width of the second strap is 1.5inch.

7. The device as claimed in claim 1, wherein length of the padding unit is 7inch.

8. The device as claimed in claim 1, wherein width of the padding unit is 2inch.

9. The device as claimed in claim 1, wherein thickness of the padding unit is 2mm.

10. The device as claimed in claim 1, wherein the buckle is 15 inch-buckles.

Dated this 25rd day of August, 2018

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For the Applicant

To,
The Controller of Patents,
The Patent Office
At Mumbai

ABSTRACT

"A DEVICE FOR PHYSICALLY RESTRAING MOVEMENT"

Disclosed is a device for physically restraining movement comprising first strap (1) and second strap (2); the second trap being placed within the first strap; plurality of buckles (3,4) having a slide release mechanism; the said buckle being made up of polypropylene derivative; a padding unit (5) being made of the sheet which consists of polyethylene vinyl acetate; wherein the first strap being made up a polymer selected from a combination of polyamide: polystyrene: polyacrylamide; wherein polyamide: polystyrene: polyacrylamide is 1.0:0.7:0.5 by weight. Figure 1

FORM-2

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(SECTION 10, RULE 13)

TITLE

"AN INJECTION GUIDE"

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to an injection guide. More particularly, the present invention relates to an injection guide that provides the delivery process of intravenous, intramuscular, intradermal, subcutaneous etc more accurately and safely.

BACKGROUND OF THE INVENTION

Injections are administered in various angles. Intramuscular injection is administered at 90°, subcutaneous injection at 45°, intravenous injection administered at 20° and intradermal injection at 10 to15°.

Currently, what are the practices to determine these angles:

i) At present injections angles are decided manually;
ii) Devices are available for insertion of Jelcos/scalp veins for administration of Intravenous (IV) fluids/transfusions. Other devices are available to hold syringe i.e. Infusion pumps for intravenous infusion of micro-dose or IV fluids;
iii) charts/Figures of various angles of administration of injections are available.

Many times errors in administration of injections were noted by health care professionals and as a result patient suffers from the complications which sometimes very severe and even in the case, the death might be happened due to this error.

PRIOR ART

US3063449 discloses a syringe holder for supporting a syringe in a desired position such as an inclined position or location. According to US'449' the syringe can be moved from the remote location so a medical professional will be protected from a harmful drug. US'449' may be effective for intravenous process only. Also, the

mechanism of US'449' is electrically operated. Further, overall process of the administration is costlier.

US4332248 discloses an apparatus or guide to aid in inserting the needle of syringes and the like into body conduits such as veins. The apparatus includes a pair of members which are placed on the opposite sides of a vein, parallel to the longitudinal axis thereof, thereby preventing lateral movement of the vein while it is being pierced by the needle. A guide of US'248' is provided to aid in inserting the needle to the desired depth. US'248' is silent how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process.

US2008/0269671 relates to a volume-adjustable micro-injection device. The device includes a base structure having a syringe positioning structure and a grip, in which the syringe positioning structure can flexibly accommodate injection syringes with different volumes; a holding structure capable of flexibly adjusting an injection angle of syringe content for easier operation; a qualitative controller capable of accurately controlling injection volume; a pressure pushing structure to hold and push a plunger; an injection controller interlinked with the qualitative controller and the pressure pushing structure; and an eject structure facilitating the operation and replacement of injection syringes. US'671' states in abstract that *"In contrast to conventional structures, the present invention provides advantages that control injection volume more accurately, address better injection angle control, allow for the syringe contents to be free from air exposure, require no special syringes, and allow for single-handed replacement of the injection syringe".* However, how such better angle control is done is not disclosed in US'671'. Also, US'248' is silent on how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process. Further, the mechanism of US'671' is electrically operated and overall process of the administration is costlier.

US2007/0232999 relates to an artery stabilizer device, with a slide over which a technician can guide a syringe, is provided for restraining a targeted artery while the

technician inserts the needle of the syringe into the artery. A pair of stabilizer fingers holds the artery in place while the syringe is maneuvered over the slide of a shaft which is connected to a base above the stabilizer fingers. US'999' discloses a finger-hold platform emanates from the bottom of the shaft, and a gauze dressing member with a gauze pad is removably attached to the bottom of the platform, allowing the technician to quickly apply a dressing over the wound created by the needle insertion procedure. An artery stabilizer adjustment track allows the technician to alter the width between each stabilizer finger. US'999' is silent on how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process.

US2012/0000571 discloses a holding devices and methods for using the same. The holding device configured to hold a container having a dose or multiple doses of a liquid medicine with a needle-piercable cap. The holding device includes a holder for the container, a base, and an angular adjustment linkage between the base and the holder. Another aspect of the invention provides a method of loading a syringe with a liquid medicament held in a container. The method includes: providing a holding device including a holder for the container, a base, and an angular adjustment linkage between the base and the holder; placing the holding device on a surface; placing the container into the holder; and using two hands to draw the liquid medicament from the container into the syringe. The purpose of US'571' is to hold the vial only, not to administer into any route of injection.

WO2009047512 discloses an intravenous injection guide and a method of using such a guide which comprising a supporting base frame and one or more guider arms connected to the base frame whereby the guider arm or arms can be used so as to engage with a protrusion from a transfusion set in such a way that the contour of the guider arm or arms helps guide the trajectory of the transfusion needle into the vein of the patient during the act by a user of attempting veni-puncture access for medicinal infusion or blood sampling. It is basically a guiding apparatus for winged type infusion set where the needle of the latter can be assisted to follow a

fixed or adjustable or feel enhanced injection tranjectory path aided by guide thus enabling IV process made easier safe. The apparatus assists only for insertion of shaft of venous accesses needles/iv cannulas to superficial and deeper veins, not helps for vein identification/stabilization. The prior art doesn't point how to pierce the vein at 20° (which is the exact angle for intravenous injection) to give single dose of IV injection by simple manner i.e. injection needle attached with syringe. Also, WO'512' is winged type infusion set to which an additional syringe can be attached to give IV injection. The process is therefore is not cost-effective. Further, WO'512' is required transfusion set in conjunction with the specially G-transfusion set (wing type transfusion set) to locate the injection site. WO'512' is silent on how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process.

Prior art findings limited to intravenous process only. Existing devices are not accurate and safe for other route of injection such as intramuscular, subcutaneous and intradermal with addition to intravenous process as there is no provision of determining the exact angle for the injection. Further, the existing devices are electrically operated and costlier in view of construction and overall mode of the treatment.

Accordingly, there is a need to provide an injection guide that could facilitate to determine the exact angle of an injection includes intravenous, intramuscular, subcutaneous and intradermal process.

OBJECT OF THE INVENTION

It is an objective of the invention is to overcome the aforesaid drawbacks and accordingly provide an injection guide.

It is another objective of the invention is to provide an injection guide that provides the delivery process of intravenous, intramuscular, intradermal, subcutaneous more accurately and safely.

It is yet another objective of the invention is to provide an injection guide which facilities intravenous process without use of jelcos/scalpel.

It is yet another objective of the invention is to provide a manually operated injection guide.

It is yet another objective of the invention is to provide injection process that can be carried out accurately with single needle.

It is yet another objective of the invention is to provide an injection guide which can be operated without any uncertainty and fear.

It is yet another objective of the invention is to provide an injection guide which can be operated by one who is under healthcare training.

It is yet another objective of the invention is to provide a cost effective injection process.

It is further objective of the invention is to provide an easy to handle injection guide.

SUMMARY OF THE INVENTION

There is provided an injection guide comprises

a holder (1) being cylindrical shape, said holder is having a provision for insertion of a syringe;

a base frame (6) means to support for the syringe holder;

primary angle unit (2) and secondary angle unit (4), said units having a predetermined degree of angle varying from 10° to 90°;

a primary pointer (3) and a secondary pointer (5);the primary pointer and the secondary pointer being connected to primary angle unit (2) and secondary angle unit (4) respectively;

a slit (7) being oval shape means to insert the needle; said slit being centrally placed in the said injection guide;

wherein the syringe holder (1) being fixed to the primary unit system (2,3) or the secondary unit system (4, 5) such that the needle of the syringe can attain an angle varying from 10° to 90°;

wherein length of the syringe holder is 46.92mm.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1a and 1b illustrates an injection guide in accordance with present invention;

Figure 2 illustrates a cylindrical shape of syringe holder in accordance with present invention;

Figure 3 illustrates the oval slit in accordance with present invention;

Figure 4 illustrates a side view (4a) and front view (4b) of the device in accordance with present invention; &

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Present invention provides an injection guide for safe and accurate delivery process of the drug through the route selected from intravenous, intramuscular, intradermal and subcutaneous.

Referring now to Figure 1 (a & b), the injection guide according to present invention consists of:

a syringe holder (1);

a primary angle unit (2);

a primary pointer (3);

a secondary angle unit (4):

a secondary pointer (5);

a base (6);

a central slit (7);

a screw (8);

a nut (9);

a stopper (10);

Syringe holder:

The syringe holder (1) according to present invention is cylindrical shape (Figure 2) in which there is a provision of insertion of a syringe of 1cc (for 1mL), 2cc (for 2mL), 5cc (for 5mL) and 10cc (for 10mL) which is as per the need. The internal and external diameter of the syringe holder is as per the width of the syringe. The length of the syringe holder according to present invention is so as to adjust the syringe to get the desired angle for the injection. The critical length of the syringe holder according to present invention is 46.96mm.

Base:

The present invention includes a base (6) for stability while the injection is administered. The length of base according to present invention is as per the type of injection. In preferred embodiment, the length of the base is 26.83-54.5mm while the width is 16-28.8mm.

Primary and secondary angle unit:

According to present invention, left side on the base, there is primary angle unit (2) which presents a chart of 15°, 45° and 90°. One could select 45° for subcutaneous injection and 90° for intramuscular injection. The primary pointer (3) on the primary angle chart shows the current degree on chart.

On the other hand, at right side on the base, there is secondary angle unit (4) which presents a chart of 10° divisions up to 90°. One could select 10°-15° for intradermal injection and 20° for intravenous injection. The secondary pointer (5) on the secondary angle chart shows the current degree on chart. Primary angle unit along with primary pointer and secondary angle unit along with secondary here is primary unit system and secondary unit system respectively.

Other components:

The present invention also comprises an oval slit (7) which is centrally located in the design [Figure 3] means to insert the needle into the skin layer. The width of the slit is 4mm while the length is 45mm. The present device includes a screw with nut to attach syringe holder to the angle charts such as herein described. The present invention also includes a stopper to limit the injection holder to move above 90°. The syringe holder, the base and the other major components as used in the said injection guider is made of plastic known in art.

As shown in Figure 4a and 4b, the present inventor illustrates a side view and front view respectively of the device

Now, the invention is illustrated by non-limiting examples:

Example 1:

Injection guide for subcutaneous injection:

Insulin injection (1cc syringe along with needle, 1mL dose) through subcutaneous route (45° as standard angle) was performed on diabetic patient at **Krishna Institute of Nursing Sciences and Krishna Hospital, Karad** wherein

i) Syringe holder:

Length of the syringe holder: 25mm, 35mm, 46.92mm and 55mm

External diameter of the syringe holder: 10mm

Internal diameter of the syringe holder: 7mm

ii) Base:

Length of the base: 26.83mm

Width of the base: 16mm

iii) Primary and secondary unit angle along with pointer and other component as above

For intravenous (20° angle), intramuscular (90° angle) and intradermal (10° angle) injection, except length of the syringe holder, the dimension of other components was varied and it was selected as per the type of the injection.

Table 1: Observation (Relation between length of the syringe holder and angle of the injection)

Length of syringe holder of the injection	Injection route (angle)			
	10°	20°	45°	90°

guide	(intradermal)	(intravenous)	(subcutaneous)	(intramuscular)
25mm (comparative example)	unstable syringe	unstable syringe	unstable syringe	unstable syringe
35mm (comparative example)	unstable syringe	unstable syringe	unstable syringe	unstable syringe
46.92mm **(inventive example)**	stable syringe	stable syringe	stable syringe	stable syringe
55mm (comparative example)	Syringe is not moved	Syringe is not moved	Syringe is not moved	Syringe is not moved

Accordingly, the present inventor concludes that not only primary and secondary angle unit of the device but also length of the syringe holder is critical in order to achieve the desired angle for the injection.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described

to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim,

1. An injection guide comprises

   a holder (1) being cylindrical shape, said holder is having a provision for insertion of a syringe;

   a base frame (6) means to support for the syringe holder;

   primary angle unit (2) and secondary angle unit (4), said units having a predetermined degree of angle varying from 10° to 90°;

   a primary pointer (3) and a secondary pointer (5);the primary pointer and the secondary pointer being connected to primary angle unit (2) and secondary angle unit (4) respectively;

   a slit (7) being oval shape means to insert the needle; said slit being centrally placed in the said injection guide;

   wherein the syringe holder (1) being fixed to the primary unit system (2,3) or the secondary unit system (4, 5) such that the needle of the syringe can attain an angle varying from 10° to 90°;

   wherein length of the syringe holder is 46.92mm.

2. The guide as claimed in claim 1, wherein the syringe is 1cc syringe, 2cc syringe, 5cc syringe or 10cc syringe.

3. The guide as claimed in claim 1, wherein length of the base is 26.83-54.5mm.

4. The guide as claimed in claim 1, wherein width of the base is 16-28.8mm.

5. The guide as claimed in claim 1 is made up of a plastic known to person-skilled-in-art.

6. The device as claimed in claim 1 is for an injection selected from a group consisting of intravenous, intramuscular, subcutaneous or intradermal.

Dated this 24rd day of August, 2018

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For the Applicant

To,
The Controller of Patents,
The Patent Office
At Mumbai

ABSTRACT

"AN INJECTION GUIDE"

Disclosed is an injection guide comprises a holder (1) being cylindrical shape, said holder is having a provision for insertion of a syringe; a base frame (6) means to support for the syringe holder; primary angle unit (2) and secondary angle unit (4), said units having a predetermined degree of angle varying from 10° to 90°; a primary pointer (3) and a secondary pointer (5);the primary pointer and the secondary pointer being connected to primary angle unit (2) and secondary angle unit (4) respectively; a slit (7) being oval shape means to insert the needle; said slit being centrally placed in the said injection guide; wherein the syringe holder (1) being fixed to the primary unit system (2,3) or the secondary unit system (4, 5) such that the needle of the syringe can attain an angle varying from 10° to 90°; wherein the length of the syringe holder is 46.92mm. The said device is used for intravenous, intramuscular, subcutaneous or intradermal injection. Figure 1

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THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"SIMULATION TRAINING DEVICE FOR ASSESSMENT OF THE CERVICAL DILATATION"

APPLICANT(S)

KRISHNA INSTITUTE OF MEDICAL SCIENCES, Deemed to be University declared U/s 3 of UGC Act 1956 vide notification no. F.9-15/2001-U-3 of the Ministry of Human Resource Development Govt. of India having an address of Krishna Institute of Medical Sciences, near Dhebewadi Road, Malkapur, Karad, Pin code- 415110, Maharashtra, India

The following specification particularly describes the nature of the invention and the manner in which it is to be performed

TECHNICAL FIELD:

The present invention relates to the field of Medical Sciences as a training tool for assessment of cervical dilatation for (i) undergraduate and postgraduate students form obstetrics & gynecology (ii) Nursing students and professionals, (iii) traditional birth attendants.

BACKGROUND OF THE INVENTION:

At present, the assessment of cervical dilatation is done by a teacher in obstetrics and gynaecology and then the student is asked to do internal examination of the woman and told size of cervix which the student has to remember and fix in his mind as a particular size of cervix either in fingers or in cms.

When series of students palpate internally there is risk of infection to the patient due to repeated internal examinations apart from psychological trauma and physical botheration of getting examined vaginally.

This training is transferring subjective impression of one person to another person without facilitating visual guidance about actual size of the cervix.

Each and every student of medicine and nursing has to undergo such training without facilities for forming their judgment on a dummy model. Such training is far from perfect and is likely to result in lacunae in training and the trained person is likely to have inaccurate judgment of size of the cervix.

SUMMARY OF THE INVENTION:

A novel innovative device is made available for training in obstetrics and gynaecology for judgment of size of cervical dilatation from 3cms to 10cms on an inanimate object before embarking on vaginal examination for judging cervical dilatation in a live subject.

Hence this simulation training device for the assessment of the cervical dilatation was designed so that one can practice and perfect oneself in judging the size of hole accurately before actually performing internal vaginal examination for assessing size of cervix in a live subject.

Rubber Rings from 3cms to 10cms are fitted on corresponding sized holes on the rotating drum. The handle attached to it can be put at desired cervical size to get that size on the drum which can be palpated by fingers inserted from the round opening kept on the front side of the rectangular box of the device. Once one is accustomed to the size of the opening visually and by palpation, the opaque piece of cloth of the device can be made to block the vision of the person learning to judge the size of the opening by palpation thus simulating vaginal examination where one has to judge the size of cervix without advantage of visually seeing it.

The device has a block board platform (10) for supporting the parts of the machine. The device has a rotating plastic drum or cylinder (6) which has eight holes from 3 cm to 10 cm diameter on which rubber rings are fitted (8). The cylinder is closed on both sides by plastic discs which are glued to the cylinder, which in turn are connected to the shaft (12) through one wooded hub (15) on each side. The hub is screwed to the disc and to the shaft. Thus the cylinder is rigidly connected to the shaft.

The cylinder is covered by the box (1) to ensure that the holes on the cylinder can't be seen from outside and also to protect the inner parts. The front side of the box (1) has an opening (5) which is covered by the curtain (13).

The shaft is mounted in two wooden bearings (14) which are fixed on the block board platform (10) through support for the bearings (11) on both the sides. The indexing mechanism is on the right hand side. This mechanism consists of spring loaded lock (9) and slotted indexing wheel (2). The slotted indexing wheel is fixed to the shaft by means of a screw. The indexing allows the drum to rotate in one direction only. The direction is marked on the turn wheel (16). By rotating indexing wheel (2), rubber ring fitted holes (8) can be brought in the centre of the opening (5) on the box (1) one at a time. The axial central position of the holes is ensured by the suitable spacers (7). The indexing mechanism synchronizes the hole size with the number indicated by the indicator arrow on the circular scale (3). By rotating the turn wheel the holes on the cylinder come one by one in line with the opening (5) on the box (1).

The shaft extends out of the box (1) from the right hand side. The turn wheel (16) is mounted on the shaft on the outside of the box (1). This has a handle (4) for rotation. It also has a indicator arrow and a direction arrow showing direction of rotation. A

circular scale (3) is printed on the box just below the turn wheel. The turn wheel (16), the cylinder (6) and the indexing mechanism are so synchronized that the diameter of the hole on the cylinder (6) in front of the opening on the box is correctly shown by the indicator arrow on the turn wheel. The trainee student has to learn judging the diameter of the hole by sensing the hole diameter only with the touch and correlating with corresponding number indicated by the arrow.

The hole on the box is covered with the curtain. This facilitates selective viewing of the holes and palpating it at the same time. After this, blind palpitation can be undertaken for each of the holes by the trainee student. After gaining confidence of his judgment of the side of the hole by way of repeated blind palpitations on the machine, he is now ready for learning on the live subjects.

STATEMENT OF THE INVENTION

Such as herein a simulating training device (17) for viewing and palpating assessment of the cervical dilatation consisting of a wooden box (1), the said box comprises of a circular opening (5) and an opaque curtain (13), a drum (6) having eight holes of diameter of 3-10 cm, rings (8), a shaft (12), spacers (7), a locking system (9) and an indexing wheel (2) and a turn wheel (16) wherein said wheel (2) allows the drum (6) to rotate in one direction,

a platform (10) means to support the box;

a handle (4) means to rotate;

a circular scale (3);

characterized in that the said ring (8) being fixed onto the said hole and the said wheel (16) being fixed outside the box; and

said shaft (12) being extended to the outside box (1) and said wheel (16) being connected to the extended shaft (12); and

said wheel (2) being fixed onto the shaft (12) and said scale (3) being fixed below the wheel (16);

such that the ring fitted hole (8) attains the central position of the opening (5) of the box (1) one at a time upon rotation of the indexing wheel (2) and the ring fitted hole (8) attains the central position of the opening (5) of the box (1) one by one in line upon rotation of the turn wheel (16).

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS:

Fig. No. 1 is the schematic representation (cross-sectional top view) of the simulation training device for assessment of the cervical dilatation showing the two wooden hubs (15) and slotted indexing wheel (2) in accordance with the present invention;

Fig. No. 2 is the schematic representation (cross-sectional view) of the training device consists of the rotating plastic drum or cylinder (6), support houses the spring loaded lock (9) of the indexing mechanism, a block board platform (10), the shaft (12), two wooden bearings (14), two supports for the bearing (11) and suitable spacer (7) in accordance with the present invention;

Fig. No. 3 is the schematic representation (top view) of the training device consists of the handle (4) for rotation in accordance with the present invention;

Fig. No. 4 is the schematic representation (front view) of the training device consists of the box (1), an opening in the box (5), which is covered by the curtain (13), the turn wheel (16) and rubber rings fitted hole (8) in accordance with the present invention;

Fig. No. 5 is the schematic representation (side view) of the training device having a circular scale (3) in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Fig. No. 1-5, the training device for viewing and palpating assessment of cervical dilation consist of the two wooden hubs (15) and slotted indexing wheel (2). The two wooden hubs are connected to the shaft through one wooden hub (15) on each side. The slotted indexing wheel (2) is fixed to the shaft by means of the screw. The indexing allows the drum to rotate in one direction. The device also consist of the

rotating plastic drum or cylinder (6), spring loaded lock (9), a block board platform (10), the shaft (12), two wooden bearings (14) and suitable spacer (7).. The cylinder (6) is closed on both sides by plastic discs which are glued to the cylinder, which in turn are connected to the shaft (12) through one wooden hub (15) on each side. The hub (15) is screwed to the disc and to the shaft. Thus the cylinder (6) is rigidly connected to the shaft (12). The shaft (12) is mounted in two wooden bearings (14) which are fixed on the block board platform (10) through support for the bearing (11) on both the sides. The right hand side of the support for the bearing (11) houses the spring loaded lock (9). The device further consists of the handle (4) for rotation. It also has an indicator arrow (17) and a direction arrow showing direction of rotation. The device consists of the box (1), an opening (5), which is covered by the curtain (13), the turn wheel (16) the rubber ring fitted holes (8). The cylinder (6) is covered by the box (1) to ensure that the holes on the cylinder (6) can't be seen from outside and also to protect the inner parts. The box (1) has an opening (5) which is covered by the curtain (13). The direction is marked on the turn wheel (16). The indexing mechanism synchronizes the rubber ring fitted holes (8) on the periphery of the cylinder (6) can be brought in the centre of the opening (5) of the box (1) one at a time. By rotating the turn wheel (16) the holes (8) on the cylinder (6) come one by one in line with the opening (5) on the box (1). The device also consists of the circular scale (3) which is printed on the box just below the turn wheel (16) and the said scale is having an indicator arrow (17) for indicating the diameter of the hole (8) .

<u>To teach the cervical dilatation according to present invention, following steps are to be undertaken:</u>

1. With the rotating handle the size of opening is to be fixed.
2. The student is given a view of rubber ring fitted circular opening of desired diameter.
3. The student is made to palpate it many times till it is fixed in his memory.
4. The ability of the student is judged by blinding him/her by putting opaque curtain and making him identify the size of the opening from 3cms diameter to 10cms diameter.

5. Once the student is trained to identify the size of the opening correctly, he/she is allowed to do vaginal examination and judge the size of cervical opening in live subjects.

These steps will facilitate the student to learn size of the cervix accurately by viewing and palpatory method.

Applications/ uses:

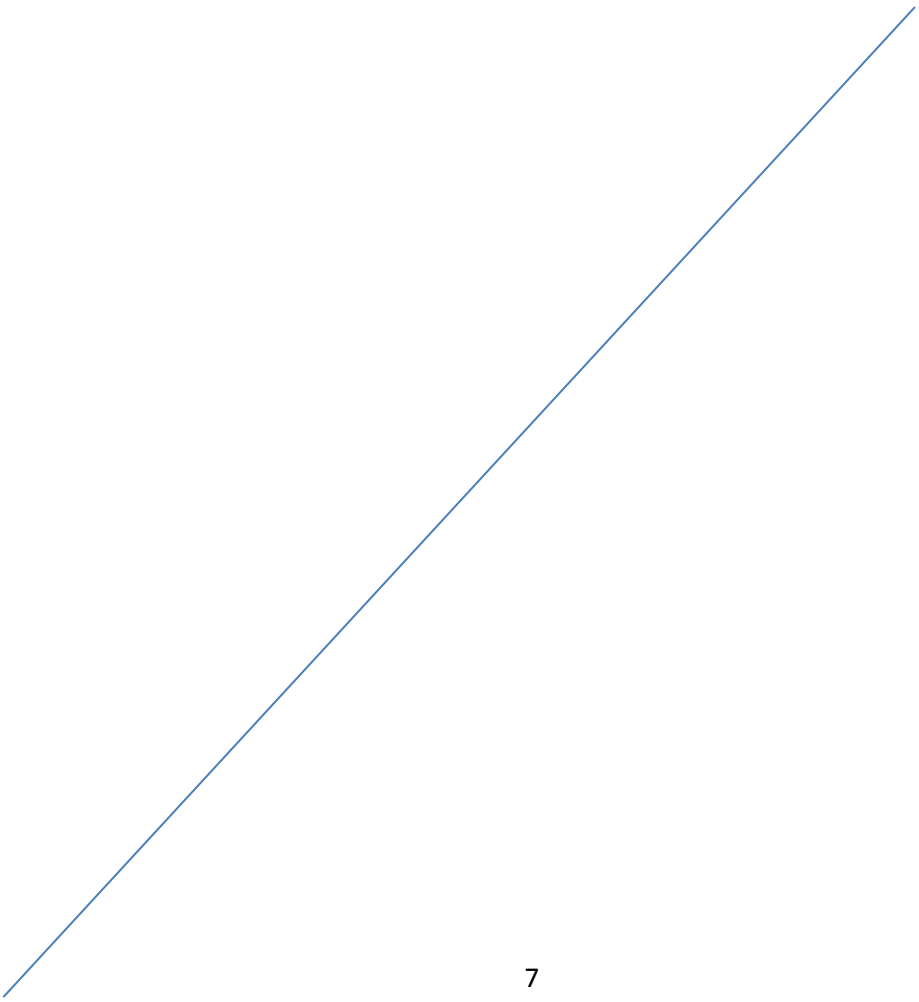
(i) Simulates vaginal examination in view of both viewing & palpating;.

(ii) Saves repeated learning attempts at judging the size on live subjects;

(iii) Readily available, can be manipulated to fix known desired size of opening on the model.; &

iv) Repeated examinations on model are possible without any harm of infection

or trauma to a live subject.



We Claim,

1. A simulating training device for viewing and palpating assessment of the cervical dilatation consisting of a wooden box (1) having rectangular shape, the said box comprises a circular opening (5) and an opaque curtain (13), a drum (6) having eight holes of diameter of 3-10 cm, rings (8), a shaft (12), spacers (7), a locking system (9) and an indexing wheel (2) and a turn wheel (16) wherein said wheel (2) allows the cylinder (6) to rotate in one direction ,

   a platform (10) means to support the box;

   a handle (4) means to rotate;

   a circular scale (3);

   characterized in that the said ring (8) being fixed onto the said hole and the said wheel (16) being fixed outside the box; and
   said shaft (12) being extended to the outside box (1) and said wheel (16) being connected to the extended shaft (12); and

   said wheel (2) being fixed onto the shaft (12) and said scale (3) being fixed below the wheel (16);

   such that the ring fitted hole (8) attains the central position of the opening (5) of the box (1) one at a time upon rotation of the indexing wheel (2) and the ring fitted hole (8) attains the central position of the opening (5) of the box (1) one by one in line upon rotation of the turn wheel (16).

Dated this 09th day of March, 2010

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(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)

To,
The Controller of Patents,
The Patent Office
Mumbai

ABSTRACT

"SIMULATION TRAINING DEVICE FOR ASSESSMENT OF THE CERVICAL DILATATION"

Disclosed is a simulating training device for assessment of the cervical dilatation. The said device basically is a wooden box (1) with a circular opening (5) and an opaque curtain (13). Inside the wooden box there is rotating drum/cylinder (6) with a handle (4). Circular opening with diameter a desired size can be brought in the centre of the orifice with the handle. By putting index and middle fingers in the orifice the opening can be palpated under vision or as a blind procedure. After mastering the judgment of the size of the opening from 3cms to 10cms diameter, on the model, actual training of vaginal examination in a living being can be undertaken for further skill development of judgment of cervical dilatation minimizing risk of infection and botheration to the delivering women. Figure 2 & 4

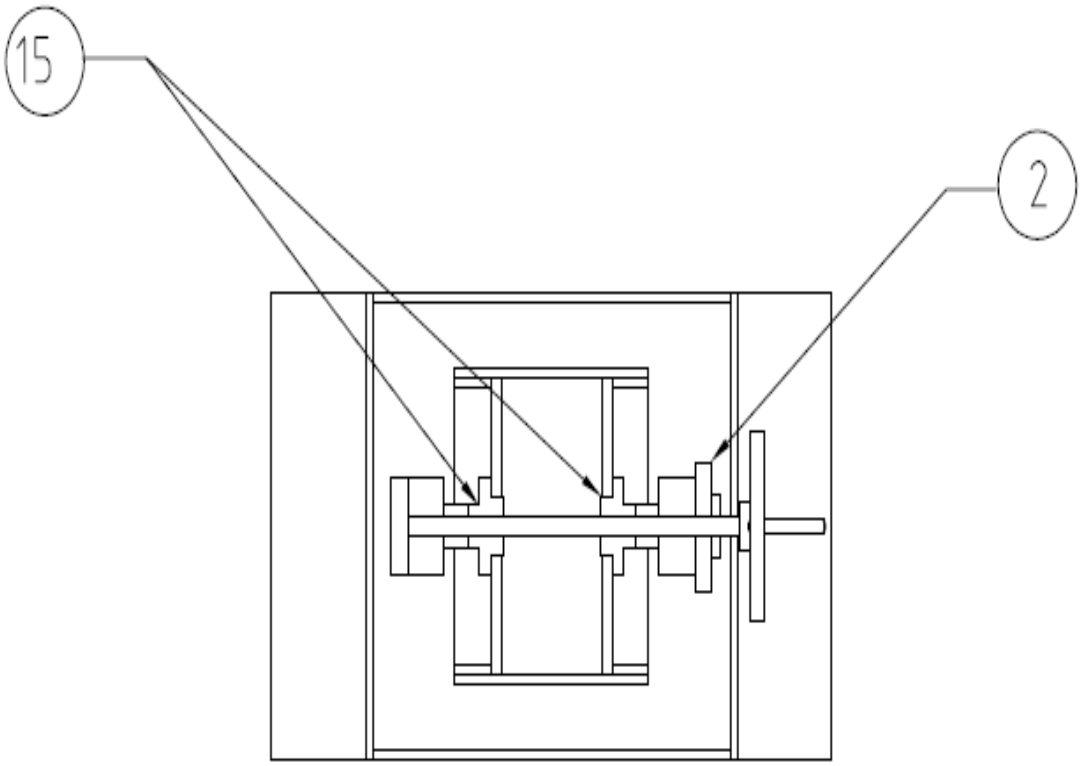

Figure 1

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For the Applicant(s)

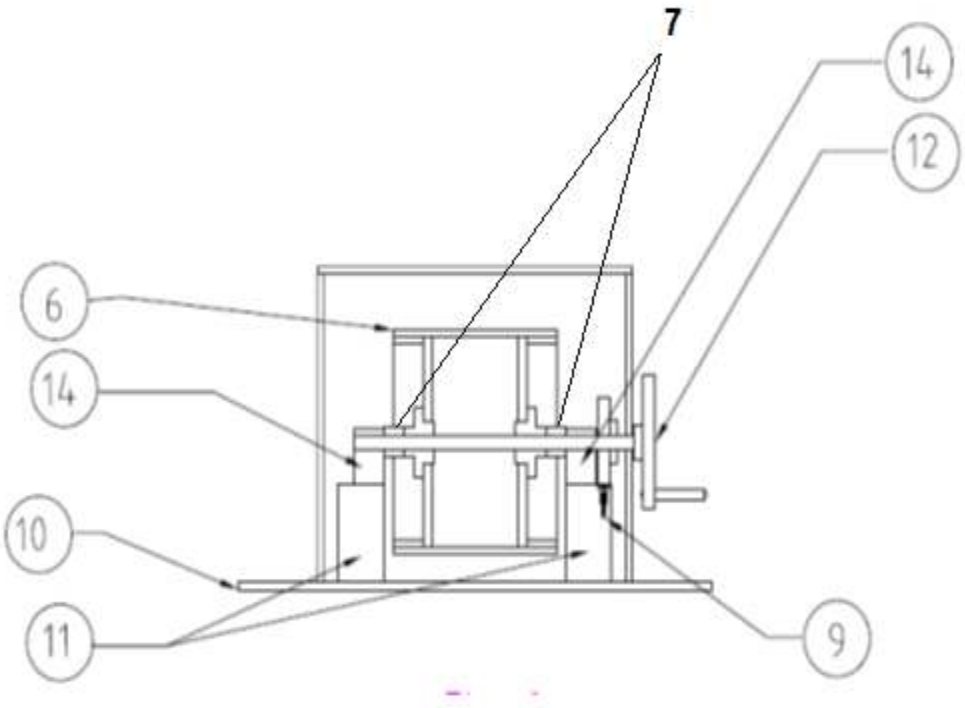

Figure 2

(Arghya Ashis Roy)

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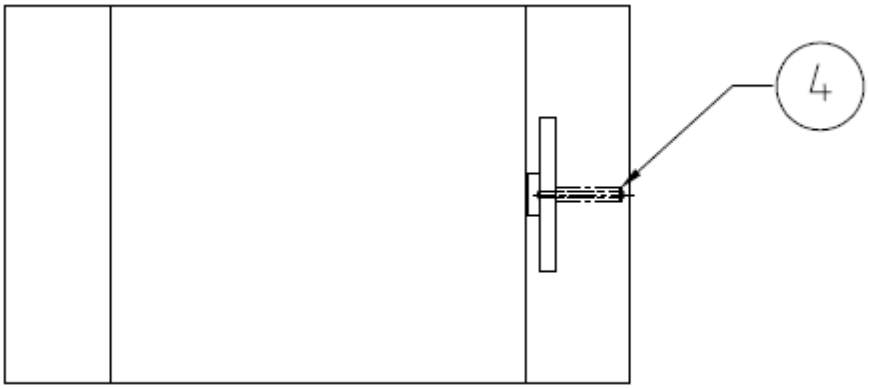

Figure 3

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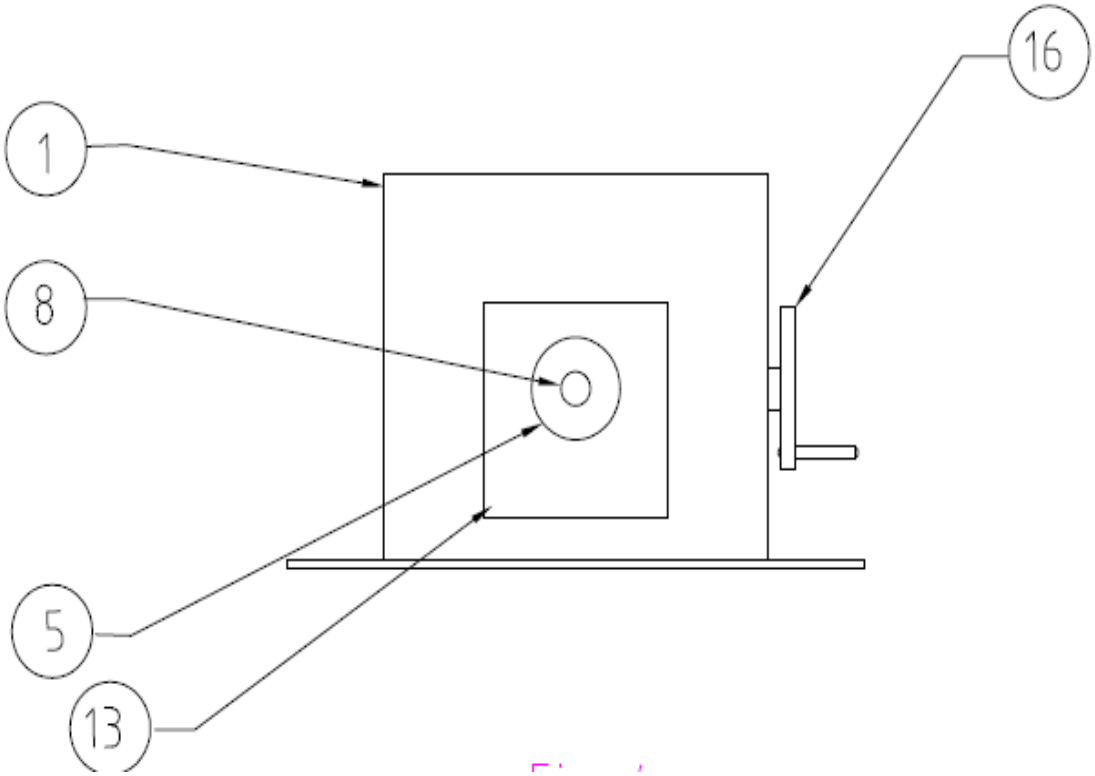

Figure-4

(Arghya Ashis Roy)
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For the Applicant(s)

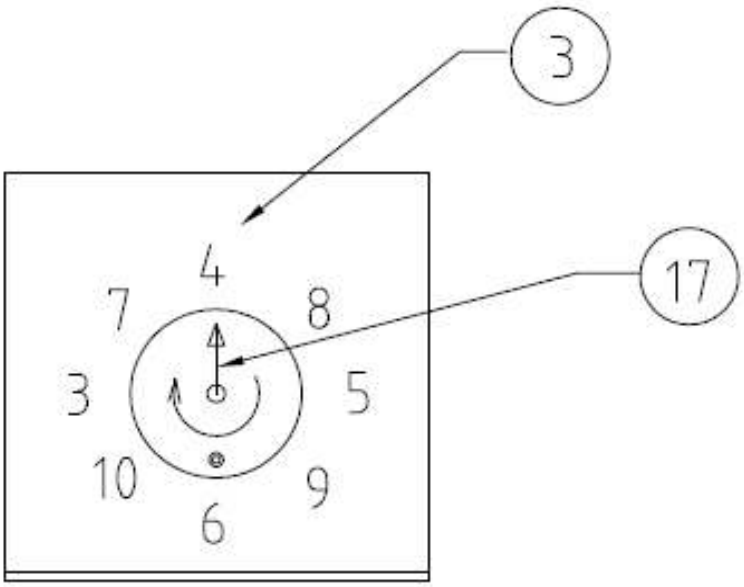

Figure-5

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FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

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THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"ENDOCERVICAL & ECTOCERVICAL SPATULA FOR COLLECTION OF SAMPLE FOR CERVICAL CYTOLOGY"

APPLICANT

KRISHNA INSTITUTE OF MEDICAL SCIENCES, Deemed to be University declared U/s 3 of UGC Act 1956 vide notification no. F.9-15/2001-U-3 of the Ministry of Human Resource Development Govt. of India having an address of Krishna Institute of Medical Sciences, near Dhebewadi Road, Malkapur, Karad, Pin code- 415110, Maharashtra, India

The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION:

The present invention relates to medical science in the field of Obstetrics and Gynecology. It is for early detection of lesions of uterine cervix in general and cervical precancerous lesions in particular.

BACKGROUND OF THE INVENTION:

The cancer of uterine cervix is still most prevalent cancer in rural India. So many group check ups and camps are arranged in rural areas for early diagnosis of pre cancers and cancers.

The spatula used for collection of cervical smear is not suited for commonly found variations in the cervical anatomy like length breadth, thickness etc.

In order to overcome the problems of variation in cervical size while taking endocervical smears, at present endocervical disposable brush is used in selected cases. This adds to the cost and increases time for taking smears. If such brush is not available the endocervical smear taken is of inferior quality.

The samples are collected during camps and sent to pathologists for diagnosis. But many of the samples are not of satisfactory quality and that is why the sensitivity rate of Pap smear is very low. There is need for better collection of samples which will improve the detection of early cancers and other cervical lesions.

SUMMARY OF THE INVENTION:

Accordingly, there is provided a spatula for simultaneous collection of endocervicaland ectocervical smear for cervical cytology is designed.

The spatula of the present invention isthe device which can take smear from any type of cervix. Since it enters endocervical canal there is no need for separate brush to take endocervical smears. It is made up of wood. It can take good scraping of endo cervix and transformation zone also. It gives very good scrapes without bleeding.

Newly devised spatula is sturdy & can withstand repeated sterilization & reuse cycles. New spatula saves on resources, increases efficiently & quality of smears.

The spatula is adapted to all commonly found variations in length, breadth and thickness of uterine cervices. The quality of smears taken would be of better quality.

The spatula as designed would be economical as there is no need of separate device of endocervical brush for taking endocervical smears.

The spatula is made of good quality wooden material and as the corners of the spatula are rounded off, good cervical scrapings would be obtained without traumatizing the cervix.

The wooden spatula as designed is sturdy and can withstand sterilization by autoclaving saving the resources.

STATEMENT OF THE INVENTION:

Accordingly, there is provide a brush free wooden spatula for collection of the endocervical and ectocervical sample characterized in that the said spatula consisting of

two curvilinear ends (B and B1), each said end (B or B1) having first protrusion (C), second protrusion (D) and third protrusion (E) wherein each said protrusion having a rounded edge wherein the second protrusion (D) is asymmetrical to the third protrusion (E);
a shaft (A) being placed between two said ends (B and B1);
two connecting points (F and G) being positioned between second protrusion (D) and third protrusion (E);
a central axis (H) means to direct the first protrusion (C);
wherein the distance between the second protrusion (D) and the central axis (H) is 14mm;
wherein the distance between the third protrusion (E) and the central axis (H) is 16mm;
wherein the distance between the first protrusion (C) and the connecting point (F) is 15mm;

wherein the distance between the protrusion (C) and the connecting point (G) is 12mm; and
wherein the length of the shaft is 144mm.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS:

Fig. No. 1 is the schematic representation of the spatula in accordance with the present invention; and

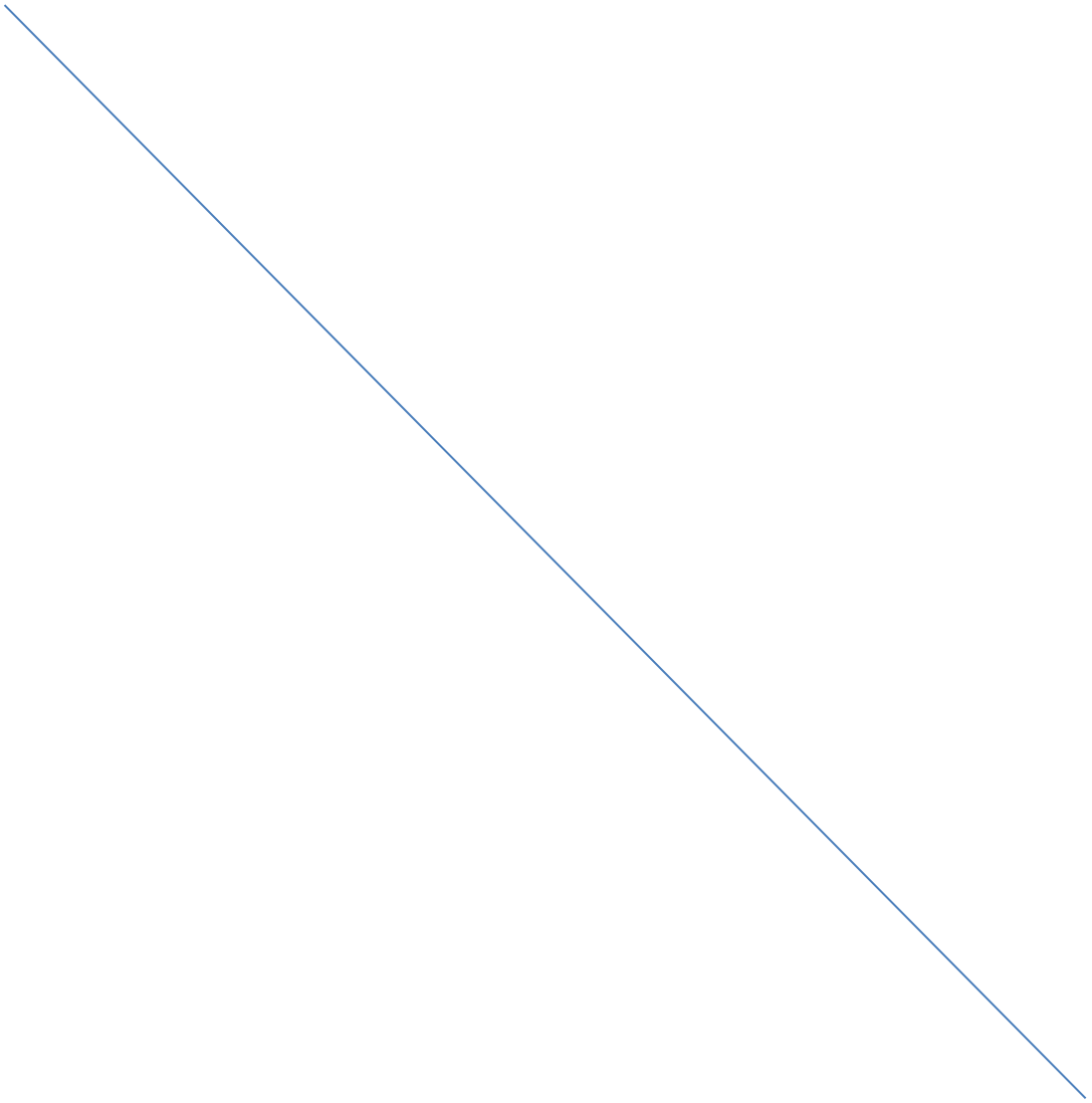
Fig. No. 2 schematically illustrates the working of the spatula in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION:

As shown in Figure 1, the total length of spatula of the present invention is 210mm. The spatulahas a shaft (A) which is approximately 144mm long and has a width of 10mm. It has two curvilinear ends (B, B1) at both the sides which are devised for conducting two different sampling for two different female wherein one curvilinear end (B or B1) is made in such a way that one can take outer (ectocervical) and inner (endocervical) scrapings of the uterine cervix. For this function each curvilinear end (B or B1) is designed to have three protrusions i.e. first protrusion (C) second protrusion (D) & third protrusion (E) wherein the first protrusion (C) is in the axial direction in the elongated form which forms the extreme end of the spatula. In each curvilinear end, the second protrusion (D) and third protrusion (E) protrusions are asymmetrical and are connected through the points F and G. For each curvilinear end (B or B1) the maximum distance for second protrusion (D) is 14mm from the central axis (H) while the distance for third protrusion (E) from the central axis (H) is 16mm. The first protrusion (C) has a length of 15mm from the point (F) and 12mm from the point (G) which has been deliberately made asymmetrical to suit different sizes of cervices. All the edges of the protrusion are rounded and made smooth to avoid any injury. The spatula has been made from good quality, of thin wooden plank to give it the desired strength, scraping surface, as well as ability to withstand sterilization by autoclaving.

As shown in Figure 2, working of the device of the present invention is described where the spatula (4) first enters through the vaginal cavity (5) and then the aforesaid first

protrusion (C) goes inside to the endocervix (2) and at the same time second protrusion (D) and third protrusion (E) as above mentioned is for ectocervix (3) wherein 14mm as the distance between the central axis (H) and the second protrusion (D) and 16mm as the distance between central axis (H) and the third protrusion (E) is maintained thereby allow to scrap the smear sample from both the canal without bleeding.



We claim:

1. A brush free wooden spatula for collection of the endocervical and ectocervical sample characterized in that the said spatula consisting of

two curvilinear ends (B and B1), each said end (B or B1) having first protrusion (C), second protrusion (D) and third protrusion (E) wherein each said protrusion having an rounded edge wherein the second protrusion (D) is asymmetrical to the third protrusion (E);

a shaft (A) being placed between two said ends (B and B1);

two connecting points (F and G) being positioned between second protrusion (D) and third protrusion (E);

a central axis (H) means to direct the first protrusion (C);

wherein the distance between the second protrusion (D) and the central axis (H) is 14mm;

wherein the distance between the third protrusion (E) and the central axis (H) is 16mm;

wherein the distance between the first protrusion (C) and the connecting point (F) is 15mm;

wherein the distance between the first protrusion (C) and the connecting point (G) is 12mm; and

wherein the length of the shaft is 144mm.

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Dated this 24th day of January, 2011

Arghya Ashis Roy
Patent Agent (IN/PA 2346)
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For the Applicant

To,
The Controller of Patents,
The Patent Office,
Mumbai

ABSTRACT

"ENDOCERVICAL & ECTOCERVICAL SPATULA FOR COLLECTION OF SAMPLE FOR CERVICAL CYTOLOGY"

Disclosed is a brush free spatula for collection of endocervical and ectocervical sample for cervical cytology,comprises of one shaft (A), two curvilinear ends (B and B1) wherein each curvilinear end having three protrusion (D, E & F) and the said spatula can take smear from any type of cervix. Since it enters endocervical canal there is no need for separate brush to take endocervical smears. It is made up of wood. It can take good scraping of endocervix and transformation zone also. It gives very good scrapes without bleeding. Newly devised spatula is sturdy & can withstand repeated sterilization & reuse cycles. New spatula saves on resources, increases efficiently and quality of smears. Figure 1

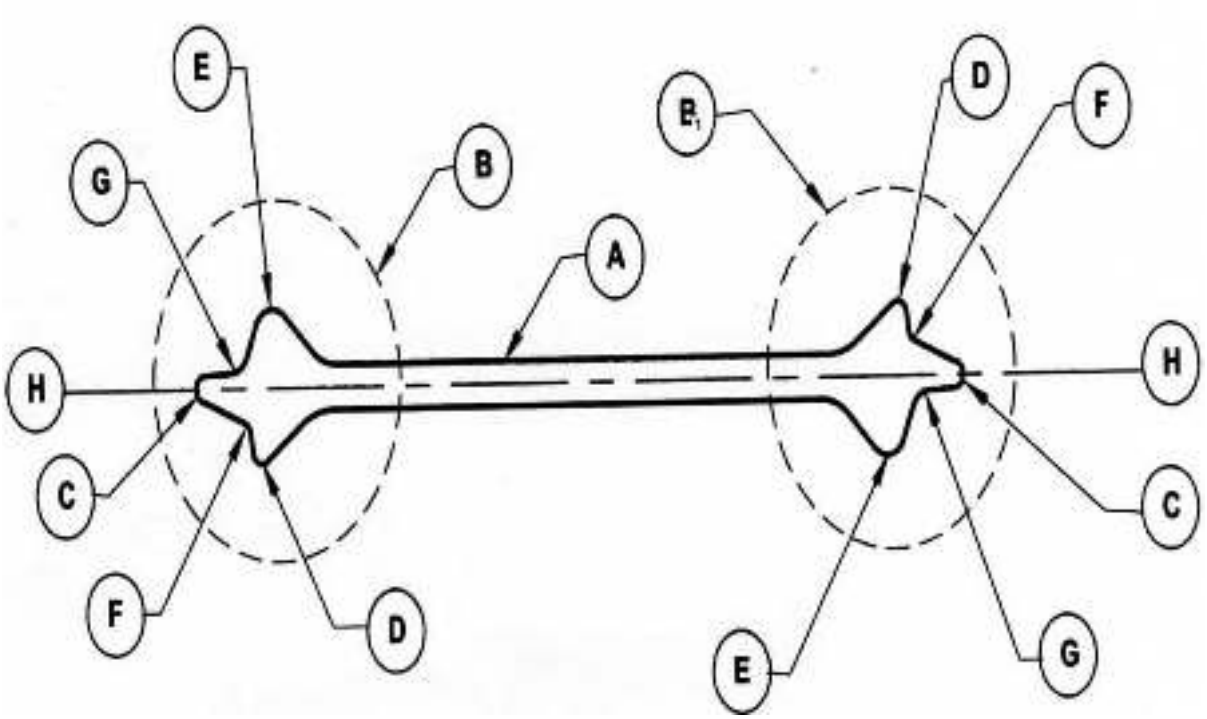

Figure 1

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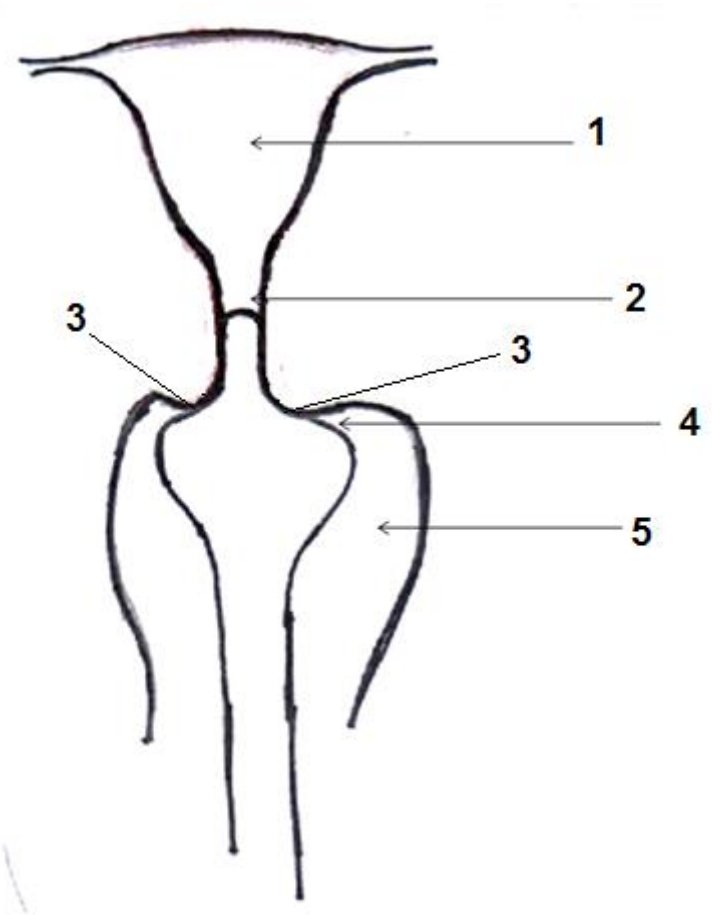

Figure 2

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For the Applicant

FORM 2
THE PATENT ACT 1970
AND
THE PATENTS RULES, 2003
COMPLETE SPECIFICATION
(SEE SECTION 10 AND RULE 13)

1. TITLE OF THE INVENTION: **"**An Orthotic Device for Supporting a Shoulder Joint of a User**."**

2. APPLICANT(s):

(a)NAME:	**Krishna Institute of Medical Science "Deemed to be University".**
(b)NATIONALITY:	**Indian Deemed Institute**
(c)ADDRESS:	**NH 4, Near Dhebewadi Road, Malkapur, Karad - 415539, Maharashtra.**

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification deseribes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed

Field of the Invention

[0001] The present invention relates to an orthotic device. More specifically, the present invention relates to an orthotic device for supporting a shoulder joint of a user. The orthotic device can be an orthosis.

Background of the Invention

[0002] Generally, orthosis is used to support body parts of patients under the circumstances such as injuries, dislocations, subluxation and the like. The orthosis is general term used for any orthotic device. These orthosis are also used to treat shoulder joint misalignments caused due to strokes (paralysis), shoulder subluxation and the like. A stroke is an acute onset of neurological dysfunction caused due to the abnormality in a cerebral blood circulation with resultant sign and symptom that correspond to the involvement of focal areas of the brain. It can give the symptoms like paralysis (hemiplegia) or weakness (hemiparesis). Shoulder subluxation is a common problem in the stroke. The subluxation causes shoulder pain and hinders activity.

[0003] Figures 1a & 1b illustrates schematic views of a shoulder joint 200 anatomy of a human (user) 500in a normal condition and a shoulder subluxation condition respectively. A shoulder joint 200 is a ball and socket type

of synovial joint with 3 degrees of freedom. It is the most mobile joint of the human body..

[0004] A normal stirring action of the force couple of supraspinatus and posterior fibers of the deltoid is affected due to a flaccid stage of the muscles. So, while abduction and flexion movement due to gravitational pull to the head of the humerus subluxates caudally. Presently, Orthotic devices (shoulder orthosis) are used to support the shoulder joint 200 to decrease the glenohumeral subluxation.

[0005] Further, when a patient (user) 500 suffering from the Shoulder subluxation condition is wearing the existing orthosis at the shoulder joint 200, an upper arm 220 of the patient can be moved away from a torso 240 up to a maximum of 30 degrees from a vertical reference 230. Whenever the patient moves the upper arm 220 away from the torso 240 (In medical terms, this movement is called an “abduction movement”) there will be a set of forces acting on the shoulder joint 200 and the upper arm 220. Angle of abduction movement can be referred as a movement angle θ_m. These set of forces are caused due to movements along a direction 250 away from the torso 240. These forces cause an enormous amount of pain to the patient even when the patient is wearing the orthosis. Furthermore, these movements also effect the subluxation condition of the patient 500, thereby reduces efficiency of the orthosis in treating the subluxation condition.

[0006] Presently existing orthosis or any such devices are not effective in reducing effects caused due to forces developed during movements of an arm 200a of the user 500 (abduction movement) and also in efficiently treating the subluxation condition during abduction movements.

[0007] Further, the existing orthosis are costly, therefore not affordable.

[0008] Therefore, there is a need for an orthotic device (orthosis), which overcomes few or more problems of the prior art.

Objects of the Invention

[0009] An object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user.

[0010] Another object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which nullifies forces caused on the user due to movements of an arm of the user while wearing the orthotic device.

[0011] Still another object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which is simple in construction.

[0012] Further an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which is easy to use.

[0013] Further an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which is economical in construction.

[0014] Furthermore, an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user for reducing the pain of the user caused due to movements of an arm of the user while wearing the orthotic device.

[0015] Also, an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user for treating the subluxation condition of the patients effectively even if any movements of an arm(hand) of a user is occurred while wearing the orthotic device.

Summary of the invention

[0016] According to the present invention there is provided with an orthotic device for supporting a first shoulder joint of a user. The first shoulder can be a right shoulder joint of the user and a second shoulder joint is a left shoulder joint of the user and vice-versa. The orthotic device may include a rigid support, at least one pair of electrodes, at least one first strap and at least one-second strap. The rigid support is having an outer surface and an inner surface. The rigid support is resting against the first shoulder.

[0017] In a preferred embodiment, the rigid support is configured according to a shape of a shoulder the user and the rigid support is arranged on the first shoulder joint of the user with a surface contact of the inner surface of the orthotic device with the skin of the user. The rigid support includes a cushioning layer arranged on the inner surface of the rigid surface for providing the comfort of the user while wearing the orthotic device.

[0018] The at least one pair of electrodes arranged on the inner surface of the rigid support for pain relief modality. The at least one pair of electrodes are connected to a power source and a control unit for supplying and controlling current flow thereto. The at least one first strap is wrapped around an upper arm of the first shoulder for securing the orthotic device on the first shoulder of the user. The at least one first strap is arranged with a pad. The pad is

configured to provide support and pressure to the upper arm when the at least one first strap is wrapped around the upper arm of the user.

[0019] The at least one-second strap is extending from the rigid support and adapted to wrap around an armpit of the second shoulder joint. The at least one-second strap is extending from the outer surface of the rigid support. In an embodiment, the at least one-second strap is extending from the outer surface of the rigid support. More specifically, the at least one-second strap is extending from a corner of a shoulder profile of the rigid support. The at least one-second strap distributes the force exerted on the first shoulder and the upper arm along the second strap towards the armpit of the second shoulder joint thereby nullifying the forces occurred during movements of a first arm (hand) of the user. Also, the at least one-second strap enables the orthosis to treat the subluxation condition of the user efficiently even if the user moves his/her arm while wearing the orthosis.

Brief Description of the Drawings

[0020] The advantages and features of the present invention will be understood better with reference to the following detailed description of some embodiments of the impact energy absorber and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which;

[0021] Figure 1a shows a schematic view of a shoulder joint of a human with a normal condition;

[0022] Figure 1b shows a schematic view of a shoulder joint of a human with a shoulder subluxation condition;

[0023] Figures 2 shows an isometric view of an orthotic device for supporting a first shoulder joint of a user in accordance with the present invention;

[0024] Figure 3 shows a front view of a preferred embodiment of an orthotic device for supporting a first shoulder joint of a user in accordance with the present invention;

[0025] Figure 4 shows a side view of figure 3;

[0026] Figure 5 shows a top view of figure 3; and

[0027] Figure 6 shows a schematic view of a user (patient) wearing the orthosis shown in figure 3.

Detailed Description of the Invention

[0028] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising, "having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items, or meant to be limited to only the listed item or items.

[0029] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0030] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0031] Referring to figures 2, 3 4, and 6, various c views of an orthotic device 100 for supporting a first shoulder joint 200 (figure 1a & 1b) of a user 500 in accordance with the present invention are illustrated. The user 500 here refers to a patient suffering from a shoulder subluxation condition or similar health alignments and aided with the orthosis 100 for treating the same. For the purpose of explanation, the first shoulder joint 200 is a left shoulder joint of the

user 500 and a second shoulder joint 400 is a right shoulder joint of the user 500. Alternatively, the first shoulder joint 200 can be a right shoulder joint of the user 500 and the second shoulder joint 400 is a left shoulder joint of the user 500, which is obvious to a person skilled in the art. The orthotic device 100 is an orthosis.

[0032] The orthotic device 100 includes a rigid support 10, at least one pair of electrodes 20a & 20b, at least one first strap 30 and at least one-second strap 40. The rigid support 10 includes a shoulder section 12 and an arm section 14. More specifically, the shoulder section 12 covers a shoulder section of the user 500 and the arm section 14 covers an upper arm 220 section of the user 500. The rigid support 10 is having an outer surface 10a and an inner surface 10b. The rigid support 10 is resting against the first shoulder joint 200.

[0033] In a preferred embodiment, the rigid support 10 is configured according to a shape of a shoulder of the user 500. The rigid support is arranged on the first shoulder joint 200 of the user 500 with a surface contact of the inner surface 10b of the orthotic device 100 with the skin of the user 500. The rigid support 10 includes a cushioning layer 16 arranged on the inner surface 10b of the rigid support for providing comfort to the user while wearing the orthotic device 100. The cushioning layer 16 can be made from materials, such as medicinal rubber or ethaflex and the like. The rigid support 10 is made from materials, such as polypropylene and the like.

[0034] The at least one pair of electrodes 20a and 20b are arranged on the inner surface 10b of the rigid support 10 for pain relief modality. The pair of electrodes 20a & 20b are connected to a power source (not show) and a control unit (not show) for supplying and controlling current flow thereto. The power source can be an external power source or at least a battery. In the present embodiment, the orthotic device 100 includes two pairs of electrodes 20a, 20b & 24a, 24b. The pair of electrodes 20a & 20bis connected to the power source and the control unit through wires 22a & 22b. The wires 22a & 22b passes through openings (not shown) configured in the rigid support 10. It may be obvious to a person skilled in the art to configure the openings for passing the wires 22a & 22b therethrough and connecting the wires 22a & 22b to the pair of electrodes 20a & 20b; and arranging the pair of electrodes 20a & 20b on the inner surface 10b. Amount of current needs to be passed to the pair of electrodes 20a and 20b for pain relief modality is according to a specific medical condition. This amount of current passed according to the specific medical condition is known to a person ordinarily skilled in the art. The person ordinarily skilled in the art can be a physiotherapist or an electrotherapist.

[0035] Further, the at least one first strap 30 is arranged on the rigid support 10 to wrap around an upper arm 220 of the first shoulder joint 200 for securing the orthotic device 100 on the first shoulder joint 200 of the user.

[0036] In the present embodiment, the orthotic device 100 includes two first straps 30a & 30b. The first straps 30a and 30b are having a securing arrangements, such as a snap lock, hook and loop arrangement or any such obvious securing engagements which are capable to secure the orthotic device 100 on the upper arm 220 of the user 500. The first straps 30a and 30b are having a pad 50. The pad 50 is arranged with the first straps 30a and 30b. The pad 50 is configured to provide support and pressure to the upper arm 220 when the first straps 30a and 30b are wrapped around the upper arm 220 of the user 500. More specifically, the pad 50 is arranged in a such a way that, when the first straps 30a & 30b are wrapped around the upper arm 220, an interior surface of the pad 50 is in contact with the skin of the upper arm 220 as shown in figure 6. In an alternative embodiment (refer figure 2), the orthotic device 100 can be configured without the pad 50.

[0037] Referring again to figure 6, a schematic view of a user 500 wearing the orthotic device 100 is shown. The at least one-second strap 40 is extending from the rigid support 10 and adapted to wrap around an armpit 410 of the second shoulder joint 400. In the present, the orthotic device 100 includes a second strap 40. . In an embodiment, the second strap 40 is extending from the outer surface 10a of the rigid support 10. More specifically, the one-second strap 40 is extending from a corner 10c of a shoulder profile of the rigid support 10. The corner here refers to a geometric area where the shoulder section 12 and the hand section 14 of the rigid support 10 meets. In the present embodiment, the

second strap 40 is pinned at the shoulder section 12 of the rigid support 10 as shown in figure 5. The at least one-second strap 40 includes securing arrangements such as a hook and loop arrangements, =for securing the -second strap 40 around a torso 240 of the user 500 at the armpit 410 of the second shoulder joint 400.

[0038] Further, when the strap 40 at a wrapped position, does not allow the user 500 to move his/ her arm 220 beyond 30 degrees (a movement angle $\theta_{m)}$ from a vertical reference 230. This restriction of movement helps in retaining a correcting position of the rigid support 10 on the first shoulder joint 200. Hence, the orthotic device 100 corrects an affected shoulder efficiently. Hence, the second strap 40 also enables the orthotic device 100 in treating a subluxation condition of the user 500 efficiently even if the user 500 moves his/her arm 220 while wearing the orthosis 100.

[0039] When the orthosis 100 is worn by the user 500 around the first shoulder joint 200, by securing the first strap 30a around the upper arm 220 and securing the second strap 40 around the torso 240 around the armpit 410 of the second shoulder joint 400, the orthotic device 100 applies pressure on the first shoulder joint 200 according to a 3 point pressure system principle. In medical industry, this 3 point pressure system is known as a Jordon's principle. In the 3 point pressure system, the applied force and two counteracting forces are in the

opposite direction to each other. Further, supplying therapeutic current through the pair of electrodes 20a & 20b results in pain relief of the user 500. This supplying therapeutic current is generally known as TENS (transcutaneous electrical nerve stimulation). More specifically, this TENS gives pain relief to the user in the shoulder subluxation condition. Therefore, the orthotic device 100 is beneficial in reducing the shoulder subluxation condition along with the pain relief effect.

[0040] Furthermore, when the user 500is wearing the orthotic device 100, if the user moves the arm 250 away from the torso 240, the second strap 40 distributes the force exerted on a first shoulder 202 and the upper arm 220 of the user 500 along the second strap 40 towards the armpit 410 of the second shoulder joint 400, thereby nullifying the forces occurred during movements of an arm 200a (first arm) of the user 500. When the forces occurred during movements of a first arm 200a of the user 500 are nullified, the resultant forces acting on the user 500 will be equal to zero. Therefore, the forces caused due to movement of the first arm 200a of the user 500 do not result in causing pain to the user 500 or any such discomforts.

[0041] Therefore, the present invention has the advantage of providing the orthotic device 100 for supporting the shoulder joint (200 or 400) of a user 500. The orthotic device 100 nullifies forces caused on the user due to movements of an arm 200a of the user 500. The orthotic device 100 is simple in construction. The orthotic device 100 is easy in use. The orthotic device 100 is

economical in construction and operations. The orthotic device 100 reduces the pain of the user 500 caused due to movements of an arm of the user 500 while wearing the orthotic device 100. The orthotic device 100 efficiently treats the subluxation condition of the patients even if any movements of an arm 200a of a user 500 is occurred while wearing the orthotic device 100.

[0042] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the present invention and its practical application, and to there by enable others skilled in the art to best utilise the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omissions and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such omissions and substitutions are intended to cover the application or implementation without departing from the scope of the claims of the present invention.

We Claim:

1. An orthotic device 100 for supporting a first shoulder joint 200 of a user, wherein the orthotic device 100 comprising:

a rigid support 10 having an outer surface 10a and an inner surface 10b, the rigid support 10 is resting against the first shoulder joint 200;

at least one pair of electrodes 20a & 20b arranged on the inner surface 10b of the rigid support 10 for pain relief modality;

at least one first strap 30 arranged on the rigid support 10, the at least one first strap 30a is wrapped around an upper arm 220 of the first shoulder joint 200 for securing the orthotic device 100 on the first shoulder joint 200 of the user; and

at least one-second strap 40 extending from the rigid support 10 and adapted to wrap around an armpit 410 of a second shoulder joint 400; wherein the at least one second strap 40 distributes the force exerted on the first shoulder joint 200 and the upper arm 220 along the second strap 40 towards the armpit 410 of the second shoulder 400 joint thereby nullifying the forces occurred during movements of the first arm 200a of the user and also efficiently treating a subluxation condition of the user even if the user moves his/her arm 220 while wearing the orthosis 100.

2. The orthotic device 100 as claimed in claim 1, wherein the first shoulder joint 200 can be a left shoulder joint of the user and the second shoulder joint 400 is a right shoulder joint of the user and vice-versa.

3. The orthotic device 100 as claimed in claim 1, wherein the rigid support 10 is configured according to a shape of a shoulder of the user and the rigid support 10 is arranged on the first shoulder joint 200 of the user with a surface contact of the inner surface 10b of the orthotic device 100 with the skin of the user.

4. The orthotic device 100 as claimed in claim 1, wherein the rigid support 10 includes a cushioning layer 16 arranged on the inner surface 10b of the rigid support 10 for providing comfort of the user while wearing the orthotic device 100.

5. The orthotic device 100 as claimed in claim 1, wherein the at least one pair of electrodes 20a & 20b are connected to a power source and a control unit for supplying and controlling current flow thereto.

6. The orthotic device 100 as claimed in claim 1, wherein the at least one first strap 30 is arranged with a pad 50, the pad 50 is configured to provide support and pressure to the upper arm 220 when the at least one first strap 30a is wrapped around the upper arm 220 of the user.

7. The orthotic device 100 as claimed in claim 1, wherein the at least one-second strap 40 is extending from the outer surface 10a of the rigid support 10.

8. The orthotic device 100 as claimed in claims 1 and 7, wherein the at least one-second strap 40 is extending from a corner 10c of a shoulder profile of the rigid support 10.

Dated this May 13, 2019

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Abstract

The present invention provides an orthotic device 100 for supporting a first shoulder joint 200 of a user 500. The orthotic device 100 includes a rigid support 10, at least one pair of electrodes 30a & 30b, at least one first strap 30 and the at least one-second strap 40. The rigid support 10 is having an outer surface 10a and an inner surface 10b and is resting against the first shoulder joint 200.The at least one first strap 30 is arranged on the rigid support 10 to wrap around an upper arm 220 of the first shoulder joint 200 for securing the orthotic device 100 on the first shoulder joint 200 of the user 500. The at least one-second strap 40 is extending from the rigid support 10 and adapted to wrap around an armpit 410 of a second shoulder joint 400 for efficiently treating a subluxation condition.

Figure 6

FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"CUSTOMISED ANKLE FOOT ORTHOTIC DEVICE"

APPLICANT(S)

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to an orthotics and physiotherapy field. More particularly, the present invention relates to an orthotic device which can be useful in foot drop problem of a patient suffering from strokes, multiple sclerosis, cerebral palsy patients, and in common peroneal nerve injury.

BACKGROUND OF THE INVENTION

Foot drop is common problem in stroke, multiple sclerosis, cerebral palsy patients, and in common peroneal nerve injury patient. Electrical stimulation and ankle foot orthosis (AFO) have been routinely used in individuals with foot drop to re-educate muscles which are weak and to keep ankle in neutral position. It is known that electrical stimulation is useful in treating individuals with foot drop. Studies (**Freeha Sharif, Samina Ghulam, Arshad Nawaz Malik and Quratulain Saeed, Effectiveness of Functional Electrical Stimulation (FES) versus Conventional Electrical Stimulation in Gait Rehabilitation of Patients with Stroke, Journal of the College of Physicians and Surgeons Pakistan 2017, Vol. 27 (11): 703-706)** showed that the functional electrical stimulation (FES) is better in foot drop than conventional electrical stimulation (EMS) in stroke patients.

<u>Existing ankle foot orthosis and its drawback:</u>

An ankle-foot orthosis, or AFO, is an orthotic device which is a support intended to control the position and motion of the ankle, compensate for weakness, or correct deformities of foot and ankle. AFOs can be used to support weak limbs, or to position a limb with contracted muscles into a more normal position. In addition, AFOs are used to control foot drop caused by a variety of neurologic and musculoskeletal disorders. Due to the common use for addressing foot drop, AFO has become synonymous with the term “foot-drop brace AFO are easy to wear, and can be easily available at orthotics.

Drawbacks:

i) AFO limits mobility and range of motion of joint as it is not movable.

ii) Movements is usually limited to certain direction..

iii) There is restriction of rotation around a joint.

iv) The aforesaid technologies failed to suggest the combined effect of AFO and cold & hot pack pouch in food drop.

Prior art:

A document **(https://www.braceworks.ca/2018/09/20/devices/lower-limbs/afo/ankle-foot-orthoses-and-functional-electrical-stimulation-for-foot-drop-in-ms/)** discloses that the people with multiple sclerosis (MS) have difficulty walking: Gait impairment, including the reduced ankle dorsiflexion of foot drop, is one of the most common indicators of disability early in the course of this progressive autoimmune disease of the central nervous system, affecting approximately 75% of people with MS. Assistive technology, such as ankle–foot orthosis (AFO) and functional electrical stimulation (FES), increases the safety of walking and the speed of ambulation (even then, only about one half of patients remain ambulatory 15 years after disease onset).Assistive technology also reduces the risk of injury to the knee and ankle and reduces the effort of ambulation**.**

Another document **(https://www.resna.org/sites/default/files/legacy/conference/proceedings/2008/SDC2008/Hadley.html)** discloses that “Cerebral Palsy (CP) is a non-progressive neurological disorder which develops in-utero or after birth. Current treatment for CP includes physical therapy and braces used to increase ambulation. Ankle-Foot Orthoses (AFOs) are lightweight plastic braces that secure the lower leg, ankle, and foot in a predetermined position, commonly used to aide dorsiflexion in CP patients. another common treatment, Functional Electrode Stimulation (FES), is administered by physical therapists in order to build muscle tone and improve dorsiflexion. FES

uses low energy electrical stimulation to excite either the common peroneal nerve or the tibialis anterior muscle, causing the patient to actively dorsiflex, increasing foot-ground clearance. Our device integrates an FES unit with a hinged AFO, to automate and improve the current physical therapy processes used to treat CP patients. This allows for the rapid and accurate placement of FES electrodes, which removes the major barrier to at-home administration of this therapy.

A literature **(Walbran et al., *Cogent Engineering* (2016), 3: 1227022 http://dx.doi.org/10.1080/23311916.2016.1227022)** discloses neuromuscular disorders and injuries such as cerebral palsy and stroke often result in foot-drop which can result in a person having great difficulty walking. Ankle foot orthoses (AFOs) or splints have been prescribed for many years now to limit the range of motion of the ankle, provide the patients with support and assist with rehabilitation. However the majority of AFOs require a long, labour-intensive manufacturing process which results in unacceptable waiting times for children that are rapidly growing and patients with varying conditions. This research proposes a new approach to AFO manufacturing that utilizes digital and additive manufacturing technologies to customise the fit and form to an individual. By implementing an interchangeable carbon fibre spring at the ankle joint the design will result in a stronger, more comfortable, more flexible AFO that can adaptively constrain ankle movement for various different activities. Three iterations of AFO design have been developed and tested to validate their efficacy. A custom machine has been designed and constructed in order to empirically test stiffness values for the AFO and allow for optimal AFO geometry based on input parameters. This machine has proven the structural integrity of the final AFO design. Progress has been made in automating parts of the design process which will significantly reduce labour requirements and hence manufacturing delay times**.**

Another literature **(Mario C. Faustini, Richard R. Neptune*, Richard H. Crawford, and Steven J. Stanhope, Manufacture of Passive Dynamic Ankle–Foot Orthoses Using Selective Laser Sintering, IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, VOL. 55, NO. 2, FEBRUARY 2008)** discloses AFO designs vary in size, shape, and functional characteristics depending on the desired clinical application. Passive Dynamic (PD) Response ankle–foot orthoses (PD-AFOs) constitute a design that seeks to improve walking ability for persons with various neuromuscular disorders by passively (like a spring) providing variable levels of support during the stance phase of gait. Current PD-AFO manufacturing technology is either labor intensive or not well suited for the detailed refinement of PD-AFO bending stiffness characteristics. The study was to explore the feasibility of using a rapid freeform prototyping technique, selective laser sintering (SLS), as a PD-AFO manufacturing process. Feasibility was determined by replicating the shape and functional characteristics of a carbon fiber AFO (CF-AFO). The study showed that a SLS-based framework is ideally suited for this application. A second objective was to determine the optimal SLS material for PD-AFOs to store and release elastic energy; considering minimizing energy dissipation through internal friction is a desired material characteristic. This study compared the mechanical damping of the CF-AFO to PD-AFOs manufactured by SLS using three different materials. Mechanical damping evaluation ranked the materials as Rilsan™ D80 (best), followed by DuraForm™ PA and DuraForm™ GF. In addition, Rilsan™ D80 was the only SLS material able to withstand large deformations.

US8512415 discloses a powered ankle-foot prosthesis, capable of providing human-like power at terminal stance that increase amputees metabolic walking economy compared to a conventional passive-elastic prosthesis. The powered prosthesis comprises a unidirectional spring, configured in parallel with a force-controllable actuator with series elasticity. The prosthesis is controlled to deliver the high mechanical power and net positive work observed in normal human walking.

US8808214 discloses an Active Ankle Foot Orthosis (AAFO) is provided where the impedance of an orthotic joint is modulated throughout the walking cycle to treat ankle foot gait pathology, such as drop foot gait. During controlled plantar flexion, a biomimetic torsional spring control is applied where orthotic joint stiffness is actively adjusted to minimize forefoot collisions with the ground. Throughout late stance, joint impedance is minimized so as not to impede powered plantar flexion movements, and during the swing phase, a torsional spring-damper (PD) control lifts the foot to provide toe clearance. To assess the clinical effects of variable-impedance control, kinetic and kinematic gait data were collected on two drop foot participants wearing the AAFO. It has been found that actively adjusting joint impedance reduces the occurrence of slap foot, allows greater powered plantar flexion, and provides for less kinematic difference during swing when compared to normal.

US8838263 discloses a computer-controlled fabrication of a patient-specific orthotic device using an automated fabrication machine capable of following computer instructions to create 3D surface contours and new developments in non-invasive three-dimensional (3D) scanning have made it possible to acquire digital models of freeform surfaces such as the surface anatomy of the human body and to then fabricate such a patient-specific device with high precision. Such a patient-specific device brings significant improvement in patient-specific fit, comfort, and function of medical devices (and, in particular, to orthoses that require a close fit to the wearer's body to act effectively). The combination of these two technologies is ideally suited for the development of patient-specific orthotic devices. A patient specific ankle-foot orthotic device using this technology is disclosed. This exemplary device is used to help stabilize the ankle-foot region, for example, in patients with impaired gait.

None of the document suggests a hot and cold pouch unit in AFO and FES system for improving foot drop of strokes, multiple sclerosis, cerebral palsy patients, and common peroneal nerve injury patients.

The existing document failed to suggest the adhesive electrode in AFO and FES system for improving foot drop of strokes, multiple sclerosis, cerebral palsy patients, and common peroneal nerve injury patients.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a customised ankle foot orthotic device with an effective hot and cold pouch unit for improving foot drop of a patient selected from strokes, multiple sclerosis, cerebral palsy patients and common peroneal nerve injury.

It is another objective of the invention is to provide a customised ankle foot orthotic device with novel adhesive electrode for the treatment of foot drop.

It is yet another objective of the invention is to provide a customised ankle foot orthotic device with novel adjustable strap for the treatment of foot drop.

It is yet another objective of the invention is to provide a novel customised foot orthotic device for improving gait and rehabilitation.

It is yet another objective of the invention is to provide a cost effective and easy to use orthotic device for foot drop problem.

It is yet another objective of the invention is to provide a device that could reduce the pain as compared to conventional AFO while treating foot drop.

It is further objective of the invention is to increase the speed of a foot drop patient in treadmill using the device.

SUMMARY OF THE INVENTION

According to first aspect of the invention, there is provided a customised ankle foot orthotic device consist of

calf piece (1);
calf strap (2);
a muscle stimulator (3);
stimulator suspension (4) includes a press button with nylon strap;
two adhesive electrodes (5);
electrical wires (6);
hinge joint (7);
JBR outsole (8);
foot piece (9);
ankle strap (10);
forefoot strap (11);
ring (12.2 and 12.3);
adjustable strap (13);
press button (14);
cold and hot pack pouch (15)
a means to provide upward projection (16); &
shank (17);

charecterized in that the adhesive strap being mounted on the the rings (12.2 and 12.3) so as to keep the plantar section of the foot piece (9) in straight position and

wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene

wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight;

wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5 wt% ammonium nitrate, 4 wt% hydropropylmethyl cellulose and 15 wt% propylene glycol; and

wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1a schematically illustrates the customised ankle foot orthotic device in accordance with the present invention;

Figure 1b schematically illustrates the side view of the device in accordance with the present invention;

Figure 1c schematically illustrates the front view of the device in accordance with the present invention;

Figure 1d schematically illustrates the rear view of the device in accordance with present invention; &

Figure 2 is the visual analogue scale for the measure of pain in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:

Expression:

The following term as used in the invention is defined:

Ankle Foot Orthosis (AFO): It is a device applied to the ankle for modifying functional characteristics of neuromuscular conditions.

Electrical Stimulator: It is an electrical device which is used for stimulating impaired structures in neuromuscular conditions and for improving strength in weak muscles.

Range Of Motion (ROM): It is a linear or angular distance that a moving object normally travels while properly attached to other. Usually it ranges or flexion and extension. Alternatively, the range of motion is defined as it is the measurement of movement around a specific joint. The range of motion is denoted by “degree”.

Foot Drop: It is the neuromuscular condition in which the muscles or nerve which are supplying to the foot are paralysed and is unable to lift the foot while walking it is called as Foot Drop.

Spasticity: It is the condition in which muscles get stiff and tight.

Stroke: It is medical condition in which there is poor blood supply to brain which may result in cell death due to interruption of blood flow there is damage to brain. Stroke caused by blocked artery or bursting of blood vessels. Due to this, brain is not functioning properly which may lead to improper body functioning.

Multiple Sclerosis: It is potentially disabling disease of brain and spinal cord. In multiple sclerosis the immune system attacks the protective sheath (myelin) that covers nerve fiber and causes communicating problem between the brain and rest of body.

Cerebral Palsy: It is a congenital disorder of movement muscle tone and posture that appear in early childhood.

Visual analog scale (VAS): It is a psychometric response scale which can be used in questionnaires. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points.

The present invention provides a customised ankle foot orthotic device for improving foot drop of a patient selected from strokes, multiple sclerosis, cerebral palsy patients and common peroneal nerve injury. The device (Figure 1a-1d) of the present invention consist of

1. Calf piece;
2. Calf strap;
3. Portable Muscle stimulator;
4. Stimulator suspension consisting of press button with nylon strap;
5. Adhesive electrode;
6. Electrical wires;
7. 2D hinge joint consisting of 4mm MS nut and bolt;
8. JBR outsole;
9. Foot piece;
10. Ankle strap;
11. Forefoot strap;
12. Ring;
13. Adjustable strap;
14. Press button;
15. Cold and Hot pack pouch;
16. Upward projection; &
17. Shank;

Referring to Figure 1a-1d, the orthosis of the present invention mainly consists of two sections: a Calf piece (1) and a Foot (9) which are articulately joined on each side of the ankle by two hinge joint of MS nuts and Bolts (7). The calf piece comprises a calf strap with an upper portion which may be wrapped around the patient's calf and secured by a velcro strap (2). The strap is attached to one side of the greave while the other end is free and is designed to loop around the calf. Below the strap (2), there is a stimulator suspension (4) which consists of press buttons in which portable muscle stimulator (3) is mounted. The greave extends downward from the calf area (1) to forward narrow shank (17) below which the greave broadens at ankle area to match the contour of the ankle. The plantar section (9) has a JBR (Johnson bros rubber) outsole (8) and an upward project on (16) which intimately wraps around heel & ankle areas of the patient. The hinge joints (7) are mounted loosely so that a plantar section (9) can rotate upward around the axis delineated by the two hinge (7). This movement of plantar section (9) provides for dorsiflexion of foot during the swing phase of gait cycle. The downward movement of plantar section (9) is stopped when the upper edge of the projection (16) comes in contact with the on the inner side of greave (2) thus, preventing the foot drop. The two sections (1) and (9) of the present device are made from thin-sheeted polypropylene material which are designed so as to counter the shape of the objects leg and foot. Ankle strap (10) is looped around the ring ankle (12.1) so as to fasten the strap tightly around the ankle. Forefoot strap (11) which is looped around the forefoot so as to fasten the strap tightly around the forefoot. Adjustable straps (13) is mounted on respective side by a ring (12.2) & (12.3) for keeping plantar section (9) in a stretched position.

Electrical muscle stimulator (3) consist of two adhesive electrodes (5) attached by electrical wire (6). Pouch (15) which is the inner aspect of calf piece of AFO includes cold and hot pack. All the straps herein are embedded by press buttons

All straps are embedded by press buttons (14).

Adhhesive electrode:

The self-adhesive hydrogel electrodes (5) according to present invention is prepared by the method as given in **Keller et al., Electrodes for transcutaneous (surface) electrical stimulation, JOURNAL OF AUTOMATIC CONTROL, UNIVERSITY OF BELGRADE, VOL. 18(2):35-45, 2008** except the amount of acrylic acid and N-vinylpyrrolidone which is 1:2 by weight in the present invention. The impulses are generated by the device and are delivered through electrodes on the skin near to the muscles being stimulated. The electrodes are generally pads that adhere to the skin. The impulses mimic the action potential that comes from the central nervous system, causing the muscles to contract.

Hot and cold pouch:

The hot and cold pouch according to present invention is prepared by the method disclosed in **US4462224:**

Table 1

Formulation code	Gel formulation					
G-I	Water solvent	Solute	Gelling agent	Wetting agent	-23°C to 10°C, Time	Ambient Viscosity
G-2	35 wt. %	35 wt. % NH_4NO_3	5wt% F4M Methocel	25wt% propylene glycol	15 minutes	>1,000,000 centipoise
G-3	42.5 wt. %	42.5 wt. % NH_4NO_3	5wt% F4M Methocel	10wt% propylene glycol	31 minutes	273,000 centipoise

G-4	41,83 wt %	41.83 wt. % NH_4NO_3	5wt% F4M Methocel	12.33wt% propylene glycol	29 minutes	>1,000,000 centipoise
G-5	40.5 wt. %	40.5 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% propylene glycol	25.6 minutes	563,000 centipoise
G-6	40 wt. %	40 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% propylene glycol	21 minutes	>1,000,000 centipoise
G-7	37.5 wt. %	37.5 wt. % NH_4NO_3	5wt% F4M Methocel	20wt% propylene glycol	13.5 minutes	>1,000,000 centipoise
G-8	40 wt. %	40 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% ethanol	17 minutes	>1,000,000 centipoise
G-9	40 wt, %	40 wt. % NH_4NO_3	5wt% SGP	15wt% propylene glycol	19 minutes	183,000 centipoise
G-10	40 wt. %	40 wt. % NH_4NO_3	5wt% gum tragacant	15wt% propylene glycol	16.5 minutes	170,000 centipoise
G-11	40 wt. %	40 wt. % NH_4NO_3	5wt% guar gum	15wt% propylene glycol	18.3 minutes	>1,000,000 centipoise
G-12	43.75 wt. %	31,25 wt. % NH_4NO_3	5wt% F4M Methocel	20wt% propylene glycol	11 minutes	>1,000,000 centipoise

G-13	51,33 wt, %	28.66 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% propylene glycol	19.5 minutes	>1,000,000 centipoise
G-14	40 wt. %	28 wt.% $CO(NH_2)_2$ and 12 wt. % KCl	5wt% F4M Methocel	15wt% propylene glycol	11 minutes	>1,000,000 centipoise
G-15	37.5 wt. %	37.5 wt. % NH_4NO_3	5wt% F4M Methocel	20wt% metahnol	11.5 minutes	780,200 centipoise

Wherein Methocel: Hydroxypropyl methyl cellulose

Adjustable strap:

The self adjusted strap herein is used for stretching purposes in which specific muscle or tendon (or muscle group) is deliberately flexed or stretched in order to improve the muscle's felt elasticity and achieve comfortable muscle tone. The result is a feeling of increased muscle control, flexibility, and range of motion. A combination of polyvinyl chloride:polypropylene:polyethylene 1:1:2 by weight according to the present invention is used for making the strap. The orthotic device of the present invention improves the gait and rehabilitation ,in previously used orthosis there were not active dorsiflexion which is very important for gait training and rehabilitative purposes we just have to wear and do gait training ,thus our device is doing dorsiflexion of ankle with the help of functional electrical stimulation through adhesive pads which is fitted on tibialis anterior muscle,this will also gives feedback.

The customised ankle foot orthotic device according to the present invention increases the speed of a foot drop patient in treadmill as compared to conventional AFO.

The invention is now illustrated by non-limiting examples.

Example 1:

Preparation of the hot and cold pouch unit and the adhesive hydrogel:

All the materials like the solute, solvent, gelling agent, wetting agent & other parameters as in Table 1, was purchased from the local market, Mumbai and prepared the gel formulation following the method disclosed in US4462224. 20 g of the gel was incorporated into the pouch for the purpose of treatment.

The adhesive electrode was prepared by the method disclosed in Keller et al in which the amount of acrylic acid and N-vinylpyrrolidone which is 1:2 by weight.

Experimental trials:

The experimental trial as to evaluate the efficacy of the present device for foot drop, was conducted in **Krishna Institute of Physiotherapy, near Dhebewadi Road, Malkapur, Karad, Pin code- 415110, Maharashtra, India**.

10 NOS patient whose average weight of 40-70 either gender, was selected for the following each groups:

Goup-I: strokes;

Goup-II: multiple sclerosis;

Goup-III: cerebral palsy patients; &

Goup-III: common peroneal nerve

Following were the steps to set the device to the patient:

Turn on the intensity:

After the electrodes were placed firmly on skin and the lead wires are plugged in the socket of device, turn the ON/ OFF control clockwise.The menu will reveal on LCD.

Select mode:

There were two EMS modes of option, S (synchronous) or A (alternate) .Select a mode by pressing the mode control when a EMS mode is selected, the LCD shows EMS on the top. After a mode is selected, press SET control to enter next setting. The patient may adjust the setting only when it is flashing and then press the increment or decrement control to change the settings.

Set Ramp Time:

The ramp time controls the time of output current that increase from 0 to the setting level, and from the setting value to 0. When the ramp time was set, each contraction was ramped up and down in order that the signals come on and come off gradually and smoothly. The ramp time was adjustable from 1 to 8 seconds.

Set ON time:

The On Time controls the time of stimulation. By pressing the “SET” control, the contraction time can be adjusted. Both channels stimulation was cycled on and off by the contraction and relaxation settings. The range is adjustable from 2 seconds to 90 seconds.

As the “ON” time including the ramp up and ramp down time, the setting of it should be no less than two times of the “RAMP” time.

Set OFF time:

The off times controls the time of relaxation. By pressing the “SET” control , the relaxation time can be adjusted. Both channels stimulation is cycled on and off by the contraction and relaxation settings. The range ios adjustable from 0 second to 90 seconds.

In alternate mode, the OFF time should be equal or more than the ON time.

Set Pulse Width:

Pulse Width was adjustable from 50 us to 300 us. Press “SET” control to enter this menu, the press “Increment or Decrement” to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 us setting.

Set Pulse Rate:

Pulse rate was adjustable from 2Hz to 150Hz. Press “SET” control to enter this menu, then press “Increment or Decrement” to adjust the setting. Unless otherwise instructed, turn the pulse rate control to the 70-120 range.

Set Timer:

The treatment time was adjustable from 1 to 60 minutes or C (continuous). Press “SET” control to enter this menu, then press “Increment” or “Decrement” to adjust the setting. Press “Increment” control when the timer shows 60 minutes, it was switched to continuous stimulation.

Compliance Meter:

This unit can store 60 sets of operation records. Total treatment time up to 999 hours can be stored.

Check and Delete individual record:

Press “MODE” control and turn on the power simultaneously. The LCD display shows the number of records and operation time. Press the “increment” and “decrement” button to each record. After all set then train the patient on flat surface with customized dynamic orthosis, and then make him to walk on treadmill with obstacles placing between them.

Comparative study of customised ankle foot orthotic device with or without hot & cold unit and adjustable strap for range of motion:

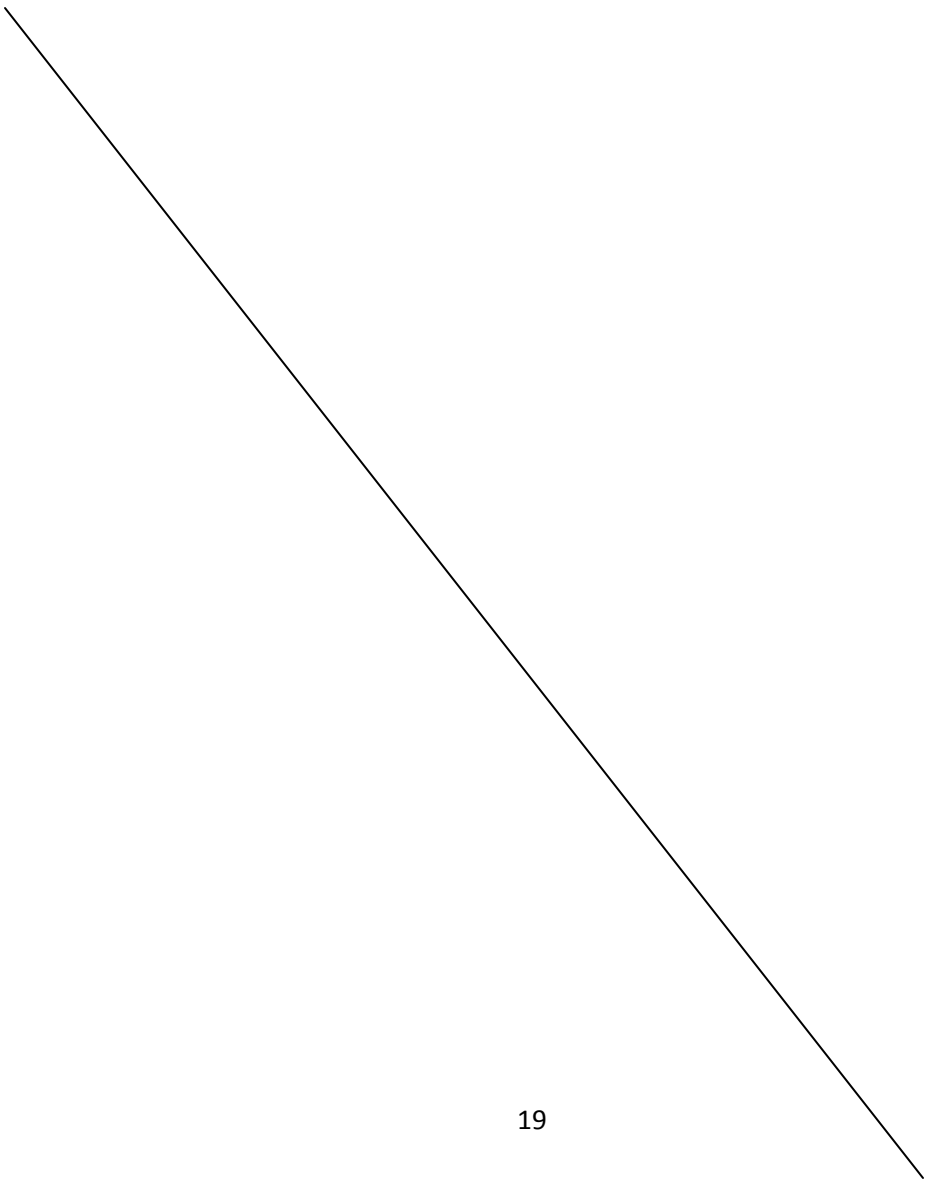

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Table 2

Sr. No.	Pre-treatment# (i.e. without customised ankle foot orthotic device) (ROM)	Post-treatment# i.e. with customised ankle foot orthotic device BUT without hot and cold unit and adjustable strap (ROM) (CE)	Post-treatment i.e. with customised ankle foot orthotic device WITH hot and cold unt (G1-G15) and the adjustable strap P:P:P 1:1:2 (ROM)														Post treatment with G4 & adjustable strap P:P:P 1:1:1 (ROM) (CE)
			G1 (CE)	G2 (CE)	G3 (CE)	G4 **(IE)**	G5 (CE)	G6 (CE)	G7 (CE)	G8 (CE)	G9 (CE)	G10 (CE)	G11 (CE)	G12 (CE)	G13 (CE)	G14 (CE)	G15 (CE)	19
1	5°	15°	17°	19°	17°	25°	16°	15°	18°	19°	18°	17°	19°	19°	17°	15°	16°	20°
2	10°	20°	20°	20°	21°	35°	21°	19°	19°	20°	19°	19°	20°	21°	19°	18°	20°	21°

3	9°	15°	15°	16°	22°	30°	23°	18°	21°	19°	18°	17°	22°	19°	21°	21°	22°	24°
4	15°	18°	19°	18°	20°	40°	22°	17°	19°	19°	20°	19°	22°	20°	20°	18°	22°	21°
5	18°	22°	22°	21°	24°	45°	20°	21°	21°	21°	21°	20°	21°	21°	22°	19°	21°	18°
6	20°	14°	14°	16°	15°	42°	19°	19°	22°	18°	17°	19°	20°	17°	16°	21°	20°	20°
7	8°	16°	16°	20°	20°	35°	21°	16°	20°	21°	19°	16°	21°	20°	19°	19°	20°	20°
8	10°	17°	17°	19°	21°	40°	21°	19°	21°	19°	17°	19°	21°	17°	21°	20°	21°	19°
9	14°	19°	20°	20°	19°	38°	19°	20°	23°	20°	21°	21°	20°	23°	20°	21°	20°	19°
10	13°	18°	18°	20°	20°	40°	19°	18°	19°	19°	19°	21°	19°	19°	18°	17°	18°	19°

Wherein #: Measurement was done with the help of goniometer

CE: Comparetive example;

IE: Inventive example; &

P:P:P = polyvinyl chloride:polypropylene:polyethylene

Table 2 shows the superior effect of hot and cold unt made up of the gel formulation G4 (40.5% water; 40.5% NH_4NO_3, 4% F4M Methocel, 15% propylene glycol) and adjustable strap made up of a combination of polyvinyl chloride:polypropylene:polyethylene 1:1:2 while evaluating range of motion (ROM) in foot drop of a stroke patient.

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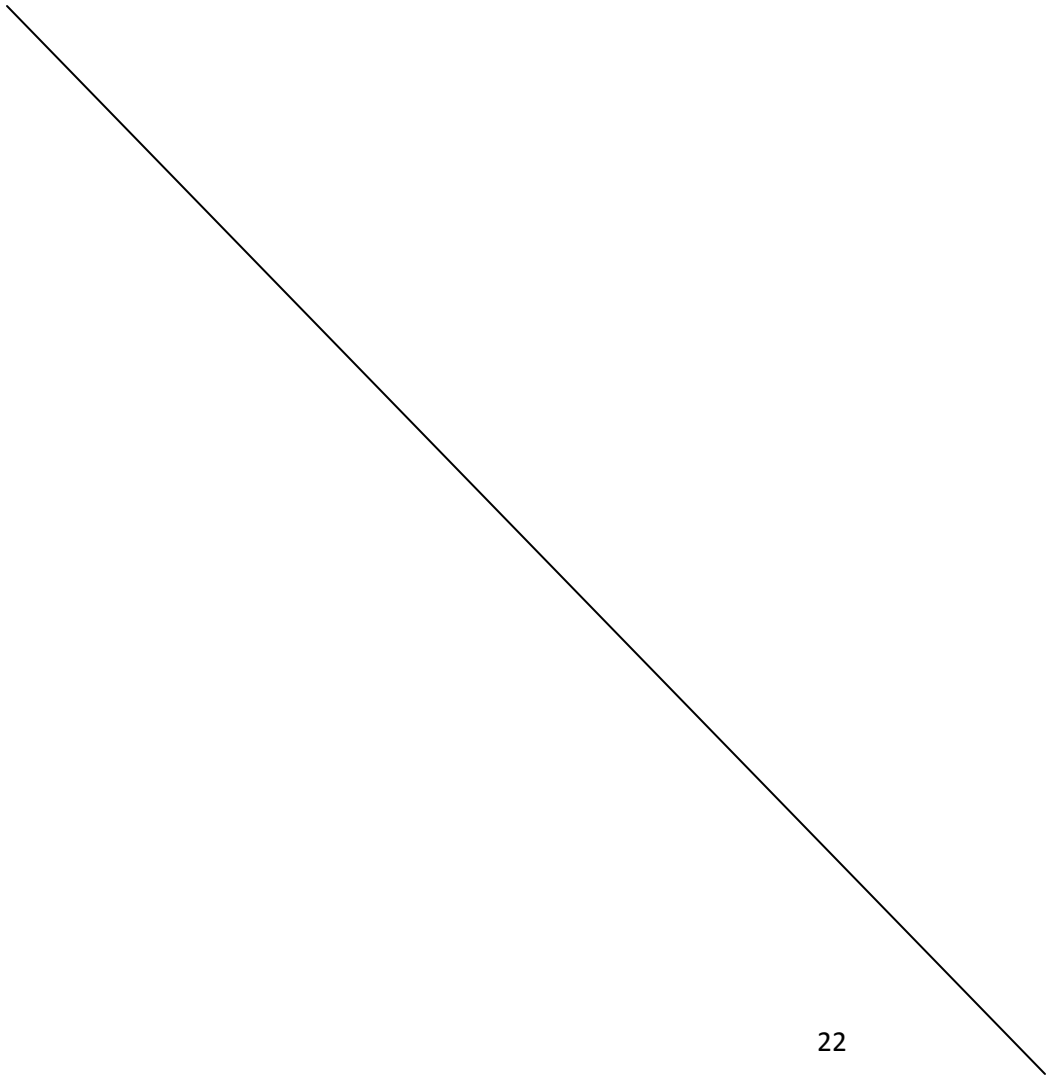
Accordingly, hot & cold pack unit (15) made up of G4 (40.5% water; 40.5% NH_4NO_3, 4% F4M Methocel, 15% propylene glycol) and adjustable strap (13) made up of a combination of polyvinyl chloride:polypropylene:polyethylene 1:1:2 both were selected for further studies.



10-meter walk test:

The present device was evaluated by 10-meter walk test and the results were noted in metres/second. The individual was walked without assistance for 10 metres, with the time measured for the intermediate 6 metres to allow for acceleration and deceleration. Assistive devices may be used, but must be kept consistent and documented for each test. Count the start time when the toes pass the 2 metre mark and stoping time when the toes pass the 8 metre mark. It can be tested at either preferred walking speed or maximum walking speed (ensure to document which was tested). This test was performed for each group of disease three times and calculated te average of the same.

Visual analogue scale/Graphic rating scale:

As shown in Figure 2, the Visual Analogue Scale (VAS) or Graphic Rating Scale was first used in psychology by Freyd in 1923, consists of a straight line with the endpoints defining extreme limits such as 'no pain at all' and 'pain as bad as it could be'. The patient was asked to mark his pain level on the line between the two endpoints. The distance between 'no pain at all' and the mark then defines the subject's pain as 0-3.99 as mild; 4-6.99 as moderate and 7-10 as severe.

Table 3: Group I (Stroke patients)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive example)**	Conventional AFO# **(Comparetive example)**	Conventional AFO# **(Comparetive example)**	Customised ankle foot orthotic device **(Inventive**

					example)
1	40	0.97	0.71	8	2
2	45	0.99	0.68	7	2
3	55	0.97	0.73	9	1
4	60	0.99	0.65	6	2
5	58	0.98	0.73	6	1
6	59	0.99	0.69	7	4
7	53	0.94	0.72	8	4
8	54	0.98	0.76	9	1
9	55	0.98	0.70	8	3
10	45	0.92	0.68	9	4

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 4: Group II (multiple sclerosis)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive example)**	Conventional AFO[#] **(Comparetive example)**	Conventional AFO[#] **(Comparetive example)**	Customised ankle foot orthotic device **(Inventive**

					example)
1	55	0.98	0.69	9	1
2	45	0.96	0.70	6	2
3	56	0.89	0.73	7	4
4	95	0.99	0.75	8	1
5	58	0.96	0.68	9	3
6	65	0.98	0.78	6	2
7	40	0.97	0.77	5	1
8	42	0.94	0.71	8	3
9	49	0.96	0.77	7	4
10	54	0.94	0.74	8	2

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 5: Group III (cerebral palsy patients)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive**	Conventional AFO[#] **(Comparetive example)**	Conventional AFO[#] **(Comparetive example)**	Customised ankle foot orthotic device

		example)			(Inventive example)
1	14	0.85	0.65	5	2
2	15	0.89	0.68	7	3
3	25	0.90	0.70	6	1
4	21	0.87	0.68	9	2
5	11	0.90	0.69	4	1
6	25	0.91	0.65	7	1
7	18	0.92	0.66	5	3
8	14	0.85	0.68	6	1
9	19	0.86	0.70	3	2
10	12	0.87	0.75	2	1

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 6: Group IV (common peroneal nerve)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device	Conventional AFO# **(Comparetive**	Conventional AFO# **(Comparetive**	Customised ankle foot orthotic

		(Inventive example)	**example)**	**example)**	device **(Inventive example)**
1	25	1.02	0.85	7	3
2	18	1.05	0.89	8	2
3	42	1.50	0.90	9	2
4	35	0.99	0.78	6	3
5	28	1.23	0.91	8	1
6	45	1.7	0.86	5	2
7	54	1.56	0.87	7	3
8	52	1.22	0.83	8	2
9	70	1.23	0.92	7	1
10	22	1.11	0.89	9	2

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 3-6 showed the superior effect of customized ankle foot orthotic device as compared to conventional AFO in view of both 10-meters walk test and the visual analogue scale for different diseases conditions.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications

disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim,

1. A customised ankle foot orthotic device consist of
   calf piece (1);
   calf strap (2);
   a muscle stimulator (3);
   stimulator suspension (4) includes a press button with nylon strap;
   two adhesive electrodes (5);
   electrical wires (6);
   hinge joint (7);
   a rubber outsole (8);
   foot piece (9);
   ankle strap (10);
   forefoot strap (11);
   ring (12.2 and 12.3);
   adjustable strap (13);
   press button (14);
   cold and hot pack pouch (15)
   a means to provide upward projection (16); &
   shank (17);

   charecterized in that the adhesive strap being mounted on the the rings (12.2 and 12.3) so as to keep the plantar section of the foot piece (9) in straight position and

   wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene

   wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight;

   wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5 wt% ammonium nitrate, 4 wt% hydropropylmethyl cellulose and 15 wt% propylene glycol; and

wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone.

2. The customised ankle foot orthotic device as claimed in claim 1, wherein the ratio of acrylic acid and N-vinylpyrrolidone is 1:2 by weight.

3. The customised ankle foot orthotic device as claimed in claim 1, wherein the downward movement of plantar section (9) is stopped when the upper edge of the projection (16) comes in contact with the inner side of greave (2).

4. The customised ankle foot orthotic device as claimed in claim 1, wherein the calf piece (1) and foot piece (9) is made up of polypropylene material.

5. The customised ankle foot orthotic device as claimed in claim 1, wherein the straps are embedded by the press botton (14).

6. The customised ankle foot orthotic device as and when used for foot drop of the disease condition selected from a group consisting of strokes, multiple sclerosis, cerebral palsy or common peroneal nerve injury.

Dated this 29th day of March, 2019

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Of Lex-Regia
For the Applicant

To,
The Controller of Patents,
The Patent Office
Mumbai

ABSTRACT

"CUSTOMISED ANKLE FOOT ORTHOTIC DEVICE"

A customised ankle foot orthotic device consist of calf piece (1); calf strap (2); a muscle stimulator (3); stimulator suspension (4) includes a press button with nylon strap; two adhesive electrodes (5); electrical wires (6); hinge joint (7); JBR outsole (8); foot piece (9); snkle strap (10); forefoot strap (11); ring (12.2 and 12.3); adjustable strap (13); press button (14); cold and hot pack pouch (15); a means to provide upward projection (16); & shank (17); charecterized in that the adhesive strap being mounted on the the rings (12.2 and 12.3) so as to keep the plantar section of the foot piece (9) in straight position and wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight; wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5 wt% ammonium nitrate, 4 wt% hydropropylmethyl cellulose and 15 wt% propylene glycol; and wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone. Figure (1a-1d)

FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A LIP POSTURE CORRECTOR"

APPLICANT(S)

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Maharashtra, India

The following specification componenticularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to a medical device. More particularly, the present invention relates to a device (could be medically said as a “corrector”) which can improve the lip posture of a patient suffering from facial paralysis.

BACKGROUND OF THE INVENTION

Facial paralysis is a debilitating condition that is often associated with dramatic functional, psychological, and cosmetic sequel. Varied functional deficits pose significant physiologic challenges. The inability to express oneself with spontaneous facial expression or intelligible speech can have extraordinary psychological ramifications, and facial asymmetry can scar a patient’s self-image, rendering him or her less secure in everyday interactions with the world.

Manifestations of facial nerve paralysis are the facial laxity, asymmetric smile, lower lip asymmetry at rest, droopy oral commissure (from the weakened major and minor zygomatic muscles), inspiratory nasal collapse, oral incompetence (difficulty with mastication and speech), lower-eyelidectropion or laxity, lagophthalmos, a sense of disfigurement etc. Therefore, the goals of reconstruction of the paralyzed face may be the facial symmetry at rest, oral competence and eye closure; & voluntary facial movements with spontaneous facial expression

The surgical team has an armamentarium of surgical strategies for facial reanimation. These procedures are categorized as either dynamic or static.

Dynamic procedures aim to reanimate the face by local muscle transfer or by nerve grafting and free muscle transfer; they should be considered in every patient with facial nerve paralysis. But they may not be suitable for a patient who is debilitated or terminally ill (Why). Surgical correction, though, can be done, but it has its own limitations like prolonged treatment time, effects and consequences of surgery itself,

patients existing physical and mental condition to withstand surgery and bear its effects.

Static techniques are employed to suspend the soft tissue structures of the face, but they do not provide facial reanimation. There are often adjunctive maneuvers performed in conjunction with dynamic techniques to enhance facial symmetry.

However, static procedures may also be performed alone for patients who are not candidates for dynamic reanimation procedures (because of physical debilitation, advanced age, increased time delay from injury to repair, or poor health) but who would still benefit from the restoration of facial symmetry.

A literature reveals [Cerio DR. Static reconstruction for facial nerve paralysis. Downloaded from https://emedicine.medscape.com/article/1289348-print] that at times (e.g., in elderly patients), dynamic facial reanimation is not possible or indicated, and static reconstruction is performed. The goals of static suspension procedures are to protect the cornea by restoring eyelid competence, to enhance mastication and speech production through commissure elevation, and to achieve cosmetic improvement by restoring facial symmetry at rest. Not every patient is a suitable candidate for a dynamic procedure for facial reanimation. Patients who are severely debilitated or elderly may not be able to endure the lengthy operations required by dynamic reconstructions, nor can they wait for the delayed results generated by dynamic modalities (which sometimes take as long as 2-3 years to develop), given that their life expectancies are limited by advanced age or terminal illness. For these patients, static suspension of the lower face with autologous or alloplastic materials can provide symmetry at rest and may improve oral incompetence and nasal collapse. These improvements in function enhance quality of life despite life expectancy.

This literature also addresses that the static techniques generally are unsatisfactory as a single modality for rehabilitation of the paralyzed lower face and thus should not be used as a primary modality of reconstruction. Static procedures are most appropriate for debilitated patients who are unable or unwilling to endure the extensive operations of dynamic reanimation or those who are not expected to have a life expectancy beyond the nerve and muscle recovery period following dynamic strategies. They can also enhance dynamic reanimation by augmenting facial symmetry.

A static surgical approach suggested by Rana et al., [Rana H., Shaikh MF., Shah A., Dodia H. Static suspension technique wih fascia lata for facial reanimation in facial palsy. IOSR-JDMS:16(4);90-96] in which it was found that the static facial suspensions are an effective method of correcting facial nerve deficits in cases where nerve repair is not planned or possible.

Another literature [Iseli TA., Harris G., Dean NR., Iseli CE., Rosenthal EL. Outcomes of static and dynamic facial nerve repair in head and neck cancer. Laryngoscope 120:478-483] reveals that although elderly patients with parotid malignancy have traditionally been considered poor candidates for nerve grafting, still it was found that nerve grafting is the good method of facial nerve reconstruction.

As all the aforesaid approaches are surgical, these approaches may not be suitable for the patients who cannot be subjected for surgery due to significant health high risk issues and who have lower lip deficit causing drooping of lip and drooling of saliva, effacement /obliteration of nasolabial fold on the affected side [Affected side means the side which has been affected by paralysis due to inappropriate nerve conduction resulting in loss of muscle function. Due to this, drooping of lip and its consequences as stated above occurs].

Currently, the existing device takes the support from teeth (in persons with teeth present i.e. dentulous) or they are attached to complete dentures (in persons without any teeth i.e. edentulous). These devices are more of support to cheek than lips. Hence they are termed as cheek bumpers or cheek plumbers. They actually have no effect on correction of lip posture. Their function is to correct cheek position and is more of an aesthetic/cosmetic appliance rather than a functional appliance. When these appliances take support from teeth (in dentulous condition), they make the patients very uncomfortable and when these are component of complete denture, (in edentulous condition) these device make complete denture very heavy and reduce the ease of their use.

Currently, various synthetic polymers are used intra-orally. One of the polymers is PMMA i.e. polymethylmethacrylate acrylic resin *[(Bhola et al., Biocompatible Denture Polymers – A Review, Trends Biomater. Artif. Organs, Vol 23(3), pp 129-136 (2010)]* which may be good in view of tensile strength but leaching of MMA resulting stomatitis is reported over this literature. Further PMMA is carciogenic over Bhola et al. Therefore, it is a need of hour to provide a solution such that PMMA can be used intra-orally safely.

Regarding drug treatment, the facial paralysis or idiopathic Bell's palsy are normally treated with oral glucocorticoids such as Deltasone (prednisone) within three days of symptom onset. Individuals with severe cases often receive the combination of Deltasone (prednisone) and Valtrex (valacyclovir). Botox (botulinum toxin) injections can be beneficial for patients who do not completely recover. However, these drugs are known with the side effects.

Prior art:

JP3129305 discloses lip dysplasia correction tool in which the tool is capable of preventing a lip perfection by improving the function of the oral cavity and correcting the dentition by normalizing the posture of the tongue and the posture of the jaw.

JP'305' is applicable for correcting tongue and jaw not lip. Also, it requires the teeth support.

US9936792 discloses a facial lift device to be placed behind the lips and above the gums disposed alongside the buccal and facial surface of a living human maxilla or a human mandible no further than the most posterior tooth of one side to the most posterior tooth of the opposite side of said maxilla or mandible. The facial device embodies an outward lifting force when placed within the human mouth under the lips and alongside the anterior vestibule centered on the frenulum, such that when said facial lift device is forced behind the maxilla or mandible lips, the facial lift will forcibly lift out the dermal layer reducing and removing lower facial wrinkles within the perioral region. US'792' does not suggest the improvement of lip posture. Again it needs the teeth support.

Therefore, there is a need of hour is to provide a non-surgical approach (also could medically be said as an "external device or a lip posture corrector") that could improve/correct the lip posture of a patient suffering from facial paralysis or of those who cannot be subjected for the surgery. There is a further need to provide a solution for correcting lip posture without drugs.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a device or a corrector that could improve the lip posture of a patient who is suffering from facial paralysis.

It is another objective of the invention is to provide a lip posture corrector for those who cannot be subjected for the surgery for instance surgical sling procedure.

It is yet another objective of the invention is to provide a device for improving the lip posture without teeth support.

It is yet another objective of the invention is to provide a lip posture corrector using a novel polymeric combination.

It is yet another objective of the invention is to provide a lip posture corrector without any toxic effect on human body.

It is yet another objective of the invention is to provide a device which can be used to improve the lip posture of the patients who have undergo MRI or CT scan.

It is another objective of the invention is to provide a lip posture corrector which itself is capable of correcting the lip posture in other words, no oral or other dose is simultaneously required in order to correct the lip posture.

It is further objective of the invention is to provide a lip posture corrector which is cost effective, easy to use and having minimum discomfort.

SUMMARY OF THE INVENTION

Accordingly there is provided a lip posture corrector consists of:

an intra-oral component (1);

an ear support component (2);

a connector (3) being positioned between the intraoral component (1) and ear support component (2);

wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2;

wherein the sodium acrylate and acrylamide is 10:90 by weight.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with componenticular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates the lip posture corrector in accordance with the present invention;

Figure 2 is the image (front view) of a patient suffering from facial palsy and drooping of the affected side of the lip in accordance with present invention;

Figure 3 is the image (side view) of a patient suffering from facial palsy and drooping of the affected side of the lip in accordance with present invention;

Figure 4 is the image (front view) of a patient illustrating the clinical application of the device in accordance with the present invention;

Figure 5 is the image (side view) of a patient illustrating the clinical application of the device in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

The phrase “device”, “static suspension device”, “lip posture corrector” herein is the same and could be used interchangeably.

The phrase “static suspension” herein refers to equilibrium or balancing of the lip posture.

The present invention provides a static suspension device for improving a lip posture of a patient suffering from facial paralysis.

As shown in Figure 1, the device of the present invention consists of three components:

an intra-oral component (1)

an ear support component (2)

a connector (3) between the intraoral component (1) and ear support component (2)

In preferred embodiment of the invention, the shape of the intra-oral component and ear support component is the circular or the like.

In preferred embodiment of the invention, the diameter of the intra-oral component is 18-22mm, while the diameter of the ear support component is 41-49mm. In preferred embodiment, the length of the connector is 90-130mm.

The whole device according to the present invention is made up of a polymeric blend which should be met with the following properties i) sufficient strength such that the device would not be deformed during the use; ii) should not exhibit the toxic effect to the user; iii) should be light weight such that the user would not feel the discomfort. In preferred embodiment, the polymeric blend is a combination of polymethylmethacrylate acrylic resin (PMMA) and copolymer of sodium acrylate: acrylamide 10:90 (PAA 1115). Both the polymers are well known in pharmaceutical/medical field for various applications including thickening agent, viscosity enhancer, sustained release polymer. Use of PMMA in denture application is also known *[(Bhola et al., Biocompatible Denture Polymers – A Review, Trends Biomater. Artif. Organs, Vol 23(3), pp 129-136 (2010)].* Bhola et al., addresses PMMA as a good polymer as the strength is concerned, but it leaches the free-radicals (MMA and formaldehyde) which causes stomatitis and this prior art also addresses the MMA/PMMA as carciogenic.

The present inventor surprisingly found that a weight ratio of PMMA and PAA 1115 1:2 provides the desired effect i.e. lip-lifting without the toxic effect of PMMA to the user.

In present invention, the method for preparing the device is known flasking procedure, except the polymer ratio.

As the device of the present invention is made up without metal, it can be used in MRI, CT scan and other detection parameter.

The present invention is now illustrated with non-limiting examples:

Example 1:

PAA 1115 (sodium acrylate: acrylamide 10:90) was purchased from Suyog Chemical, Nagpur, Maharashtra, India and PMMA was procured from SMCO International, Mumbai India.

The working of the device to establish the advantageous effect of the present invention is demonstrated in Figure 2 and 5. The studies were performed at **Krishna Institute of Medical Sciences and Krishna Hospital, Karad** and 10 elder patients suffering from drooping of lip (facial paralysis) and not be subjected to the surgery were chosen from each group as follows:

Group 1: The static suspension device using PMMA and PAA 1115 1:1; &

Group 2: The static suspension device using PMMA and PAA 1115 1:2

Both front (Figure 2 & 4) and side view (Figure 3 & 5) of the patient (Patient 5, Age 68) was taken before and after using the device. The patients (Group 1 & 2) were worn (Figure 4 & 5) the device in which the Intra-oral component (1) was retained through the buccal mucosa and another component (2) was retained through the ear support in a manner like a spectacle (Through connector 3). The patients were given the prescribed oral doses as required for other purposes for instance the patient who was suffering from diabetes and facial paralysis, the prescribed dose of metformin HCl was given but no oral/parenteral dose of the glucocorticoid (as referred in the background) was given to him/her.

The improvement (100%) was evaluated by correcting the lip posture to its original position of above patients and there was symmetry of the lip bilaterally (both left side and right side of the face). For example, if the lip had dropped to 1cm below its

normal level (here normal level means position of the lip on the other unaffected side), and if the device brings the lip position back to its normal position by lifting it to 1cm.

Table 1

Group 1 (The static suspension device using PMMA and PAA 1115 1:1)	Lip drooping/Lip lifting		Side effects
	Lip drooping	Lip lifting	
Patient 1 (Age 60)	0.8cm	0.8cm	Stomatitis
Patient 2 (Age 62)	0.5cm	0.5cm	Stomatitis
Patient 3 (Age 64)	0.9cm	0.7cm	Stomatitis
Patient 4 (Age 66)	0.8cm	0.6cm	Stomatitis
Patient 5 (Age 68)	1.0cm	1.0cm	Stomatitis and allergic reaction
Patient 6 (Age 70)	0.8cm	0.7cm	Stomatitis
Patient 7 (Age 72)	0.8cm	0.7cm	Stomatitis
Patient 8 (Age 74)	0.8cm	0.6cm	Stomatitis
Patient 9 (Age 76)	0.8cm	0.5cm	Stomatitis
Patient 10 (Age 80)	0.9cm	0.9cm	Stomatitis, allergic reaction

Wherein the patient was worn the device up to 6 months from the date of first using the device.

Table 2

Group 2 (The static suspension device using PMMA and PAA 1115 1:2)	Lip drooping/Lip lifting		Side effects
	Lip drooping	Lip lifting	
Patient 1 (Age 60)	0.8cm	0.8cm	No sign of stomatitis and allergic reaction
Patient 2 (Age 62)	0.5cm	0.5cm	
Patient 3 (Age 64)	0.9cm	0.9cm	
Patient 4 (Age 66)	0.8cm	0.7cm	
Patient 5 (Age 68)	1.0cm	1.0cm	
Patient 6 (Age 70)	0.8cm	0.8cm	
Patient 7 (Age 72)	0.8cm	0.8cm	
Patient 8 (Age 74)	0.8cm	0.8cm	
Patient 9 (Age 76)	0.8cm	0.8cm	
Patient 10 (Age 80)	0.9cm	0.9cm	

Wherein the patient was worn the device up to 6 months from the date of first using the device.

Figure 4 & 5 shows the clinical improvement of the lip posture.

The present inventors found that the static suspension device using PMMA and PAA 1115 1:2 shows the desired effects i.e. 100% lip-lifting effect without toxicity (Patient 5, Table 2). Further, the present inventors found that the static suspension

device itself is a sufficient in order to correct the lip posture i.e. without glucocorticoid.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the componenticular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

We Claim,

1. A lip posture corrector consists of:

   an intra-oral component (1);

   an ear support component (2);

   a connector (3) being positioned between the intraoral component (1) and ear support component (2);

   wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2;

   wherein the sodium acrylate and acrylamide is 10:90 by weight.

2. The lip posture corrector as claimed in claim 1, wherein the shape of the intra-oral component is circular or the like.

3. The lip posture corrector as claimed in claim 1, wherein the shape of the ear support component is circular or the like.

4. The lip posture corrector as claimed in claim 1, wherein the length of the connector is 90-130mm.

5. The lip posture corrector as claimed in claim 1, wherein the diameter of the intra-oral component is 18-22mm.

6. The lip posture corrector as claimed in claim 1, wherein the diameter of the ear support component is 41-49mm.

Dated this 18th day of June, 2019

Durga Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346) of
Lex-Regia
For the Applicant(s)

To,
The Controller of Patents,
The Patent Office
At Mumbai

ABSTRACT

"A LIP POSTURE CORRECTOR"

Disclosed is a lip posture corrector consists of consist of an intra-oral component (1); an ear support component (2); a connector (3) being positioned between the intraoral component (1) and ear support component (2); wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2; wherein the sodium acrylate and acrylamide is 10:90 by weight. Figure 1

FORM 2

THE PATENT ACT 1970

(39 OF 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See SECTION 10, RULE 13)

1. TITLE OF THE INVENTION :

"SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR"

2. APPLICANTS

NAME : KRISHNA INSTITUTE OF MEDICAL SCIENCES

NATIONALITY: DEEMED TO BE UNIVERSITY DECLARED U/S 3 OF UGC ACT, 1956 VIDE NOTIFICATION NO. F.9-15 / 2001 – U-3 OF THE MINISTRY OF HUMAN RESOURCES DEVELOPMENT, GOVT.OF INDIA

ADDRESS : KRISHNA INSTITUTE OF MEDICAL SCIENCES, NEAR DHEBEWADI ROAD, MALKAPUR, KARAD 415110, MAHARASHTRA, INDIA

3. PREAMBLE TO THE DESCRIPTION

PROVISIONAL	COMPLETE
N / A	The following Specification particularly describes the nature of this invention and the manner in which it is to be performed :

4. TECHNICAL FIELD

Spinal and Epidural Anaesthesia is most commonly used Regional anaesthetic technique today in our country, which is a safe, effective and most economic mode of anaesthesia. It is essential that the student must learn detailed anatomy, understand the details, develop basic skills with hands on training and realise the difficulties on a dummy simulator before practicing on live human being & we devised and developed an innovative simulator to be used in the skill lab. In view of the above facts we planned and developed a spinal anaesthesia simulator which closely mimics a living patient with facilities of mobility of bony spinal column ensuring detailed anatomical relations which in medical terms called as fidelity simulator in a minimum of cost. It should prove a great asset in the development of Skill Lab.

Learning of gross anatomy of adult patient in sitting and lateral positions, with the entire bony landmark to feel. Detailed anatomical relations from skin to bones (Spine). Different structures that come in the way while inserting a needle. Changes in the curvatures of spine, in different body positions. Hands on experience of doing lumbar puncture with five different approaches. Understanding the difficulties and causation of complications of procedure. Useful for teaching under graduate, post graduate students, junior teachers etc.

5. BACKGROUND

The Health Care services is going through a significant change in recent years due to society getting easy access to health care information from various media. The developed countries have passed through this phase decades ago and therefore the students there are not allowed to learn the anaesthetic techniques - be it General or Regional anaesthesia – directly on the live patients without undergoing adequate and satisfactory training in the Skill Lab with a variety of simulators available for learning and developing necessary basic skills. Only then they are allowed to do the procedures in live patients under the supervision of experienced teaching staff, resulting in minimum of problems and improved standard of healthcare.

6. SUMMERY

Setting up of a Skill Lab is the need of the day and for this we decided to develop a simulator for spinal and epidural technique which is used for giving anaesthesia. In-house designed, matching a life size and realistic in

nature with facility of spinal bones movement, the fidelity simulator was prepared at a very low cost. This simulator is used to teach students spinal and epidural anaesthesia technique with exact knowledge about technique to give them hands on training and achieve expertise before they use the same on actual live patients. This will surely save operation theatre man-hours, improved quality of patient care and confidence of the practitioner.

7. BRIEF DESCRIPTION OF DRAWING:

Fig I is the schematic representation of SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR.
Fig II is the schematic representation of SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR.
Fig III is the schematic representation of SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR.
Fig IV is the schematic representation of SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR.
Fig V is the schematic representation of SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR.

8. DETAILED DESCRIPTION OF DRAWINGS :

Fig – I

The simulator simulates a human being in sitting position showing details of lower back (1) on backside and abdomen (2) on front side. The buttocks rest on the ground surface (3) firmly with stability, supporting waist (4) and the thighs in front of body (5)

Fig – II

It is designed and constructed basically from heavy wooden logs considering the dimensions in real situation (life size), giving accurate placement of normal bony prominences like iliac crest (6), Thigh bones (7), Greater Trochonter (8) and Ischeal Tuberosity (9) etc.

Fig – III

Shows the construction of the main Central Wooden Board with the nut (11) and bolt (12) fixed in the centre of the board (10).

Fig - IV

A strong central wooden board (13) mounted in the main wooden frame (14) is prepared by mounting all vertebral bodies (16 and 17) on to this board with the help of a pair of Titanium elastic nails (15). Bent metal rods represent bony ridge of ileac crest (18) and the lower part of sacral bone is covered with a leather pouch (19)

Fig – V

The fully developed simulator with exposed back cover (20) shows the whole body development by Leather sheet (21), the wooden block at the top with anatomic diagrams (22) and vertebrae covered with thick and tough rubber pads (23) For hands on training, the backside is covered with the leather sheet (20) fixing it in place by Velcro ribbon (24) The central vertebral canal (26) accommodates the PVC tube (25) representing the dural tube.

1. A life size simulator resembling an adult patient in the sitting position (1) is constructed using a strong and heavy wooden frame, steel bars, foam and leather covering.

2. The simulator can be put in either sitting position or in lateral position with adequate stability (both these positions being used for giving spinal anaesthesia).

3. The design of wooden frame and bars is made in such a way that all the bony prominence of the pelvis bone and backbone are matched exactly to a living person's dimensions and can be felt by hand easily (2).

4. The mid vertical portion of the simulator on backside is designed to mount the Lumbar and Sacral vertebrae (natural) with help of Titanium elastic nail (TEN) with elastic discs interposed between each two vertebral bodies, on to a strong wooden board which can be removed or fixed into the main body frame very firmly (3).

5. The wooden board used for mounting vertebral column has a midline hole opposite lumbar 3 – 4 vertebrae, to which a hexagonal threaded screw is fitted firmly on back side. A long length nut with a suitable wheel is threaded through the screw to point at the curved vertebral column (back bone) which is protected from screw movement by interposition of a thick block rubber pad.

6. When the screw wheel is moved by clockwise rotation from anteriorly, its shaft pushes the spinal curvature backwards; on unscrewing (anticlockwise) the spinal curvature regains its natural curvature due to the TEN threaded through the vertebrae.

7. In the canal which naturally accommodates spinal cord with its

coverings a blind ended PVC tube of 0.8 mm diameter is inserted for simulation. It is filled with a coloured fluid when needed to simulate cerebrospinal fluid in life situation.

8. The top portion of vertebral canal is covered to the skin level to accommodate two wooden blocks which depict coloured drawings of the anatomical structures in real life situation in horizontal as well as mid vertical plain (4).

9. Top part of the vertebral column also shows the different important structures (ligaments) which in natural situations support the vertebral curvatures and protect the underlying spinal cord.

10. The lower half of the lumbar vertebrae are padded by a tough block rubber piece to give the similar resistance to needle prick in life situation. The lumbar puncture is done in this region of the spine in anaesthesia practice.

11. The sacral bone is covered by a special leather pouch to give it a natural look and feel of the underlying bone which in practical situation is necessary while giving caudal epidural anaesthesia.

12. The open upper half of the backbone facilitates the trainer or supervisor in viewing the course of the needle tip when a learner is trying the lumbar puncture and pointing out the common problems or difficulties the learner faces along with demonstrating the mistakes he has committed during the procedure.

13. The wrong placement of needle can give rise to different post anaesthesia complications which can be precisely demonstrated and taught to the learner thereby to avoid the same.

9. I claim

1. The SPINAL AND EPIDURAL ANAESTHESIA SIMULATOR developed is a near life model which shows movements of spinal curvatures with change in the body posture and is realistic or fidelity simulator and is developed as a teaching and training aid for undergraduates and post graduate students, junior teachers etc. as the SIMULATOR teaching and training in the days to come is becoming essential step for PG students of anaesthesia who are going to practice this technique as their speciality in their carrier as an anaesthesiologist and should result into safe practices and procedures to improve safety and better healthcare to general population.

Dated this 6th June, 2013.

DR.M.V.GHORPADE
(REGISTRAR)
FOR KRISHNA INSTITUTE OF MEDICAL SCIENCES

REGISTRAR
KRISHNA INSTITUTE OF MEDICAL SCIENCES
UNIVERSITY
KARAD

To
The Controller of Patents,
The patent office,
At Mumbai – 400 037

10. ABSTRACT OF THE INVENT

Increasing awareness in the society about the healthcare has resulted in heightened expectations of improved surgical outcome, patient safety and care. The junior doctors, who are going to practice spinal and epidural anaesthesia on patients, therefore must go through an initial step of training in skill lab which can make him a well learned adequately trained in skills and a wise health provider than one without it. To achieve this goal, we intend to develop an innovative, life size simulator to be used with full advantage in the skill lab.

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FORM 2

THE PATENT ACT 1970

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(SEE SECTION 10 AND RULE 13)

1. **TITLE OF THE INVENTION: "A Device for Measuring Tension in a Wire of an Orthodontic Braces"**

2. **APPLICANT(s):**

(a) NAME:	**KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY"**
(b)NATIONALITY:	Indian University
(c) ADDRESS:	NH 4, Near Dhebewadi Road, Malkapur, Karad - 415539, Maharashtra.

3. **PREAMBLE TO THE DESCRIPTION:**

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed

Field of the Invention

[0001] The present invention relates to a medical diagnostic instrument. More particularly, the present invention relates to a device for measuring tension in a wire of an orthodontic braces for effective tooth movement

Background of the Invention

[0002] Orthodontics in dentistry is associated with improvement of the general appearance of a patient's teeth and deals with the diagnosis, prevention and correction of misaligned or mal-positioned teeth and jaws. Orthodontics braces are the device which is used for correction of misaligned or mal-positioned teeth and jaws. Orthodontics braces are provided with wires and brackets. The brackets are fixed with each of the teeth and wires are winded around the teeth and are fixed with the brackets. The medical practitioner (orthodontist) adjusts the required tension on the wires depending on the complexity of misaligned teeth. Further, periodic adjustment of the wires is required for the proper alignment of the misaligned or mal-positioned teeth and jaws. The wires may be replaced with a rubber band or rubber chain or any other elastic material.

[0003] If the tension required on the wire arranged between the mal-aligned teeth is known to the practitioner at each stage of the treatment, the alignment period and the diagnosis term can be substantially reduced. Improper adjustment of the wire in varied tension may unnecessarily extend the term of diagnosis and thereby delaying the alignment period. Wires or elastic materials are available with predefined tension which can be applied across the brackets. However, these wires cannot be customised according to the need of the patient.

[0004] Hence there is a requirement of a dental device which can measure the tension of the wire / elastic wound around a bracket of two teeth in an orthodontic brace treatment which may overcome few or all drawbacks of the existing dental devices.

Objects of the Invention

[0005] An object of the present invention is to provide a device for measuring tension in a wire configured around a bracket of two teeth in an orthodontic brace treatment.

[0006] Another object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which substantially shortens the time duration of treatment.

[0007] Yet another object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which provides accurate and precise historical data of the wire tension allowing the medical practitioner to ease the examination procedure.

[0008] One more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which reduces the alignment period of the treatment.

[0009] Further object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which has a lesser complexity in operation.

[0010] One more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which can measure extra oral force accurately and precisely so that we can modify growing facial structures.

[0011] Still one more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which measures and records force or tension in the wire simultaneously which helps in further research and studies.

[0012] Further one more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, in which the recorded force can be used for monitoring patient in future appointment and medico-legal purposes .

Summary of the invention

[0013] According to the present invention, a device used for an orthodontic (brace) treatment is provided. The device is specifically for measuring tension in a wire of an orthodontic braces. In the orthodontic braces treatment, wires, elastic members or the like are used to adjust the tension between the teeth. In the orthodontic braces, brackets are attached with each tooth, and the wires are configured around the brackets of two teeth. The wire is having a closed circumference and is capable of being wind in a winding position around the brackets of two teeth. The wires can be attached with the adjacent brackets. The wires are tightened according to the required tension. Once the tension is set across the brackets, the device can be used to verify the tension across the wire.

[0014] The device is a force measuring instrument having an anchoring member, a holding portion and a display. The anchoring member is adapted to attach with the wire. Specifically, a first end of the anchoring member which is the distal end of the device is attachable with the wire in the winding position. A second end of the anchoring member is attached to the holding portion

of the device. In an embodiment, the anchoring member can be detachable from the holding portion and can be replaced with anchoring members of different length and sizes. Upon pulling the device after anchoring the anchoring member with the wire along the length of the anchoring member and away from the wire facilitates the device to measure the tension across the wire. The device measures the tension across the wire and displays the measured data on the display attached therewith.

Brief Description of the Drawings

[0015] The advantages and features of the present invention will be understood better with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0016] Figure 1 illustrates a device for measuring tension in a wire of an orthodontic brace in accordance with the present invention; and

[0017] Figure 2 illustrates a schematic view of the device in accordance with the present invention.

Detailed Description of the Invention

[0018] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising, "having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items, or meant to be limited to only the listed item or items.

[0019] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0020] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0021] Referring to figures 1 and 2, a device 100 used for an orthodontic brace treatment in accordance with the present invention is illustrated. The device 100 is specifically for measuring tension in a wire 110 of an orthodontic brace 200. In the orthodontic brace treatment, wires, elastic members or the like are used to adjust the tension between the teeth. If the tension is adjusted between the teeth according to the need, the teeth are likely to be aligned in a proper orientation which may help the patient an easy recovery.

[0022] In the orthodontic braces 200, brackets 210 are attached with each tooth, and the wires 110 are configured around the brackets 210 of two teeth. The wire 110 is having a closed circumference and are capable of being wind in a winding position (as shown in figure 1) around the brackets 210 of two teeth. The wire 110 can be attached with the adjacent brackets 210. The wire 110 can be replaced with elastic members such as rubber bands, and the like. The wires 110 are tightened according to the required tension. Once the tension is set across the brackets 210, the device 100 can be used to verify the tension across the wire 110.

[0023] Referring to figure 2, the device 100 is a force measuring instrument having an anchoring member 120, a holding portion 130 and a display 140. The anchoring member 120 is adapted to attach with the wire 110. The anchoring member 120 is an elongated member having a hookable portion configured on a first end 120a of the anchoring member 120 for anchoring the device 100 with the wire 110. Specifically, the first end 120a of the anchoring member 120 which is the distal end of the device 100 is attachable with the wire 110 in the winding position. The tension across the wires 110 are at the maximum in the winding position.

[0024] A second end 120b of the anchoring member 120 is attached to the holding portion 130 of the device 100. In the present embodiment, the anchoring member 120 is fixed with the holding portion 130 of the device 100. In an embodiment, the second end 120b of the anchoring member 120 is

connected pivotally and detachably with the holding portion 130 to provide enough degree of freedom for the anchoring member 120. The anchoring member may be detachable from the holding portion 130 and can be replaced with anchoring members 120 of different length and sizes. The holding portion 130 is for holding and providing sufficient gripping to the device 100.

[0025] Upon pulling the device 100 after anchoring the anchoring member 120 with the wire 110 along the length of the anchoring member 120 and away from the wire 110 facilitates the device 100 to measure the tension across the wire 110. Specifically, the device 100 measures the tension across the wire 110 and displays the measured data on the display 140 attached therewith. The display 140 can be either analogue or digital. The holding portion 130 and the display 140 are integral to the device 100.

[0026] Therefore the present invention has an advantage of providing a device 100 for measuring tension in a wire 110 configured around a bracket 210 of two teeth in an orthodontic brace treatment. The device 100 substantially shortens the time duration of treatment. It also provides accurate and precise historical data of the wire 110 tension allowing the medical practitioner to ease the examination procedure. Further, the device 100 reduces the alignment period of the treatment. Also, the device 100 has a lesser complexity in operation.

[0027] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description.

They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the present invention and its practical application, and to thereby enable others skilled in the art to best utilise the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omissions and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such omissions and substitutions are intended to cover the application or implementation without departing from the scope of the claims of the present invention.

We Claim:

1. A device 100 for measuring tension in a wire 110 of an orthodontic brace 200, the wire 110 is having a closed circumference and capable of being winded around brackets 210 of two teeth, the device 100 comprising:

an anchoring member 120 having a first end 120a attachable with the wire 110 in a winding position and a second end 120b attachable with a holding portion 130 of the device 100, the holding portion 130 is for holding and gripping the device 100; and

a display 140

wherein the device 100 upon pulling the wire 110 by anchoring the anchoring member 120, measures the tension exerted by the wire 110 between the teeth and displays the measured data on the display 140.

2. The device 100 as claimed in claim 1 wherein the anchoring member 120 and the display 140 are integral to the device 100.

3. The device 100 as claimed in claim 1 wherein the anchoring member 120 is an elongated member having a hookable portion configured on the first end 120a for anchoring the device 100 with the wire 110.

4. The device 100 as claimed in claim 1, wherein the second end 120b of the anchoring member 120 is connected pivotally and detachably with the holding portion 130 to provide enough degree of freedom for the anchoring member 120.

Dated this June 05, 2019

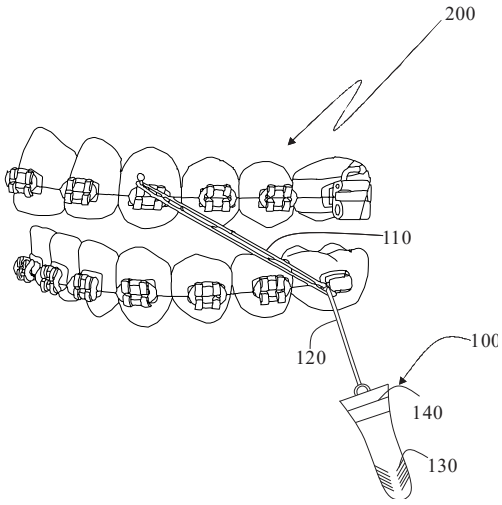
Suneet Baliram Sabale
(Agent for Applicant)

Abstract

Title: A device for measuring tension in a wire of an orthodontic brace.

The present invention is to provide a device 100 for measuring tension in a wire 110 of an orthodontic brace 200. The wire 110 is having a closed circumference and capable of being wind in a winding position around brackets 210 of two teeth. The device 100 includes an anchoring member 120, a holding portion 130 and a display 140. The anchoring member 120 is having a first end 120a attachable with the wire 110 in the winding position and a second end 120b attachable with the holding portion 130 of the device 100. The device 100 upon pulling the wire 110 by anchoring the anchoring member 120 along with its length, measures the tension exerted by the wire 110 on the teeth and displays the measured data on the display 140 of the device 100.

Figure 1



FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A process for preparing 2-chloro-n-{[4-(pyrimidin-2-ylsulfamoyl)phenyl] carbamothioyl} benzamide and the pharmaceutical utility thereof"

APPLICANT

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to a novel benzamide compound. More particularly, the present invention relates to a process for preparing 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl) phenyl] carbamothioyl} benzamide and the anti-inflammatory activitythereof.

BACKGROUND OF THE INVENTION

Two basic moiety i.e. thiourea and sulfonamide which encompasses continuously absorbed attention of the medicinal chemists in view of their intense range in biological activities such as anti-inflammatory and antimicrobial [A.P. Keche, G.D. Hatnapure, R.H. Tale, A.H. Rodge, S.S. Birajdar, V.M. Kamble, A novel pyrimidine derivatives with aryl urea, thiourea and sulfonamide moieties: synthesis, anti-inflammatory and antimicrobial evaluation, Bioorg. Med. Chem. Lett. 22(2012), 3445-3448].

Mahadevi et al. [Mohammad Mahdavi et al. Synthesis, biological evaluation and docking study of 3-aroyl-1-(4-sulfamoylphenyl)thiourea derivatives as 15-lipoxygenase inhibitors European Journal of Medicinal Chemistry, 82 (2014) 308-313] seems to be the closest prior art which combines thiourea and sulfonamide moiety in order to form the thiourea derivatives [3-aroyl-1-(4-sulfamoylphenyl)thiourea] as an potent anti-oxidant compound. This literature also addresses that thiourea derivatives are employed as anti-inflammatory and anti-microbial anti-malarial, anti-tumoral, pesticidal and anti-cancer agents and sulfonamides comprise a significant class of drugs with diverse biological properties such as anti-microbial anti-cancer, anti-inflammatory, and anti-viral activitiesas well as HIV protease inhibitors.

Drawbacks associated with Mahadevi et al.:

i) Yield of the intermediate compound (benzoyl isothiocyanate derivative) is less which is found by the present inventors;

ii) the yield of the final compound is comparatively less i.e. not more than 80%; &

iii) This document doesn't suggest the anti-inflammatory activity of final compound [3-aroyl-1-(4-sulfamoylphenyl)thiourea derivatives].

Present invention provides an improved process that results the appreciable yield of the intermediate & final compound and provides a novel anti-inflammatory compound and the formulation.

OBJECTIVE OF THE INVENTION

It is object of the invention is to provide a process for preparing substituted benzamide compound using a novel reactant 4-amino-N-pyrimidin-2-ylbenzenesulfonamide.

It is another object of the invention is to provide a process for preparing 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl) phenyl] carbamothioyl} benzamide with better yield.

It is yet another object of the invention is to provide a process for preparing the intermediate compound (2-chloro benzoyl isothiocyanate) with better yield.

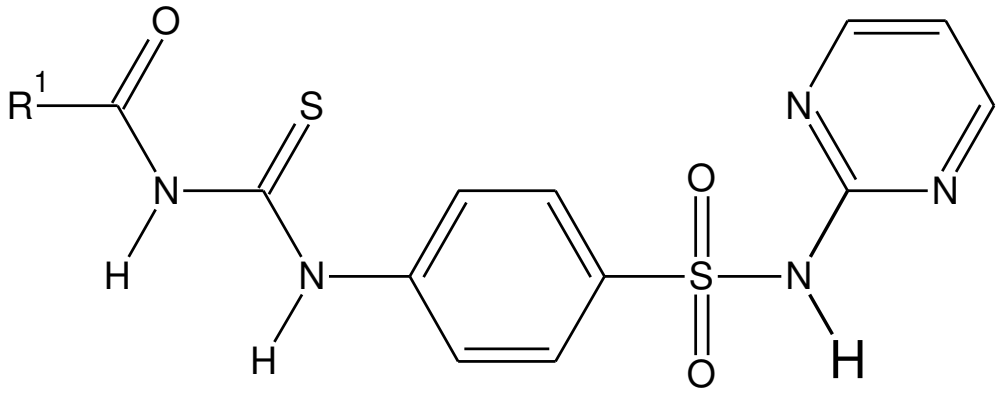
It is yet another object of the invention is to provide a simple & cost effective process for preparing substituted benzamide compound.

It is yet another object of the invention is to provide a novel anti-inflammatory compound.

It is further object of the invention is to provide an anti-inflammatory formulation comprising 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl) phenyl] carbamothioyl} benzamide.

SUMMARY OF THE INVENTION

According to one aspect of the invention there is provided a process for preparing the compound of Formula I



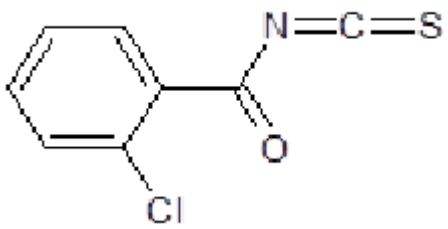
Formula I

wherein,

R_1 is selected from a group consisting of hydrogen, chloro group, nitro group or fluoro group,

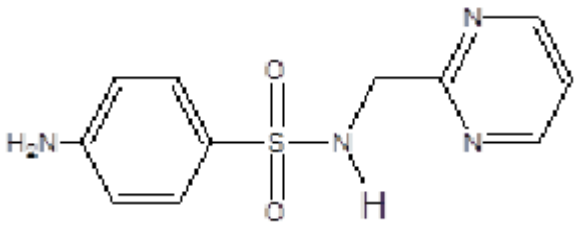
the said process comprising the steps of

i) preparing a compound of Formula II by adding 2-chloro benzoyl chloride, ammonium thiocyanate and acetone and subjecting the same for reflux at 50°C for 40 to 60 minute;



(Formula II)

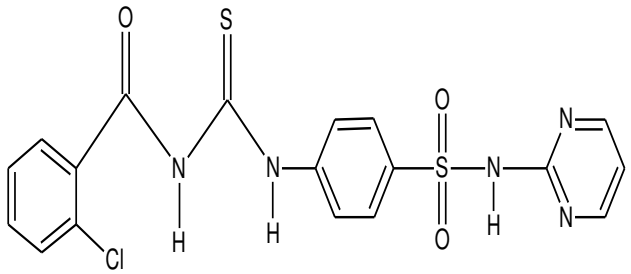
ii) adding the compound of Formula II as obtained in step (i) to a compound of Formula III and subjecting the same for reflux at 50°C for 40 to 60 minute



Formula III

wherein the molar ratio of Formula II and Formula III is 2:4.

According to second aspect of the invention there is provided an anti-inflammatory compound having a following structure



According to third aspect of the invention there is provided an anti-inflammatory formulation comprises of the compound of Formula I and a pharmaceutical acceptable excipient and I.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates FTIR spectra of the developed compound (2c) in accordance with the present invention;

Figure 2 illustrates NMR spectra of the developed compound (2c) in accordance with present invention;

Figure 3 illustrates Mass spectra of the developed compound (2c) in accordance with present invention;

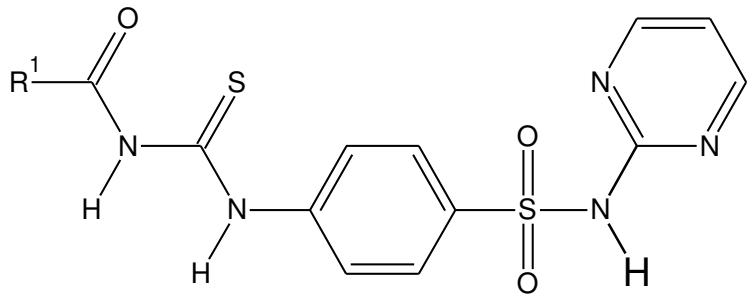
Figure 4 illustrates the anti-inflammatory receptor docking representation wherein 4a shows the docking poses of the developed compound (2c) &4b shows 2D-representation of docking poses of the developed compound (2c) in accordance with the present invention; &

Figure 5 illustrates comparative in-vivo anti-inflammatory data in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides an improved process for preparing the compound of Formula I



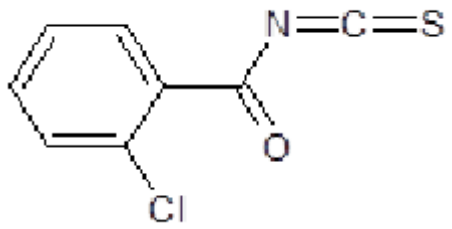
Formula I

wherein,

Wherein R_1 is selected from a group consisting of hydrogen, chloro group, nitro group or fluoro group,

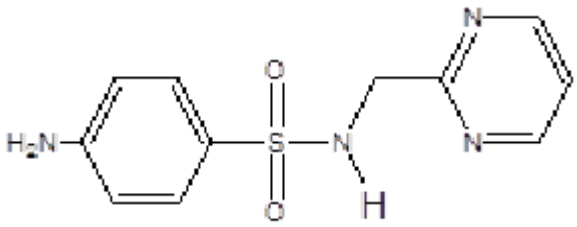
the said process comprising the steps of

i) preparing substituted benzoyl isothiocyanate compound (Formula II which is an intermediate compound) by adding 2-chloro benzoyl chloride, ammonium thiocyanate and acetone and subjecting the same for reflux at 50°C for 40 to 60 min;



(Formula II)

ii) adding the compound (Formula II) as obtained in step (i) to Formula III and subjecting the same for reflux at 50°C for 40 to 60 min



Formula III

In preferred embodiment of the invention, the molar ratio of the aroyl compound and ammonium thiocyanate and acetone in step (i) is1:1:2.

In preferred embodiment of the invention, the molar ratio of Formula II and Formula III in step (ii) is 2:4.

In an embodiment of the invention, the intermediate compound (Formula II) is selected from group consisting of 2-chloro benzoyl isothiocyanate, 4-Nitro benzoyl

isothiocyanate, 4-chloro benzoyl isothiocyanate, 4-methoxy benzoyl isothiocyanate, or dichloro (isothiocyanatocarbonyl) sulfanium.

In preferred embodiment, the intermediate compound (Formula II) is 2-chloro benzoyl isothiocyanate.

The compound of Formula (III) is 4-amino-N-pyrimidin-2-ylbenzenesulfonamide.

The present invention provides an oral anti-inflammatory formulation comprising the compound of Formula (I) and pharmaceutical acceptable excipients.

The pharmaceutical acceptable excipient according to present invention is selected from a group consisting of suitable diluent, binder, glident, lubricating agent or a combination thereof.

In preferred embodiment, the formulation is tablet.

In preferred embodiment, the diluent is anhydrous lactose.

In preferred embodiment, the binder is microcrystalline cellulose.

In preferred embodiment, the glidant is fumed silica.

In preferred embodiment, the lubricating agent is magnesium stearate NF/EP/JP.

The invention is now illustrated by non-limiting examples:

Example 1

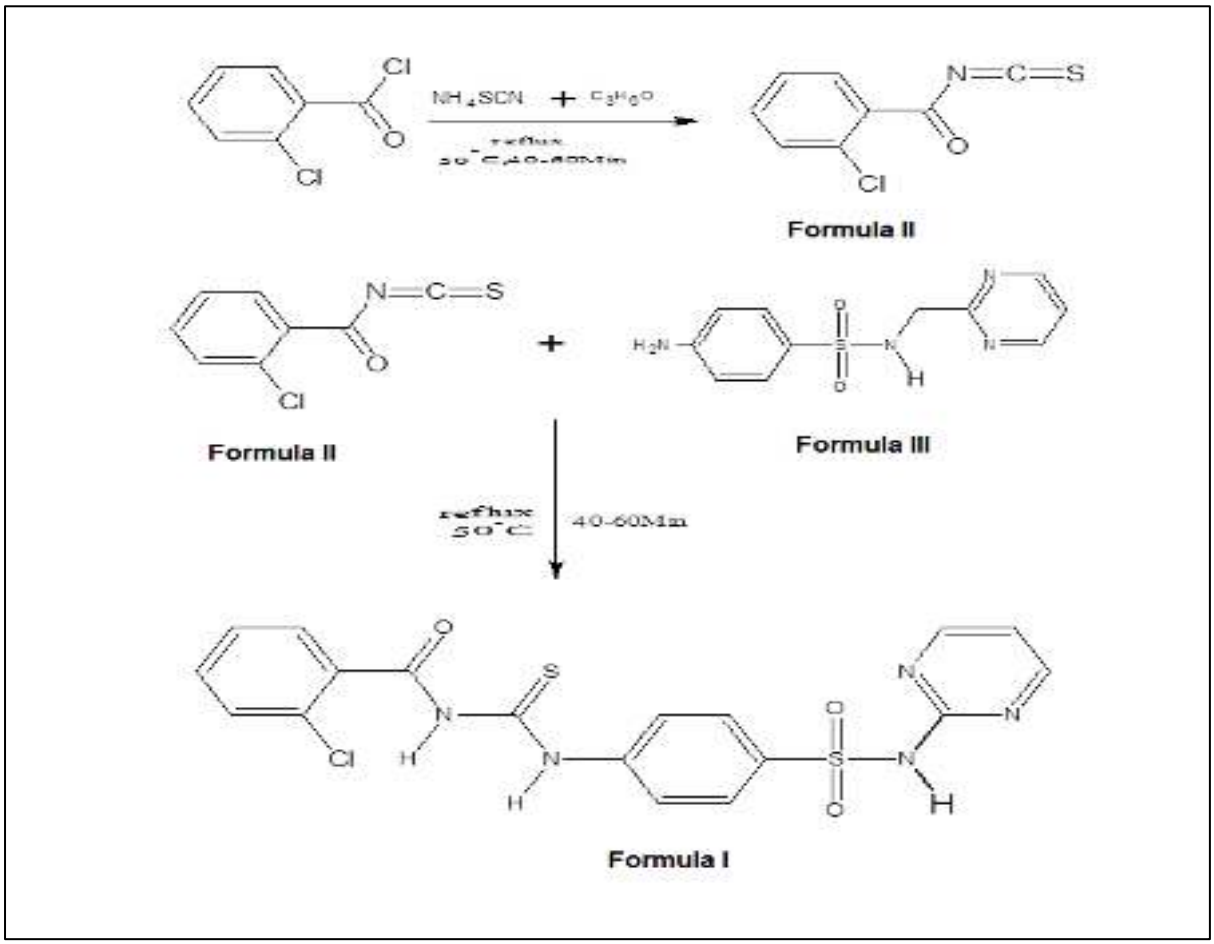
Materials:

2-chloro benzoyl chloride, ammonium thiocyanate and acetone were purchased from Research laboratory, Mumbai.4-Nitro benzoyl chloride, 4-chloro benzoyl chloride were purchased from MARCK laboratory, Mumbai and the 4-methoxy benzoyl chloride, Dichloro (isothiocyanatocarbonyl) sulfanium were purchased from S.D Fine-chem. limited, Mumbai. The chemical required for TLC mobile phase such as

Toluene – Acetic acid was issued from Research Laboratory of Rajarambapu college of pharmacy, kasegaon. In addition, some other chemical required for animal activity study such as CMC and Carrageenan wascollectedfrom the same research laboratory.

Preparation of substituted benzamide compound:

Scheme:



Method:

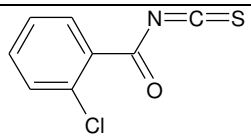
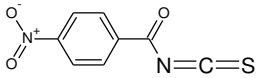
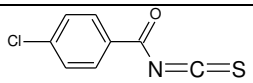
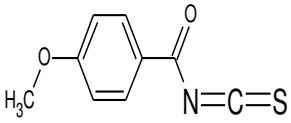
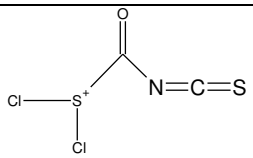
<u>i) Preparation of intermediate compound (substituted benzoyl isothiocyanate compound):</u>

2-chloro benzoyl chloride, ammonium thiocyanate and acetone in a molar ratio of 1:1:2 were added in 500 mL of round bottom flaskand then the said mixture was

subjected for reflux at 50°C for 40 to 60 min to obtain 2-chloro benzoyl isothiocyanate.

Similarly, 4-Nitro benzoyl isothiocyanate, 4-chloro benzoyl isothiocyanate, 4-methoxy benzoyl isothiocyanate, or dichloro (isothiocyanatocarbonyl) sulfanium were prepared.

TABLE 1: Characterization data of Intermediate compound (benzoyl isothiocyanate compound)

INTERMEDIATE NAME	STRUCTURE	MELTING POINT	Percentage Yield (% Yield)
2-chloro benzoyl isothiocyanate		198-210^{0}c	91.20%
4-Nitro benzoyl isothiocyanate		170-180^{0}c	90.75%
4-chloro benzoyl isothiocyanate		185-210^{0}c	65.96%
4-methoxy benzoyl isothiocyanate		150-170^{0}c	69.52%
Dichloro (isothiocyanatocarbonyl) sulfanium		120-130^{0}c	69.45%

The maximum yield of the intermediate compound was found for 2-chloro benzoyl isothiocyanate (91.20%).

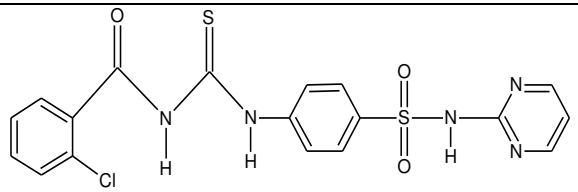
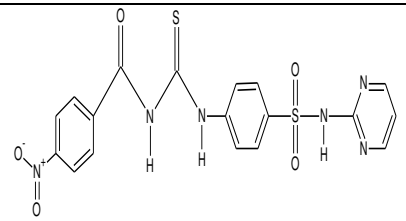
ii) Preparation of final compound:

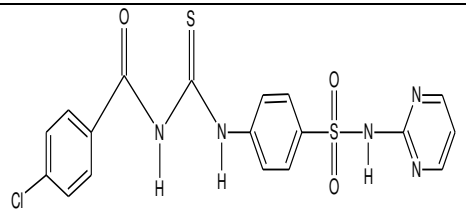
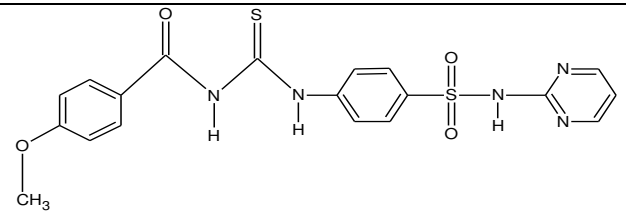
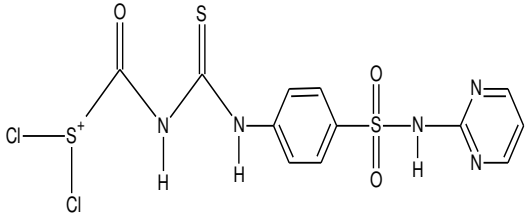
2-chloro benzoyl isothiocyanate (primary reactant) and 4-Amino-N-pyrimidin-2-ylbenzenesulfonamide (secondary reactant) in a molar ratio of 2:4 were added in500 mL of round bottom flask and the said mixture was then subjected for reflux at 50°C for 40 to 60 min to obtain 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl)

phenyl] carbamothioyl} benzamide (compound 2c). The compound (2C) was further purified by the chromatography and re-crystallization technique. The purity of synthesized compound (2C) was checked by TLC using the mobile phase Toluene – Acetic acid (7:3).

Similarly, compound 2c-1, 2c-2, 2c-3, 2c-4 was prepared by changing the primary reactant.

TABLE 2: Characterization data of final compound

COMPOUND	STRUCTURE	Primary reactant	Secondary reactant	Melting Point	Percentage Yield (% Yield)
2c		2-chloro benzoyl isothiocyanate	4-Amino-N-pyrimidin-2-ylbenzenesulfonamide	200-210^{0}c	97.75%
2c-1		4-Nitro benzoyl isothiocyanate		203-205^{0}c	97.00%

2c-2		4-chloro benzoyl isothiocyanate		199-205^{0}c	68.96%
2c-3		4-methoxy benzoyl isothiocyanate		200-210^{0}c	70.60%
2c-4		Dichloro (isothiocyanatocarbonyl) sulfanium		180-200^{0}c	72.52%

Comparative example:

Preparation of intermediate compound (2-chloro benzoyl isothiocyanate):

2-chloro benzoyl chloride, ammonium thiocyanate and acetone in a molar ratio of 1:1:2 were added in 500 mL of round bottom flask and then the said mixture was subjected for reflux at 50°C for 10-20 min to obtain 2-chloro benzoyl isothiocyanate. The yield of the intermediate was found to be 44.85%.

Preparation of compound 2c:

2-chloro benzoyl isothiocyanate (primary reactant) and 4-Amino-N-pyrimidin-2-ylbenzenesulfonamide (secondary reactant) in a molar ratio of 2:2 or 2:3 were added in500 mL of round bottom flask and the said mixture was then subjected for reflux at 50°C for 40-60 min to obtain 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl) phenyl] carbamothioyl} benzamide (compound 2c). The yield of compound 2c using the molar ratio 2:2 and 2:3 is 48.35% and 50.10% respectively.

Characterization of compound 2c (2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl) phenyl] carbamothioyl} benzamide):

IR Spectrum IR (KBr): 2938, 1691, 1531, 1438, 1164, 835 cm^{-1} (Figure 1).

NMR Spectrum: ^{1}H NMR (400 MHz, DMSO-d6): 12.71 (s, 1H, NH), 11.95 (s, 1H, NH), 8.43,8.41,8.17 (t, J ¼ 7.7, 1.2 Hz, 2H, H2, H6), 7.96,7.52,7.50 (d, J ¼ 8.5 Hz, 2H, sulfamoylphenyl), 7.47 (dd, J ¼ 8.5 Hz, 2H, sulfamoylphenyl), 7.40 (s, 1H, NH2), 6.94(dd, J ¼ 8.5 Hz, 2H, sulfamoylphenyl) (Figure 2).

MASS Spectrum: MS (70 eV): m/ z ¼ 391.89 [Mþ_]. Anal. Calcd for $C_{18}H_{14}ClNO_3S_2$: C, 55.17; H, 3.6; N, 3.57. Found: C, 67.91; H, 7.44; N, 18.89 (Figure 3).

ANTI-INFLAMMATORY RECEPTOR DOCKING RESULTS:

Molecular docking Software: - Vlife QSAR 4.6 Version

Receptors used for Molecular Docking: lipoxygenas-3 soybean complex (PDB Code- IIK3)

Table 3: Summary of Molecular docking

Sr.No	Molecule Name	Final Energy	Final GRMS	Dock score
1	2c	74.62	0.9415	-70.00
2	2c-1	68.86	0.8248	-67.33
3	2c-2	46.57	0.6439	-53.95
4	2c-3	83.19	1.1112	-50.19
5	2c-4	47.71	1.0858	-49.90

Table 3 shows that the dock score of compound 2c was-70.00 shown minimum dock score than other compounds. The docking score of compound 2c was compared to the literature [S. Suresh, Sethu. Gunasekaran, and Shanmugam Srinivasan, Quantum Chemical Calculations and MolecularcDocking Studies of Some NSAID Drugs (Aceclofenac, Salicylic Acid, and Piroxicam) as 1PGE Inhibitors, Inter. J. Spectro. 1(2016), 1-7] indicating that the designed compounds have good binding affinity to receptor of **lipoxygenas-3 soybean complex** (**PDB Code- IIK3**). The pose obtained by docking results is givenin Figure 4a which shows the interaction between ligand and receptor. All designed compound adopt a very similar conformation at lipoxygenas-3 soybean complex binding pocket, showing vander waals binding with amino acid of GLY559A,ASN556A, LYS21A, ASP25A, VAL28A, GLU197A, ARG260A, ASP255A, LYS278A, VAL256A, LEU 503A,LEU560A. Which shown by 2D representation diagram (Figure 4b).

Table 4: Interaction between compound 2c with Amino Acid

Amino acid	Atom of Ligand	Type of Interaction
ASP 25 A	5N	H-Bond Interaction

GLY 559 A	27C	VDW Interaction
ASN 556 A	28C	VDW Interaction
LYS 21 A	5N	VDW Interaction
VAL 26 A	16C,17C	VDW Interaction
GLU 197 A	8C	VDW Interaction
ARG 260 A	7C	VDW Interaction
ASP 255 A	25C	VDW Interaction
LYS 278 A	1N	VDW Interaction
VAL 256 A	25C,26C	VDW Interaction
LEU 563 A	25C,26C	VDW Interaction
LEU 560 A	26C,27C,28C	VDW Interaction

ANIMAL STUDIES:

Acute Toxicity Study:

Animals:

Animals Wistar rats (150–200 g) and Swiss albino mice (18–30 g) of either sex were used in this study were purchased from the Animal House of the National Institute of Biociences, Pune. The animals were maintained under standard laboratory conditions (12 h light/dark cycles at 22 ± 2◦C) and fed standard rodent pellets (National Institute of Biociences, Pune, Maharashtra) and water. The protocol was approved by the Committee for the purpose of control and supervision of experiments on animals (Reg.No. 1290/PO/Re/S/09/CPCSEA 19/01/17).

Acute Toxicity Study:

Acute Oral Toxicity- Up and Down procedure: The test procedure described as per the OECD guideline required to estimate the acute oral toxicity of a new chemical compound (such as herein 2c) was adopted. *[G. Mariappan, L. Sutharson, K. Roy, D. Kumar, B. Hazarika and S. Saha, Antidiabetic and Toxicity Studies of Some NovelOxazolone Derivatives, Inter. j. pharma. chem.sci., 2(2013), 844-850]*. The acute toxicity test consists of a single ordered dose progression in which animals dosed, once at a time at a minimum of 48-hour intervals. All animals fasted overnight before starting the dosing and the dosing was been initiated with a dose of

175mg/kg. The test compound 2c was orally administered in the form of suspension with 0.5% CMC. The first animal received 175mg/kg b.w. Dose and then doses were increased by factor of 3.2 up to 2000mg/kg b.w. The animals were observed individually during the first 30 min after dosing, periodically during the first 24 hours (with special attention given during the first 4 hours) and daily thereafter, for a total 14 days. All the signs of toxicity are to be record during the period. It was confirmed that this synthesized 2C compound was safe up to 1500mg/kg b.w.

<u>*IN-VIVO* ANTI-INFLAMMATORY ACTIVITY:</u>

Carrageenan-induced paw edema method: Increase in the rat hind paw lin-ear circumference induced by plantar injection of the phlogistic agent used for measurement of acute inflammation [Yulong Sun, Jia Liu, Tao Sun, Xiaoyuan Zhang, Jia Yao, Ming Kai,Xianxing Jiang, Rui Wang "Anti-cancer small molecule JP-8g exhibits potent in vivo anti-inflammatory activity" Sci.Rep 4(2014) 1-5]. The animals were divided into three groups of each as control, standard and test (compound 2c). All these groups are to be kipped for fasting overnight and only allowed water ad libitum. The test rats (n = 6) were received the synthesized compound 2c at dose 20 mg/kg, oral. While the standard rats ware received aceclofenac (10 mg/kg,oral). One hour after treatment, 0.1 ml of carrageenan (1%, w/v in normal saline) administered into the sub-plantar tissue of the right hind paw of both test and standard groups. The linear paw circumference measured for all the animals before starting the dosing procedures such as before injecting the phlogistic agent (carrageenan). After injecting, the carrageenan linear paw circumference was measured for the three groups such control, test and standard. The groups linear paw circumference was recorded after an interval of every 30 minutes for each group up to 4 hours by using the cotton thread method [C.K. Khatri, K.S. Indalkar, C.R. Patil, S.N. Goyal, G.U. Chaturbhuj,*"Novel 2-phenyl-4, 5, 6, 7tetrahydro[b]benzothiophene analogues as selective COX-2 inhibitors: Design, synthesis, anti-inflammatory evaluation, and molecular docking studies." Bio Med. Chem Let.27 (2017)1721-1726]*. Anti-inflammatory activity was determined by analyzing the reduction in edema size and calculating % inhibition of edema. A mean reduction in edema when compared with control and an increase percentage inhibition in the treated groups is an indication of anti-inflammatory activity (Figure 5).

Table 5. Comparative % inhibition

Sr.No	Compound	% Rise in Paw Volume						
		0 Min	30 Min	60 Min	90 Min	120 Min	150 Min	180 Min
1.	Control	0.0	48.97	51.37	53.92	60.65	72.12	48.95
2.	Standard (aceclofenac)	0.0	26.89	26.99	28.21	41.95	60.99	43.36
3.	Compound (2c)	0.0	22.09	25.57	32.60	40.67	58.17	42.06

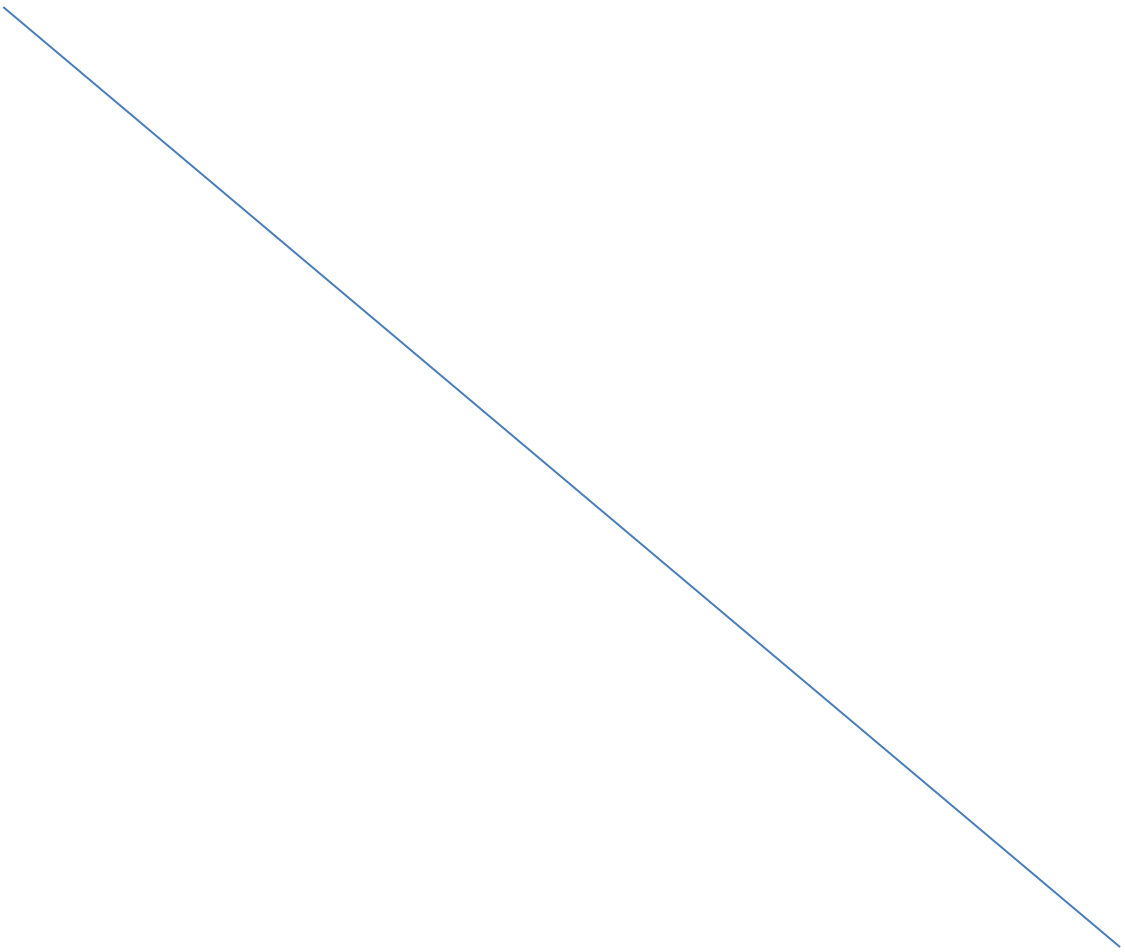
The results are expressed as mean ± SEM (n = 6). The statistical significance of difference across the groups was determined using ANOVA followed by Dunnett's multiple comparisons test. Table 5 clearly shows the similar results between aceclofenac and compound 2c.

**** P < 0.0001 vs. control (one-way ANOVA, Dunnett's multiple comparisons).

Findings of the invention:

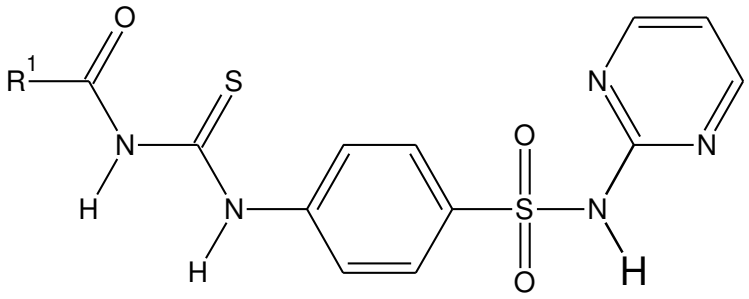
1) In order to get the better yield of the intermediate compound, 40-60 minutes as the duration of heating is a critical step;
2) In order to get the better yield of the final compound, the molar ratio 2:4 of Formula II and Formula III is a critical step;
3) 4-Amino-N-pyrimidin-2-ylbenzenesulfonamide (Formula III) which is used first time as a reactant; &
4) The present invention results a novel anti-inflammatory compound i.e. 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl) phenyl] carbamothioyl} benzamide.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been present for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which departs from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.



I Claim,

1. A process for preparing the compound of Formula I



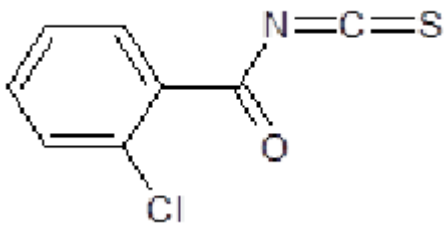
Formula I

wherein,

Wherein R_1 is selected from a group consisting of hydrogen, chloro group, nitro group or fluoro group,

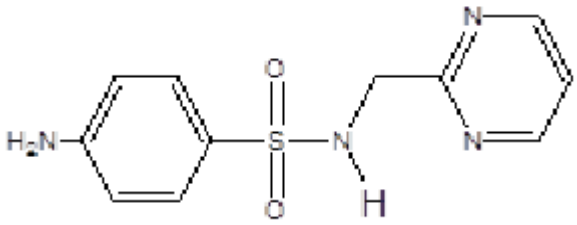
the said process comprising the steps of

i) preparing a compound of Formula II by adding 2-chloro benzoyl chloride, ammonium thiocyanate and acetone and subjecting the same for reflux at 50°C for 40 to 60 minute;



(Formula II)

ii) adding the compound of Formula II as obtained in step (i) to a compound of Formula III and subjecting the same for reflux at 50°C for 40 to 60 minute



Formula III

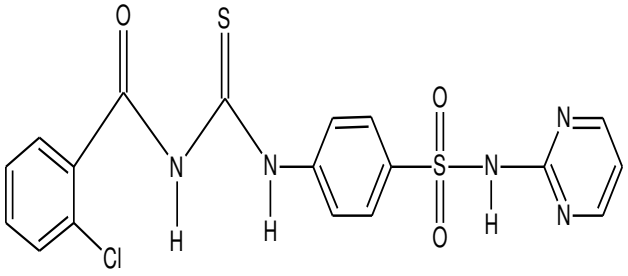
wherein the molar ratio of Formula II and Formula III is 2:4.

2. The process as claimed in claim 1, wherein the molar ratio of 2-chloro benzoyl chloride, ammonium thiocyanate and acetone is 1:1:2.

3. The process as claimed in claim 1, wherein the compound of Formula III is 4-Amino-N-pyrimidin-2-ylbenzenesulfonamide.

4. The process as claimed in claim 1, wherein the compound of Formula I is 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl)phenyl] carbamothioyl} benzamide.

5. An anti-inflammatory compound having following structure



6. The compound as claimed in claim 5 is 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl)phenyl] carbamothioyl} benzamide.

7. An anti-inflammatory formulation comprises of the compound as claimed in claim 5 and a pharmaceutical acceptable excipient.

8. The formulation as claimed in claim 7, wherein the excipient is selected from a group consisting of diluent, binder, glident, lubricating agent or a combination thereof.

9. The formulation as claimed in claim 7 is tablet.

10. The formulation as claimed in claim 7 is for oral administration.

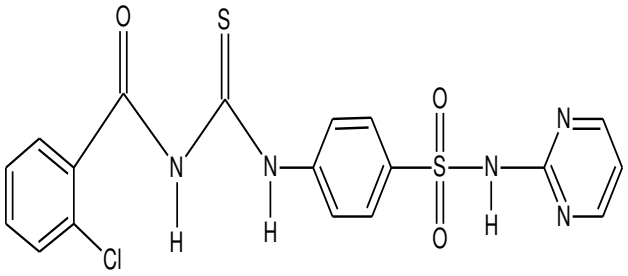
Dated this 3rd day of January, 2020

Arghya Ashis Roy
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant

ABSTRACT

"A process for preparing 2-chloro-n-{[4-(pyrimidin-2-ylsulfamoyl)phenyl] carbamothioyl} benzamide and the pharmaceutical utility thereof"

Disclosed is a process for preparing 2-chloro-N-{[4-(pyrimidin-2-ylsulfamoyl)phenyl] carbamothioyl} benzamide (compound 2c).



Compound 2c

FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A PACKAGING COMPOSITE AND THE PROCESS FOR PREPARING SUCH COMPOSITE"

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to a packaging system. More particularly, the present invention relates to a packaging composite comprises of a special combination of polymeric matrix and metal oxide nano-filler and also relates to a process for preparing such composite.

BACKGROUND OF THE INVENTION

Traditionally, food packaged in a material, which has passive barriers designed to delay the adverse effect of the environment. In the industry, food product is packed using a variety of conventional packaging materials such as trays, bags, boxes, cans, cartons, sheets, pallets and wrappers made of plastic, metal, ceramic, glass and paper. There is a growing need to protect stored food using suitable packaging material which serves to be safe under its intended conditions of use and should be inert, cheap to produce, light weight, easily degradable, reusable, able to persist in extreme conditions during processing, storage, transport conditions and resistant to physical abuse. The packaging expected to protect food from dirt or dust, oxygen, light, pathogenic, food spoiling microorganisms, moisture as well as other destructive and harmful substances. However, in addition to performing the above tasks expected from a packaging material advanced packaging should inhibit the microorganisms responsible for food spoilage and poisoning.

In this context, a single packaging material cannot offer all the vital properties therefore; it can achieve by merging different packaging materials into a multi-layer packaging film. Multi-layer film is the combination of two or more polymers and possibly metallic foil, paper etc. into a composite to provide functional, shielding and decorative properties. Such packaging are used to provide customized properties of each polymer in combination, which includes barrier (to light, moisture and gases) properties, seal ability, chemical resistance, strength, rigidity and stiffness that would otherwise be very difficult to achieve with a single polymer. However, multi-layer film packaging has

created a global environmental issue related to its waste. Since, multi-layer films have number of components; it is very difficult to recycle and hence must have separated before recycling.

Despite the numerous advantages offered by polymers in food packaging, the present scenario of food industry demands the path breaking approach where the polymers not only perform the passive role of food packaging, but also they must actively participate in food stability by killing the microbes responsible for spoilage, controlling migration of gases and moisture into food. The need also exists in the art is to provide an approach that could protect the food for a longer period.

A non-patent literature (*Silvestre C, Duraccio D & Cimmino S (2011) Food packaging based on polymer nanomaterials. Prog. Polym. Sci., 36: 1766-1782*) reveals that that any material intended for food contact must be suitable, inactive and able to avoid the substances which can be transferred to products in quantities harming human health or bringing about an unacceptable change in food composition or properties. Although, the existing packaging composite have emerged as an attractive alternative to preserve food quality, extend shelf-life, and prevent microbial spoilage, it allows direct exposure of nanomaterials to humans due to leakage from packaging material into the food substance and the food substance is therefore not at all safe in such existing packaging composite. Therefore the need exists in the art is to provide a packaging composite with no leakage problem.

In another non-patent literature [*Pawar, Jayant & Kunchiraman, Bipinraj & Singh, E. & Nikam, Nikhil. (2012). Determination and Partial Characterization of Antimicrobial Material of Pseudomonas aeruginosa Isolated from Milk. Research & Reviews: A Journal of Food Science & Technology. 1. 16-23*], owing to rapid increase of resistance in pathogenic and food spoiling microorganisms for numerous traditional antimicrobials, it is mandatory to find out suitable alternatives. Inorganic nanoparticles are found to be more advantageous due to

their easy dispersion into the polymer matrix to form functional antimicrobial packaging nanocomposite which may remain as biocidal material for a long period of time *(Duncan, T. V. (2011). Applications of nanotechnology in food packaging and food safety: barrier materials, antimicrobials and sensors. Journal of colloid and interface science, 363(1), 1-24.).* Furthermore, lesser amount of nano-sized antimicrobial materials in polymer evinces greater efficiency against microorganisms as compared to large quantity of micro-sized counterparts (Armentano, I., Arciola, C. R., Fortunati, E., Ferrari, D., Mattioli, S., Amoroso, C. F., ... & Visai, L. (2014). The interaction of bacteria with engineered nanostructured polymeric materials: a review. *The Scientific World Journal*, *2014*). Carbon nanofillers like CNTs, Graphene, Graphene Oxide etc. has used in many packaging composites to improve the polymer properties such as antimicrobial, physical, mechanical, thermal and electrical properties, which makes it attractive alternatives for traditional fillers. For instance, MWCNTs (multi-walled carbon nanotubes) were used as an antimicrobial agent in the hyperbranched polyurethane (HBPU) (Yadav, S. K., Mahapatra, S. S., & Cho, J. W. (2012). Synthesis of mechanically robust antimicrobial nanocomposites by click coupling of hyperbranched polyurethane and carbon nanotubes. *Polymer*, *53*(10), 2023-2031.). But the biggest disadvantages, for the use of carbon nanofillers in such polymers, are its intrinsic zero band-gap energy and low solubility in organic and aqueous solvents (Jamróz, E., Kulawik, P., & Kopel, P. (2019). The effect of nanofillers on the functional properties of biopolymer-based films: A review. *Polymers*, *11*(4), 675.), which leads to create problem in uniform distribution and in contact inhibition of the microorganisms present in packet.

Therefore, there is a need to overcome the drawback of the existing technologies.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a packaging composite.

It is another objective of the present invention is to provide a packaging composite which could protect the food and other goods for a longer period.

It is yet another objective of the present invention is to provide a packaging composite that could provide broad-spectrum antagonistic activity against bacteria, fungus, algae etc.

It is yet another objective of the invention is to provide a packaging system which could protect the food from a wide variety of microorganisms in particular *Schizosaccharomyces pombe*, *Torulaspora delbrueckii, Debaryomyces hansenii, Candida krusei, Staphylococcus aureus*, *Bacillus subtilis, Listeria monocytogenes or Serratia marcescens.*

It is yet another objective of the invention is to provide a packaging system which could protect the different type of food in particular, a solid food, a semi-solid food or a liquid food.

It is yet another objective of the invention is to provide a packaging composite which could solve the existing leakage problem.

It is yet another objective of the invention is to provide a packaging composite wherein the metal oxide nano-particle is non-carbon in origin, biocompatible and safe.

It is yet another objective of the invention is to provide a process for preparing the composite.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided a packaging composite comprises of

a first layer, a second layer and a third layer, the second layer being laminated by the third layer and the said laminated layer being positioned towards a substance placed inside the said composite;

wherein, the first layer is made up of polyethylene terephthalate;

the second layer is made up of ethylene-vinyl acetate;

the third layer is made up of metal-oxide nanoparticles;

wherein the amount of ethylene-vinyl acetate is 34 % by weight;

the amount of polyethylene terephthalate is 44% by weight;

the amount of metal-oxide nanoparticles is 22% by weight.

According to another aspect of the invention, there is provided a process for preparing the composite, the said process comprising the steps of

i) preparing a film which comprises of an first layer and an second layer wherein the first layer being made up of polyethylene terephthalate and the second layer being made up of ethylene-vinyl acetate;

ii) spreading the metal oxide nanoparticles onto the second layer of said film of step (i);

iii) subjecting the product as obtained in step (ii) into a heating roller at 80-110°C;

iv) allowing the product as obtained in step (iii) to cool at room temperature for 2 hours;

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates the layered arrangement of the packaging composite (PET, EVA & MONs) in accordance with the present invention;

Figure 2 illustrates the surface image of PET-EVA-MON film by spray coating technique (2a), CBD technique (2b) and the surface image of PET-EVA-MON film by the spreading & heating technique (2c) in accordance with the present invention;

Figure 3 illustrates the FTIR spectra of the packaging composites wherein 3a is the control (PET & EVA), 3b test composite 1 (PET, EVA & Cu_2O); 3c is the test composite 2 (PET, EVA & ZnO) & 3d is the test composite 3 (PET, EVA & MgO_2) in accordance with the present invention;

Figure 4 illustrates the surface morphology of the packaging composites wherein 4a is the control (PET & EVA); 4b is test composite 1 (PET, EVA & Cu_2O); 4c is test composite 2 (PET, EVA & MgO_2) & 4d is test composite 3 (PET, EVA & ZnO) in accordance with the present invention;

Figure 5 is the SEM image of the packaging composites wherein Figure 5a is the Control (PET & EVA); 5b is the test composite 1 (PET, EVA & Cu_2O); 5c is the test composite 2 (PET, EVA & ZnO) & 5d is the test composite 3 (PET, EVA & MgO_2) in accordance with the present invention.

Figure 6 illustrates the UV-Vis transmittance spectra of the various packaging composites in accordance with the present invention; &

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Expression:

PET: polyethylene terephthalate;

EVA: ethylene-vinyl acetate;

"Packaging composite" herein is a system or a device or a tool or a mean to protect a substance (being placed inside the composite) from wide variety of microbes for instance *Schizosaccharomyces pombe, Torulaspora delbrueckii, Debaryomyces hansenii, Candida krusei, Staphylococcus aureus, Bacillus subtilis, Listeria monocytogenes or Serratia marcescens* for a longer duration in particular 8 days*;*

'MONs' or 'nano-fillers' or 'nano-particles' or 'nano-composite' herein is carbon free metal-oxide particles which is used to coat the PET-EVA film; &

'PET-EVA film' or a 'polymeric film' or 'polymer matrix' herein is a film having two layers i.e. first layer and second layer in which the first layer of the film is made up of polyethylene terephthalate (PET) and the second layer of the film is made up of ethylene-vinyl acetate (EVA).

As shown in Figure 1, the present invention provides a packaging composite which comprises of first layer, second layer & third layer. The second layer according to present invention is laminated by a third layer. The laminated layer according to the present invention comes into contact the substance being placed inside the composite. In an embodiment of the invention, the composite itself is a laminated film.

In preferred embodiment of the invention, the first layer is made up of polyethylene terephthalate while the second layer is made up of ethylene-vinyl acetate. The third layer is made up of carbon free metal-oxide nano particles which is biocompatible and safe.

In preferred embodiment, size of the metal oxide nanoparticles is 10-60nm.

In an embodiment of the invention, the metal oxide is selected from a group consisting of copper (I) oxide (Cu_2O), zinc oxide (ZnO) and magnesium peroxide (MgO_2).

In preferred embodiment of the invention, the metal oxide is copper (I) oxide (Cu_2O).

In preferred embodiment of the invention, the amount of EVA is 34% by weight while the amount of PET is 44% by weight and the amount of MONs is 22% by weight.

As the metal oxide is herein carbon free, the nano-filler particles would attain the recurring resistance and occurrence of resistant strains is therefore minimized in present invention.

The mass density (σ) of the metal-oxide particles according to the present invention is 125.

As the coating of the PET-EVA film by the nano-fillers according to present invention is done through a lamination technique (spreading and heatng), the present invention reduces the chance of leakage.

In an embodiment of the invention, the substance being placed inside the packaging composite for protection is food products or other goods.

In preferred embodiment of the invention, the substance is a food product.

In an embodiment of the invention, the food product is selected from a group consisting of solid, semi-solid or liquid.

In an embodiment of the invention, the liquid food product is milk.

In an embodiment of the invention, the substance is cement, cloths, or medicines.

The packaging composite according to present invention is prepared by a lamination technique, the process comprising the steps of:

i) preparing a film which comprises of an first layer and an second layer wherein the first layer being made up of polyethylene terephthalate and the second layer being made up of ethylene-vinyl acetate;

ii) spreading the metal oxide nanoparticles onto the said film as obtained in step (i);

iii) subjecting the product as obtained in step (ii) to a heating roller;

iv) allowing the product as obtained in step (iii) to cool at room temperature for 2 hours;

In preferred embodiment of the invention, thickness of the film in step (i) is 177.8 µm.

According to the present invention, the spreading (step ii) and the heating (step iii) together is called as “lamination technique”

In preferred embodiment of the invention, the temperature of the heating roller in step (iii) is 118-122°C. It may be noted that the properties like peel strength, tensile strength, cold crystallization and molecular orientation of the laminating film would be hampered if the temperature is above122°C. On the other hand, proper lamination would be peeled off if the temperature is below 118°C.

In preferred embodiment of the invention, the pressure in step (iii) is 10-20MPa.

In an embodiment, the present invention provides a food packaging system comprises the aforesaid composite for protection of the food product from various microorganisms.

In preferred embodiment of the invention, the microorganism is selected from a group consisting of *Schizosaccharomyces pombe, Torulaspora*

delbrueckii, Debaryomyces hansenii, Candida krusei, Staphylococcus aureus, Bacillus subtilis, Listeria monocytogenes or Serratia marcescens.

The invention is now illustrated by non-limiting examples:

Example 1:

The PET-EVA films was prepared as per the hot-pressing method as exemplified in *Zhong et al., Flexible PET/EVA-based piezoelectret generator for energy harvesting in harsh environments. Nano Energy, 2017, 37, 268-274* except the amount of PET and EVA.

The metal oxide nanoparticles of Cu_2O, ZnO & MgO_2 were prepared as per the semi-solvo thermal method as exemplified in *Jayant Pawar et al., Application of semi-solvo thermally synthesized zinc oxide (ZnO) nanoparticles in food technology and their characterization,* International Journal of Nanotechnology and Applications, Volume 11, Number 1 (2017), pp. 75-80.

Preparation of the packaging composite:

Formula A (Inventive formula)

Sr. No.	Ingredient	Amount (%wt)
1	PET (first layer)	44%
2	EVA (second layer)	34%
3	MONs: Cu_2O, ZnO or MgO_2 (third coating layer)	22%
		100%

Method: After preparing PET-EVA film using aforesaid quantity (177.8 µm as the thickness), the aforesaid MONs (50nm as the particle size) were spread onto that film and then the product was subjected into a heating roller at 80-110°C wherein the pressure is 10-20 MPa. The product thus obtained was allowed to cool at room temperature for 2 hours. In this method, mass density (σ) of the MON particles is 125.

Alternatively, other approaches were applied for coating of MON particles onto the PET-EVA film for instance spraying only (i.e. without the heating step) and chemical bath deposition (CBD) technique. However, it was observed that these coatings are easily deformed upon a slight friction. Also, uniform distribution was not found with these coatings (Figure 2a and 2b). Contrarily, uniform distribution with no distortion was observed with the spreading & heating (lamination) technique (Figure 2c).

Formula B (Comparative formula):

Sr. No.	Ingredient	Amount (%wt)
1	PET (first layer)	50.00%
2	EVA (second layer)	37.50%
3	MON: CU_2O, ZNO or MGO_2 (third coating layer)	12.50%
		100%

Comparative Method: After preparing PET-EVA film using aforesaid quantity (177.8 µm as the thickness), the aforesaid MONs (50nm as particle size) were spread onto that film and then the product was subjected into a heating roller

at 80-110°C wherein the pressure is 10-20 MPa. The product thus obtained was allowed to cool at room temperature for 2 hours. In this method, mass density (σ) of the MON particles is 62.5.

Evaluation of the packaging composites (Formula A & B):

i) Characterization studies:

As shown in Figure 3, the spectra of all PET-EVA-MONs films displayed characteristic peaks in the range of 3500 cm^{-1} - 450 cm^{-1}. The transmittance of the PET-EVA-MONs film decreased as compared to the control (PET-EVA films), which might be due to the interaction of MONs with the polymer matrix. It observed that the transmittance of PET-EVA film was more than the PET-EVA-MONs based film signifying the test films (PET-EVA-MONs) are more opaque when compared with PET-EVA film. The observation made of the control (PET-EVA) and PET-EVA-MONs films under stereoscopic microscope at low magnification, typically using light reflected from the surface of a film to know the uniform distribution of MONs over a PET-EVA film. The uniform distribution of MONs on PET-EVA films was observed under stereomicroscope (Labomed, CZM4) at 400 X magnification (Figure 4). The resultant composite (test composite 1, 2 & 3) showed increased surface roughness as compared to the Control (PET-EVA). The SEM images of PET-EVA-MONs film (test composite 1,2 & 3) also confirmed the distribution of MONs on the PET surface (Figure 5).

As shown in Figure 6, UV-spectra of the control (PET-EVA) and the test composites (PET-EVA-CU_2O or PET-EVA-ZNO or PET-EVA-MGO_2) were analyzed in which the opacity of the nano-composites were observed in the order of PET-EVA-Cu_2O > PET-EVA-ZnO > PET-EVA-MgO_2. In case of PET-EVA-Cu_2O film was found with lower transmittance value when compared with control film and other nano-composite films, which may due to its color and large particle size i.e. 50nm absorbs more visible light and does not allow more light to pass through the polymer nanocomposite. Therefore, the transmittance

of the nano-composite is inversely proportional to the concentration and uniform distribution of nanofillers onto the matrix, which would help in contact inhibition of microorganisms.

ii) Comparative microbial evaluation:

To determine the antimicrobial activity of the test composites (PET-EVA-MONs) for both the film A and B, yeasts species viz. *Schizosaccharomyces pombe, Torulaspora delbrueckii, Debaryomyces hansenii* and *Candida krusei* and bacterial species viz. *Staphylococcus aureus* and *Bacillus subtilis* (Gram positive), *Listeria monocytogenes* and *Serratia marcescens* (Gram negative) were selected and the results were tabulated as hereinbelow:

Table 1: Quantitative estimation of antifungal activity of PET/EVA/MONs films against food spoilage yeast cultures by cell count method

Yeast Cultures (CFU/mL)	Culture Control	Culture with normal film	PET/EVA/ ZnO		PET/EVA/Cu_2O		PET/EVA/MgO 2	
			Film A	Film B	Film A	Film B	Film A	Film B
Schizosaccharomyces pombe	1.489X10^8	1.421X10^8	4.68 X10^7	8.93 X10^7	2.14 X10^7	3.6 X10^7	5.1 X10^7	9.5 X10^7
Torulaspora delbrueckii	3.01 X10^7	3.76 X10^7	9.3 X10^6	1.8 X10^7	7.15 X10^6	1.4 X10^7	1.7 X10^7	2.1 X10^7
Debaryomyces hansenii	8.995 X10^7	8.840 X10^7	6.20 X10^6	3.14 X10^7	1.155 X10^6	5.565 X10^7	1.6 X10^7	3.1 X10^7
Candida krusei	5.945 X10^7	5.825 X10^7	9.845X 10^6	1.50 X10^7	7.15 X10^5	4.10X1 0^6	2.1X1 0^7	5.8 X10^7

Table 2: Quantitative estimation of antibacterial activity of PET/EVA/MONs films against food spoilage bacterial cultures by optical density method at 600 nm

Bacterial Cultures (CFU/mL)	Culture Control	Control (PET-EVA)	PET/EVA/ ZnO		PET/EVA/Cu_2O		PET/EVA/MgO 2	
			Film A	Film B	Film A	Film B	Film A	Film B
Staphylococcus aureus	0.42	0.41	0.19	0.32	0.15	0.28	0.28	0.39
Bacillus subtilis	0.63	0.60	0.18	0.37	0.16	0.35	0.38	0.53
Listeria monocytogenes	0.29	0.30	0.17	0.34	0.14	0.29	0.19	0.26
Serratia marcescens	0.56	0.59	0.21	0.38	0.17	0.36	0.32	0.51

Note: (a) Composition of Film A contains PET (44.44 %), EVA (33.33 %) and MONs (22.22 %); (b) Composition of Film B contains PET (50%), EVA (37.5%) and MONs (12.5%)

With regard to both anti-fungal (Table 1) and anti-bacterial (Table 2) activity, film A corresponding to PET-44%, EVA-34% & MON-22% showed the superior effect over film B (PET-50%, EVA-37.5% & MON-12.5%). It was also observed that the PET-EVA-Cu_2O films (A) showed better antibacterial effect against all model microorganisms compared to PET-EVA-ZnO and PET-EVA-MgO_2 films.

iii) Shelf life of the food product:

To understand the effect of PET-EVA-MONs on shelf life of perishable food product, the pasteurized milk was taken for study. The pasteurized milk was stored into the punnet made out of PET-EVA-MONs and same was tested for spoilage by considering parameters like titratable acidity, organoleptic properties (texture, colour, odour, taste etc.) and total microbial count etc.

Table 3: Evaluation of packaging films by determination of shelf life of milk

Packaging Films		PET/EVA/ ZnO		PET/EVA/Cu_2 O		PET/EVA/Mg O_2	
Test parameters	Incubation Time (Days)	Film A	Film B	Film A	Film B	Film A	Film B
Titratable Acidity (%)	4	0.140	0.960	0.135	0.925	0.540	0.953
	8	0.950	ND	0.910	ND	ND	ND
Organoleptic Test	4	Good	Spoiled	Good	Spoiled	Poor	Spoiled
	8	Spoile		Spoile		ND	ND

		d	ND	d	ND		
Total Microbial Count	4	+	++	+	++	++	++
	8	++	ND	++	ND	ND	ND

Indication: + : < 10 CFU/mL; ++ : < 50 CFU/mL; ND: Not Determined

Table 4 shows that After extended storage of milk for 8 days at 5°C, we found that the milk stored in the punnet made up of film A (PET:EVA:MONs is 44:34:22) spoiled after 8 days while the milk stored in the punnet made up of film B (PET:EVA:MONs is 50%:37.5%:12.5%) spoiled after 4 days. It was also observed that the milk stored in the punnet made up of the film PET:EVA:Cu_2O and PET:EVA:ZnO spoiled after 8 days while milk stored in the punnet made up of the film PET:EVA:MgO_2 spoiled after 4 days.

Principal findings of the invention:

i) The higher quantity of the nano-filler (Film A) is required for acheiving two major effects i. anti-microbial properties & ii. Longer protection and the present invention is therefore contrary to the teaching of *Armentano et al* as stated in the background of the invention;

ii) As the unexpected effects (as above mentioned) are found at a particular ratio of PET:EVA:MONs (i.e. 44:34:22), the present composition is not to be appeared as mere admixture;

iii) Non-carbon based nano-fillers are advantageous as the food packaging system is concerned;

iii) With regard to the leakage problem, the sprading (step ii) and heating step (iii) jointly [would be appeared as 'lamination step'] is advantageous.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim,

1. A packaging composite comprises of

a first layer, a second layer and a third layer, the second layer being laminated by the third layer and the said laminated layer being positioned towards a substance placed inside the said composite;

wherein, the first layer is made up of polyethylene terephthalate;

the second layer is made up of ethylene-vinyl acetate;

the third layer is made up of metal-oxide nanoparticles;

wherein the amount of ethylene-vinyl acetate is 34% by weight;

the amount of polyethylene terephthalate is 44% by weight;

the amount of metal-oxide nanoparticles is 22% by weight.

2. The composite as claimed in claim 1, wherein the metal-oxide particles is carbon-free.

3. The composite as claimed in claim 1, wherein the metal oxide is selected from a group consisting of copper oxide (Cu_2O), zinc oxide (ZnO) and magnesium peroxide (MgO_2).

4. The composite as claimed in claim 1, wherein size of the metal-oxide nanoparticles is 10-60nm.

5. The composite as claimed in claim 1, wherein mass density (σ) of the metal-oxide particles is 125.

6. The composite as claimed in claim 1, wherein the said composite is a laminated film.

7. The composite as claimed in claim 1, wherein the substance is a food product.

8. The composite as claimed in claim 7, wherein the food product is selected from a group consisting of solid, semi-solid or liquid.

9. A process for preparing packaging composite comprising the steps of

i) preparing a film which comprises of an first layer and an second layer wherein the first layer being made up of polyethylene terephthalate and the second layer being made up of ethylene-vinyl acetate;

ii) spreading the metal oxide nanoparticles onto the second layer of said film of step (i);

iii) subjecting the product as obtained in step (ii) into a heating roller at 80-110°C;

iv) allowing the product as obtained in step (iii) to cool at room temperature for 2 hours;

wherein thickness of the film in step (i) is 177.8 µm;

wherein temperature of the heating roller in step (iii) is 80-110°C;

wherein the pressure in step (iii) is 10-20 MPa; &

wherein the metal-oxide particle in step (ii) is carbon-free.

10. A food packaging system comprises the composite as claimed in claim 1 for protection of the food product from a microorganism selected from a group consisting of *Schizosaccharomyces pombe, Torulaspora delbrueckii, Debaryomyces hansenii, Candida krusei, Staphylococcus aureus, Bacillus subtilis, Listeria monocytogenes or Serratia marcescens.*

Dated this 20th day of April, 2020

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
of
Lex-Regia
For the Applicant

To,
The Controller of Patents,
The Patent Office
At Mumbai

ABSTRACT

“A PACKAGING COMPOSITE AND THE PROCESS FOR PREPARING SUCH COMPOSITE”

Disclosed is a packaging composite comprises of a first layer, a second layer and a third layer, the second layer being laminated by the third layer; wherein, the first layer is made up of ethylene-vinyl acetate; the second layer is made up of polyethylene terephthalate; the third layer is made up of metal-oxide particles; wherein amount of the ethylene-vinyl acetate is 34% by weight; amount of the polyethylene terephthalate is 44% by weight; and amount of the metal-oxide particles is 22% by weight. Also provided is a method of manufacturing the composite. Figure 1

FORM 2

THE PATENT ACT 1970

(39 OF 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See SECTION 10, RULE 13)

1.TITLE OF THE INVENTION :

"A Knee Traction Device"

2.APPLICANT

NAME : KRISHNA INSTITUTE OF MEDICAL SCIENCES

NATIONALITY: AN INDIAN DEEMED UNIVERSITY

ADDRESS: KRISHNA INSTITUTE OF MEDICAL SCIENCES NEAR DHEBEWADI ROAD, MALKAPUR, KARAD, 415110, MAHARASHTRA, INDIA.

3.PREAMBLE TO THE DESCRIPTION

PROVISIONAL	**COMPLETE**
N / A	The following Specification particularly describes the nature of this invention and the manner in which it is to be performed.

Field of the Invention

[0001] The present invention relates to medical sciences. More particularly the present invention relates to a knee traction device used for physiotherapy, such as treating osteoarthritis of knee joint.

Background of the Invention

[0002] Nowadays osteoarthritis is a common problem. There is no easy device to distract the knee joint and to give intermittent traction so as to relive the symptoms, thus helping user to get back to their functional activities. “Mechanical traction is a technique of applying distracting force to produce either a realignment of a structural abnormality or to relieve abnormal pressure on nociceptive receptor systems.” So until now most routinely non-invasive mechanical traction was used for distracting cervical & lumbar spine but never used for distracting knee joint in osteoarthritis.

[0003] Briefly stating, our invention relates to a mechanical traction device designed to allow the user to apply mechanical traction to knee joint. Conventionally skin traction which is used for lower limb traction can't be used to apply traction above 5 kg. So it can't be used effectively for treatment of osteoarthritis where more traction for the knee may be required. Skeletal traction which is used for lower limb in fracture & other cases is invasive method & requires

insertion of pins or wires into the bone either during open surgery or pierced through the skin.

[0004] The main complications of it are:

1. Traction force may be applied incorrectly.
2. If traction is too tight, the nerves & blood vessels can be impaired or can cause skin lesions.
3. Infection can occur around pins/ wires.
4. Bone inflammation can occur as a response to a foreign material introduced in the body (skeletal traction).
5. Excessive joint separation (over distraction) can occur if the traction weight is too great. Over distraction can cause nerve damage.
6. Prolonged bed rest is associated with long-term traction which may lead to bedsores, deep vein thrombosis, urinary tract infection etc.

[0005] Usually Bohler-Braun frame & Thomas splint which are used mainly for lower limb traction which can't be used effectively for knee joint traction. By using them we can't adjust hip & knee in ninety degree flexion which is required for effective distraction of knee joint in osteoarthritis.

[0006] Conventionally manual traction is used for treating osteoarthritis of knee but it has following limitations:

i. Limited maximum traction force.

ii. Amount of force can't be easily replicated or specifically recorded.

iii. Traction force can't be applied for prolonged time & requires a skilled clinician.

Objects of the Invention

[0007] The object of the present invention is to provide a knee traction device.

[0008] Another object of the present invention is to provide a knee traction device, which is used by physiotherapist to treat the osteoarthritis of knee joint.

[0009] Further object of the present invention is to provide a knee traction device, which is capable of treating multiple users effectively by a single device, without use of any additional support.

[0010] Furthermore object of the present invention is to provide a knee traction device, which is robust and handy.

[0011] One object of the present invention is to provide a knee traction device, which eliminates the cumbersome use of manual traction in osteoarthritis cases.

[0012] Still one object of the present invention is to provide a knee traction device, which overcome the limits of manual joint distraction like limited maximum traction force, an amount of force can't be easily replicated or specifically recorded, also required force can't be applied for prolonged period of time and requires skilled physiotherapist.

[0013] Still one more object of the present invention is to provide a knee traction device, which helps in positioning the subject in ninety degree hip-knee flexion.

[0014] Further object of the present invention is to provide a knee traction device, which eliminate need of exertion of physiotherapist while giving manual distraction to the knee joint.

[0015] Furthermore object of the present invention is to provide a knee traction device, which reduce the physiotherapist work.

[0016] Further again one object of the present invention is to provide a knee traction device, which is affordable.

Summary of the Invention

[0017] According to the present invention, there is provided a knee traction device to position a ninety degree hip-knee flexion. The device is provided with a base frame and a two vertical arms have five slots in upper portion of the both vertical arms. A pulley is attached to the fixed pulley bar which is then fitted to the vertical arms. The height of the pulley is be adjusted according to requirement. Once the required position is reached, the fixed pulley bar is locked with screws to the vertical arms. Once the screws are tightened, the mechanism gets fixed in its position and stability is achieved.

[0018] The movable stands are fitted to the horizontal arms of the main frame base support. The horizontal arms is having five slots each in the distal end to allow the shift and lock mechanism. This allows a user to shift the movable stand in horizontal direction as per the need. Once the required position is achieved, the movable stand is locked with the help of bolts. Once the bolts are tightened, the mechanism gets fixed in its position and stability is achieved.

[0019] The adjustable stool is used to rest user's knee in ninety degree flexion. The stool is rectangular in shape and well cushioned. Further, the stool is fixed to the stool stand which can be inserted into movable stand and adjust the height of the stool as per the need and then once the required position is achieved, the stool stand is locked with the screw in the movable stand. Once the screws are tightened, the mechanism gets fixed in its position and stability is achieved.

[0020] The pulley is attached to the fixed pulley bar. A traction unit rope runs through the pulley so the direction of the applied traction force can be well maintained. Thus the device can help in giving mechanical traction to the knee joint according to every user's need.

[0021] The knee traction device can be used by physiotherapist to treat the osteoarthritis of knee joint. A single device can be effectively used for treating multiple users. The device is handy so easily carried for routine clinical work as well as for clinicians. It will be an effective treatment option for osteoarthritis. The device eliminates need of exertion of physiotherapist while giving manual distraction to knee joint. Also reduces the physiotherapist work.

[0022] The present invention overcomes the above mentioned drawbacks in the following way:

1. The hip & knee flexion of ninety degree can be effectively maintained using adjustable traction frame thus effective force can be applied at the knee joint.

2. The angle of pull can be effectively maintained using adjustable pulley.

3. The exact effective force required for knee joint distraction can be given using mechanical traction unit.

4. By using mechanical traction the force & time can be well controlled, readily graded & is replicable.

5. Thus the compressive force acting on knee joint which causes deterioration of joint structures & articular cartilage leading to narrowing of joint space causing osteoarthritis. The compressive force can be reduced by mechanical traction.

Brief Description of the Drawings:

[0023] Fig. 1 shows isometric view of a knee traction device showing components of the frame;

[0024] Fig. 2 shows top view of the knee traction device showing adjustable screws and slots on horizontal bars; and

[0025] Fig. 3 shows side view of the knee traction device showing slots on vertical arms, slots on horizontal bars and adjustable screws.

Detailed description of the Invention:

[0026] Referring to Figures 1, 2 and 3, a knee traction device to position a ninety degree hip-knee flexion. The device 100 is provided with a main base frame 1. The main base frame 1 is attached with a two vertical arms 2 and a two horizontal arms 5. The vertical arms 2 is having a five slots 10 in each of their upper portion. A pulley 4 is attached to a fixed pulley bars 3. The fixed pulley bars 3 are fitted to these vertical arms 2. The height of the pulley 4 can be adjusted as

required. Once the required position is reached, the fixed pulley 4 bars are locked with a screws 9 with the vertical arms 2. Once the screws 9 are tightened, the pulley bars 3 gets fixed in its position and stability is achieved.

[0027] The stool stand 7 is a movable stand. The stool stand 7 is fitted to the horizontal arms 5 of the main base frame 1. The horizontal arms 5 is having five slots 10 in the distal end to allow the shift and lock the pulley bars 3. This allows a user to shift the pulley bar 3 in horizontal direction as per the need. Once the required position is achieved, the pulley bars 3 are locked with the help of a screws 9. Once the screws 9 are tightened, the pulley bars 3 gets fixed in its position and stability is achieved.

[0028] Further, the stool stand 7 with two legs are fitted to the horizontal arms 5 of the main base frame 1. The horizontal arms 5 have ten slots 11 in the distal end to allow the shift and lock stool stand 7. This allows the user to shift the stool stand 7 in horizontal direction as per requirement. Once the required position is achieved, the stool stand 7 is locked with the help of screws 8. Once the screws 8 are tightened, the stool stand 7 gets fixed in its position and stability is achieved.

[0029] A adjustable stool 6 is fixed to a stool stand 7. The adjustable stool 6 is used for resting an user's knee in ninety degree flexion. The stool is well cushioned. Further, the adjustable stool which can be inserted into a movable stand

(not shown). Specifically, the stool stand 7 is inserted into the movable stand which is for adjusting the height of the stool as per requirement of the user. Further, once the required position is achieved, the stool stand 7 is locked in the movable stand by using the screws 8. Once the screws 8 are tightened, the stool stand 7 gets fixed in its position and stability is achieved.

[0030] Further, a traction unit rope (not shown) runs through the pulley 4. By using the traction unit rope, the direction of the traction force applied is well maintained. Thus, the device 100 can help in giving mechanical traction to the knee joint according to every user's need. By using mechanical traction, the force and the time is well controlled, readily graded and replicated. Thus, the device 100 provides an effective way for treating osteoarthritis problem of the user's knee joint.

[0031] Referring now to figure 2, a top view showing the components 5, 9, and 11 of the device 100. Also, it shows the horizontal arms 5, screws 9 fitting the pulley bar 3 to the vertical arms 2 and ten slots 11 each on horizontal arms 5.

[0032] Further referring to the figure 3, a side view of the device 100, showing the components 8, 10, and 11. Also, it shows the adjustable screws 8 on the movable stand, the five slots (10) on the vertical arms (2) and the ten slots (11) each on the horizontal arm.

[0033] The present invention. Thus by using mechanical traction the above limitations are overcome & the force & time can be well controlled, readily graded & replicated. Thus the said invention may prove to be an effective alternative for treating osteoarthritis of knee joint.

[0034] The device 100 overcomes the above mentioned drawbacks in the following way:

1. The hip & knee flexion of ninety degree can be effectively maintained using adjustable traction frame thus effective force can be applied at the knee joint.

2. The angle of pull can be effectively maintained using adjustable pulley.

3. The exact effective force required for knee joint distraction can be given using mechanical traction unit.

4. By using mechanical traction the force & time can be well controlled, readily graded & is replicable.

5. Thus the compressive force acting on knee joint which causes deterioration of joint structures & articular cartilage leading to narrowing of joint space causing osteoarthritis. The compressive force can be reduced by mechanical traction.

[0035] Therefore the advantages of the present invention are to provide a knee traction device. The device is used by physiotherapist, especially to treat the osteoarthritis of knee joint. The device is capable of treating multiple users effectively by a single device, without use of any additional supports. Also, the device is robust and handy which eliminates the cumbersome use of manual traction

in osteoarthritis cases. Further, the device overcome the limits of manual joint distraction like limited maximum traction force, an amount of force can't be easily replicated or specifically recorded, also required force can't be applied for prolonged period of time and requires skilled physiotherapist. The device helps in positioning the subject in ninety degree hip-knee flexion without requiring any other alternative support or device. Also, eliminate need of exertion of physiotherapist while giving manual distraction to knee joint. The cost of the device is affordable.

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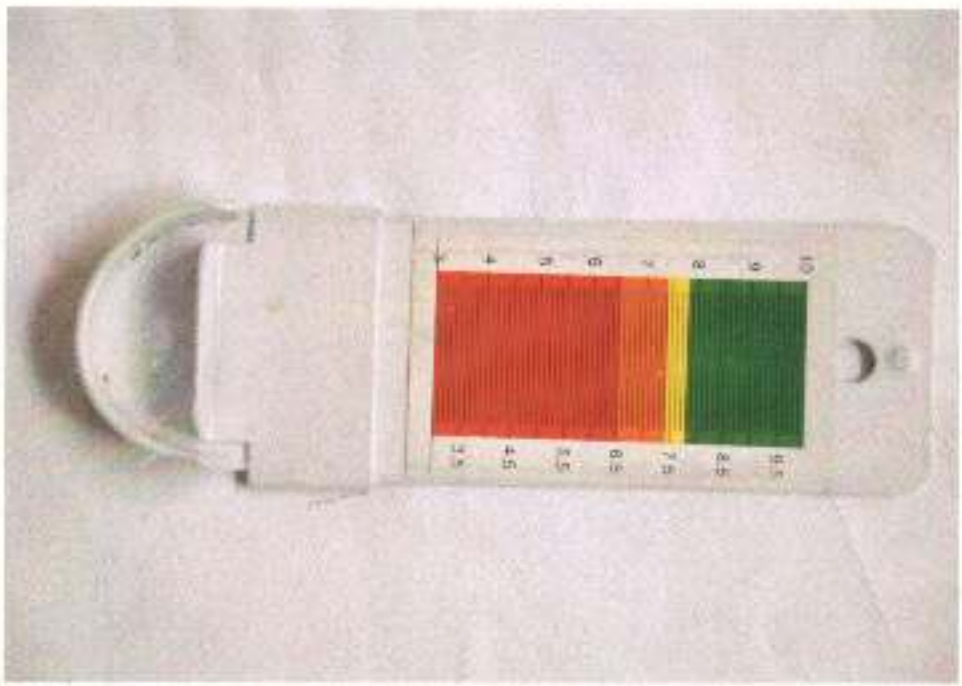
NO. OF SHEETS- 1
SHEET NO.: - 1



Top view

The novelty resides in the shape, configuration & colour combination of the Foot length caliper ~~to check malnutrition in new born babies~~ as illustrated.
No claim is made by virtue of this registration of respect any mechanical or other action of any mechanism whether or in respect of any mode or principle of construction of the Article.
No claim is made by virtue of this registration to any right to the exclusive use of the words, letters, numbers, or trademarks appearing in the copies of the representation if the designs.

Dated: 3rd April, 2013

DR.M.V.GHORPADE
For KRISHNA INSTITUTE OF MEDICAL SCIENCES

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NO. OF SHEETS- 1
SHEET NO.: - 1

Front view

The novelty resides in the shape, configuration & colour of the "NAIL SHADE DEVICE FOR SCREENING OF ANEMIA" as illustrated.

No claim is made by virtue of this registration of respect any mechanical or other action of any mechanism whether or in respect of any mode or principle of construction of the Article.

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NO. OF SHEETS- 3
SHEET NO.: - 2

Left View

Ridht View

The novelty resides in the shape, configuration & colour of the "NAIL SHADE DEVICE FOR SCREENING OF ANEMIA" as illustrated.

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Top View

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SHEET NO.: - 1

Front view

The novelty resides in the shape, configuration & surface pattern of the "~~DIET SURVEY~~ CONTAINER ~~KIT~~" as illustrated.

No claim is made by virtue of this registration of respect any mechanical or other action of any mechanism whether or in respect of any mode or principle of construction of the Article.

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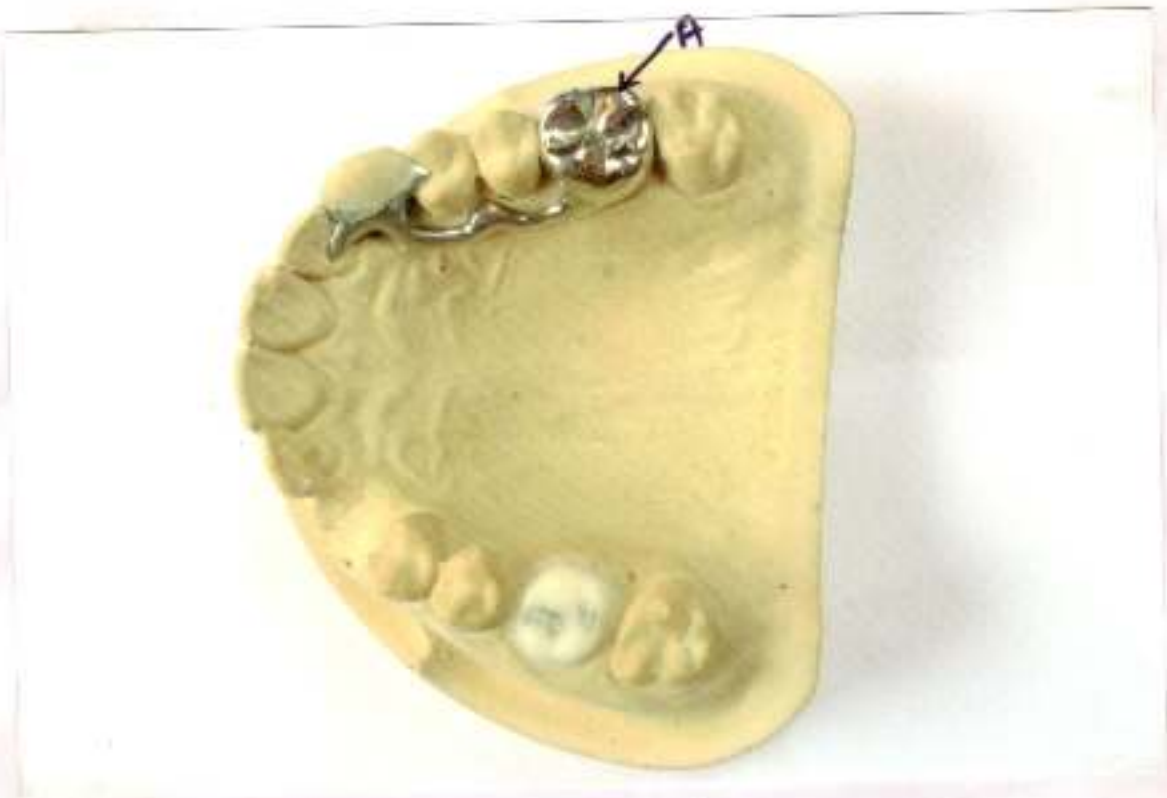
SHEET NO.: - 1



Top view

The novelty resides in the shape & configuration of the Dental implement particularly in portion marked A as illustrated.

No claim is made by virtue of this registration of respect any mechanical or other action of any mechanism whether or in respect of any mode or principle of construction of the Article.

No claim is made by virtue of this registration to any right to the exclusive use of the words, * letters, numbers, or trademarks appearing in the copies of the representation if the designs & the mould.

* ornaments - written

Dated: 3rd April, 2013

DR.M.V.GHORPADE
For KRISHNA INSTITUTE OF MEDICAL SCIENCES

253328

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KRISHNA INSTITUTE OF MEDICAL SCIENCES NO. OF SHEETS- 3
SHEET NO.: 2

Right Side View

Left Side View

The novelty resides in the shape & configuration of the "~~SS BAR BRIDGE~~" Dental implement Particularly as ~~illustrated~~. in the portion marked 'A' as illustrated

No claim is made by virtue of this registration of respect any mechanical or other action of any mechanism whether or in respect of any mode or principle of construction of the Article.

No claim is made by virtue of this registration to any right to the exclusive use of the words,letters, numbers, or trademarks appearing in the copies of the representation if the designs.

Dated: 3rd April, 2013

DR.M.V.GHORPADE
For KRISHNA INSTITUTE OF MEDICAL SCIENCES

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253328

23 APR 2013

KRISHNA INSTITUTE OF MEDICAL SCIENCES

NO. OF SHEETS- 3
SHEET NO.: - 3

Front View

Back View

The novelty resides in the Shape & configuration of the "Dental Element" Particularly in the Portion marked 'A' as illustrated.

No Claim is made by virtue of this registration in respect any mechanical or other action of any mechanism whether or in respect of any mode or Principle or construction of the Article.

No claim is made by virtue of this registration having right to the exclusive use of the words/letters, numbers, or trademarks appearing in the copies of the representation is the designs.

Date- 3rd April 2013

* Extraneous matter.

DR.M.V.GHORPADE
For KRISHNA INSTITUTE OF MEDICAL SCIENCES

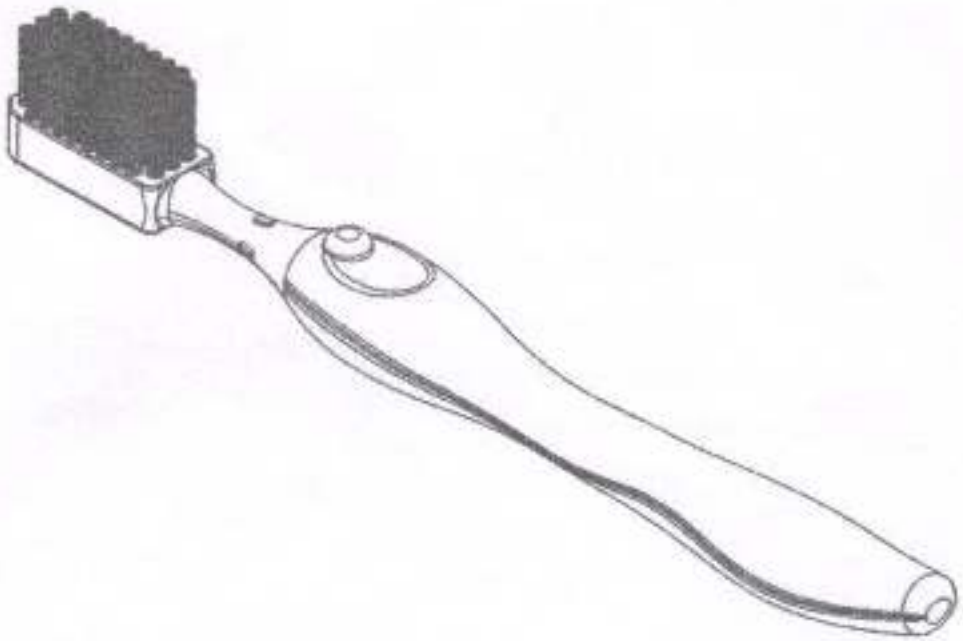
REGISTRAR
KRISHNA INSTITUTE OF MEDICAL SCIENCES
UNIVERSITY
KARAD

253328

23 APR 2013

Applicant(s): GIRISH SURAGIMATH and ASHWINIRANI SR 4-sheets

Application number: 314161-001 Sheet-1



PERSPECTIVE VIEW

The novelty resides in the shape and configuration of "TOOTHBRUSH" as illustrated.

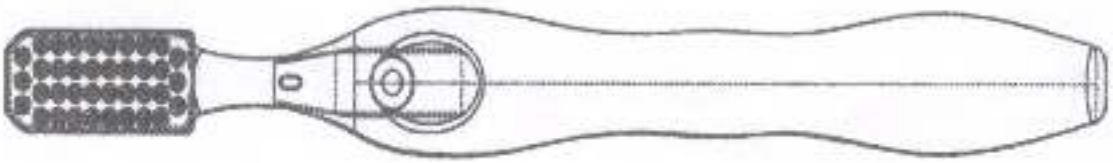
No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim is being made by virtue of registration to any right to the exclusive use of the words, letters, numbers, colour, colour combination or Trade Marks as appearing in the representation.

Dated this 23rd day of January, 2019

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)



TOP VIEW

The novelty resides in the shape and configuration of "TOOTHBRUSH" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

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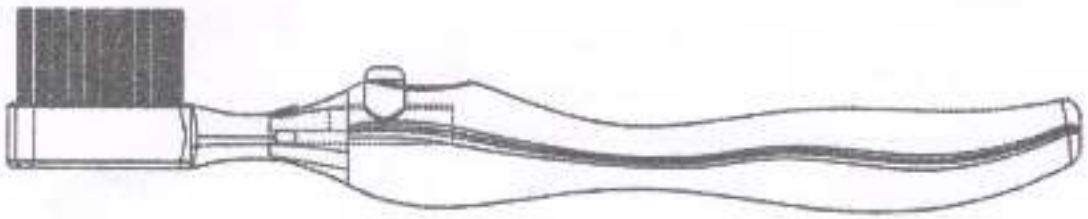
Dated this 23rd day of January, 2019

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)



SIDE VIEW

The novelty resides in the shape and configuration of "TOOTHBRUSH" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

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Dated this 23rd day of January, 2019

Arghya Roy

(Arghya Ashis Roy)
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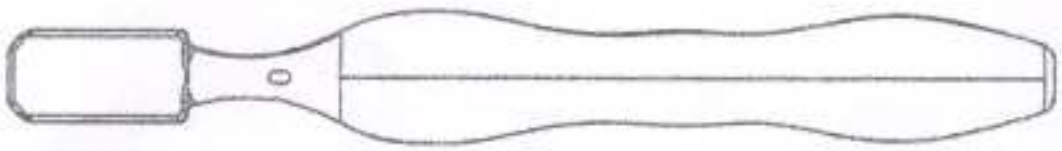
For the Applicant(s)



BOTTOM VIEW

The novelty resides in the shape and configuration of "TOOTHBRUSH" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim is being made by virtue of registration to any right to the exclusive use of the words, letters, numbers, colour, colour combination or Trade Marks as appearing in the representation.

Dated this 23rd day of January, 2019

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)

Applicant(s): KARUNA G. PAWASHE;
SHIVSAGAR TEWARY; &
PRONOB SANYAL

4-sheets
Sheet-1

Application No.:

PERSPECTIVE VIEW

The novelty resides in the shape and configuration of "HAND-FREE DENTAL MIRROR" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim is being made by virtue of registration to any right to the exclusive use of the words, letters, numbers, colour, colour combination or Trade Marks as appearing in the representation.

Dated this 03rd day of February, 2020

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)

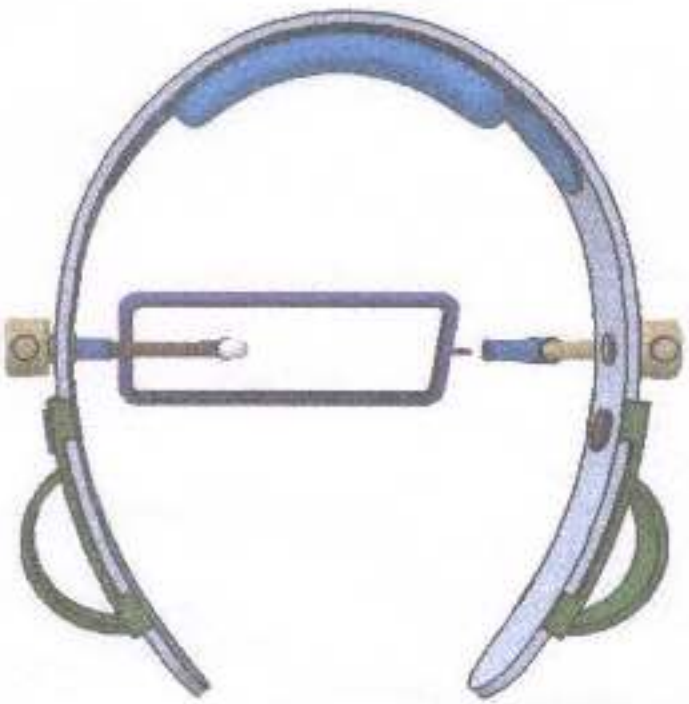
326727-001

03 FEB 2020

Applicant(s): KARUNA G. PAWASHE;
SHIVSAGAR TEWARY; &
PRONOB SANYAL

Application No.:

4-sheets
Sheet-2



TOP VIEW

The novelty resides in the shape and configuration of "HAND-FREE DENTAL MIRROR" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim is being made by virtue of registration to any right to the exclusive use of the words, letters, numbers, colour, colour combination or Trade Marks as appearing in the representation.

Dated this 03rd day of February, 2020

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)

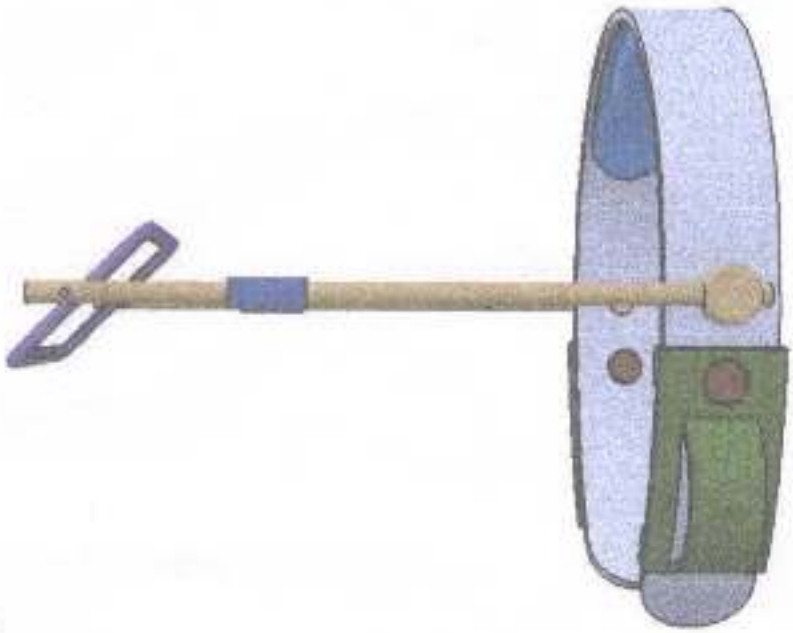
326727-001

03 FEB 2020

Applicant(s): KARUNA G. PAWASHE;
SHIVSAGAR TEWARY; &
PRONOB SANYAL

4-sheets
Sheet-3

Application No.:



SIDE VIEW

The novelty resides in the shape and configuration of "HAND-FREE DENTAL MIRROR" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

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Dated this 03rd day of February, 2020

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)

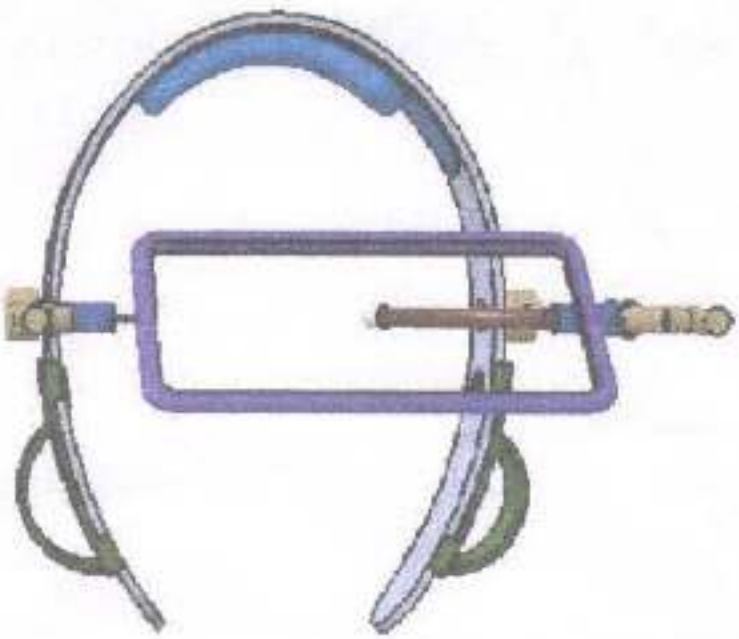
326727-001

03 FEB 2020

Applicant(s): KARUNA G. PAWASHE;
SHIVSAGAR TEWARY; &
PRONOB SANYAL

4-sheets
Sheet-4

Application No.:



BOTTOM VIEW

The novelty resides in the shape and configuration of "HAND-FREE DENTAL MIRROR" as illustrated.

No claim is made by virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim is being made by virtue of registration to any right to the exclusive use of the words, letters, numbers, colour, colour combination or Trade Marks as appearing in the representation.

Dated this 03rd day of February, 2020

Arghya Roy

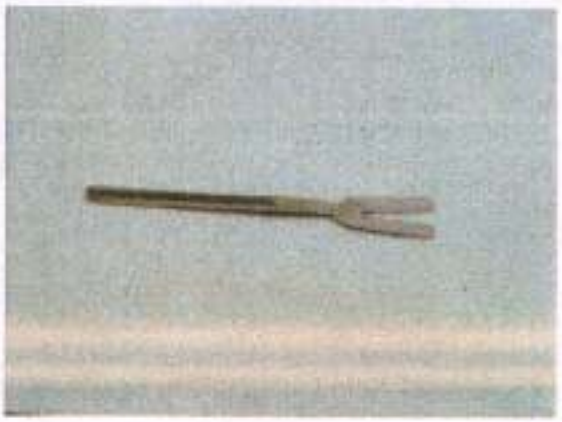
(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant(s)

326727-001

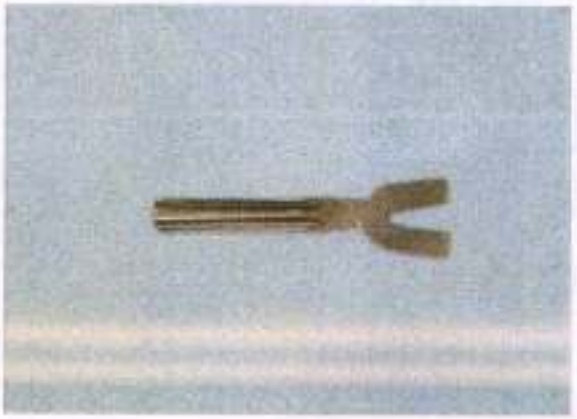
03 FEB 2020

Applicant: Ashok Yadavrao Kshirsagar.

Total Sheet - 2
Sheet No - 1



RIGHT PERSPECTIVE VIEW



TOP VIEW

The novelty resides in the shape, and configuration ~~and surface pattern of~~ "Tongue-tie retractor" as illustrated.

No claim has been made by the virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim has been made by the virtue of registration to any right to the exclusive use of the words, letters, numbers, colors, colors combination or Trademark as appearing in the representation.

Dated this 23rd day of September, 2019

(Dr. Ushushi Guha)
Patent Agent (IN/PA 720)
Of Lex-Regia
For the Applicant

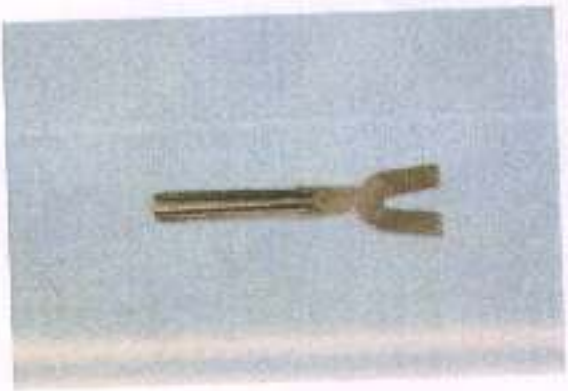
321902-001

23 SEP 2019

Applicant: Ashok Yadavrao Kshirsagar.

Total Sheet - 2
Sheet No. -2

LEFT PERSPECTIVE VIEW



BOTTOM VIEW

The novelty resides in the shape, configuration ~~and surface pattern of~~ "Tongue-tie retractor" as illustrated.

No claim has been made by the virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim has been made by the virtue of registration to any right to the exclusive use of the words, letters, numbers, colors, colors combination or Trademark as appearing in the representation.

Dated this 23rd day of September, 2019

(Dr. Ushoshi Guha)
Patent Agent (IN/PA 720)
Of Lex-Regia
For the Applicant

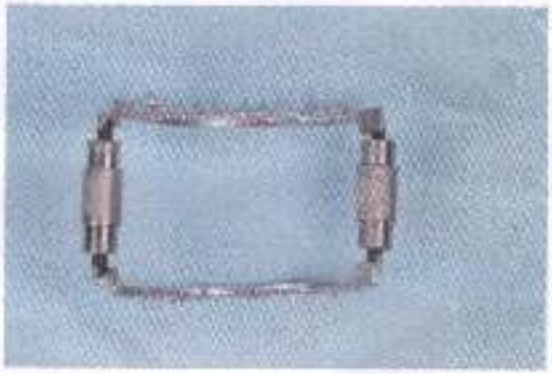
321902-001

23 SEP 2019

Applicant: Ashok Yadavrao Kshirsagar.

Total Sheet - 3
Sheet No. -1

PERSPECTIVE VIEW



TOP VIEW

The novelty resides in the shape, and configuration ~~and surface pattern~~ of "Self- Retaining Thyroid Retractor" as illustrated.

No claim has been made by the virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim has been made by the virtue of registration to any right to the exclusive use of the words, letters, numbers, colors, colors combination or Trademark as appearing in the representation.

Dated this 23rd day of September, 2019

(Dr. Ushoshi Guha)
Patent Agent (IN/PA 720)
Of Lex-Regia
For the Applicant

321904-001

23 SEP 2019

Applicant: Ashok Yadavrao Kshirsagar.

Total Sheet - 2
Sheet No. -2

SIDE VIEW

OTHER SIDE VIEW

The novelty resides in the shape, configuration and surface pattern of "Self- Retaining Thyroid Retractor" as illustrated.

No claim has been made by the virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim has been made by the virtue of registration to any right to the exclusive use of the words, letters, numbers, colors, colors combination or Trademark as appearing in the representation.

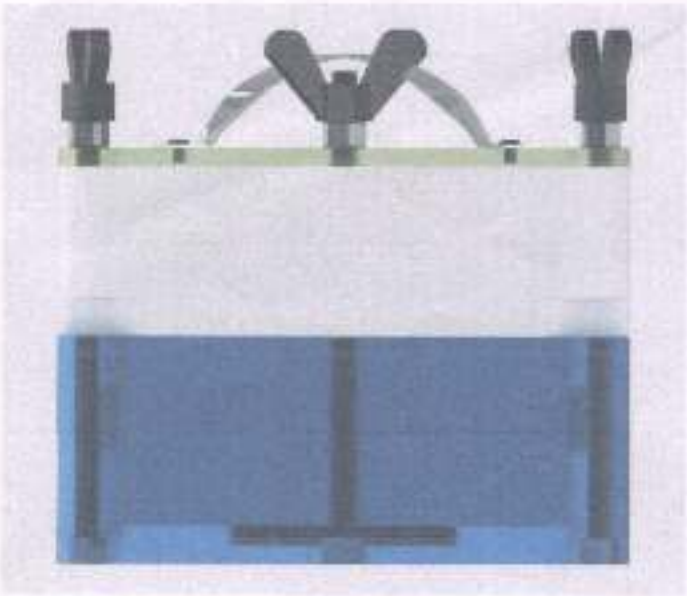
Dated this 23rd day of September, 2019

(Dr. Ushoshi Guha)
Patent Agent (IN/PA 720)
Of Lex-Regia
For the Applicant

321904 - 001

23 SEP 2019

Krishna Institute of Medical Sciences "Deemed to be University" Total Sheets 7
Sheet No: 1



Side View 1

1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.

2. No claim is made by virtue of this representation in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.

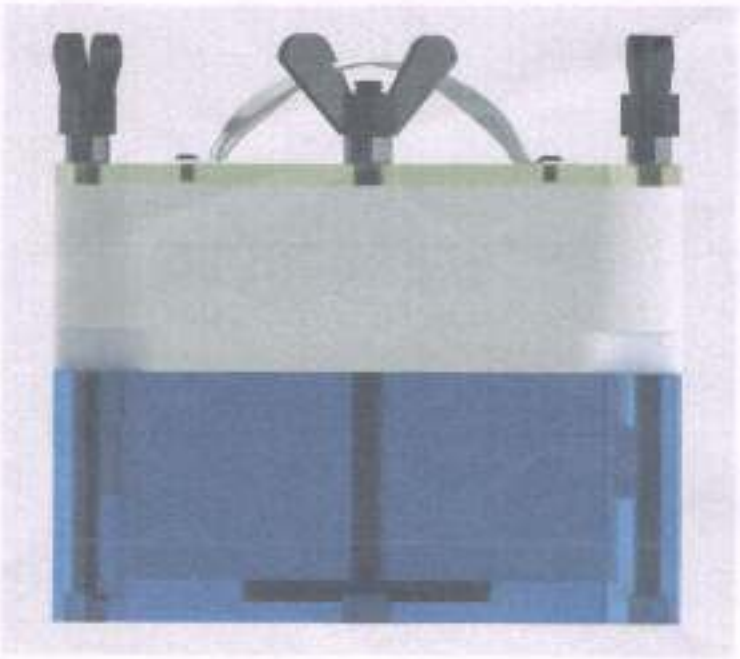
3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

Dated this December 23, 2019

Suneet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700091

324946-001



Side View 2

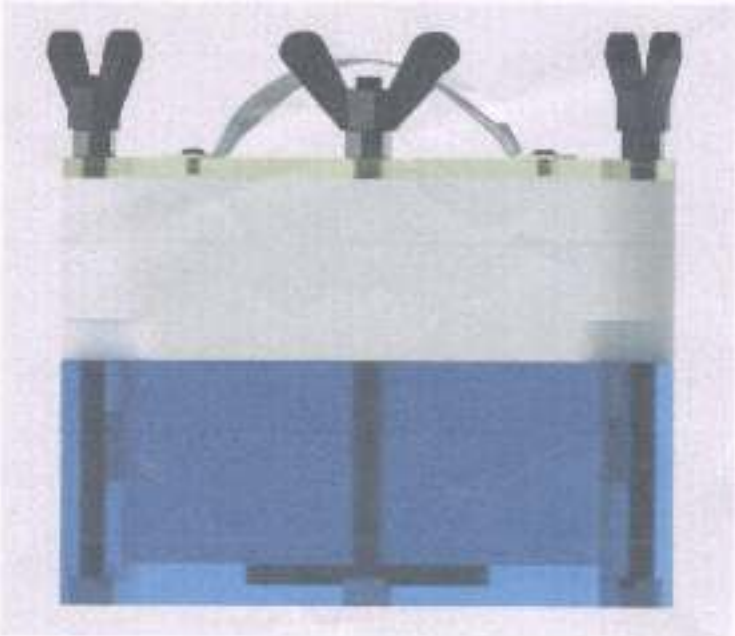
1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.
2. No claim is made by virtue of this representation in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.
3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

Dated this December 23, 2019

Suneet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700 091

324946 - 001



Side View 3

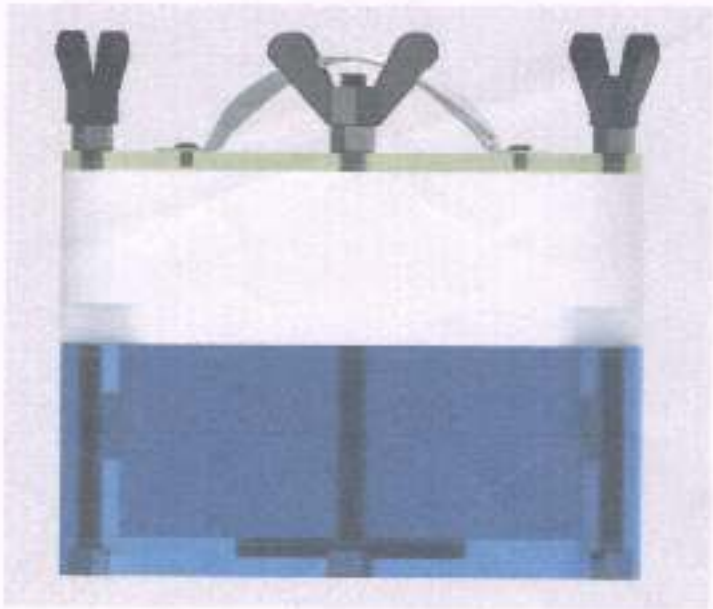
1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.
2. No claim is made by virtue of this representation-in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.
3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

Dated this December 23, 2019

Suneet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700 091

324946 - 001



Side View 4

1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.

2. No claim is made by virtue of this representation in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.

3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

Dated this December 23, 2019

Suneet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700 091

324946 - 001

Top View

1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.
2. No claim is made by virtue of this representation in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.
3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

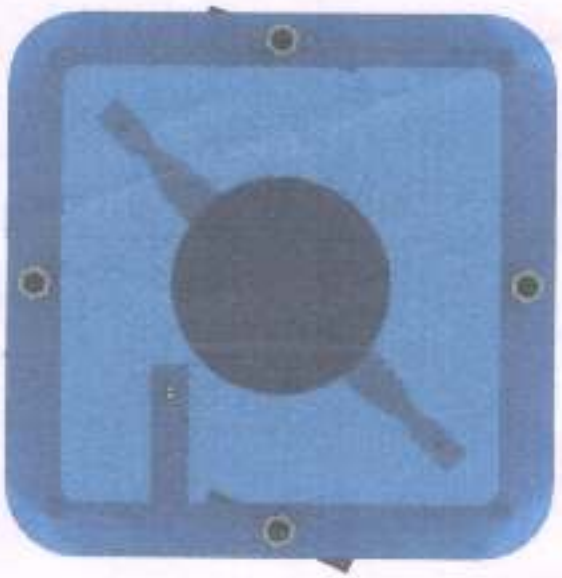
Dated this December 23, 2019

Sumeet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700 091

324946-001
5

23 DEC 2019



Bottom View

1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.
2. No claim is made by virtue of this representation in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.
3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

Dated this December 23, 2019

Suneet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700 091

Perspective View

1. Novelty resides in the shape and configuration of the **Dental Flask** as illustrated.
2. No claim is made by virtue of this representation in respect of any mechanical or other action of the mechanism whatever or in respect of any mode or principle of the construction of the **Dental Flask**.
3. No claim is made by virtue of this registration in respect of any word, letter, number, trademark and colour or colour combination appearing on the **Dental Flask**.

Dated this December 23, 2019

Sumeet Baliram Sabale
(Agent for Applicant)

To
The Controller of Designs,
Kolkata-700 091

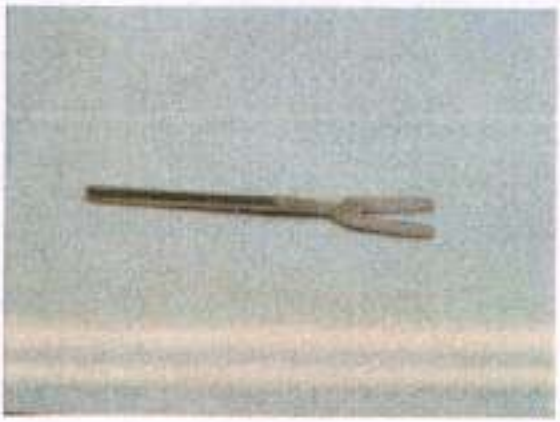
324946-001

7

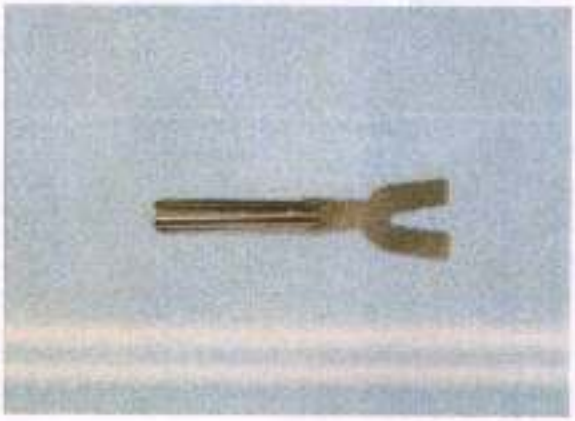
23 DEC 2019

Applicant: Ashok Yadavrao Kshirsagar.

Total Sheet - 2
Sheet No. - 1



RIGHT PERSPECTIVE VIEW



TOP VIEW

The novelty resides in the shape, configuration and ~~surface pattern of~~ "Tongue-tie retractor" as illustrated.

No claim has been made by the virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

No claim has been made by the virtue of registration to any right to the exclusive use of the words, letters, numbers, colors, colors combination or Trademark as appearing in the representation.

Dated this 23rd day of September, 2019

(Dr. Ushoshi Guha)
Patent Agent (IN/PA 720)
Of Lex-Regia
For the Applicant

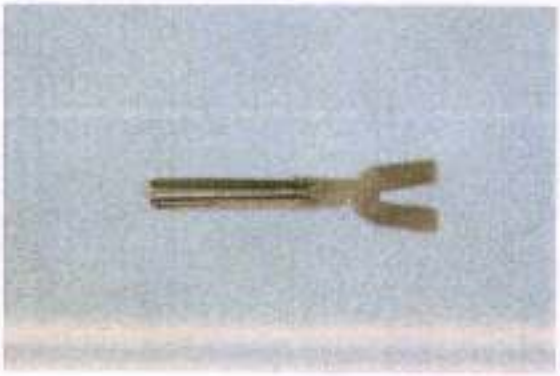
321902-001

23 SEP 2019

Applicant: Ashok Yadavrao Kshirsagar.

Total Sheet - 2
Sheet No. -2

LEFT PERSPECTIVE VIEW



BOTTOM VIEW

The novelty resides in the shape, configuration and ~~surface pattern of~~ "Tongue-tie retractor" as illustrated.

No claim has been made by the virtue of registration in respect of any mechanical or other action of mechanism whatsoever or in respect of any mode or principle of construction of this article.

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Dated this 23rd day of September, 2019

(Dr. Ushnshi Guha)
Patent Agent (IN/PA 720)
Of Lex-Regia
For the Applicant

321902-001

23 SEP 2019

PATENT PUBLISHED

Patent write-up

FORM 2

THE PATENT ACT 1970

(39 OF 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See SECTION 10, RULE 13)

1. TITLE OF THE INVENTION :

KRISHNA INJECTION SYRINGE

2. APPLICANT:

NAME: KRISHNA INSTITUTE OF MEDICAL SCIENCES

NATIONALITY: DEEMED TO BE UNIVERSITY DECLARED U/S 3 OF UGC ACT, 1956 VIDE NOTIFICATION NO. F.9-15 / 2001 – U-3 OF THE MINISTRY OF HUMAN RESOURCES DEVELOPMENT, GOVT.OF INDIA

ADDRESS: KRISHNA INSTITUTE OF MEDICAL SCIENCES,

NEAR DHEBEWADI ROAD, MALKAPUR, KARAD 415110, MAHARASHTRA, INDIA

3. PREAMBLE TO THE DESCRIPTION:

The following complete specification particularly describes the nature of this invention and the manner in which it is to be performed:

4. TECHNICAL FIELD

The present invention relates to medical sciences. This invention is directed towards structuring of injection syringe so as to reduce the risk of needle injuries during recapping. Thus using thisKRISHNA INJECTION SYRINGE we can reduce the risk of needle injuries during recapping and reduce risk of infection from contaminated needles.

5. Prior Art:

Needle stick injuries are wounds caused by needles that accidently puncture the skin. WHO estimates that 2 million needle stick injuries occur per year. A considerable percentage of these occur during recapping. The risk is greatest amongst medical students taking their first steps in the medical profession. Recapping needles puts personnel at risk for an accidental needle stick injuries. Recapping is a procedure to insert the syringe needle tip deep into the plastic protective cap and secure it in place. A needle stick injury from a contaminated needle can result in infection of blood borne virus, especially viruses that causes AIDS (Human Immunodeficiency Virus), Hepatitis B virus (HBV), Hepatitis C virus (HCV) and other blood borne pathogens. So until now most routinely recapping of syringe was avoided, whenever possible needles were disposed immediately without recapping them. If recapping was necessary in situations like when the patient needed to be injected several times in a single procedure, injecting to an uncooperative patient, if there is delay in use of injection or there is need to transport the syringe before or after the administration. In these situations if recapping was to be done then single-handed scoop technique was used. Single-handed recapping process is the process in which the cap should not be held by the other hand during the capping process.

Drawbacks of routine Single-handed recapping technique:

1) It increases the risk of getting pierced by needle

2) As scooping by single hand takes time so this technique is time consuming

3) During single-handed scoop technique the cap should be placed on flat surface for ease of capping, which may not be possible always.

4) Uncapped needles are not safe for transportation.

Drawbacks of routine roller protector syringe :

1) Protective shield is not handy and so recapping may take time

2) As needle end remains open it is not completely encapsulated.

3) As needle remains open, it is a hazardous during transporting.

6. Objective:

The main objective of the present invention is to provide a novel machine which aids in Reduces risk of needle stick injury.

Yet another object of the present invention is to overcome drawbacks of single-handed capping technique.

Yet another object of the present invention is to make recapping easy and safe.

Yet another object of the present invention is to reduce risk of uncapped syringe.

Yet another object of the present invention is to make it simple to use.

Yet another object of the present invention is to make recapping using this special structured syringe can be done rapidly and easily without much time consumption.

Yet another object of the present invention is to make the cap encapsulates the syringe completely and maintains hygiene.

7. Statement:

Hence the invention of this new device 'KRISHNA INJECTION SYRINGE' was made to overcome the drawbacks in the following ways:

The said invention overcomes these drawbacks in the following way:

1) Reduces risk of needle stick injury.

2) Overcomes drawbacks of single-handed capping technique.

3) Makes recapping easy and safe.

4) Reduces risk of uncapped syringe.

5) It is simple to use.

6) Recapping using this special structured syringe can be done rapidly and easily without much time consumption.

7) The cap encapsulates the syringe completely and maintains hygiene.

Advantages:

This device is time saving and cheaper. It helps in applying effective force required for recapping of syringe. Makes recapping simple, easy and safe. Recapping using this special structured syringe can be done rapidly and easily without much time consumption. The cap encapsulates the syringe completely and maintains hygiene. This reduces risk of needle stick injury. Since needle stick injuries are more common in health care providers this syringe can prove useful in reducing risk.

Working of the device:

The said invention works in the following manner:

1) The syringe barrel has an outer tubular covering which can be pushed out or pulled in with the help of a pusher. The pusher is a small knob like elevation on the protection capsule.

2) At the free end of the protector sheath, a cap is placed.

3) The user has to remove the cap, and pull the pusher inwards with her thumb to expose the needle.

4) Once the filling of medication and injection procedure is over, the user pushes the pusher, thereby pushing out the protector sheath.

5) The free end can be again capped thereby securing the needle.

6) The protective sheath is made up of transparent material thereby not impeding with the visibility of the markings of the barrel.

8. BRIEF DESCRIPTION OF DRAWING:

Fig No. 1 is the schematic representation of the KRISHNA INJECTION SYRINGE.

9. DETAILED DESCRIPTION OF DRAWINGS:

Fig. No. 1 is the isometric view of the articulator which has

1) Syringe has a barrel (2) which is a hollow cylinder that holds the medication. Barrel has calibrations on the outer surface to measure the medication.

2) The barrel is fitted with push protector sheath (3) which has a pusher (4) which helps to easily slide the push protector sheath back and forth.

3) The plunger (1) fits in the barrel and is moved back and forth. Pulling back on the plunger draws medications or air into the syringe. Pushing in the plunger forces air or medication out of the syringe.

4) The other end of the barrel has a needle adapter (5) to which a needle hub (6) is attached which holds the needle shaft (7) with bevel (8).

5) A protective sheath with a pusher at its base encapsulated the barrel.

6) Push protector sheath (3) helps in recapping the syringe rapidly and easily by pressing the pusher (4).

7) The cap (10) is fitted on the other end of push protector sheath which helps in completely encapsulate the needle syringe. If required protective cover (9) can be applied to the needle end prior to application of the cap (10) which ensures complete double security and safety.

10. Claims:

1. The KRISHNA INJECTION SYRINGE comprises of:

a) Plunger (1)

b) Barrel (2)

c) Push protector sheath (3)

d) Pusher (4)

e) Needle adapter (5)

f) Needle hub (6)

g) Needle shaft (7)

h) Bevel (8)

i) Protective cover (9)

j) Cap (10)

which works as follows-

The KRISHNA INJECTION SYRINGE has a barrel (2) which is a hollow cylinder that holds the medication. Barrel has calibrations on the outer surface to measure the medication.The barrel is fitted with push protector sheath (3) which has a pusher (4) which helps to easily slide the push protector sheath back and forth. The plunger (1) fits in the barrel and is moved back and forth. Pulling back on the plunger draws medications or air into the syringe. Pushing in the plunger (1) forces air or medication out of the syringe.The other end of the barrel has a needle adapter (5) to which a needle hub (6) is attached which holds the needle shaft (7) with bevel (8).A protective sheath with a pusher (4) at its base encapsulated the barrel (2).Push protector sheath (3) helps in recapping the syringe rapidly and easily by pressing the pusher (4).The cap (10) is fitted on the other end of push protector sheath which helps in completely encapsulate the needle syringe. If required protective cover (9) can be

applied to the needle end prior to application of the cap (10) which ensures complete double security and safety.

Dated this 13th December 2016

DR.M.V.GHORPADE

(REGISTRAR)

FOR KRISHNA INSTITUTE OF MEDICAL SCIENCES

To

The Controller of Patents,

The patent office,

At Mumbai – 400 037

11. ABSTRACT OF THE INVENTION

KRISHNA INJECTION SYRINGE can be used by health practitioners to reduce risk of needle injury during recapping. The said invention will come in handy for routine clinical work as well as for students. The risk of injury during recapping and cumbersome method of recapping will be eliminated. Medical students and nurses who are at risk of needle injury because of their clinical inexperience will be controlled. The said invention will overcome the limits of conventional injection syringe like:

a) Risk of getting pierced by needle syringe.

b) Cumbersome and time consuming single handed scooping technique during recapping.

c) Uncapped needles are not safe for transportation.

Thus by using KRISHNA INJECTION SYRINGE the above limitations are overcome & injection recapping and transportation becomes safe. Thus the said invention can prove to be safe and cost effective alternative to prevent needle injuries.

Krishna Institute of Medical Sciences, Deemed University, Karad

DR.M.V.GHORPADE

(REGISTRAR)

FOR KRISHNA INSTITUTE OF MEDICAL SCIENCES

FORM 2

THE PATENT ACT 1970

(39 OF 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See SECTION 10, RULE 13)

1. TITLE OF THE INVENTION :

PAA ARTICULATOR

2. APPLICANT:

NAME: KRISHNA INSTITUTE OF MEDICAL SCIENCES, DEEMED UNIVERSITY

NATIONALITY: DEEMED TO BE UNIVERSITY DECLARED U/S 3 OF UGC ACT, 1956 VIDE NOTIFICATION NO. F.9-15 / 2001 – U-3 OF THE MINISTRY OF HUMAN RESOURCES DEVELOPMENT, GOVT.OF INDIA

ADDRESS: KRISHNA INSTITUTE OF MEDICAL SCIENCES, DEEMED UNIVERSITY NEAR DHEBEWADI ROAD, MALKAPUR, KARAD 415110, MAHARASHTRA, INDIA

3. PREAMBLE TO THE DESCRIPTION:

The following specification particularly describes the nature of this invention and the manner in which it is to be performed:

4. TECHNICAL FIELD

This invention relates to medical science; specifically to the field of dental science. This articulator has been invented to simulate the stomatognathic system.

This machine is to be used to mimic the articulating system of the oral cavity and helps in the personalized alignment of the teeth according to each patient.

5. PRIOR ART:

An articulator is defined as a mechanical instrument that represents the temporomandibular joints and jaws, to which maxillary and mandibular casts may be attached to simulate some or all mandibular movement.

There have been many major modifications and inventions in this field of stomato-mechanics in order to facilitate the orientation of the jaws during static and functional movements.

Drawbacks of Existing Methods of measuring wear –

The current mean value articulator is a simplistic design which is utilized by many undergraduates and postgraduates for mounting casts followed by various teeth arrangements. The lack of a few tools may hamper the orientation of the casts before mounting and hold it in position. The inaccuracy of 'thread relation' for determining the occlusal plane is well known. Teeth arrangement has been performed since decades according to the glass plate relation while working on the mean value articulator.This arbitrary method of mounting and teeth arrangement, both are overcome in this invention.

6. OBJECTIVE:

The main objective of the present invention is to provide a novel machine which aids in simulating the temporo-mandibular joint and jaws by using with high accuracy tool for precise & easy mounting & compensatory curved plates for detailed teeth arrangement.

Yet another object of the present invention is to make an articulator that makes orientation and midline location accurate along with a precise occlusal plane provider and compensatory curve plate.

Yet another object is to provide a process wherein, this customized mean value articulator consists of an aluminium framework which houses an upper and lower member containing mounting plates for the casts.

Yet another object of the present invention is to provide a process wherein, it has an occlusal plane orientor which will help in accurate positioning of the casts during mounting.

Yet another object of the present invention is to provide a process wherein, it has a compensatory plate provided to apply the compensatory curves to the try in dentures for teeth arrangement.

Yet another object of the present invention is to provide a process wherein, the lingual midline indicator helps in locating the accurate midline along with the incisal pin provided anteriorly.

7. STATEMENT:

Accordingly the present invention provides the gen-next articulator which comprises:

1) The Compensatory Curve plates compensates for the curve of Wilson and Curve of Spee which together comprise the Curve of Monson.
2) Occlusal Plane Orientor helps in the placement and orientation of the casts during mounting. This establishes a horizontal guide in order to recognise any deviation from the original position.
3) Lingual midline indicator
4) A Pinrest to support all of the above,
5) The Upper and Lower members of an articulator.

6) The articulator also contains fixed condylar guidance.

7) The entire articulator is supported through the L-frame.

The Aluminium framework which is weighted to lend stability to the entire machine so as to prevent toppling. The upper and lower members (15 & 7) contain the mounting plates (8) which will help in the mounting of casts and retaining it. The L- frame helps in supporting the entire assembly. The Incisal Guide (9) table rests the Incisal Rod (10) and the Incisal Pin (11). It is static at 10 degrees and not customizable. The Incisal Rod (9) supports the Incisal pin (11). The posterior rod is called the Pinrest (1) which supports the thumbscrews (3, 13 & 4) of the assembly. The right and left Occlusal Plane Orientors & thumbscrews(4, 5, 13,18) help in the precise orientation of the casts during mounting. The Lingual Midline Locator (12) has a slit to slide in the compensatory curve plates (6 & 17). The condylar guidance (2) simulates the temporomandibular joint. Hence, it opens and closes the articulator.

Procedure:

After the jaw relations procedure, casts should be placed on the wax studs to orient the casts for mounting. The occlusal plane should coincide with the occlusal plane orientors, lingual midline locator and the incisal pin (3- point guidance). This is a more accurate method compared to the arbitrary thread relation we use. After coinciding the occlusal plane orientors then proceed ahead with the mounting. The plaster should be mixed with the water powder ratio provided by the manufacturer.After skillful mixing, load the material on the casts and wait for it to set accurately.

After the setting of the material, teeth arrangement is commenced. Arrange the anterior teeth precisely after which the posterior teeth should be arranged according to the compensatory curved plates inserted into the lingual midline locator. The arrangement automatically sets in the direction of the desired compensatory curve of specific dimensions. The flat plates provided in the assembly help in the mounting of single complete dentures.

Novel features of the improvised articulator

1. Occlusal Plane Orientors.
2. Lingual Midline Indicator.
3. Compensatory curved plates.
4. Pinrest.

Utility of the improvised articulator:

1. Occlusal plane orientor which helps in the orientation of the casts during mounting
2. Lingual midline indicator which will help in 2 point midline location along with the incisal pin.
3. Compensatory curved plates to provide the curve of Spee and Wilson on the artificial dentures.
4. A pinrest to provide space for the central screw and the two occlusal plane orientors.

Advantages:

1. Precise Mounting
2. Detailed teeth arrangement
3. Accurate midline positioning
4. Precise orientation of casts.
5. Easier and simplified technique.
6. Acknowledges any error in the mounting.

This articulator aids in helping dentists make accurate dentures using a regularly used mean value articulator. It will not only improve the quality but also the efficiency of work among dental students and professionals. These additional features will help us accomplish patient's satisfaction. This aids in ascertaining the best prosthodontic care to patients.

The aim of this invention is to make an articulator that makes orientation and midline location accurate along with a precise occlusal plane provider and compensatory curve plate. The articulator using technical drawing software was initially performed. The material selected was aluminium due to its light weight and durability. Intricate Welding was performed for minor additions and corrections. The various features of the invention have helped in easy and simplified mounting of the casts and providing the curve of spee and Wilson which are usually difficult to inculcate in the dentures.

8. BRIEF DESCRIPTION OF DRAWING:

Fig No.1 is the schematic representation of the showing the isometric view of the PAA ARTICULATOR with flat plate

Fig No. 2 is the schematic representation of the showing the isometric view of the PAA ARTICULATOR with compensatory curved plates.

Fig No. 3 is the schematic representation of the showing the profile view with flat plate of the PAA ARTICULATOR.

Fig No. 4 is the schematic representation of the showing the profile view with curved compensatory plate of the PAA ARTICULATOR.

9. DETAILED DESCRIPTION OF DRAWINGS:

Fig. No. 1 is the isometric view of the PAA ARTICULATOR which has

1) The posterior rod is called the Pinrest (1) which supports the thumbscrews of the assembly
2) The condylar guidance (2) simulates the temporomandibular joint. Hence, it opens and closes the articulator
3) The Lingual Midline thumbscrew (3) helps in the placement , removal and adjustment of the lingual midline locater (12)

4) The right and left Occlusal Plane Orientors (18 & 5) help in the precise orientation of the casts during mounting.

5) The right and left Occlusal Plane Orientor Thumbscrews (13 & 4) help in the precise fixation of the orientors during mounting.

6) Flat plate (6)

7) The upper (15) and lower member (7) contain the mounting plates (8) which will help in the mounting of casts and retaining it.

8) The Incisal Guide table rests (9) the Incisal Rod (10) and the Incisal Pin (11). It is static at 10 degrees and not customizable

9) The Incisal Rod supports the Incisal pin (11).

10) The Lingual Midline Locator (12) helps in marking the Midline of the teeth arrangement using the anterior incisal pins as 2- point guidance.

11) Incisal Thumbscrew (14) helps in the adjustment of the length of the incisal rod. It is mandatory during mounting that the upper terminal of this rod completely flushes with the upper member.

12) Mounting screws (16) help to place the mounting plates in place.

13) The L- frame helps in supporting the entire assembly.

Fig No. 2 is the schematic representation of the showing the isometric view of the PAA ARTICULATOR with compensatory curved plates which has

1) The posterior rod is called the Pinrest (1) which supports the thumbscrews of the assembly

2) The condylar guidance (2) simulates the temporomandibular joint. Hence, it opens and closes the articulator

3) The Lingual Midline thumbscrew (3) helps in the placement , removal and adjustment of the lingual midline locater (12)

4) The right and left Occlusal Plane Orientors (18 & 5) help in the precise orientation of the casts during mounting.

5) The right and left Occlusal Plane Orientor Thumbscrews (13 & 4) help in the precise fixation of the orientors during mounting.

6) Flat plate (6)

7) The upper (15) and lower member (7) contain the mounting plates (8) which will help in the mounting of casts and retaining it.

8) The Incisal Guide table rests (9) the Incisal Rod (10) and the Incisal Pin (11). It is static at 10 degrees and not customizable

9) The Incisal Rod (10) supports the Incisal pin (11).

10) The Lingual Midline Locator (12) helps in marking the Midline of the teeth arrangement using the anterior incisal pins as 2- point guidance.

11) Incisal Thumbscrew (14) helps in the adjustment of the length of the incisal rod (10) . It is mandatory during mounting that the upper terminal of this rod completely flushes with the upper member.

12) Mounting screws (16) help to place the mounting plates in place.

13) Curved Compensatory Plate (17) is used to facilitate teeth arrangement within the confined of the articulator and to attain the standard curve of spee.

Fig No. 3 is the schematic representation of the showing the profile view with flat plate (6) of the PAA ARTICULATOR.

Fig No. 4 is the schematic representation of the showing the profile view with curved compensatory plate (17) of the PAA ARTICULATOR

10. CLAIMS:

1. The PAA ARTICULATOR comprises of :
    a) Pinrest (1)
    b) The condylar guidance (2)
    c) The lingual midline thumbscrew (3)
    d) The left occlusal plane orientor thumbscrew (4)
    e) The left occlusal plane orientor (5)
    f) The flat plate (6)
    g) The lower member (7)
    h) The mounting plates (8)
    i) The incisal Guide table rests at 10 degrees (9)
    j) The incisal Rod (10)
    k) The incisal pin (11)
    l) The lingual midline locator (12)
    m) The right occlusal plane orientor thumbscrew(13)
    n) The incisal Thumbscrew (14)
    o) The upper members (15)
    p) The mounting screws (16)
    q) The curved compensatory plate (17)
    r) The right occlusal plane orientor (18);

which works as follows-

The Aluminium framework which is weighted to lend stability to the entire machine so as to prevent toppling. The upper and lower members (15 & 7) contain the mounting plates (8) which will help in the mounting of casts and retaining it. The L- frame helps in supporting the entire assembly. The Incisal Guide table (9) rests the Incisal Rod (10) and the Incisal Pin

(11). It is static at 10 degrees and not customizable. The Incisal Rod (10) supports the Incisal pin (11). The posterior rod is called the Pinrest (1) which supports the thumbscrews (3, 4 & 13) of the assembly. The right and left Occlusal Plane Orientors & Thumbscrews (4, 5, 13,18) help in the precise orientation of the casts during mounting. The Lingual Midline Locator (12) has a slit to slide in the compensatory curve plates & flat plates (6 & 17). The condylar guidance (2) simulates the temporomandibular joint. Hence, it opens and closes the articulator.

2. As claimed in claim 1, after the jaw relations procedure, casts should be placed on the wax studs to orient the casts for mounting. The occlusal plane should coincide with the occlusal plane orientor, lingual midline locator and the incisal pin (3- point guidance). This is a more accurate method compared to the arbitrary thread relation we use. After coinciding the occlusal plane orientors then proceed ahead with the mounting. The plaster should be mixed with the water powder ratio provided by the manufacturer.After skillful mixing, load the material on the casts and wait for it to set accurately.
3. As claimed in claim 1, after the setting of the material, teeth arrangement is commenced. Arrange the anterior teeth precisely after which the posterior teeth should be arranged according to the compensatory curved plates inserted into the lingual midline locator. The arrangement automatically sets in the direction of the desired compensatory curve of specific dimensions. The flat plates provided in the assembly help in the mounting of single complete dentures.
4. The L- frame, as claimed in claim 1, helps in supporting the entire assembly.
5. The Occlusal plane orientor as claimed in claim 1, helps in cast orientation during mounting.

6. The compensatory curved plates as claimed in claim 1, are of all dimensions which help in the arrangement of teeth along the curve of Spee and curve of Wilson.
7. Lingual Midline locator as claimed in claim 1, are of all dimensions that helps in the location of midline.
8. Pinrest as claimed in claim 1 holds all locators together.
9. The flat plates as claimed in claim 1, are of all dimensions that help in single arch mounting.

Dated this 30th December 2016.

DR.M.V.GHORPADE

(REGISTRAR)

FOR KRISHNA INSTITUTE OF MEDICAL SCIENCES

Krishna Institute of Medical Sciences, Deemed University, Karad

To

The Controller of Patents,

The patent office,

At Mumbai – 400 037

11. ABSTRACT OF THE INVENTION

The aim of this invention is to make an articulator that makes orientation and midline location accurate along with a precise occlusal plane provider and compensatory curve plate. The articulator using technical drawing software was initially performed. The material selected was aluminium due to its light weight and durability.Intricate Welding was performed for minor additions and corrections.The various features of the invention have helped in easy and simplified mounting of the casts and providing the curve of spee and Wilson which are usually difficult to inculcate in the dentures.

DR.M.V.GHORPADE

(REGISTRAR)

FOR KRISHNA INSTITUTE OF MEDICAL SCIENCES

FORM 2

THE PATENTS ACT, 1970
(Act 39 of 1970)
AND
THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See section 10; rule 13)

TITLE OF THE INVENTION
BIOARTIFICIAL PANCREAS

APPLICANTS

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2) Krishna Institute of Medical Sciences
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INVENTORS

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Powai, Mumbai-400076, Maharashtra, India;
5) Kadam, Sachin of Krishna Institute of Medical Sciences, Department of Genetics,
Malkapur, Karad-415539, District Satara, Maharashtra, India
All Indian Nationals

PREAMBLE TO THE DESCRIPTION

The following specification particularly describes the invention and the manner in which it is to be performed.

FIELD OF THE INVENTION

The present invention relates to bioartificial pancreas for releasing insulin comprising a composite hollow fiber membrane (HFM) consisting of polysulfone and Vitamin E polyethylene glycol succinate (ETPGS) wherein said HFM encapsulates an insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby. The present invention also relates to a process for preparing the bioartificial pancreas.

It particularly originates from the composite article disclosed in our co-pending Indian Patent Application No. 2697/MUM/2010 covering articles made from polysulfone and Vitamin E polyethylene glycol succinate (ETPGS) which are biocompatible and have enhanced permeability and a process for producing the same.

BACKGROUND OF THE INVENTION

Diabetes is the most common endocrine disease in developed and developing countries with devastating human, social and economic impact. Type 1 is insulin dependent diabetes in which the pancreas ceases to produce insulin. The current methods of treatment include insulin injections, insulin pump therapy and islet or whole pancreas transplantation. Out of the above methods, islet transplantation is seen as a potential treatment method due to advantage of insulin being produced when needed by the body. This has led to the development of bio-artificial pancreas (BAP). A BAP contains pancreatic islets (allogeneic or xenogeneic) or differentiated islets encapsulated within a synthetic biocompatible semipermeable membrane and are meant to fully mimic the behavior and function of a healthy pancreas. Encapsulation of islets solves the problem of giving the immune-suppressive drugs to the patient's life-long. Major concerns for the BAP are the availability of islets and their immune protection.

Scarcity due to unavailability of the donor pancreas is a major hurdle in islet transplantation as 2-3 organ donors are required for a single recipient. This has led to a quest for the finding of alternate sources of islets. Human embryonic stem (ES) cells possess a viable option for differentiation to the pancreatic lineage, but the problem with ES is that no one has shown these cells are truly similar to normal beta cells. Also, ethical issues and tumorogeniticity problem surrounding ES cells are major concern. Immunoisolation is ideally achieved by encapsulating insulin-producing biologic tissue and protecting it with a semipermeable membrane, to prevent tissue destruction by patient's own immune system and at the same time dispensing with drug immunosuppression therapy. The ideal characteristics of membrane should be biocompatibility with good diffusional properties, easy retrievability of device, maintenance of cell viability and functionality for long periods of time. Oxygen delivery, which may be compromised by virtue of membrane diffusional properties, is further hampered when an immune reaction to the transplanted cells or immuno-barrier material results in presence of cells adhering to the outside of the device. These cells consume oxygen and further reduce access of oxygen to cells in the device interior. Immunoisolation techniques can be classified into intravascular macrocapsule, extravascular macrocapsule and extravascular microcapsule with each having their pro and cons.

Intravascular devices are usually made up of hollow fibers in which blood flows through the lumen, but have major problem in needing vascular surgery. Extravascular devices usually have microcaspules made up of alginate in most cases, having diffusion advantage over some other type of devices. They suffer from issue of post-surgical retrieval of the implant needed for renewal. Macrocapsular devices have flat sheets, hollow fibers and macrospheres. These hollow fibers have advantages in terms of large surface area, self-supporting and excellent scalability. Insulin absorption on membranes of Thomapro (polyamide), Cuprophane, HDF (cellulose) and Amicon XM-50 (poly vinyl chloride) was

found to be the reason for graft failure. Instead of the release, the insulin was adsorbed onto membrane surface.

US2002/0151055 A1 describes the development of artificial pancreas device comprising agar micro-beads. Physiologically active pancreatic islet cells capable of producing insulin, encapsulate within a semi-permeable sphere agar gel membrane. However, the device is difficult to retrieve and is less bio-acceptable and the secreted insulin is not available properly.

US5262055 discloses the development of implantable and refillable bio-hybrid artificial pancreas. More particularly, this invention relates to a rechargeable system comprising pancreatic islets suspended in a thermo-sensitive polymer matrix which is water soluble at lower temperatures but solidifies to a gel at body temperature contained within a rechargeable membrane pouch permeable to insulin but impermeable to immune-substances such as immune-globulins, antibodies and the like. The device described in this patent has a convoluted structure which makes it relatively difficult to handle and requires frequent refilling of islets due to hypoxic conditions inside the polymer pouch.

US2004/0158232A1 describes artificial pancreas comprising reservoirs for retaining insulin, and therapeutic agents. This disclosure relates to an implantable artificial pancreas. In particular, this relates to a closed loop insulin delivery system that is implantable and functions as an artificial pancreas. However, the device is structurally complicated and requires continuous monitoring for effective glucose clearance.

RU137198 describes the implant which contains cellular component and biocompatible matrix-carrier for implanting liver and pancreatic cells. In particular, micro-particles of spherical form by the size of 130-380 m from the porous cross-linked gelatin with the sizes of times 6-22 m. However, the device is

difficult to retrieve and is less bio-acceptable and the secreted insulin is not available properly.

To circumvent the above problem, the present invention provides a composite hollow fiber membrane based BAP which is biocompatible and bio-acceptable by host system that can also provide protection to encapsulated islets against the host immune system. The present invention optimizes for pancreatic application the levels of the additive Vitamin E polyethylene glycol succinate (ETPGS) and then prepares Polysulfone (Psf)/ETPGS composite hollow fiber membrane (HFM). The optimized HFM exhibited uniformed structure with low insulin adsorption and selectivity. Psf/ETPGS HFM were used to encapsulate the stem cells differentiated islet and pancreatic islets, preferably porcine islets as a xenogenic source.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides a bioartificial pancreas for releasing insulin comprising: a composite hollow fiber membrane (HFM) consisting of polysulfone and Vitamin E polyethylene glycol succinate (ETPGS) wherein said HFM encapsulates an insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby.

In another aspect, the present invention provides a process for preparing bioartificial pancreas for releasing insulin comprising:

a) preparing a composite hollow fiber membrane (HFM) comprising polysulfone and Vitamin E polyethylene glycol succinate (ETPGS); and

b) encapsulating an insulin producing cellular moiety inside said membrane.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of the invention will be better understood when read in conjunction with the appended drawings. For the purpose of assisting in the explanation of the invention, there are shown in the drawings embodiments which are presently preferred and considered illustrative. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentation shown therein.

Figure 1: Schematic diagram of hollow fiber spinning pilot plant.

Figure 2: (A) SEM microstructure of different HFMs prepared by phase inversion using syringe pump setup; Insulin adsorption is seen on different types of membranes by FTIR spectra (B) and through colourimetric protein adsorption (C); and (D) represents change in ultrafiltration coefficient due to fouling in the membranes.

Figure 3: (A) SEM microstructure of different PT membranes with increasing TPGS concentration, SEM micrographs of PT20 membranes showing the magnified view of asymmetric cross section (b) with inner pores in nanometer range (a) and outer macroporous membrane structure (c); (B) diffusion of glucose and (C) insulin across different PT membranes.

Figure 4: (A) The isolated MSCs shows a fibroblast like morphology in DIC image (a) and (b) shows confocal micrograph where actin filament is stained green with red nucleus of MSCs; (B) Immunofluorescence staining of hUCMSCs cells showing the expression of surface markers like a) nestin; b) fibronectin and c) vimentin; (C) hUCMSCs showed homogenous mesenchymal population stained positive for CD90, CD105, oct-4 and negative for CD34.

Figure 5: (A) Multilineage differentiation potential of umbilical cord isolated MSCs; (B) differentiation stages of hUCMSCs a) seeded cells at day 0; b) migration of cells towards each other at day 3; c) formation of immature ILCs at day 6; and d) maturation of formed ILCs; (C) Differentiated islet showed positive dithiozone test of stem cells differentiated islets (a) and porcine islets (c) and isolated porcine islets (b).

Figure 6: (A) Z-scan imaging of islets from 1-23μm showing the secretion of insulin by differentiated islets; (B) imaging of porcine pancreatic section showing secretion of insulin and glucagon.

Figure 7: Step by process of implantation of HFM in the mouse, a) shows shaved mouse, b) shows implantation of fibers in peritoneal cavity and c) shows suture.

Figure 8: The graph showing (A) blood glucose levels in implanted mouse model for a period of 30 days and (B) IPGTT for an interval of 2 hrs.

Figure 9: The image showing normal control pancreas (a) and test group pancreas (b, c) stained for mouse specific insulin and nuclei by DAPI.

Figure 10: Histopathological analysis of implant by hematoxylin and eosin stain. (A) Optical photomicrograph of hematoxylin and eosin stained hollow fiber integrated tissue section of SHAM mouse (a), porcine islets encapsulated HFM (b) and stem cell differentiated islets (c); (B) Morphology of normal pancreatic islets (a), encapsulated porcine islets (b) and stem cell differentiated islets (c).

Figure 11: Histopathological analysis of implant by hematoxylin and eosin stain. (A) Hollow fiber integrated tissue section of porcine islets encapsulated HFM (a) and stem cell differentiated islets (b). (*- Vascularization; <- polymorphonuclear leukocyte (PMN) and - Endothelial cells).

DESCRIPTION OF THE INVENTION

In describing the invention, the following terminology will be used in accordance with the definitions set forth below. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are described herein. As used herein, each of the following terms has the meaning associated with it in this section. Specific and preferred values listed below for individual process parameters, substituents, and ranges are for illustration only; they do not exclude other defined values or other values falling within the preferred defined ranges. All publications mentioned herein are incorporated by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

As used herein, the singular forms "a," "an," and "the" include plural reference unless the context clearly dictates otherwise.

The terms “preferred” and “preferably” refer to embodiments of the invention that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the invention.

When the term “about” is used in describing a value or an endpoint of a range, the disclosure should be understood to include both the specific value or end-point referred to.

As used herein, the terms “comprises”, “comprising”, “includes”, “including”, “containing”, “characterized by”, “having” or any other variation thereof, are intended to cover a non-exclusive inclusion.

In one aspect, the present invention provides a bioartificial pancreas for releasing insulin comprising: a composite hollow fiber membrane (HFM) consisting of polysulfone and Vitamin E polyethylene glycol succinate (ETPGS) wherein said HFM encapsulates an insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby. The composite HFMs may be used as a semi-permeable, biocompatible, implantable and immune-competent bioartificial pancreas for the treatment of type 1 diabetes.

The HFM of the present invention comprises 5 wt% to 25 wt% of Vitamin E polyethylene glycol succinate (ETPGS) based on the weight of polysulfone. The polyethylene glycol of Vitamin E polyethylene glycol succinate (ETPGS) has a molecular weight ranging from 400 to 40000 Da.

The HFM has a thickness of 130-160μm and a macro porous and a nano porous region, said macro porous region and nano porous region each independently located either on the inner or the outer surface. Increase in the TPGS concentration leads to increase in wall thickness of the HFMs. The hollow fiber membranes have an asymmetric structure. Inner side of membrane have skin layer which have pores in the nano range and is responsible for separation. Rest of the membrane is more porous and has macrovoids which provides support. The outer surface is smooth with macropores in microstructure. The inner pores of the membranes have a diameter in the nanometer range, and the Molecular weight cut off (MWCO) is 25-30K which will permit the passage of insulin and at the same time the diffusion of IgG will be hindered. The outer pores are larges in diameter; this is an ideal condition so that there should not be any interference of diffusion

due to outer pores. The skin layer responsible for separation is only few microns thick (5-10 μm) and the rest of the membrane act as a porous support.

Suitable insulin cellular moieties are selected from the group consisting of islets from xeno-sources such as pancreatic islets, precursor to pancreatic islets or stem cells differentiated islets. These cellular moieties have an average diameter of 100-150μm.

The pancreatic islets may be selected from the group consisting of but not limited to porcine islets, bovine islets, rat islets, mouse islets, feline islets, canine islets or equine islets. In an embodiment of the present invention, the preferred pancreatic islets are porcine islets isolated from the porcine pancreas collected at Brihan Mumbai Municipal Corporation Deonar abattoir in pig unit. Porcine amino acid sequences have considerable sequence homology with human insulin and therefore a preferred source of pancreatic islets.

The stem cells differentiated islets are islet like clusters derived from mesenchymal stem cells. In an embodiment of the present invention, the mesenchymal stem cells are isolated from human umbilical cord Wharton's jelly.

In a preferred embodiment of the present invention, the HFM consists of polysulfone and 20 wt% of Vitamin E polyethylene glycol succinate (ETPGS) and encapsulates and insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby.

In another aspect, the present invention provides a process for preparing bioartificial pancreas for releasing insulin comprising: a) preparing a composite hollow fiber membrane (HFM) comprising polysulfone and Vitamin E polyethylene glycol succinate (ETPGS); and b) encapsulating an insulin producing cellular moiety inside said membrane.

The HFM is prepared comprising the steps of:

a) mixing a solution of Vitamin E polyethylene glycol succinate (ETPGS) with a solution of polysulfone in an organic solvent to produce a homogenous dope solution;

b) extruding said dope solution coaxially with water through spinnerets to form hollow filaments;

c) passing said filaments through an airgap;

d) coagulating and precipitating said filaments; and

e) rinsing and winding said filaments and forming HFM.

In an embodiment of the present invention, the polyethylene glycol (PEG) of Vitamin E polyethylene glycol succinate (ETPGS) has a molecular range of 400 to 40000 Da and is present in the range of 1 to 40 wt% based on the total weight of polysulfone and organic solvent.

The flow rate of the dope solution and water is in the range of 0.5 to 5 ml/min and water bore is in range of 0.5 to 20 ml/min and the airgap is between 20 to 50 cm.

The step of coagulating said filaments is carried out in a medium selected from water and lower alcohols of the range C_1 to C_5 or mixture thereof at a temperature range of 5 to 30ºC; said filaments are rinsed with water in a bath at a temperature of 25ºC to 50ºC and wound at a speed of 1 to 60 m/min.

Suitable organic solvents which may be used are selected from N-methylpyrrolidone, dimethylacetamide, dimethylformamide, dimethylsulphoxide and tetrahydrofuran.

The insulin producing cellular moiety are encapsulated inside said HFM by transferring a solution containing said cellular moiety into said HFM using a syringe followed by heat sealing the open ends of said HFM, wherein the solution

of insulin producing cellular moiety are prepared in 1% sodium alginate solution at a ratio of 100 islets per HFM piece.

The bioartificial pancreas of the present invention offers the following advantages:

1) Low insulin adsorption on the membrane surface leading to more insulin availability for diffusion.

2) Increased survival of islets due to anti-oxidation property of membrane due to presence of vitamin E.

3) Biocompatibility of material and reduced rejection of implanted device as it promotes angiogenesis.

4) Dimensions preventing hypoxia during immunoisolation. Due to optimized inner dimension of HFM, islet mass will not form at single site and leading to less necrosis due to hypoxia at center.

Thus, the present invention provides Psf-TPGS composite hollow fiber membrane that can be used as an implantable, immune-competent bioartificial pancreas as a therapy for type 1 diabetes. The selection of umbilical cord was done for mesenchymal stem cell isolation to as the cord is considered a biological waste and generally discarded after the birth of child. The additives used for making composite membrane and the concentration for maximum insulin and glucose diffusion were optimized. The pancreatic islets and stem cells differentiated islets were implanted into mouse model and have shown reversal of diabetes for a study period of one month. The bioartificial pancreas of the present invention has shown promise as immunoisolation device for xenotransplantation also considering the scarcity of available islet sources.

The following examples are provided to better illustrate the present invention and are not to be interpreted in any way as limiting the scope of the invention. All specific materials and methods described below, in whole or in part, fall within the scope of the invention. These specific compositions, materials, and methods

are not intended to limit the invention, but merely to illustrate specific embodiments falling within the scope of the invention. One skilled in the art may develop equivalent materials, and methods without the exercise of inventive capacity and without departing from the scope of the invention. It will be understood that many variations can be made in the procedures herein described while still remaining within the bounds of the invention. It is the intention of the inventors that such variations are included within the scope of the invention.

Examples:

Materials and Methods

1.1 Hollow fiber spinning setup

An indigenously developed HFM spinning pilot plant as described in the paper Dahe et.al. (Dahe, Teotia et al. 2012,"Correlation between spinning temperature, membrane morphology, and performance of Psf/PVP/NMP/Water hollow fiber membrane forming system." Journal of Applied Polymer Science 124(S1): E134-E146) with some modification was used for making fibers and schematically shown in Figure 1. Broadly, the set-up consists of two lines for bore and dope solutions containing pressure vessels, mesh filters, needle valves and gear pumps. Line components are connected in series through standard swagelok tubings and their outputs are joined to coaxial spinneret. Spinneret is mounted on top of coagulation tank to vary air gap. Spun fiber is coagulated in coagulation bath.

The schematic of designed pilot-scale continuous hollow fiber spinning plant is shown in Figure 1. The set-up consists of two lines for bore and dope solutions containing pressure vessels, mesh filters, needle valves and gear pumps. Line components are connected in series through standard swagelok tubings and their outputs are joined to the coaxial spinneret. The spinneret is mounted on top of the coagulation tank to vary the air gap. Material of construction used for all of the above components is SS316 and the whole plant is housed in a controlled humidity room.

The various components of the hollow fiber spinning plant depicted in Figure 1 are as follows:

Sr. No.	Description
1	Nitrogen Supply
2	Pressure Relief Valve
3	Pressure Gauge
4	Dope Solution Jacketed Pressure Vessel
5	Bore Solution Jacketed Pressure Vessel
6	Cryostat
7	Mesh Filter
8	Gear Pump
9	Needle Valve
10	Insulated Vessel Containing Coolant
11	Coiled Tube
12	Temperature Indicator
13	Spinneret
14	Spinneret Jacket for Maintaining Spinneret Temperature
15	Coagulation Tank

Specific details of plant components are as follows:

Pressure vessels: Two cylindrical jacketed pressure vessels of 1.5 lit capacities have been used for bore and dope solution feed at different temperatures. Each pressure vessel top is equipped with pressure gauge, safety relief valve, nitrogen inlet, thermowell for temperature measurement and their bottoms have tapered outlets.

Cryostat: A cryostat has been used to control and regulate the temperature of solutions in jacketed pressure vessels from 5 – 60ºC. The cryostat liquid bath is circulated through the jackets of pressure vessels.

Mesh filter: Mesh filters of 5µ and 10µrating have been used for bore and dope solutions, respectively. Mesh filters remove suspended particles in the solutions and aid in avoiding choking of the gear pump.

Needle valves: Needle valves have been used to control bore and dope solution flow rates, during spinning startup and shutdown.

Gear pumps: Two micro-annular gear pumps of flow rate 0.048 – 288 ml/min have been used for pulse-less extrusion of bore and dope solutions through the spinneret. An additional gear reduction assembly has been used for extruding viscous dope solution.

Spinneret: The spinneret consists of two coaxial tubes connected with inlets with the inner and outer tube dimensions as 0.4/0.8 mm (ID/OD) and 1.4 mm (ID), respectively. Bore and dope solutions flow simultaneously through the center tube and annulus of spinneret, respectively.

Coagulation tank: An open-top, tank has been used to coagulate hollow fibers. Residence time of fibers in the coagulation tank is based on the time taken for complete precipitation of polymer solution in non-solvent.

1.2 Preparation of hollow fiber membrane (HFM)

Polysulfone (UDEL^{TM} P-3500 LCD MB7-BULK) was procured from M/s. Solvay Advanced Polymers, USA. Polysulfone was dried in vacuum oven for 24 h at 90°C for removal of absorbed water. Vitamin E TPGS (NF grade) was generously gifted by M/s. Isochem SA (Paris, France) and used without further purification. Polyethylene glycol (PEG) and Polyvinylpyrrolidone (PVP) additive, and N-methyl-2-pyrrolidone (NMP) solvent, were procured from S.D. Fine-Chem Ltd., India.

Four different type of dope solution were used for preparation of 4 different HFMs viz.

1) Plane polysulfone (P): Psf/NMP HFM (20/80)
2) Polysulfone with TPGS additive (PT): Psf/TPGS/NMP (20/10/70)
3) Polysulfone with PVP additive (PV): (20/5/75) Psf/PVP/NMP
4) Polysulfone with PEG additive (PG): (20/10/70) Psf/PEG/NMP

The spinning parameters values are shown in table 1 and were kept constant for all fibers. These prepared fibers were kept in water for one day to remove residual NMP solvent and use for further studies. The process parameters used for spinning are listed in Table 1.

Table 1: Process parameters used for hollow fiber membrane preparation using the syringe pump setup.

Ambient Temperature (ºC)	25
Relative Humidity (%)	50-60
Dope Solution Composition (wt %)	(Psf/Additive/NMP)= 20/10/70
Bore Solution Composition	Deionized Water
Dope Solution Temperature (ºC)	Room Temperature (RT)
Bore Solution Temperature (ºC)	RT
Dope Flow Rate (ml/min)	2
Bore Flow Rate (ml/min)	4
Spinneret ID/OD (mm)	0.8/1.4
Air Gap (cm)	45
Coagulation Bath Composition	Reverse Osmosis Water
Coagulation Bath Temperature (ºC)	RT

1.3 Morphological study of HFMs by scanning electron microscopy

Morphology studies of HFMs were carried out using scanning electron microscope (SEM). Hollow fibers were freeze fractured in liquid nitrogen for preventing structure damage and dried. HFMs were coated with platinum by sputter coating using Auto fine coater JFC-1600 (JEOL, Japan). Samples were observed under scanning electron microscope at 5-10 kV (JSM- 7600F, Jeol).

1.4 Insulin absorption on HFM by Fourier transform infrared (FTIR)

FTIR measurements were performed on a hyperion 3000 Bruker spectrometer (Germany); 256 scans were signal averaged at a resolution of 4 cm^{-1}. The attenuated total reflection (ATR) spectra were obtained using a KRS-5 prism. For

getting the FTIR spectra of inner side of HFM, small piece of hollow fiber was cut in middle, opened and stuck on double-sided adhesive cellophane tape so as to get flat surface for analysis. Standard insulin solution (Mixtard) was poured over the dried HFMs inner surface. Then the insulin was allowed to adsorb at 37˚C for 2 h. After incubation, 3-5 times gentle washing of HFMs was done. Spectra of these samples were taken after drying them completely. Similarly, quantification of insulin absorption on both inner and outer side of HFM was done by Micro BCA protein detection kit. In brief, hollow fibers were cut in half so as to allow the absorption on their both, inner as well as outer surface. Standard insulin solution (Mixtard) was poured overdried HFMs inner and outer surface. Then the protein was allowed to adsorb at 37˚C for 2 h. After incubation, HFMs pieces were placed in 24 well plates and rinsed gently with PBS. Aqueous solution of sodium dodecyl sulfate (SDS, 1 wt %) was used to remove adsorbed protein on surface. These 24 well plates containing membranes and SDS solution were then shaken for 60 min and sampled. The amount of proteins adsorbed on membrane surface was calculated from the concentration of proteins in SDS solution using a protein analysis kit (Micro BCA Protein Assay Kit, Pierce Biotechnology, IL, USA). Data are expressed as means ± SD of four independent measurements.

1.5 Preparation of Psf-TPGS with different TPGS concentration

Post optimization of additive, the Psf-TPGS was chosen for further studies. Different concentrations of TPGS additive were added to the polymer dope composition. PT5, PT10,PT15 and PT20 having TPGS concentration of 5%, 10%, 15% and 20% respectively were used for HFM preparation.

1.6 Diffusion of Glucose and Insulin across the membrane

Three pieces of 5 cm of different HFM were used for the diffusion studies. Standard insulin solution (Mixtard) and glucose solution was put into the lumen of hollow fiber and both ends were heat sealed. These samples were kept in water to allow diffusion of the insulin for a time interval of 0.5, 1, 3, 5, 10 and 30 min.

Diffusion of glucose was measured as per manufacturers instruction using commercially available kit and insulin was checked by UV.

1.7 Isolation of mesenchymal stem cells from human umbilical cord

Umbilical cords (UC) were collected from Krishna Institute of Medical Sciences University (KIMSU), Karad after proper consent from parents of new born child. The protocol for isolation of MSCs from Umbilical cord is adapted from Kadam et.al. ("Simultaneous isolation of vascular endothelial cells and mesenchymal stem cells from the human umbilical cord." In Vitro Cellular and Developmental Biology - Animal 45(1-2): 23-27). Briefly, cord blood was drained and clots were flushed from vessels using sterile phosphate buffer saline (PBS). After cleaning, the umbilical cord was processed for isolation of human umbilical cord derived mesenchymal stem cells (hUCMSCs). To isolate hUCMSCs, blood vessels from the UC were removed by blunt dissection and remaining portion of cord was chopped into pieces of 1-2 mm length using sterile surgical blade. The tissue was then digested for 30 min in an enzyme cocktail (Collagenase Type IV: Dispase, 7:1 v/v, Sigma, Roche) on a magnetic orbital shaker at 37°C. Tissue was then transferred to a mixture of Trypsin (0.05%) and EDTA (0.02%), (Himedia, India) and was further incubated for 15-20 min as before. The homogenate was then filtered using sterile muslin cloth and a cell pellet was obtained by centrifuging filtrate at 1500 rpm for 10 min. Finally, the cells were washed and cultured in Dulbeco's Modified Eagles Medium, supplemented with 10 penicillin (100 U/mL), streptomycin (100µg/mL) and 10% FBS and incubated for 48 h at 37°C and 5% CO_2.

1.8 Characterization using immunocytochemistry and flow cytometry

The cells from early passages (4 to 6) were used for characterization studies. Cells were grown in mono- layers on coverslips and fixed using 4% paraformaldehyde. The cells were then permeabilized using 50% methanol for 5 min, followed by blocking using 5% bovine serum albumin (BSA) in PBS for 1 h. The cells were then exposed to primary non-labeled mouse anti- human antibodies, namely

nestin, vimentin, fibronectin (1:100 dilutions; BD, USA), for 12 h at 4°C, followed by respective secondary antibodies (Invitrogen) for 1 h at 37°C. Coverslips were mounted in mounting medium containing antifade (Vectashield; Vector Laboratory, USA) and 4′, 6-diamidoino-2-phenylindole (DAPI). These slides were then viewed using a confocal laser scanning microscope (Olympus Fluoview, FV-500, Japan). DAPI (Invitrogen) was used for nuclei visualization.

1.9 Characterization of isolated cells using flow cytometry

The isolated hUCMSCs from 3rd passage were dislodged using 0.05% trypsin 0.02% EDTA in PBS and re-suspended in DMEM. These cells were fixed in chilled 70% ethanol and incubated in mouse anti human FITC/PE conjugated antibodies against Oct4, CD34, CD44, CD45, CD90, CD105 and CD117 (1:100 dilution) for 1 h on ice (all the antibodies were purchased from Becton Dickinson, San Diego, CA). The events were acquired using a BD-FACS Aria flow cytometer with laser 488 nm (Becton Dickinson, NJ) and data was analyzed using FCS express software.

1.10 Differentiation of human mesenchymal stem cells

Differentiation of MSCs into multi-linage depends on the cocktail of growth factors added to facilitate cells towards a particular lineage. For osteogenic differentiation 5 nM dexamethasone, 250 μM L-ascorbic acid 2-phosphate, 10 mM β-glycerophoshate (Sigma-Aldrich) was used. For chondrogenic differentiation studies, hMSCs were seeded and maintained in a chemically defined medium containing serum-free DMEM, ascorbate, 0.1mM dexamethasone, 40m g/mL L -proline, 100m g/mL sodium pyruvate, ITS-plus (Collaborative Biomedical Products, Cambridge, MA), antibiotics, and 10ng/mL recombinant human transforming growth factor- b1 (TGF- b1; R&D Systems, Minneapolis, MN). Adipogenesis was induced using DMEM supplemented with 10% FBS, 1 mM dexamethasone, 0.5mM 3-isobutyl-1-methylxanthine, 1 mg/mL insulin, and antibiotics. For pancreatic differentiation, hUCMSCs on reaching 80% confluency were seeded in serum free medium (SFM) [DMEM; insulin,

transferrin and selenium (ITS)] for 72 h at 37°C. By day 3 hUCMSCs start forming cell aggregates. On day 4 SFM was supplemented with 0.3 mM taurine. On day 10 these ILCs were induced with a mixture of 100 mM nicotinamide, 3 mM taurine and 100 nM glucagon like peptide 1 (GLP1). The floating islets were collected and used for in-vitro and in-vivo characterization and functional studies.

1.11 Identification of Insulin producing cells by Dithizone staining

Dithizone (DTZ), a zinc-chelating agent, is known to selectively stain pancreatic β cells crimson red, as they contain a large amount of zinc. The culture dishes were incubated at37°C for 15 min in the DTZ solution. After incubation the dishes were rinsed three times with HBSS, clusters stained crimson red were examined under inverted microscope.

1.12 Isolation of Porcine islets

The collection of porcine pancreas was done by digestion with collagenase solution. Briefly, the pancreas was chopped into small pieces; these pieces were digested with the collagenase solution for a time period of 10 minutes on a magnetic stirrer. Digested tissue was filtered through a muslin cloth and recovered islets were centrifuged at 800 rpm. The centrifugation was done 3-4 times and the islets were cultured in the complete RPMI medium for a day and then later encapsulated.

1.13 ILC transplantation into streptozotocin-induced diabetic animals

Balb/C male mice, 6-8 weeks old, were obtained from an inbred colony maintained at experimental animal facility of KIMSU, Karad. The animals were housed under controlled conditions of light (12 h light and 12 h darkness), temperature (24 °C) and humidity (50%) and maintained on normal chow and water. Animal experimental protocols were approved by the KIMSU animal ethical committee. After 6 – 8 h of fasting, the mice were injected intraperitoneally (i.p.) with freshly prepared streptozotocin (STZ; Sigma Aldrich) (200 mg/kg body weight). Blood from the tail vein of 6 – 8 h fasted mice was

assessed for blood glucose (BG) concentrations after 24 h, using an Accutrend sensor comfort blood glucose meter (Roche Diagnostic, Penzberg, Germany) to confirm the diabetic status of animals. Body weights were also recorded at the same time. Mice showing BG consistently more than 300 mg/dL were considered diabetic and glucose clearance impaired.

1.14 Encapsulation of ILC in HFM for transplantation in diabetic mice

A total of five groups with detail in Table 2, with five animals in each group, were created to study in vivo functionality of differentiated ILC as well as porcine islets. A biocompatible and immunoisolatory Psf-TPGS HFMs were used to encapsulate islets to avoid immune-rejection. All encapsulation procedures were carried out under strictly aseptic conditions by UV sterilization of HFMs.

Table 2: Details of the experimental group for implantation study

Group	Material	Detail
1	SI	Stem cells differentiated islets implanted in 3 HFM
2	PI	Porcine islets implanted in 3 HFM
3	Sham	3 HFM implanted with no islets
4	Control	Normal non-diabetic mouse
5	Diabetic	Diabetic mouse

Before transplantation all but negative control group animals were made diabetic by STZ induction. Post confirmation of frank diabetic status of these animals they were used for transplantation study. For transplantation, around 1000 islet-equivalent clusters were suspended in 1% sodium alginate solution at a ratio of 1000 islets/100µL alginate solution. The solution containing ILC was then transferred into HFMs and open end of the membranes were heat sealed.

Animals were fasted overnight and anesthetized by i.p. administration of thiopental sodium at a dose of 40 mg/kg body weight. About 2-mm long incisions were made on the abdomen, and HFMs with and/or without islets were implanted into designated mice group into peritoneal cavity. Animals from experimental group one (SI) received HFMs packed with ILCs derived from hUCMSCs; second group (PI) of animals were transplanted with HFM containing porcine islets; while third group (Sham) of animals received 3 empty HFMs; in the fourth group (control), non-transplanted diabetic animals were considered as positive controls, while non-diabetic untreated animals were considered as untreated diabetic in the fifth group. Incisions were sutured using absorbable 6-0 catgut sutures (Stericat Gutstrings, Delhi, India) and auto-clipper (Becton Dickinson, Bedford, MA, USA). All animals (control and experimental) received an i.p. injection of gentamycin (3 mg/kg body weight), ampicillin and cloxacillin (20 mg/kg body weight) and diclofenac sodium (0.5 mg/kg body weight) for 3consecutive days (starting from the day of operation) in addition to topical ointments (soframycin).

Blood glucose (BG) and body weights were monitored for all groups after every 48 h (values for every 5th day have been represented here). One month after transplantation, animals from ILC transplantation group and undifferentiated hUCMSC group were subjected to an intraperitoneal glucose tolerance test (IPGTT) as described.

1.15 Histological evaluation

Post completion of study all animals from various groups were sacrificed. All major organs viz. heart, kidney, liver, pancreas, spleen from each animals were excised and collected along with implants with the surrounding tissue and fixed with 10% formalin. These fixed tissues organs were embedded in paraffin, sectioned (2–3mm thick) with a microtome at three different distances from the surface, and stained with hematoxylin and eosin (H&E) (Sigma Aldrich, MO, USA) as per standard protocol.

All the organs section were examined for cellular abnormality if any and implants were studied for neovasuclarisation around the external surface of HFM, presence of fibrin, exudates etc.

Results

2.1 Morphology of the HFM by SEM

Dry-wet phase inversion spinning method is most commonly used for preparation of porous HFM. During preparation of membrane, the polymer solution is transformed in a controlled manner from liquid to solid state. Overview of all these HFM membranes (Psf, abbreviated as P; Psf-TPGS, abbreviated as PT; Psf-PVP, abbreviated as PV; and Psf-PEG, abbreviated as PG) shows an asymmetric membrane throughout the fiber as seen in Figure 2A. The wall thickness of the HFMs ranged between 130-160μm depending on dope solution used.

2.2 Insulin absorption by Fourier transform infrared (FTIR)

Insulin absorption is an important test for development of the membranes for BAP application. Monomeric insulin is characterized by a peak at 1654cm^{-1} characteristic of α-helical proteins. In the amide I region, altogether 11 peaks in 1620-1700cm^{-1} region can be recognized. FTIR spectra of the different membranes in the range of wavenumber (1600-1700cm-^{1}) can be seen in Figure 2B. This spectra shows minimal peak for TPGS membrane which is indicative of low insulin absorption on the membrane. TPGS is known to make membrane hydrophilic. Similar trend is observed in plot of quantification (Figure 2C) of insulin absorption on complete fibers (both outer side and inner side of the membranes). Low protein (insulin) absorption is a highly desirable property for the development of materials for BAP. Insulin absorption on membranes of Thomapro, Cuprophane, HDF (cellulose) and Amicon XM-50 was found to be reason for graft failure. Instead of the release, the insulin was adsorbed onto membrane surface. Psf being hydrophobic absorbs more insulin than PVP membranes. Higher concentration of insulin in PEG membranes can be due to complete leaching of PEG molecule from the membrane during formation and

creating more porous, hydrophobic structure which allows for absorption of more insulin. Protein absorption on membranes creates fouling and reduces diffusion properties of the membranes. The PT membranes have lower fouling due to less protein absorption compared to other types of membranes as seen in Figure 2D and were used for the further experiments.

2.3 Preparation of Psf-TPGS with different TPGS concentration

Vitamin E improves glycemic control in people with diabetes. HFM with different concentrations of TPGS were prepared using phase inversion process and microstructure is shown in Figure 3A. Increase in the TPGS concentration leads to increase in wall thickness of the HFMs. This is expected due to increase in dope viscosity by increasing additive with decrease in solvent. The hollow fiber membranes have an asymmetric structure. Inner side of membrane have skin layer which have pores in the nano range and is responsible for separation. Rest of the membrane is more porous and has macrovoids which provides support. The outer surface is smooth with macropores in microstructure. The inner pores of the membranes have a diameter in the nanometer range, and the MWCO is 25-30K which will permit the passage of insulin and at the same time the diffusion of IgG will be hindered. The outer pores are larges in diameter; this is an ideal condition so that there should not be any interference of diffusion due to outer pores. The skin layer responsible for separation is only few microns thick (5-10 μm) and the rest of the membrane act as a porous support.

The average diameter of the human islets is range of 100-150 μm and porcine islets is in the range of 100-150 μm. The inner diameter of the HFMs is in the range of 900 μm, the dimension is suitable to prevent the aggregation of the islets in the hollow fiber tube and at the same time insertion of the islets into the lumen through a needle is possible. The islets will be distributed throughout the lumen edges and chances of necrosis for the center of lumen islets will be less.

2.4 Diffusion of Glucose and Insulin across the membrane

Diffusion of both insulin and glucose across various membranes can be seen in Figure 3B and 3C and was found to be higher in case of PT 20 membranes. This is due to increase in the number of pores in PT 20 membranes formed by leaching of PEG moiety of TPGS material. TPGS molecules have inter-molecular interaction by hydrogen bonding with Psf chains. TPGS loading in Psf HFMs does not increase significantly with increasing TPGS concentration in dope. TPGS holding ability of cluster could be saturated at 5% TPGS in dope. Excess of TPGS molecules diffuse out easily due to its small size and compatibility with water. This induces more porous structure in HFMs which ultimately influence the performance. Increase in water permeability of the membranes is due to increase in pores of membrane by increasing concentration of TPGS in additive. PT 20 was finalized for animal studies. Although thickness of PT 20 is more than the lower TPGS concentration membranes, but porosity of the membrane is more and is also robust to handle while working in animal implantation.

2.5 Isolation of cells from umbilical cord

Umbilical cord of a child is usually discarded after their birth. It has been proved that the Wharton's jelly part of umbilical cord is a rich source of MSCs and has gained attention due to their easy sourcing, culture and differentiability into several tissues. The frequency of mesenchymal stem cells in Wharton's jelly is 1 in 300 cells, unlike cord blood where the frequency is much less, which is 1 in 200 million cells. These mesenchymal stem cells were successfully isolated from the cord. Isolated cells showed fibroblast like morphology as seen in Figure 4A. The confocal staining showed actin filaments and nucleus of the cells grown on a glass surface.

2.6 Characterization of surface markers by confocal microscopy

Isolated cells were tested for the presence of mesenchymal markers by confocal microscopy. Confocal microscopic study showed that hUCMSCs were positive for mesenchymal markers such as nestin, fibronectin and vimentin as seen in

Figure 4B. Correlation between nestin positive stem cells with endocrine development brings out importance of nestin in MSCs making them prospective candidates for islet neogenesis. Vimentin is an intermediated filament protein which is used as a marker of epithelial to mesenchymal transition. Fibronectin is extracellular matrix glycoproteins which binds integrins and other cells extracellular matrix proteins which are involved in cell migration and differentiation. Fibronectin and laminin are known to promote differentiation of human mesenchymal stem cells into insulin producing cells.

2.7 Characterization of stem cells by flow cytometry

Flow cytometric analysis of hUCMSCs showed that they were strongly positive for CD105 (90.27%), CD90 (93.29%), Oct4 (81.12%) and negative for CD34 (Figure 4C). The expression of embryonic marker Oct4 was also observed as Wharton's jelly is the connective tissue between umbilical cord vessels and WJ-derived MSCs possess multipotent properties between embryonic stem cells and adult stem cells.

2.8 Multilineage differentiation of MSCs

Wharton's Jelly MSCs can differentiate into ectodermal, mesodermal and endodermal cellular lineages and successfully expanded ex vivo and cryopreserved. The multipotent nature of isolated MSCs is confirmed by their differentiation into adipogenic, chondrogenic and osteogenic lineage as seen in Figure 5A. MSCs were allowed to differentiate for a period of 21 days. After 21 days, process of osteoblast differentiation was assessed by Alizarin Red S staining. These differentiated cells have shown visible red staining, indicating accumulation of extracellular calcium-containing deposits. By phase-contrast microscopy, it is possible to observe presence of multiple intracellular vacuoles, only in differentiated cells, as demonstrated by Oil Red O staining, which allowed to highlight the presence of multiple neutral lipid vacuoles of different sizes in adipocyte-like cells, resembling multivacuolar adipocytes of brown fat. For

chondrogenic differentiation, only differentiated cells featured the expected formation of lacunae.

2.9 Differentiation of hUCMSCs into ILCs and their functionality

The potential of the isolated hUCMSCs was tested towards differentiation into pancreatic lineage using the 10 day protocol with different cocktail of growth factors. Induction of hUCMSCs with serum free medium containing a cocktail of ITS, nicotinamide, taurine and glucagon like peptide1 (GLP-1) showed a progressive cell clustering from day 2-3 onwards which led to typical islets like clusters (ILCs) formation at the day 6 and their maturation at day 9, as seen in Figure 5B. Role of these growth factors in pancreatic lineage differentiation is evidenced. The differentiated islets were further tested by DTZ stain, which is known to selectively stain pancreatic beta cells because of their high zinc content islets were stained positive as seen by red color in the differentiated islets (Figure 5C (a)).

2.10 Isolation of the porcine islets

Porcine amino acid sequences have considerable sequence homology with human insulin and therefore preferred source for xenotransplantation. Porcine islets were isolated and cultured for a day before macro-encapsulation in HFMs. Islets were found to be viable and functional as seen in the micrographs in figure 3.5A. The islets were of different sizes ranging from 50-200μm.

2.11 Insulin production by the differentiated islets

Immunofluorescence staining of differentiated islets shows the presence of insulin (Figure 6) which emits green fluorescence with FITC. Cell nuclei are blue stained with DAPI. The z-scan shows insulin fluorescence after a depth of 6-10μm at the center of islets. In normal human islets, β-cells (producing insulin) are found in center with alpha and delta cells on periphery of islets.

2.12 ILC transplantation to STZ-induced diabetic animals

One of the important factors leading to successful implantation is biocompatibility of membrane used. β-cells are highly vulnerable to oxidative stress and studies have shown that addition of antioxidants during isolation and encapsulation improves islet functionality. TPGS is water soluble and has both hydrophobic and hydrophilic groups, which help in formation of hydrophobic-hydrophilic micro domain structure. hydrophobic-hydrophilic micro domain structure of membrane results in favorable biocompatibility. The Figure 7 shows surgical steps in implantation of fibers in peritoneal cavity of mouse.

Mice in sham diabetic group transplanted with empty HFM did not show any signs of graft rejection. Untreated diabetic mice showed hyperglycemia throughout the study period and died after 20 days. Non-transplanted, non-diabetic mice showed normal BG values. Mice in SI and PI transplanted group showed a reduction in BG levels and reversal of experimental diabetes after 15 days, which were maintained at less than 140 mg/dL. A standard 2-h IPGTT test resulted in a bell-shaped curve plotted for time versus BG (Figure 8). No significant difference was obtained for SI and PI transplanted mice, and negative control mice when subjected to IPGTT. Upon surgical retrieval of implanted HFM after 30 days of study, very less fibrotic growth was observed on surface of capsules, while the mice died after retrieval with hyperglycemia.

2.13 Confirmation of STZ destruction of Pancreas

After the experimental time interval, pancreas of different group were excised and checked for destruction.

Figure 9 shows the insulin production in pancreas of normal control non-diabetic mouse while there was no fluorescence in test groups, confirming destruction of the pancreas by STZ.

2.14 Histology

At the end of study period that is 30 days mice from all groups were sacrificed and implants along with major organs like heart, kidney, liver, pancreas, spleen were excised and collected.

Morphological and pathological analysis of these excised organ sections and implant sections were performed using optical microscopy based histological evaluation. The organ sections were studied for any morphological cellular abnormality and immune cell infiltration along with fibrosis. Results clearly indicate minimal angiogenesis in all organs but kidney where it is completely absent. Angiogenesis is indicative of normal functional tissue or organs with standard diffusion exchange of nutrients and metabolites. Macrophage or lymphocyte infiltration was not observed in any of tissue indicating no adverse effect of implants on host system and on its key organs.

Tissue reactions with reference to implants are summarized in Table 3 and optical micrographs of respective histological sections are shown in Figure 10 and 11. Relatively higher infiltrations of fibroblast around implants were observed in all groups of animals. Even the higher angiogenesis or neovascularization degree was seen in all the surrounding tissues of implants. Some degree of polymorphonuclears (PMNs), macrophage and lymphocyte infiltrations were also observed in most of the implants. Although the degree of infiltration was seen varied in all the implants, it was to minimal level only. The transverse section of implants clearly shows the intact islets inside HFMs without any adverse reaction or cell disintegration. Similar results were observed in porcine islets and human islet like cell clusters derived from Human MSCs.

These histological studies exhibit favorable tissue response to all groups of implants indicating biocompatibility of HFMs. Neovascularisation in surrounded tissue of implants shows the normal function of host system with good acceptance of graft. These angiogenesis will be helpful for cells which are encapsulated inside the HFMs reducing the hypoxic condition and better survivability of graft. Intact

xenotransplant indicates well accepted graft without any immune rejection or reaction with a good degree of immunoisolation by HFMs.

Table 3: Inflammatory evaluation of intraperitoneal HFMs implants

Implant Type	PMNs	Macrophages	Lymphocytes	Fibroblast	Angiogenesis	Collagen Bundles
SHAM	+	+	+	++	++	Thick
SI	++	++	+	++	++	Thick
PI	+	+	+	++	++	Thick

WE CLAIM:

1) A bioartificial pancreas for releasing insulin comprising: a composite hollow fiber membrane (HFM) consisting of polysulfone and Vitamin E polyethylene glycol succinate (ETPGS) wherein said HFM encapsulates an insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby.

2) The bioartificial pancreas as claimed in claim 1, wherein said HFM comprises 5 wt% to 25 wt% of Vitamin E polyethylene glycol succinate (ETPGS) based on the weight of polysulfone.

3) The bioartificial pancreas as claimed in claim 1, wherein the polyethylene glycol of Vitamin E polyethylene glycol succinate (ETPGS) has a molecular weight ranging from 400 to 40000 Da.

4) The bioartificial pancreas as claimed in claim 1, wherein said cellular moiety is selected from the group consisting of pancreatic islets or stem cells differentiated islets.

5) The bioartificial pancreas as claimed in claim 4, wherein said pancreatic islets are selected from the group consisting of porcine islets, bovine islets, rat islets, mouse islets, feline islets, canine islets or equine islets.

6) The bioartificial pancreas as claimed in claim 4, wherein said stem cells differentiated islets are islet like clusters derived from mesenchymal stem cells.

7) The bioartificial pancreas as claimed in claim 6, wherein said mesenchymal stem cells are isolated from human umbilical cord Wharton's jelly.

8) The bioartificial pancreas as claimed in claim 1, wherein said HFM is semi-permeable, biocompatible and implantable.

9) The bioartificial pancreas as claimed in claim 1, wherein said HFM has a macro porous and a nano porous region, said macro porous region and nano porous region each independently located either on the inner or the outer surface.

10) The bioartificial pancreas as claimed in claim 1, wherein said HFM has a thickness of 130-160μm.

11) The bioartificial pancreas as claimed in claim 1, wherein said cellular moiety has an average diameter of 100-150μm.

12) The bioartificial pancreas as claimed in claim 1, wherein said HFM consists of polysulfone and 20 wt % of Vitamin E polyethylene glycol succinate (ETPGS) and encapsulates an insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby.

13) A process for preparing bioartificial pancreas for releasing insulin comprising:

a) preparing a composite hollow fiber membrane (HFM) comprising polysulfone and Vitamin E polyethylene glycol succinate (ETPGS); and

b) encapsulating an insulin producing cellular moiety inside said membrane.

14) The process for preparing bioartificial pancreas as claimed in claim 13, wherein said HFM is prepared comprising the steps of:

a) mixing a solution of Vitamin E polyethylene glycol succinate (ETPGS) with a solution of polysulfone in an organic solvent to produce a homogenous dope solution;

b) extruding said dope solution coaxially with water through spinnerets to form hollow filaments;

c) passing said filaments through an airgap;

d) coagulating and precipitating said filaments; and

e) rinsing and winding said filaments and forming HFM.

15) The process for preparing bioartificial pancreas as claimed in claim 14, wherein the polyethylene glycol (PEG) of Vitamin E polyethylene glycol succinate (ETPGS) has a molecular range of 400 to 40000 Da and is present in the range of 1 to 40 wt% based on the total weight of polysulfone and organic solvent.

16) The process for preparing bioartificial pancreas as claimed in claim 14, wherein the flow rate of the dope solution and water is in the range of 0.5 to 5 ml/min and water bore is in range of 0.5 to 20 ml/min and the airgap is between 20 to 50 cm.

17) The process for preparing bioartificial pancreas as claimed in claim 14, wherein the step of coagulating said filaments is carried out in a medium selected from water and lower alcohols of the range C_1 to C_5 or mixture thereof at a temperature range of 5 to 30ºC; said filaments are rinsed with water in a bath at a temperature of 25ºC to 50ºC and wound at a speed of 1 to 60 m/min.

18) The process for preparing bioartificial pancreas as claimed in claim 14, wherein said organic solvent is selected from N-methylpyrrolidone, dimethylacetamide, dimethylformamide, dimethylsulphoxide and tetrahydrofuran.

19) The process for preparing bioartificial pancreas as claimed in claim 13, wherein the insulin producing cellular moiety are encapsulated inside said HFM by transferring a solution containing said cellular moiety into said HFM using a syringe followed by heat sealing the open ends of said HFM.

20) The process for preparing bioartificial pancreas as claimed in claim 19, wherein the solution of insulin producing cellular moiety are prepared in 1% sodium alginate solution at a ratio of 100 islets per HFM piece.

Dated this 8th day of July 2016

1) Indian Institute of Technology, Bombay
2) Krishna Institute of Medical Sciences
3) Department of Biotechnology
By their Agent & Attorney
Digitally signed
Karuna Goleria
REG. No. IN/PA-584
of De PENNING & De PENNING

ABSTRACT

BIOARTIFICIAL PANCREAS

The present invention provides bioartificial pancreas for releasing insulin comprising a composite hollow fiber membrane (HFM) consisting of polysulfone and Vitamin E polyethylene glycol succinate (ETPGS) wherein said HFM encapsulates an insulin producing cellular moiety and has a porosity blocking passage therethrough of immunogenic agents and permitting passage therethrough of nutrients for said cellular moiety and the insulin produced thereby. The present invention also provides a process for preparing the bioartificial pancreas.

FORM 2

THE PATENT ACT 1970

(39 OF 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See SECTION 10, RULE 13)

1. TITLE OF THE INVENTION :

KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO

2. APPLICANT:

NAME: KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY

NATIONALITY: DEEMED TO BE UNIVERSITY DECLARED U/S 3 OF UGC ACT, 1956 VIDE NOTIFICATION NO. F.9-15 / 2001 – U-3 OF THE MINISTRY OF HUMAN RESOURCES DEVELOPMENT, GOVT.OF INDIA

ADDRESS: KRISHNA INSTITUTE OF MEDICAL SCIENCES,

NEAR DHEBEWADI ROAD, MALKAPUR, KARAD 415110, MAHARASHTRA, INDIA

3. PREAMBLE TO THE DESCRIPTION:

The following complete specification particularly describes the nature of this invention and the manner in which it is to be performed:

4. TECHNICAL FIELD

The present invention relates to medical sciences. This invention is directed towards structuring of modified goniometer so as to reduce the time needed to assess range of motion, limb length and limb girth and make it more easy and convenient to use. Thus using thisKRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO we can reduce the time consumed during repositioning of patients several times while assessing range of motion, limb girth and limb length and make it more handy and easy to use.

5. Prior Art:

Goniometer is a device used to measure range of motion of a joint in the body. Basically, the process of measuring ROM (range of motion) consists of patient positioned in comfortable position and then the ROM is assessed using goniometer. To assess ROM by universal goniometer, the fulcrum is placed on the bony prominence. The stationary arm is aligned with the stable segment of the body part and movable arm is aligned parallel to the moving segment of the body part whose ROM is to be measured. The patient is asked to do the movement and again same alignment is repeated to measure the angle.

Hence we need a device which can be secured in place firmly even during the movement. Many a times the reference line or bony reference is at distance from the arms of goniometer and so have to consider an imaginary line for the references. Because of the consideration of an imaginary line for the arm placement error occurs and hence to improve the accuracy we need to have goniometer with arms which can be extended enough to reach bony prominences. Routinely goniometer is used to measure ROM and inch tape is used to measure limb girth and limb length but for this we need to take all the assessment separately and for the same we have to repetitively do patients positioning which is sometimes

cumbersome for the parent. Hence there is need of a device using which we can assess patient's ROM, limb girth and limb length simultaneously.

- So until now most routinely goniometer and inch tape were used separately to assess ROM, limb girth and limb length which is time consuming and cumbersome for the patients.

- Also goniometer with straps and extendable arms don't come together so it causes errors in measurement of ROM and makes fixation difficult.

- Briefly stating, our invention is related to a goniometer designed to allow the user to : simultaneously assess ROM, limb girth and limb length while securing the goniometer firmly on the part during movement providing feedback to the patient and placing the arms of the goniometer exactly on the bony reference point so as to avoid the error while placing goniometer and measuring ROM.

Drawbacks of routine range of motion, limb girth and limb length assessment tools like goniometer and inch tape:

1) Goniometer gets easily displaced from the place when patient moves his/her body part from starting assessment position to end range of motion.
2) Hence this type of goniometer can't be used during movement or during exercise simultaneously.
3) As the arms of the goniometer don't reach up to the reference landmark therefore the therapist has to assume an imaginary line connecting the arms with the reference bony landmark. For this reason some goniometers are with long arms but long arms are inconvenient while carrying goniometer and so the goniometer becomes non portable.
4) Even some goniometers have an extendable arm but they are without any calibrations on them and hence they can't be used simultaneously to measure limb length.

5) Straps with calibrations are not used routinely to fix the goniometer in place and so securing the goniometer in place during movement is cumbersome and also limb girth measurement can't be done simultaneously.

6. Objective:

The main objective of the present invention is to provide a Goniometer which does not get easily displaced from the place when patient moves his/her body part from starting assessment position to end range of motion

Yet another object of the present invention is to overcome drawbacks of goniometer which can't be used during movement or during exercise simultaneously.

Yet another object of the present invention is to make the goniometer which reach up to the reference landmark so that the therapist without assuming an imaginary line connecting the arms with the reference bony landmark easily.

Yet another object of the present invention is to provide the Goniometer which will be convenient while carrying and portable.

Yet another object of the present invention is to provide the Goniometer have with calibrations on them and hence can be used simultaneously to measure limb length.

7. Statement:

Hence the invention of this new device 'KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO' was made to overcome the drawbacks in the following ways:

The said invention overcomes these drawbacks in the following way:

1) Straps help to secure the goniometer in place even during movement.
2) Calibrations on the strap help to assess the limb girth simultaneously.

3) Because of the straps there is no need of therapist to hold the goniometer during patient's movement and so therapist's hands are free.
4) Since this goniometer can be secured in place even during patient's exercise therefore error due to repositioning can be avoided and also it can act as biofeedback to the patient during exercise.
5) Telescopic arms of goniometer which can be extended to reach to reference bony landmark help to overcome drawback of short arms and hence it eliminates error due to assumption of imaginary line connecting short arm with reference bony landmark.
6) Calibrated arms of goniometer and calibrated straps help to measure limb length and limb girth simultaneously.
7) It is simple to use.
8) Assessing range of motion, limb length and limb girth can be done easily and rapidly at same time with little time consumption and without the need of patient to be positioned again and again for the same and also errors of measurement can be minimized.

Novel features:

1. Calibrated arms on goniometer.
2. Extendable telescopic arms with 10 cm extension and 10 cm basic calibration providing about total 20 cm extension of arms of goniometer in either direction.
3. Detachable calibrated Velcro straps on goniometer to place it firmly on the part during assessment.

Utility of the Invention:

1. The said invention will come in handy for orthopedician, therapists, students and patients.
2. It will decrease the time consumed for assessing ROM, limb girth and limb length.

3. The said invention will make ROM, limb girth and limb length measurement easy and simultaneous.
4. The said invention will eliminate the errors due to repositioning of goniometer and those errors caused due to the short arms of goniometer.
5. The said invention will be used as biofeedback for the patient.
6. The said invention will be easy and portable to carry.

Advantages:

1. Time saving device.
2. Cheaper, since it eliminates the need for multiple assessment tools separately.
3. It eliminates errors associated with holding and repositioning of the goniometer as it has Velcro straps which can be fasten to secure the goniometer in place, so it is student friendly.
4. Detachable straps and telescopic arms makes it portable.
5. It is useful to assess ROM, limb girth and limb length simultaneously and so it relives patient's discomfort of repetitive repositioning during assessment, hence it is patient friendly.
6. Patients can do the exercises with the said invention put on simultaneously and so it can act as biofeedback for the patient.
7. Calibrations on the straps and arms of goniometer helps to measure ROM, limb length and limb girth accurately and simultaneously.
8. Telescopic antenna arms of goniometer which can be extended to reach upto reference bony landmark helps to overcome drawback of short arms and hence it eliminates error due to assumption of imaginary line connecting short arm with refcrence bony landmark.

Working of the device:

The said invention works in the following manner:

1) Protractor of 180^0 or 360^0 can be used. It has fulcrum in center at which telescopic arms of modified goniometer are attached.
2) Patient is positioned in comfortable starting position to measure ROM.
3) To assess ROM by modified goniometer, the fulcrum is placed on the bony prominence of the joint whose ROM is to be measured.
4) The arms of modified goniometer has extendable telescopic antenna arms with calibrations on it which can be dragged out to reach reference bony landmark and once the assessment is over, the user pushes it inside by holding at the end point., thereby minimizing the length of the arms.
5) The stationary telescopic arm with calibration is aligned parallel with the stable segment of the body part and the movable telescopic arm with calibration is aligned parallel to the moving segment of the body part whose ROM is to be measured.
6) There are two calibrated Velcro straps which can be attached on each arm by passing the arms of goniometer through the loops on the straps.
7) The calibrated Velcro straps can be fastened on proximal and distal parts of the joint during ROM measurement to secure arms of the modified goniometer at place.
8) After adjusting the calibrated telescopic arms of goniometer with the reference bony landmark and then after fastening the goniometer at place with the help of calibrated Velcro straps, the initial measurement of ROM is noted and also the limb length and limb girth noted.
9) For bilateral comparison of limb girth, the exact level at which the limb girth is recorded can be noted using the calibrations on the arms of the goniometer.

10) Then the patient is asked to perform the movement and the final ROM at end range is noted, while patient does the movement only the moveable telescopic arm moves along with the patient's part while the stationary telescopic arm remains at fixed initial site.

11) The calibrations on the telescopic arms of the modified goniometer help to measure the limb length simultaneously while measuring ROM.

12) The calibrated Velcro straps help to measure limb girth simultaneously.

13) After the assessment is over, the user pushes the telescopic antenna arms of the modified goniometer inside, thereby making the modified goniometer portable.

KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO is used by health practitioners to measure ROM, limb length and limb girth simultaneously. The said invention is handy for routine clinical work for practitioners as well as for students. It is time saving as ROM, limb length and limb girth can be simultaneously measured at a time. Frequent repositioning of the patient to measure ROM, limb length and limb girth is not required, so it saves patient's time and efforts. The said invention is secured firmly on the patient's part during movement providing feedback to the patient and also placing telescopic arms of the goniometer exactly on bony reference point eliminates the error during placement and measurement.

The said invention overcomes the limits of conventional goniometer like:

a) Goniometer needs to be held by the practitioner from starting assessment position to end range assessment as there are no straps to secure the goniometer in place.

b) Conventional goniometer can't be placed on the part firmly as there are no straps on it and hence patient can't secure the goniometer on the part during the movement.

c) Error due to short arms of goniometer.

d) Even though some goniometers are with long arms but then portability becomes difficult because of the length of the arms.

e) Even if some goniometers have extendable arms but then they are without any calibrations on them and hence they can't be used simultaneously to measure limb length.

f) Routine universal goniometer doesn't have any calibrated straps on them and so limb girth can't be measured simultaneously and also securing the goniometer in place during movement becomes difficult.

g) Cumbersome and time consuming method of assessing ROM, limb length and limb girth.

Thus by using KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO the above limitations are overcome & assessing ROM, limb length and limb girth becomes easy, accurate, non-cumbersome and simultaneous. Thus the said invention is to be useful and cost effective.

8. BRIEF DESCRIPTION OF DRAWING:

Fig No. 1 is the schematic representation of the ANTERIOR VIEW of KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO.

Fig No. 2 is the schematic representation of the POSTERIOR VIEW of KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO.

9. DETAILED DESCRIPTION OF DRAWINGS:

Fig. No. 1 is the anterior view of the KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO

1) Goniometer has a protractor (1) with arc of 180 or 360 degree calibration.

2) Goniometer has fulcrum (2) in center at which point the two (3,4) arms of goniometer are attached.

3) The stationary telescopic arm (3) and movable telescopic arm (4) has calibrations on them and can be extended to move back and forth.

4) Pulling the extendable telescopic arms out help to reach to the reference bony landmark. Pushing the telescopic arms help to shorten the arm size of goniometer and make it portable.

5) The calibrations on the telescopic arms of goniometer help to assess and measure limb length.

6) The calibrated Velcro straps (5) have calibrations on them. These straps have eyelet like loop (6) for passing of telescopic arms through them.

7) One end of Velcro strap has calibrations on anterior surface which is called as Velcro loop (7) while the other end called as Velcro hook (8) has rough adhesive surface on anterior surface.

8) The calibrated Velcro straps help in assessing limb girth.

Fig. No. 2 is the posterior view of the KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO

1) The posterior view of goniometer shows protractor (1), stationary telescopic arm (3) and movable telescopic arm (4) with fulcrum (2) in centre.

2) The posterior view of Velcro strap has Velcro loop end (7) which is smooth surface with eyelet like loop (6) at the other end extended further as Velcro hook (8) which is rough surface of Velcro strap.

3) Velcro hook (8) on strap has adhesive rough surface on anterior aspect and smooth surface on posterior aspect.

10. Claims:

1. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO comprises of:

a) Protractor (1)

b) Fulcrum (2)

c) Stationary telescopic arm (3)

d) Movable telescopic arm (4)

e) Calibrated Velcro straps (5)

f) Eyelet like loop (6)

g) Velcro loop (7)

h) Velcro hook (8)

which works as follows-

a) Protractor of 180^{0} or 360^{0} can be used. It has fulcrum in center at which telescopic arms of modified goniometer are attached.

b) Patient is positioned in comfortable starting position to measure ROM.

c) To assess ROM by modified goniometer, the fulcrum is placed on the bony prominence of the joint whose ROM is to be measured.

d) The arms of modified goniometer has extendable telescopic antenna arms with calibrations on it which can be dragged out to reach reference bony landmark and once the assessment is over, the user pushes it inside by holding at the end point., thereby minimizing the length of the arms.

e) The stationary telescopic arm with calibration is aligned parallel with the stable segment of the body part and the movable telescopic arm with calibration is aligned parallel to the moving segment of the body part whose ROM is to be measured.

f) There are two calibrated Velcro straps which can be attached on each arm by passing the arms of goniometer through the loops on the straps.

g) The calibrated Velcro straps can be fastened on proximal and distal parts of the joint during ROM measurement to secure arms of the modified goniometer at place.

h) After adjusting the calibrated telescopic arms of goniometer with the reference bony landmark and then after fastening the goniometer at place with the help of calibrated Velcro straps, the initial measurement of ROM is noted and also the limb length and limb girth noted.

i) For bilateral comparison of limb girth, the exact level at which the limb girth is recorded can be noted using the calibrations on the arms of the goniometer.

j) Then the patient is asked to perform the movement and the final ROM at end range is noted, while patient does the movement only the moveable telescopic arm moves along with the patient's part while the stationary telescopic arm remains at fixed initial site.

k) The calibrations on the telescopic arms of the modified goniometer help to measure the limb length simultaneously while measuring ROM.

l) The calibrated Velcro straps help to measure limb girth simultaneously.

m) After the assessment is over, the user pushes the telescopic antenna arms of the modified goniometer inside, thereby making the modified goniometer portable.

2. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, helps in easy securing of goniometer in place with the help of straps.

3. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, helps to retain the position of goniometer firmly even during continuous exercise.

4. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, helps to fasten the goniometer in place by the straps and hence it eliminates cumbersome use of goniometer while measuring ROM by the therapist.

5. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, acts as biofeedback to the patient while doing exercises.

6. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, Calibrated arms of goniometer and calibrated straps of this said invention helps to record the ROM, limb length and limb girth easily and more accurately.

7. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, Calibrated arms of goniometer and calibrated straps of this said invention helps to record the ROM, limb length and limb girth simultaneously without the need of patient to be repositioned for several times for assessing differently.

8. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, helps in bilateral comparison of limb girth, as the exact level at which the limb girth is recorded on one side can be noted using the calibrations on the arms of the goniometer and same procedure can be repeated on opposite side for bilateral comparison.

9. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, helps in minimizing measuring errors.

10. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, the said invention is a time saving device.

11. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, eliminates errors associated with holding and repositioning of the goniometer, so it is student friendly.

12. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, an extendable arm of the said invention helps in reaching upto the reference bony landmark hence ROM and limb length can be measured more accurately.

13. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, the arc of protractor of goniometer can be of 180^0 or 360^0 and same components of the said invention can be applied.

14. The KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO as claimed in claim 1, the detachable Velcro straps and telescopic antenna like extendable arms of the goniometer makes it more portable.

Dated this 17th March 2017

DR.M.V.GHORPADE

(REGISTRAR)

FOR KRISHNA INSTITUTE OF

MEDICAL SCIENCES DEEMED UNIVERSITY

To

The Controller of Patents,

The patent office,

At Mumbai – 400 037

11. ABSTRACT OF THE INVENTION

KRISHNA GONIOMETER, LIMB LENGTH AND LIMB GIRTH COMBO is used by health practitioners to measure ROM, limb length and limb girth simultaneously. The said invention is handy for routine clinical work for practitioners as well as for students. It is time saving as ROM, limb length and limb girth can be simultaneously measured at a time. Frequent repositioning of the patient to measure ROM, limb length and limb girth is not required, so it saves patient's time and efforts. The said invention is secured firmly on the patient's part during movement providing feedback to the patient and also placing telescopic arms of the goniometer exactly on bony reference point eliminates the error during placement and measurement.

DR.M.V.GHORPADE

(REGISTRAR)

FOR KRISHNA INSTITUTE OF

MEDICAL SCIENCES DEEMED UNIVERSITY

FORM 2

THE PATENT ACT 1970

(39 OF 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See SECTION 10, RULE 13)

1. TITLE OF THE INVENTION :

VISI PAP FLASK

2. APPLICANT:

NAME: KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD

NATIONALITY: "DEEMED TO BE UNIVERSITY" DECLARED U/S 3 OF UGC ACT, 1956 VIDE NOTIFICATION NO. F.9-15 / 2001 – U-3 OF THE MINISTRY OF HUMAN RESOURCES DEVELOPMENT, GOVT.OF INDIA

ADDRESS: KRISHNA INSTITUTE OF MEDICAL SCIENCES, "DEEMED TO BE UNIVERSITY", NEAR DHEBEWADI ROAD, MALKAPUR, KARAD 415110, MAHARASHTRA, INDIA

3. PREAMBLE TO THE DESCRIPTION:

The following complete specification particularly describes the nature of this invention and the manner in which it is to be performed:

4. TECHNICAL FIELD

The present invention relates to medical sciences, specifically to the field of dental science.This invention "VISI PAP FLASK" is to design a flask that is easy to use which makes processing procedure precise to reduce error in increase in vertical dimension and reduces tooth displacement in the prosthesis.

5. Prior Art:

There are errors that occur during the processing of the removable dental prosthesis. These errors are responsible for increase in vertical dimension and tooth movement in the removable dental prosthesis. It helps in easy and precise fabrication of removable prosthesis. Currently, there are no known ways to solve the problem. To correct the error, clinician has to do another laboratory step that is laboratory remount. With the new design the processing errors will be decreased.

6. Objective:

1) The main aim of the present invention is to provide the dental flask which is invented to minimize the errors that may occur during the processing of the removable dental prosthesis.

2) Yet another objective of the present invention is to decrease the error in increase in vertical dimension.

3) Yet another objective of the present invention is to prevent increased vertical dimension in the prosthesis.

4) Yet another objective of the present invention is to provide accuracy of determining tooth level.

5) Yet another objective of the present invention is to provide sufficient space for excess material to flow out which in turn will reduce the error in tooth displacement and increased vertical dimension in the processed prosthesis.

6) Yet another objective of the present invention is to prevent the plaster adherence on the rims of the counterflask which can lead to lack of metal to metal contact between the flask.

7) Yet another objective of the present invention is to provide the dental flask which overcomes the problem of Rusting as in case of the conventional flask.

8) Yet another objective of the present invention is to provide the dental flask which has uniform pressure which overcomes lack of orientation of the clamp head leading to uneven pressure in conventional flask.

7. Statement:

Hence the invention possesses significant advantages over the prior art dental flasks. In accordance with the present inventionthe new innovative VISI-PAP FLASKis a simplistic design which will be utilized by many undergraduates, postgraduates and laboratory technicians for flasking of removable dental prosthesis. The inaccuracy of determining tooth level and excess material can lead to tooth displacement in the processed prosthesis. The plaster adherence on the rims of the counterflask can lead to lack of metal to metal contact between the counterparts of the flask and inadequate removal of excess material during packing all this leads to increase in vertical dimension error. Fabrication of removable prosthesis has been performed since decades with the help of conventional flasking. This arbitrary method in conventional flask is overcome in this invention.

Working of the device:

The said invention works in the following manner:

Working of the "VISI-PAP FLASK"

1. The customized innovative flask consist of a step like design on the base flask for avoiding plaster adherence on the rims of the flask which helps in achieving proper metal to metal contact thus helps in reducing increase in vertical dimension error.
2. The flask is made up of complete chromium material which aids in removal of plaster adhered on the rims of the flask and has antirust property
3. It has two vent holes in between the base flask and counterflask for the ease of removal of wax during dewaxing and removal of excess acrylic material during packing.
4. Rods placed in the vent holes creates pathway for excess wax removal during dewaxing and for removal of excess acrylic material during packing.It also aids in closure of vent holes after packing.
5. It has transparent toughened glass window in the counterflask for determining the tooth level in the prosthesis to avoid displacement of tooth after fabrication in the prosthesis.
6. The lid portion has a big round depression for orientation of the disk in the clamp so that there is even pressure during closure. Lid also consists of four holes for the excess material to flow during flasking.

The said invention overcomes the limits of conventional:

1. Increased vertical dimension in the prosthesis
2. Inaccuracy of determining tooth level
3. Inability for excess material to flow out leading to tooth displacement and increased vertical dimension in the processed prosthesis
4. Plaster adherence on the rims of the counterflask can lead to lack of metal to metal contact between the flask
5. Rusting of the conventional flask

6. No uniform pressure
7. Lack of orientation of the clamp head leading to uneven pressure

Thus the said invention is to be useful and cost effective.

Material: Chromium-antirust material

Alignment:Step design aids in orientation along with plugging rods placed

8. BRIEF DESCRIPTION OF DRAWING:

Fig. No. 1 is the isometric view of view of the VISI-PAP FLASK.

Fig. No. 2 a) is the isometric vies of the upper lid top view.

Fig. No. 2 b) is the isometric vies of the upper lidbottom view.

Fig. No. 3 a) is the isometric view of the VISI-PAP FLASK's counter flask: front view.

Fig. No. 3 b) is the isometric view of the VISI-PAP FLASK's counter flask: articulation of two halves.

Fig. No. 4 a) is the isometric view of VISI-PAP FLASK's base flask: side view.

Fig. No. 4 b) is the isometric view of VISI-PAP FLASK's base flask: top view.

Fig No. 4c) is the isometric view of VISI-PAP FLASK's base flask: front view.

Fig. No. 5 a) is the isometric view of base flask with rods: side view

Fig. No. 5 b) is the isometric view of counterflaskplaced on base flask with rods: side view.

Fig. No. 5 c) is the isometric view of VISI-PAP FLASK

Fig. No. 6 is the isometric view of vent hole plugging rod:front view

9. DETAILED DESCRIPTION OF DRAWINGS:

The entire flask is a new innovative flask made up of chromium material,which has anticorrosive and high polishing property which prevents rusting of the flask and polished surface of the chromium prevents plaster adherence on the rims of the flask.

FIG.1 ISOMETRIC VIEW OF VISIPAP FLASK

UPPER LID (1) -uppermost part of the flask which articulates with counterflask

COUNTERFLASK (2) -middle portion of the flask which articulates with base flask

BASE FLASK (3) - lowermost portion of flask

DEPRESSION IN UPPER LID (4) - Depressed central portion in the lid of the flask will help in orientation of the disc of the clamp centrally and for equalization of pressure during packing.

PLASTER VENT HOLE (5) - present in the lid portion for ease of removal of excess of plaster.

TRANSPARENT TOUGHENEDGLASS WINDOW (6) - present in the counterflask for tooth level judgment during flasking to prevent displacement of tooth.

LEFT VENT HOLE PLUGGING ROD (7) - closure of the vent holes.

RIGHT VENT HOLE PLUGGING ROD (8) - closure of the vent holes.

FIG.2 a &b) ISOMETRIC VIEW OF UPPER LID: TOP VIEW& BOTTOM VIEW

Upper lid (1) has a diameter of 10cm and 5mm in height. the DEPRESSION IN UPPER LID (4) -depression is 7cm in diameter and 1mm deep, the PLASTER VENT HOLE (5) -6mm in diameter and NOTCH IN LOWER PART OF LID (9) - this part of upper lid engages in upper part of counterflask.

FIG.3 a) ISOMETRIC VIEW OF COUNTERFLASK: FRONT VIEW

Counterflask (2) is 27cm in height having TRANSPARENT TOUGHENED GLASS WINDOW (6) which is 1.5cm in height and 8.5cm in width, RIGHT VENT HOLE FOR ACRYLIC AND WAX OUTLET (10) - Vent holes in between the base flask and

counterflask for the ease of removal of wax during dewaxing and removal of excess acrylic material during packing. LEFT VENT HOLE FOR ACRYLIC AND WAX OUTLET (11) - Vent holes in between the base flask and counterflask for the ease of removal of wax during dewaxing and removal of excess acrylic material during packing, STEP DESIGN ON INNER SIDE OF COUNTERFLASK (12) - Step design on inner side of counterflask is 4mm in height,helps in locking with the step design present on the base flask which helps in achieving tight contact of the two halves of the flask thus there is appropriate metal to metal contact.

FIG 3.b)ISOMETRIC VIEW OF ARTICULATION OF TWO HALVES OF FLASK

STEP DESIGN ON INNER SIDE OF COUNTERFLASK (12) - Step design on inner side of counterflask is 4mm in height,helps in locking with the step design present on the base flask which helps in achieving tight contact of the two halves of the flask thus there is appropriate metal to metal contact, STEP DESIGN ON OUTER SIDE OF BASE FLASK (13) - Step design on outer side of base flask is 2mm in width,which engages with the step design present on the inner side of counterflask which helps in achieving tight contact of the two halves of the flask thus there is appropriate metal to metal contact, STEP DESIGN ON INNER SIDE OF BASE FLASK (14) -serves as a guide for the level of the first pour of the plaster so that plaster doesn't adhere on the rims of the flask which lead to improper closure of the two halves of the flask and there is appropriate metal to metal contact of the two halves of the flask.

FIG.4 a) ISOMETRIC VIEW OF BASE FLASK: SIDE VIEW

RIGHT VENT HOLE FOR ACRYLIC AND WAX OUTLET (10) - Vent holes in between the base flask and counterflask for the ease of removal of wax during dewaxing and removal of excess acrylic material during packing, the LEFT VENT HOLE FOR ACRYLIC AND WAX OUTLET (11) - Vent holes in between the base flask and counterflask for the ease of

removal of wax during dewaxing and removal of excess acrylic material during packing. STEP DESIGN ON OUTER SIDE OF BASE FLASK (13) - Step design on outer side of base flask is 2mm in width, helps in locking with the step design present on the inner side of counterflask which helps in achieving tight contact of the two halves of the flask thus there is appropriate metal to metal contact. STEP DESIGN ON INNER SIDE OF BASE FLASK- serves as a guide for the level of the first pour of the plaster so that plaster doesn't adhere on the rims of the flask which lead to improper closure of the two halves of the flask.and there is appropriate metal to metal contact of the two halves of the flask.

FIG.4 b) ISOMETRIC VIEW OF BASE FLASK: TOP VIEW

The DEFLASKING DISK (15) and LEDGE FOR DEFLASKING DISC (16) -3mm in width

FIG.4 c) ISOMETRIC VIEW OF BASE FLASK: FRONT VIEW

The height of the base flask from the base till the base of the step design is 3cm and the height of the upper step design is 4mm in height.

Fig.5.a) ISOMETRIC VIEW OF BASE WITH RODS: SIDE VIEW

Describes the view of the flask with rods placed in the vent holes

Fig.5.b) ISOMETRIC VIEW OF COUNTERFLASK PLACED ON BASE FLASK WITH RODS: SIDE VIEW

Describes the view of counterflask placed on the base flask with rods placed in vent holes.**Fig.5.c) ISOMETRIC VIEW OF VISI-PAP FLASK**

FIG.6. ISOMETRIC VIEW OF VENT HOLE PLUGGING ROD: FRONT VIEW

Vent hole plugging rods (7& 8) are used during flasking procedure and after the packing procedure LEFT VENT HOLE PLUGGING ROD (7) - closure of the vent holes and RIGHT VENT HOLE PLUGGING ROD (8) - closure of the vent holes, the height of the head of the vent hole plugging rod -5mm, the body of the vent hole plugging rod -1.1cm, the width of

the head of the vent hole plugging rod -1.6cm, the height of the vent hole plugging rod -

4.5cm.

10. We claim:

1. The VISI-PAP FLASKcomprises of:

a) UPPER LID (1)

b) COUNTERFLASK (2)

c) BASE FLASK (3)

d) DEPRESSION IN UPPER LID (4)

e) PLASTER VENT HOLE (5)

f) TRANSPARENT TOUGHENEDGLASS WINDOW (6)

g) LEFT VENT HOLE PLUGGING ROD (7)

h) RIGHT VENT HOLE PLUGGING ROD (8)

i) NOTCH IN LOWER PART OF LID (9)

j) RIGHT VENT HOLE FOR ACRYLIC AND WAX OUTLET (10)

k)LEFT VENT HOLE FOR ACRYLIC AND WAX OUTLET (11)

l) STEP DESIGN ON INNER SIDE OF COUNTERFLASK (12)

m) STEP DESIGN ON OUTER SIDE OF BASE FLASK (13)

n) STEP DESIGN ON INNER SIDE OF BASE FLASK (14)

o) DEFLASKING DISK (15)

p) LEDGE FOR DEFLASKING DISC (16);

which works as follows-

Vaseline is applied to the base flask (3) and to the deflasking disk (15) and the disk is placed in the ledge made for deflasking disc (16).First pour of plaster is mixed and placed in the base flask (3) and the cast is placed in the centre of the flask and the left vent hole plugging rod (7) and right vent hole plugging rod (8) is placed in the right vent hole outlet (10) and left vent hole outlet (11) respectively.The left vent hole plugging rod (7) and right vent hole plugging rod (8) will create a channel for the excess wax and acrylic to flow out during dewaxing and packing of acrylic material. The plaster will be present

at the level of step design on inner side of base flask (14) so that excess plaster will not accommodate between the two halves of flask and thus metal to metal contact of the flask is achieved. The provision for excess removal of wax and acrylic is not present in conventional flask.Improper metal to metal contact remains in conventional flask leading to increase in vertical dimension of the prosthesis this is prevented in VISI PAP FLASK.The provision for excess removal of wax and acrylic is not present in conventional flask.After flasking procedure the counterflask (2) is articulated on the base flask (3) .Step design on inner side of counterflask (12) and step design on outer side of base flask (13) helps in articulating the two halves of the flask and thus maintaining metal to metal contact and preventing excess plaster coming out through the two halves of the flask.After this the level of teeth is determined because of the transparent toughened glass window (6).Then the second pour is completed with the help of plaster followed by the third pour. Upper lid (1) is placed on the counterflask (2) with the help of notch in lower part of lid (9) excess plaster comes out from the plaster vent hole (5). Disc of the clamp is placed on the depression present on the upper lid (4) and pressure is applied excess plaster comes out from the plaster vent hole.The depression in the upper lid helps in the orientation of the disc portion of the clamp and also uniform pressure is applied.This provision is absent in conventional flask leading to uneven pressure.The flask is then kept for dewaxing procedure in the dewaxing unit the wax gets access through the channel created by the left vent hole plugging rod (7) and right vent hole plugging rod (8) and flows through the right vent hole (10) and left vent hole (11).After the dewaxing procedure the flask is opened the left vent hole plugging rod (7) and right vent hole plugging rod (8) is removed and the separating medium is applied on the cast and the plaster, packing is done with acrylic and the counterflask (2) is placed excess acrylic gets removed through channel created by the left vent hole plugging rod (7) and right vent

hole plugging rod. Disc of the clamp is placed on the depression in the upper lid (4) and the pressure is applied excess acrylic comes out through the right vent hole (10) and left vent hole (11).The left vent hole plugging rod (7) and right vent hole plugging rod (8) is placed again respectively and the flask is kept in acrylizer for curing.After curing deflasking is done with the help of deflasking disk (15).

2) The "VISI-PAP FLASK" as claimed in claim 1, is the customized innovative flask consists of a step like design on the base flask for avoiding plaster adherence on the rims of the flask which helps in achieving proper metal to metal contact thus helps in reducing increase in vertical dimension error which is made up of complete chromium material which aids in removal of plaster adhered on the rims of the flask and has antirust property

3) The "VISI-PAP FLASK" as claimed in claim 1,has two vent holes in between the base flask and counterflask for the ease of removal of wax during dewaxing and removal of excess acrylic material during packing.

4) The "VISI-PAP FLASK" as claimed in claim 1, has rods which are placed in the vent holes creates pathway for excess wax removal during dewaxing and for removal of excess acrylic material during packing.It also aids in closure of vent holes after packing.

5) The "VISI-PAP FLASK" as claimed in claim 1,has transparent toughened glass window in the counterflask for determining the tooth level in the prosthesis to avoid displacement of tooth after fabrication in the prosthesis.

6) The "VISI-PAP FLASK" as claimed in claim 1, the lid portion has a big round depression for orientation of the disk in the clamp so that there is even pressure during closure. Lid also consists of four holes for the excess material to flow during flasking.

7) The "VISI-PAP FLASK" as claimed in claim 1, is made up of chromium material, which has anticorrosive and high polishing property which prevents rusting of the flask and polished surface of the chromium prevents plaster adherence on the rims of the flask.

Dated this 10th October 2018

DR.M.V.GHORPADE

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To

The Controller of Patents,

The patent office,

At Mumbai – 400 037

11. ABSTRACT OF THE INVENTION

Laboratory procedure for fabrication of removable dental prosthesis is an important procedure for each dental student and technician, the use of flask is instilled from the second year of dental education itself. With the increasing demand, there have been several flasks that have become available in the market today. Even with innumerable designs available, none satisfy the needs of a beginner's skill. The major problems faced by a beginner has been incorrect cast orientation, incorrect tooth level judgement, tooth displacement, increase in vertical dimensioned. This is a unique design made in order to make it easier for dentists, dental students and technician for flasking procedure and avoid these above problems.

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FORM 2

THE PATENTS ACT, 1970

(39 of 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

TITLE – HYBRID HYGIENIC FUSED TOOTH BRUSH AND TOOTHPASTE

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Preamble of the Description:

The following specification particularly describes the invention and the manner in which it is to be performed.

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TITLE: 'HYBRID HYGIENIC FUSED TOOTH BRUSH AND TOOTHPASTE

FIELD OF THE INVENTION

The present invention relates to the field of fused tooth brush assembly where toothpaste is carried along with the toothbrush.

This fusion-tooth brush makes it very easy to use as tooth paste is engraved inside the tooth brush assembly itself, so as to avoid contamination with others tooth brush or paste and bring comfort.

BACKGROUND OF INVENTION:

Routinely in our day today life we use tooth paste and it was shared by all the family members, but chances of infection spread is very high, if any of our family members is having any kind of oral infections it will spread to other members of the family through either sharing tooth brush or tooth paste thus it is very unhygienic practice

SUMMARY OF THE INVENTION

The present invention is a toothbrush which is adapted to contain a significant quantity of toothpaste therein and to dispense the toothpaste onto the toothbrush bristles. The toothbrush generally comprises a hollow handle having a brush head formed integrally on its top end, disposable toothpaste containing cartridge supported

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within its interior, and a piston mechanism thread ably attached to its bottom end. The piston mechanism extends into the interior of the handle and through the toothpaste cartridge so that a screw driver piston may be actuated to force the toothpaste out of the handle into a conduit formed through the brush head. The conduit leads from the interior of the handle to a plurality of outlet holes disposed below a rubber gasket layer which supports the bristles. Resilient valves adapted to be opened by the expressive force of the toothpaste flowing through the conduit are formed in the gasket layer over each outlet. The valves allow toothpaste to flow from the conduit onto the bristles of the toothbrush while preventing water or other fluids from flowing into the conduit to contaminate the toothpaste supply. A removable cap is also included to keep the brush head clean when not in use.

DETAILED DESCRIPTION:

Disclosed is a toothbrush and a hollow handle, which are connected together to dispense toothpaste from a reservoir in the handle to the bristles of the toothbrush. Within the handle is a flexible tube which is secured at one end of the handle to prevent rotation. Extending from the handle and through the toothbrush to the bristles is a conduit for extruding toothpaste to the bristles when the knob is rotated to twist the flexible tube thereby dispensing paste from the reservoir. Also provided is a cover for the toothbrush, which includes a stopper for sealing the conduit in the toothbrush.

The primary object of the invention is to provide a toothbrush that contains a stored amount of toothpaste within its handle.

Another object of the invention is to provide a toothbrush that allows the user to apply toothpaste to the brush by pushing down on the top of the toothbrush head.

Another object of the invention is to provide a toothbrush where the toothpaste is conveniently stored within a cylindrical handle portion of the toothbrush and if toothpaste gets exhausted, then can be refilled by toothpaste of your choice by opening the toothpaste conainer by moving piston backwards.

Another object of the invention is to provide an improved pumping and dispensing means.

Another object of the invention is to provide an improved design that is easier and less expensive to manufacture.

In order to keep the brush head clean and to protect it from damage, the cap is adapted to be attached to the top end of the handle over the brush head. The cap is preferably an elongate shell having an inner width slightly larger than the outer width of the handle and having a longitudinal length slightly greater than the length of the brush head.

The cap is open at its bottom end to receive the brush head and handle, and closed at its top so that the brush head is enclosed by the cap when it is placed on the top of the handle. In order to secure

the cap on the top of the handle, a groove adapted to interfit with the rib is formed in the inner surface of the cap adjacent the bottom end thereof.

TOOTH BRUSH STANDARDIZATION.

- Tooth brush bristles are grouped in tufts that are usually arranged in three to four rows (Pediatric tooth brush 3 rows –Adult brush 4 rows) This brush , at its tip it has longer uni-tufted bristle which helps to clean the corner of the mouth and also to clean interdentally areas (inter-proximal contact areas) The tip of tooth brush handle is covered with rubber base which act as cushioning effect and prevent injury to soft tissues specifically behind the last erupted teeth (corner of the oral cavity).
- Bristles with rounded ends used in this brush so it creates minimum scratches on the enamel.
- Nylon filaments used as bristles in toothbrush
- Bristle hardness is proportional to the square of the diameter and inversely proportional to the square of bristle length thus longer bristles are used in this brush.
- Diameter of common bristles range from 0.2mm soft , 0.3 medium and 0.4 hard bristles.(different brushes carries different bristles).
- Soft bristles used which are more flexible, clean slightly below the gingival margin when used with a sulucular brushing technique and

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reach further into the proximal surface.

- Soft spongy bubber pad incorporated underneath the brush so that it will help to reduce the force on the teeth and thus tissue damage will be less , damage to bristles is less as pressure (force) exerted by operator will be absorbed by brush base thus also we require less frequent change of brush.

- Detachable brush head help to change brush head instead of whole brush assembly , if bristles and brush head get spoilt it can replaced with new brush head.

A brush head and neck assembly slidably engages within the top aperture of toothpaste holding tube. Tube forms a hollow cylindrical handle portion with a floss retaining portion located at the bottom most area. An integral disk retains compression spring. Hollow tubular collar retains disk thereby preventing the toothbrush assembly from escaping upward. An internal hollow tubular channel or hollow cavity is formed in the brush neck and travels from the base of assembly to the bristle portion of assembly. A Standard check valve allows toothpaste to travel up to the brush head but not back down into tube. A self rising bottom plate retains toothpaste.

In another embodiment a spring metal washer is fixedly retained or attached to the underside of the bottom plate. Removable and replaceable brush head cover or top cap protects brush head and attached bristles. An exploded view of spring washer, slidable bottom plate and tubular toothpaste enclosure. Spring washer is comprised of a

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plurality of radically disposed fingers. The fingers are downwardly biased so that the washer can slide upward but the fingertips dig into or frictionally engage the inner side wall of toothpaste holding tube when downward pressure is applied.

Cap fixedly retains spring washer to the underside of bottom plate. The side walls of bottom plate are slidably engaged with the inner wall of tube in such a way that no toothpaste can pass by bottom plate thereby forcing all the contained toothpaste in an upward direction only. Toothpaste holding tube is constructed of injection molded polyethylene and, although semi-rigid in nature, the relatively soft nature of the wall of tube allows the fingers of spring washer to dig into the wall. The construction described herein is easy and inexpensive to manufacture. The pumping action occurs when a user presses down on the top of brush head, toothpaste is forced up into hollow cavity and out into the area of bristles. Upon the upward stroke of head assembly, the vacuum created in tube draws plate up. The next time the user presses down on brush head the fingers of spring washer dig into inner wall of tube as described above thereby forcing out more toothpaste as described above.

Toothpaste contained within tube is preferably a gel type and can be made less viscous by the addition of a thinning liquid such as food grade mineral oil which will make the toothpaste flow more easily through channel and out into bristles. Thinning provides more free flowing toothpaste than is normally available.

In this embodiment a compression spring pushes up lightly on a base plate and attached spring washer which in turn keeps bag in compression.

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This embodiment allows the hollow housing to be molded in two longitudinal halves which can then be welded or otherwise attached together.

While the invention has been described in connection with a preferred embodiment, it is not intended to limit the scope of the invention to the particular form set forth, but on the contrary, it is intended to cover such alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

This invention relates to an improved combined toothbrush, paste tube and container thereof and has particular reference to a small toothbrush and paste tube that is engraved together and hermetically sealed.

Oral health is very important for overall health of an individual. Oral hygiene practice was done by everyone throughout the world everyday as a routine oral hygiene procedure. Plaque control is one of the key elements of the healthy oral hygiene practice. It permits each person to assume responsibility for oral health on daily basis. Without this, optimal oral health cannot be achieved.

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DESCRIPTION TO DRAWINGS:

Fig 1:

Sr. No	Sr. No Part Name
1	Bristle Tufts
2	Head
3	Detachable Brush handle
4	Nozzle
5	Main Body (container)
6	Slider
7	Cover
8	Spring Button
9	Piston Assembly
10	Tooth brush cap

Fig 2:

- Bristle head length is 39.06 mm , overall length of brush head is 44.06mm and brush width will be 7.8mm .
- Bristle overall length is 17.29 mm(4 mm inside brush base)
- Brush head end has uni-tufted brush (single tuft of brush) and is 1.5 mm longer than rest of the tufts so that it can be easily cleaned interdentally and distal (corner of the mouth) to the last erupted tooth.
- In the middle of brush there are 4 -5 tufts of brushes
- Other end of brush head has M-4 threading which get engaged into counterpart in brush handle
- Width of thread house is 7.8 mm.
- Bristles are embedded into rubber base which in turn supported by plastic base.
- End of the bristle has soft rubber covering which prevent injury to soft tissues which are behind the last erupted tooth

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Fig 3:

- Brush handle has 71.16 mm in length and its diameter is 7.8 mm
- Its mesial end has m-4 threading (housing) for the m-4 thread which is there in the brush head.
- Its distal end has housing for open coil spring
- Handle has two spring buttons, one spring button present towards mesial one third and second on distal one third of the handle . Mesial spring button helps the brush to keep in its housing (case) and when brush is in use it will be released to its full length that time second spring button (distal spring button) holds it that position.

Fig 4: COVER OF THE BRUSH MAIN BODY:

- Cover - Cover of the body is half circular in nature with two extension to slide over the body during toothpaste refilling the container.
- The overall length of cover is 52 .09 mm.
- 25mm from slider extension to distal edge.
- Opening for the piston movement

Fig 5: TOOTH BRUSH CAP

- Tooth brush cap is bicylindrical longitudinally with length of 53 mm .
- Outer width of brush cap is 33.53 mm and inner width is 22.65 mm.

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STATEMENT OF CLAIMS

TITLE - HYBRID HYGIENIC FUSED TOOTH BRUSH AND TOOTHPASTE

I / We Claim:

1. Toothbrush with toothpaste loaded inside it, for re-use. A toothbrush with a short arm connected to a receptacle containing toothpaste. Connecting the brush to the receptacle through a connector located at the bottom end of the arm, will lead to an opening of a departure hole at the upper base of the receptacle. The paste will leave the receptacle through the departure hole onto a channel along the arm, up to a spring-like push-button, located on the arm. Squeezing the push-button will allow the paste to flow through the channel, up to the bristles, where it will flow through two short pipes made out of flexible material. The brush could be sealed with a transparent plastic cover. The receptacle will be shaped as an easy, comfortable handle for use.

2. A toothpaste dispensing toothbrush comprising:
   An elongate handle having a top end and a bottom end defining a longitudinal axis there between, said handle having a hollow interior adapted to contain a significant quantity of toothpaste, said handle being open at said bottom end thereof;

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A brush head formed integrally on said top end of said handle, said brush head having a front surface, a rear surface, a top end and a bottom end, said brush head having a conduit formed therein extending from said bottom end thereof to a distance from said top end thereof, said conduit being in communication with said hollow interior of said handle, said front surface of said brush head having a plurality outlet holes formed therein, each of said outlet holes being in communication with said conduit;

3. This invention relates generally to the field of toothbrushes and more specifically to an improved combination toothbrush and toothpaste dispenser.

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ABSTRACT

TITLE – HYBRID HYGIENIC FUSED TOOTH BRUSH AND TOOTHPASTE

A toothbrush which contains a toothpaste cartridge cavity located within its hollow or split handle into which a toothpaste cartridge is inserted. An outlet bore runs from the toothpaste cartridge nozzle to the bristle portion of the toothbrush. Movement of a thumb slide mounted on the handle causes the toothpaste cartridge to be compressed so that toothpaste is ejected from the cartridge through the outlet bore and onto the bristles of the toothbrush.

Prior attempts have been made to design a fountain type toothbrush, but these have proved unsuccessful due to their complicated structural designs and inefficient or difficult-to-operate dispensing means. The present invention has overcome these various problems with my invention. In the present invention the toothpaste is ejected directly onto the bristles, thereby eliminating the possibility of spillage.

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DIAGRAMATIC DESCRIPTION:

TITLE **HYBRID HYGIENIC FUSED TOOTH BRUSH AND TOOTHPASTE**

FIG 1

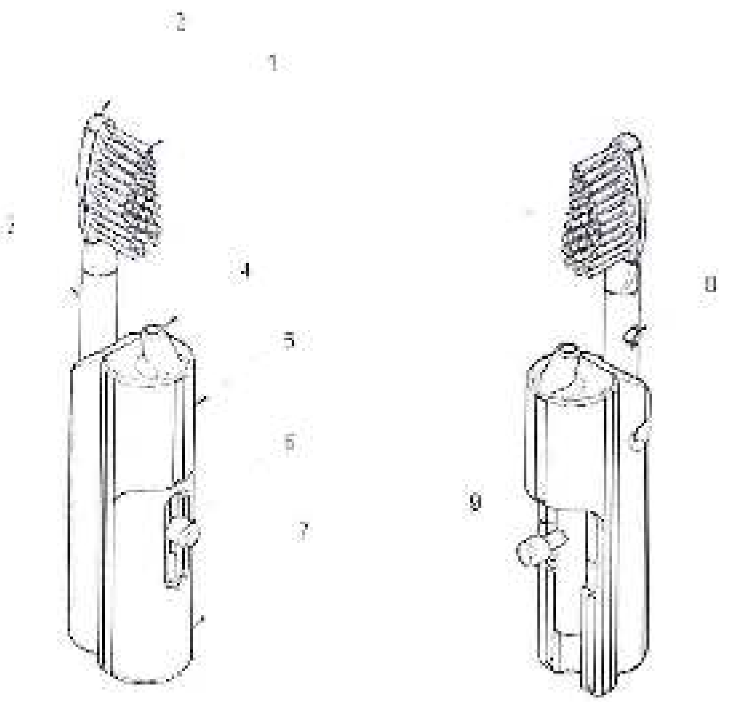

FIG 2

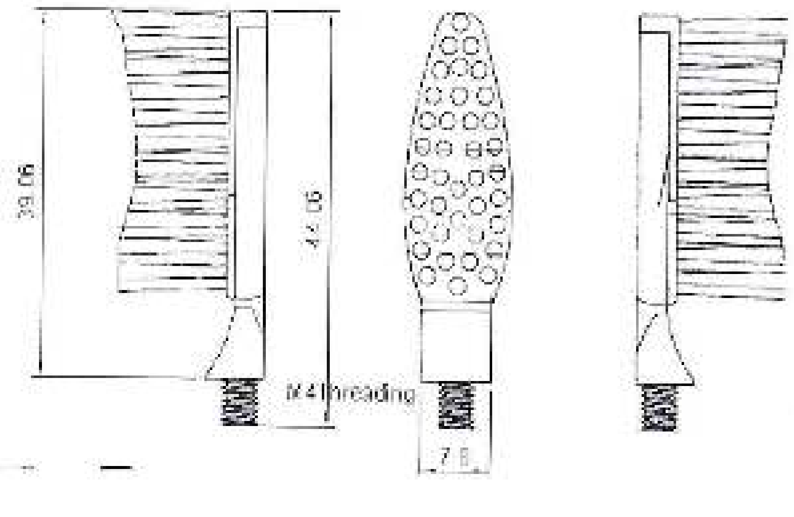

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FIG3

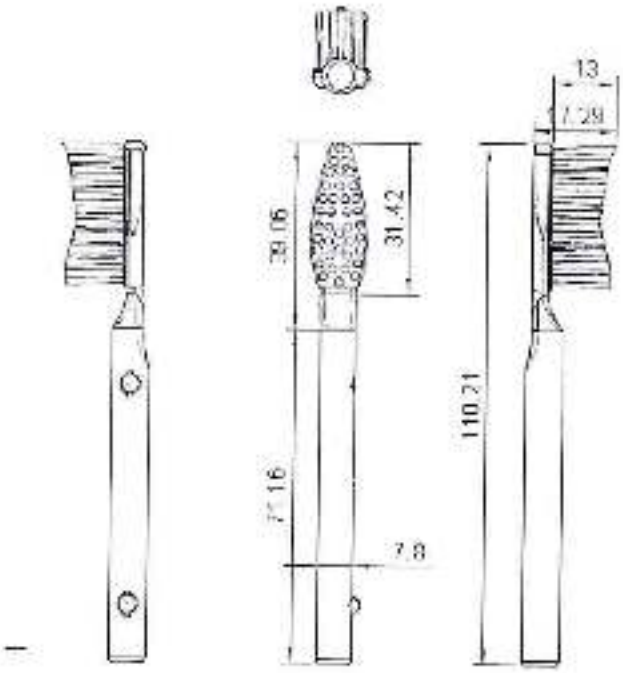

13
1.29
39.06
31.42
110.21
77.16
7.8

FIG 4

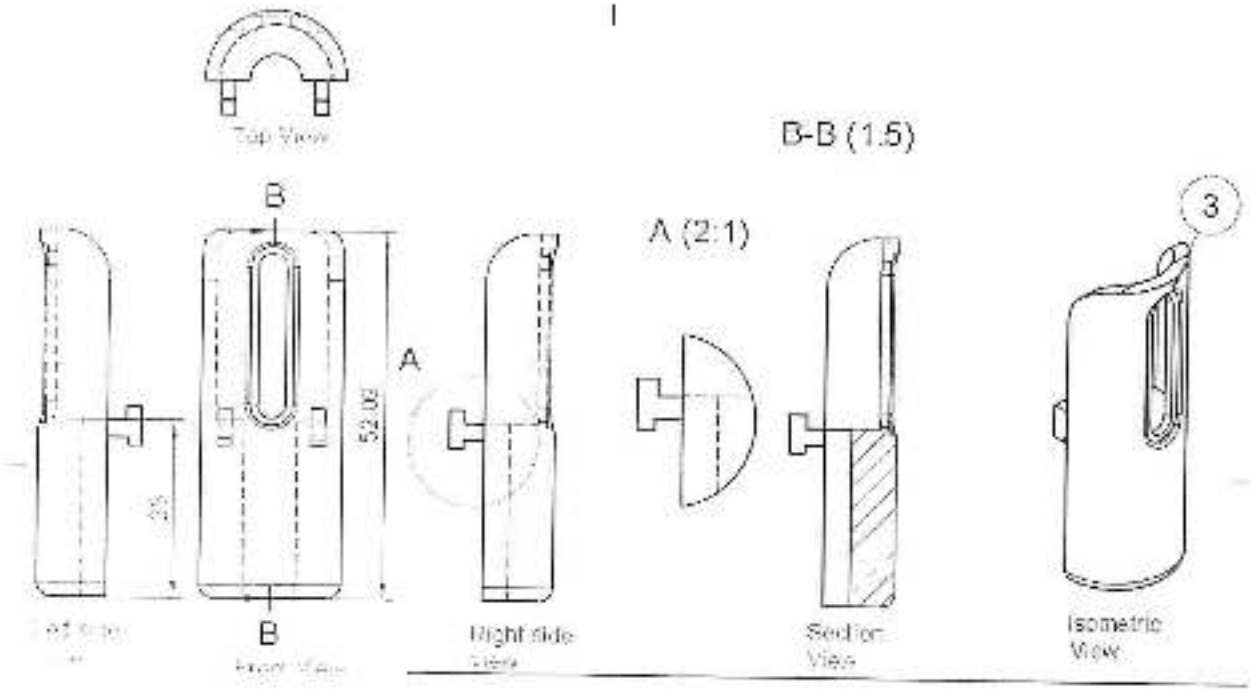
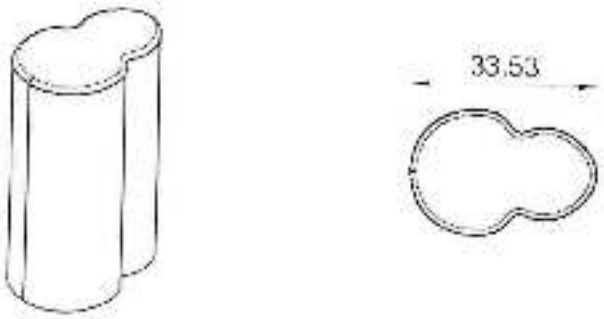

Top View
B-B (1.5)
B
A (2:1)
3
A
52.09
B
Right side View
Section View
Isometric View

FIG 5



ABSTRACT

Presently in the field of Oral & Maxillofacial Surgery, for oral lesion biopsy, conventional biopsy punch is utilized, which cannot reach inaccessible areas of oral cavity. The punch, which is used for primary and secondary surgical exposure for dental implant also has similar difficulty.

The disclosed mucosal punch can be used for oral tissue biopsy and primary and second stage surgical exposure for oral implants and it can reach any area of oral cavity with ease, as the shaft is adjusted with working sharp punch blade/tip. This instrument is autoclavable, so it can be reused, therefore, it is cost effective. The handle is aesthetically pleasing and the grip provided during biopsy procedure offers added mechanical advantage.

Form 2

The Patents Act, 1970

(39 of 1970)

&

The Patents Rules, 2003

Complete Specification

(See Section 10 and Rule 13)

1. TITLE OF THE INVENTION:

"METALLIC MUCOSAL PUNCH"

2. APPLICANT(S):

(a)	Name	Krishna Institute of Medical Sciences
(b)	Nationality	INDIAN
(c)	Address	Near Dhebewadi Road, Malkapur, Karad – 415539, Maharashtra, India

3. PREAMBLE TO THE DESCRIPTION

Complete

The following specification particularly describes the invention and the manner in which it is to be performed.

METALLIC MUCOSAL PUNCH

TECHNICAL FIELD

[001] The present invention generally relates field of tools, particularly cutting instruments, for obtaining samples of dental tissue.

BACKGROUND INFORMATION

[002] Biopsy is a medical diagnostic test used to determine the structure and composition of tissues or cells. In particular, cells or living tissues are sampled from an organ or other body part and are examined under microscope. For example, if an abnormality is found, a biopsy can be performed to determine the exact nature of the suspected abnormality. For example, a physician may perform a biopsy as part of cancer diagnosis in order to determine whether an area of concern is malignant (cancerous) or benign (not cancerous).

[003] Biopsies can be performed on a number of organs, tissues, and body sites. The type of biopsy procedure used to obtain a required tissue sample depends on a variety of factors including: the tissue or body part to be sampled, the location, size, shape and other characteristics of the abnormality, the number of abnormalities, and patient preference. A punch biopsy uses a sharp, hollow instrument (like a cookie cutter) to remove a cylindrical piece of skin, for example, from a mole.

[004] Early detection of the oral lesions is of utmost importance. Intraoral biopsy will help to diagnose the benign and malignant lesions as soon as their onset in the oral cavity. Early detection will naturally help the early treatment of the lesions preventing further complications. Presently, in the field of Oral & Maxillofacial Surgery, which is a special surgical branch of dentistry, the standard conventional biopsy punches are used. Those which are available in the market are having straight handle & working circular blade. Other option is using surgical blade No. 15 or 11 or 12 for the same procedure Many times, there is practical difficulty to access certain areas in the oral cavity, due to restricted oral opening or retro molar region, mobile soft palate areas etc. Similarly, to carryout secondary exposure for oral implants prior to prosthetic rehabilitation procedure, many times due to fibrosis of the tissues over healing cap of the implant, it

becomes difficult to have precise exposure of adequate dimension without tissue tags etc.

SUMMARY OF THE INVENTION

[005] The invention generally relates to obtaining tissue samples. The present invention alleviates the disadvantages of the prior art to a great extent by providing an angled cutting member with the ability to make the precise incision of required dimension. Also, the disclosed metallic mucosal punch will help to obtain precise well circumscribed tissue biopsy with adequate depth with minimum tissue trauma, as well as it can be used for carrying out secondary surgical exposure of implants with ease of operation.

[006] The metallic mucosal punch will be very useful for soft tissue biopsy procedures in the oral cavity with easy access due to its modified design with minimum surgical trauma, therefore good postoperative early healing can be obtained.

OBJECTS OF THE INVENTION

[007] It is an object of the invention to provide means for early detection of oral lesions which could help in early diagnosis and treatment to minimize possibility of complications.

[008] Another object of the invention is to provide means for obtaining precise predetermined dimension of the tissue for biopsy or for carrying out secondary surgical exposure of the implants.

ADVANTAGES OF THE INVENTION

[009] The present invention offers a number of benefits over the prior art inventions, some of which are:

[0010] The present invention is a very simple, handy instrument designed to reach inaccessible areas in oral cavity.

[0011] The invention uses an innovative design which is superior to conventional methods used for obtaining oral lesion biopsy.

[0012] The invention causes minimum surgical trauma thus leading to faster postoperative healing.

[0013] Using the invention depth of the tissue to be obtained can be determined.

[0014] In case of secondary surgical exposure of the implants after osseointegration, using the present invention, precise tissue can be removed to uncover the healing cap and to proceed further without tissue tags, for a final dental restoration.

[0015] The invention minimizes soreness, tenderness of biopsy site.

[0016] The instrument is reusable, as it is autoclavable.

[0017] The handle of the disclosed instrument is preferably made up of DELRIN® material, which is acetal resin. It is highly versatile engineering polymer. It has got high mechanical impact strength and rigidity with excellent resistance to moisture and excellent thermal stability. It`s custom colors are free from heavy metals.

[0018] Additional aspects, advantages, features and objects of the present disclosure would be apparent from the drawings and the detailed description of the illustrative embodiments that follow.

[0019] It will be appreciated that features of the present disclosure are susceptible to being combined in various combinations without departing from the scope of the present disclosure as defined by the appended claims.

BRIEF DESCRIPTION OF DRAWINGS

[0020] The following detailed description of illustrative embodiments is better understood when read in conjunction with the appended drawings. For the purpose of illustrating the present disclosure, exemplary constructions of the disclosure are shown in the drawings. However, the invention is not limited to specific methods and instrumentalities disclosed herein. Moreover, those in the art will understand that the drawings are not to scale. Wherever possible, like elements have been indicated by identical numbers.

[0021] Figure 1 provides a diagrammatic representation of metallic mucosal punch in accordance with the preferred embodiment of the present invention.

[0022] Figure 2 depicts the working position of disclosed punch for maxillary region, cheek, buccal mucosa, maxillary tuberosity area and mandibular area.

[0023] Figure 3 is a photograph of instrument.

[0024] Figure 4 depicts the clinical application of metallic mucosal punch

DETAIL DESCRIPTION OF DRAWINGS

[0025] The invention is described in detail below with reference to several embodiments. Such discussion is for purposes of illustration only. Modifications to examples within the spirit and scope of the present invention, set forth in the appended claims, will be readily apparent to one of skill in the art. Terminology used throughout the specification and claims herein is given its ordinary meaning as supplemented by the discussion immediately below. As used in the specification and claims, the singular forms “a”, “an” and “the” include plural references unless the context clearly dictates otherwise.

[0026] Those with ordinary skill in the art will appreciate that the elements in the Figures are illustrated for simplicity and clarity and are not necessarily drawn to scale. There may be additional components described in the foregoing application that are not depicted on one of the described drawings. In the event, such a component is described, but not depicted in a drawing, the absence of such a drawing should not be considered as an omission of such design from the specification.

[0027] Referring now to the figures, Figure 1 provides a diagrammatic representation of metallic mucosal punch in accordance with the preferred embodiment of the present invention. The metallic mucosal punch comprises of the following parts:

1(a). Handle member

1(b). Straight Shaft

1(c). Angled cutting member with punch blade/tip at the extreme distal end

[0028] The instrument has an elongated handle member **1(a)**. This handle member **1(a)** is configured to retain a thinner shaft **1(b)** which has a cutting member **1(c)** at the distal end. The handle **1(a)** is often made of plastic, while the shaft **1(b)** and cutting member **1(c)** along with punch blade/tip is often made out of surgical

steel, stainless steel or other material, often a metal, which can hold a cutting edge.

[0029] The shaft **1(b)** and cutting member **1(c)** can be held or retained on the handle **1(a)** by a wide variety of different means including press-fitting or other methods. In some embodiments, the handle itself may be metal, durable plastic, or other material that can itself maintain a cutting edge, in which case the entire instrument may be formed from a single piece of the same material.

[0030] In the preferred embodiment, the handle member is made of DELRIN® which is an acetyl resin. It is highly versatile engineering polymer. It has got high mechanical impact strength and rigidity with excellent resistance to moisture and excellent thermal stability. Its custom colors are free from heavy metals.

[0031] The shaft **1(b)** will typically have a substantially cylindrical hollow body that is retained by the handle **1(a)**. The diameter of the cylindrical body will vary. The optimum diameter for the cylindrical body will typically be between 1 and 6 mm.

[0032] The distal end of the shaft **1(b)** has an angled cutting member **1(c)**. The cutting member comprises of a cylindrical portion and a sharpened cutting edge / blade at the extreme distal portion. The total depth of the cylindrical portion of the cutting member will vary, but will usually be at least 5 mm deep. It should be apparent that when the cutting member of the instrument is pressed onto the surface of the tissue, the instrument will produce a circular incision.

[0033] It is important to recognize that the instrument is intended to be used by a working dentist to work on various regions of the jaw of a human patient. The patient must open their mouth, and the regions of the jaw nearer the front of the mouth will be more accessible than the regions near the back of the mouth. To reach all regions of the mouth, especially the back, the instrument has been given a bent configuration, rather than straight, in order to produce the appropriate cutting results in any portion of the mouth.

[0034] Here the angle between the shaft **1(b)** and the cutting member **1(c)** can vary to as much as a right angle 90-degree orientation.

[0035] In some embodiments, it may be useful to make the shaft **1(b)** demountable or removable from the handle **1(a)**. For example, a kit containing a variety of

different shafts with different cutting members attached provided with a common handle **1(a)** may be provided, and the dentist may pick which shaft and cutting member is most appropriate to the particular region, and mount the shaft onto the handle prior to use. This mounting could be done, for example, by a screw joint, snap-to fit joint, or other joint that enables the shaft to be joined to the handle without an undue amount of effort. Here ideally a hand operated connection mechanism is preferred. Alternatively, the cutting members or blades themselves may be capable of being mountable or demountable from the shaft.

[0036] Figure 2 depicts the working position of disclosed punch for various areas of the jaw and mouth. The figures show the ease with instrument cutting member can be placed at the maxillary region, cheek, buccal mucosa, maxillary tuberosity area and mandibular area.

[0037] Figure 2(A) depicts the working position of punch for maxillary region.

[0038] Figure 2(B) depicts the working position of punch for cheek, buccal mucosa.

[0039] Figure 2(C) depicts the working position of punch for maxillary tuberosity area.

[0040] Figure 2(D) depicts the working position of punch for mandibular area.

[0041] Figure 2(E) and 2(F) depicts how working mucosal punch sharp bevel can be used in any area of oral cavity.

[0042] Figure 3 is an actual photograph of metallic mucosal punch in accordance with an embodiment of the present invention.

[0043] Figure 4 depicts the clinical application of metallic mucosal punch for secondary surgical exposure of oral/dental implants for maxillary region. Here the maxillary region of the jaw is shown; exposing the gum tissue. Assume that this is the site on the jaw where the dentist wishes to extract the tissue. The dentist will make a hole in the gum tissue with the cutting member **1(c)** of the device by pressing the device into the gum tissue. The circular cutting surface of the cylindrical cutting member will press into the gum tissue and cut a hole and the displaced tissue can then be removed from the region.

[0044] The present invention has been described herein with reference to a particular embodiment for a particular application. Those having ordinary skill in the art and

access to the present teachings may recognize additional various substitutions and alterations are also possible without departing from the spirit and scope of the present invention, and as defined by the following claims.

Dated this 14th day of November, 2017

Krishna Institute of Medical Sciences

Abhinav Bhalla
IN/PA – 1885
Agent for the Applicant

We claim:

1. An instrument for removing and/or reflecting dental tissue, comprising:

   an elongated handle member configured to retain a straight shaft formed integrally on one end of said handle member;

   said straight shaft comprising a substantially cylindrical body retained by said elongated handle member and projecting therefrom to expose, on the distal end of said substantially cylindrical body, a circular cutting member;

   said circular cutting member positioned in an angled configuration from the shaft;

      wherein the cutting member comprises of a blade or tip located at the extreme distal end of a substantially cylindrical body;

      wherein the interior of cutting member of said substantially cylindrical body is hollow and at least 5 mm deep;

      wherein the diameter of said circular cutting member is between 1 and 6 mm; and

      wherein when said instrument is pressed into the surface of the tissue, said instrument produces a circular incision.

2. The instrument of claim 1, in which said cutting member is bent from the straight shaft at an angle between 90 and 180 degrees.
3. The instrument of claim 1, wherein said cutting member and said blade/tip are made from materials selected from the group consisting of surgical steel, stainless steel, and other cutting material.
4. The instrument of claim 1, wherein said elongated handle member is made from plastic or a reusable metal.
5. The instrument of claim 1, wherein the said elongated handle member is made from DELRIN® acetyl resin material.
6. The instrument of claim 1, wherein said cutting member may be detached and then remounted on said straight shaft, or said blades may be detached and then remounted on said cutting member.

7. The instrument of claim 1, wherein the said shaft may be detached and then remounted on said elongated handle member.

Dated this 14th day of November, 2017

Krishna Institute of Medical Sciences

Abhinav Bhalla
IN/PA – 1885
Agent for the Applicant

FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A PAIN-RELIEF FORMULATION AND THE METHOD THEREOF"

APPLICANT

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An Indian National,

Krishna Institute of Medical Sciences,

Near Dhebewadi Road, Malkapur, Karad, Pin code- 415110,

Maharashtra, India

The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to human body pain -relief caused by chronic muscle hyperalgesia. More particularly, the present invention relates to a pain-relief formulation comprises of a special combination of methanolic extract of *Phyllanthus amarus*leaves (Hereinater referred to as "PAME") and pharmaceutical execipientsselected from a group consisting of oil, suractant, co-surfactant & water or a combination thereof. The present invention also provides a method of manufacturing said formulation.

BACKGROUND OF THE INVENTION

The term "hyperalgesia" is an abnormally increased sensitivity to pain, which caused by damage to nociceptors or peripheral nerves and can cause hypersensitivity to stimulus. Prostaglandins E (i.e. PGE) and F (i.e. PGF) are largely responsible for sensitizing the nociceptors. Temporary increased sensitivity to pain also occurs as part of sickness behavior, the evolved response to infection. The term "fibromyalgia" is a medical condition characterized by chronic widespread pain and a heightened pain response to pressure. The common problem in both the condition is pain.

Currently, NSAIDs (Non-steroidal anti-inflammatory drugs) for example Aceclofenac, diclofenac, etc. are prescribed for previously mention medical conditions to relief from pain. However, the effect of these synthetic analogues is short-term and these drugs are known to cause many side effects include serious problems like thrombosis which can be life threatening.

Herbal-based pain-relief formulation is disclosed in Indian Patent literature1436/KOL/2009, 1334/CHE/2010, 905/DEL/2012, 342/DEL/2015, 2639/DEL/2015, 1316/KOL/2015, 201731033421 & 201814029999.
Foreign patent literature US20080107747, WO/2007/145655A1, US20110135627, WO/2011/044381A1, US20160129066, US20050123619, US20180280464, WO/2011/041542A2also discloses herbal-based pain relief composition.

However, none of the patent literature discloses single plant based herbal pain-relief formulation for treating chronic muscle hyperalgesia.

The present inventor (Atul R. Chopade) founds that PAME (i.e. active product ingredient) is useful in chronic muscle hyperalgesia [**DOCUMENT 1.** Atul R. Chopade et al., *Pain Modulation by Lignans (Phyllanthin and Hypophyllanthin) and Tannin (Corilagin) Rich Extracts of Phyllanthus amarus in Carrageenan induced Thermal and Mechanical Chronic Muscle Hyperalgesia*; Phytotherapy Research 29: 1202–1210 (2015) Published online 14 May 2015 in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/ptr.5366 & **DOCUMENT 2**. Atul R. Chopade et al, *"Antifibromyalgic activity of standardized extracts of Phyllanthus amarus and Phyllanthus fraternus in acidic saline induced chronic muscle pain"*, Biomedicine & Aging Pathology 4 (2014) 123–130].

The present inventors found in current application that not all the pharmaceutical combination/formulation of PAME is effective in treating chronic muscle hyperalgesia. The present inventorsachieved the technical effect using a special combination of PAME& the aforesaid excipients.

OBJECTIVE OF THE INVENTION

It is object of the invention is to provide an improvement over afore said DOCUMENT 1 & DOCUMENT 2.

It is another object of the invention is to provide a pain-relief formulation using single plant.

It is another object of the invention is to provide a novel anti-hyperalgesic formulation.

It is yet another object of the invention is to provide a novel anti-fibromyalgic formulation.

It is yet another object of the invention is to provide a stable, oil-in-water (O/W) anti-pain emulsion.

It is yet another object of the invention is to provide an anti-pain emulsion that could provide the faster drug release.

It is further another object of the invention is to provide an economic method for manufacturing the formulation.

SUMMARY OF THE INVENTION

According to one aspect, there is provided a pain-relief formulation comprises of

i) methanolic extract of *Phyllanthus amarus* in an amount of 1.92% by weight;

ii) an oil having specific gravity of 0.860-1.046 in an amount of 10% by weight;

iii) a surfactant in an amount of 35% by weight;

iv) a co-surfactant in an amount of 35% by weight;

v) water in quantity sufficient.

According to another aspect, there is provided a process for preparing the pain-relief formulation comprising the steps of

i) preparing a mixture containing the methanolic extract of *Phyllanthus amarus*, oil & surfactant & co-surfactant;

ii) adding the mixture as obtained in step (i) to water;

iii) subjecting the mixture as obtained in step (ii) to ultra-sonication for 45 minutes at 28°C;

wherein the ratio of oil & water is 1:2 by weight.

In accordance with these and other objects, which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates the ternary phase diagram in accordance with the present invention;

Figure 2 illustrates comparative droplet size in accordance with the present invention;

Figure 3 illustrates comparative polydispersity index in accordance with the present invention;

Figure 4 illustrates comparative entrapment efficiency in accordance with the present invention; &

Figure 5 illustrates comparative zeta potential in accordance with the present invention;

Figure 6 illustrates comparative percentage drug release wherein Figure 6a and 6b for 10 & 20 minutes respectively in accordance with the present invention;

Figure 7 illustrates 90-days stability study of developed emulsion (Formula B1-B8) wherein Figure 7a-7h shows comparative percentage drug content & Figure 7i-7p shows comparative zeta potential.

Figure 8 illustrates comparative percentage inhibition of PGE level; and

Figure 9 illustrates comparative histopathological studies in which a) normal control, b) acute inflammatory control; c) chronic inflammatory control, d) standard (Aceclofenac), e) B7, f) B1, g) B2, h) B3, i) B4, j) B5, k) B6, l) B8 in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Expression:

Myonecrosis herein is a condition of necrotic damage, specific to muscle tissue due to persistent chronic inflammation of musculoskeletal origin.

Macrophage in chronic inflammation herein increases inflammation and stimulates the immune system. Macrophages that encourage the process of inflammation are called M1 macrophages.

An fibrous exudates herein is pus-like or clear fluid composed of serum, fibrin, and white blood cells that filters from the circulatory system to lesions or areas of chronic inflammation due to injury or trauma.

The present invention provides a stable pain-relief formulation comprises of a particular combination of methanolic extract of *Phyllanthus amarus* leaves (i.e. active) and pharmaceutical excipients.

In preferred embodiment, the pharceutical excipient is selected from a group consisting of sufactant, co-suractant, oil and water or a combination thereof.

In preferred embodiment, amount of the active is 1.92% by weight.

In preferred embodiment, amount of oil is 10% by weight.

In preferred embodiment, amount of surfactant is 35% by weight.

In preferred embodiment, amount of co-surfactant is 35% by weight.

In preferred embodiment, amount of water is quantity sufficient (i.e. upto 100%).

In preferred embodiment, the oil is selected from a group having the specific gravity of 0.860-1.046.

In an embodiment of the invention, the oil is selected from a group consisting of olive oil, almond oil, castor oil, clove oil,coconut oil,rose oil or arachis oil.

In preferred embodiment of the invention, the oil is coconut oil.

In an embodiment of the invention, the surfactant is selected from a group consisting of Tween 20 or Tween 80 while the co-surfactant is selected from a group consisting of PEG 400, PEG 200, propylene glycol, carbitol or ethanol.

In preferred embodiment, the surfactant & co-surfactant is Tween 80 (Polyoxyethylenesorbitanmonooleate) and Polyethylene glycol 400 (PEG 400) respectively.

In preferred embodiment, the formulation is oil in water (o/w) type emulsion wherein the ratio of oil and water is 1:2 by weight. According to present inventor, the desired effect would not be possible if this ratio is varied.

In an embodiment of the invention, the emulsion is micro-emulsion.

In an embodiment of the invention, droplet size& polydispersity index (PDI) of the emulsion should be lower. In preferred embodiment, the droplet size & the polydispersity index is 1100-1200nm & 0.610 respectively. According to present inventor, the desired effect would not be possible if the droplet size is varied.

In one embodiment, the present invention provides a process for preparing the said emulsion comprising the steps of:

i) preparing a mixture containing PAME, the oil & surfactant & co-surfactant;
ii) adding the mixture as obtained in step (i) to water;
iii) subjecting the mixture as obtained in step (ii) to ultra-sonication.

In preferred embodiment, duration of the ultra-sonication technique in step (iii) is 45 minutes.

In preferred embodiment, temperature of the ultra-sonication technique in step (iii) is 28°C.

In preferred embodiment, the pain is selected from either hyperalgesia or fibromyalgia.

The invention is now illustrated by non-limiting examples.

Example 1:

<u>Sources of the materials:</u>

PAME contains >2.5% of Phyllanthin and Hypophyllanthin (Report No: FP1112042-PA/11LOT05) was procured as a gift sample from NATURAL REMEDIES PVT. LTD., Bangalore.

The exicipeint Tween 80, Tween 20,PEG 400,PEG 200 propylene glycol,carbitol were purchsed from Niram chemicals,Mumbai. Labrafil and Labrasol were purchased from Sigma Aldrich, Germany.

The oils were purchased from local market. Ethanol was purchased from Rajarambapu Sahakari Sugar factory LTD., Sangli, Maharashtra. Freshly prepared

Milli-Q-water (high grade purified water) was prepared by standard mathod in the Pharmaceutics Laboratory, Rajarambapu college of Pharmacy, Maharashtra, India.

Formula B1:

a) Coconut oil: 15.80 wt%
b) Tween 80: 34.60 wt%
c) PEG 400: 34.60 wt%
d) PAME: 1.92 wt%
e) Water: q.s.

Method: 0.5mg of PAME was added in 4mL of coconut oil and 9mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (4mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B2:

a) Coconut oil: 5.0 wt%
b) Tween 80: 45.0 wt%
c) PEG 400: 45.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s.

Method: 0.5mg of PAME was added in 1.3mL of coconut oil and 11.7mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (1.3mL) to obtain an emulsion. The emulsion was then subjected to20 kHZultrasonic

processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B3:

a) Coconut oil: 10.0 wt%
b) Tween 80: 40.0 wt%
c) PEG 400: 40.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s.

Method: 0.5mg of PAME was added in 2.6mL of coconut oil and 10.4mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (2.6mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B4:

a) Coconut oil: 15.0 wt%
b) Tween 80: 35.0 wt%
c) PEG 400: 35.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s.

Method: 0.5mg of PAME was added in 3.9mL of coconut oil and 9.1mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (9.1mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B5:

a) Coconut oil: 20.0 wt%
b) Tween 80: 30.0 wt%
c) PEG 400: 30.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s

Method: 0.5mg of PAME was added in 5.2mL of coconut oil and 7.8mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (5.2mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B6:

a) Coconut oil: 25.0 wt%
b) Tween 80: 25.0 wt%
c) PEG 400: 25.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s

Method: 0.5mg of PAME was added in 6.5mL of coconut oil and 6.5mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (6.5mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B7:

a) Coconut oil: 10.0 wt%
b) Tween 80: 35.0 wt%
c) PEG 400: 35.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s

Method: 0.5mg of PAME was added in 2.6mL of coconut oil and 9.1mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (5.2mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

Formula B8:

a) Coconut oil: 20.0 wt%
b) Tween 80: 35.0 wt%
c) PEG 400: 35.0 wt%
d) PAME: 1.92 wt%
e) Water: q.s

Method: 0.5mg of PAME was added in 5.2mL of coconut oil and 9.1mL each of Tween 80 & PEG400 in glass vial and this mixture was titrated with milli-Q-water (2.6mL) to obtain an emulsion. The emulsion was then subjected to20 kHZ ultrasonic processor for 45 minutes at 28°C wherein the amplitude of probe sonication was 37%.

A) In-vitro evaluation of Formula B1-B8:

i) **Ternary phase diagram:**

Pseudo ternary phase study was conducted to find out mono-phase of the developed emulsion (B1-B8) using 8 different glass tubes for 8 batches. The tube containing mixture solution (SC mixture : oil : water wherein SC mixture is surfactant & co-surfactant mixture) was homogenously mixed by vortex mixer (Thermo scientific) at room temperature for 4 min. 50 µl of water solution was added into this tube and the said mixture was vortexed again for 4 minute. After every 15 min of vortexing, addition of water was done, mixed accordingly and the sample was visually observed against a dark background. It was observed that all the batches shows monophase except B5 which may be due to the ratio of components i.e 60 % SC mixture and 20 % water and 20% oil phase (Figure 1).

ii) Droplet size (DS) and Poly-dispersity (PDI) measurements:

Formula B1-B7 was separately subjected to a Malvern Zetasizer Nano ZS using dynamic light scattering (Malvern Instruments, Malvern, UK) at 25^0C, was used to measure the droplet size and polydispersity index of the emulsion (Figure 2 & 3).

iii) Particle surface charge (zeta potential) measurements:

The Malvern Zetasizer Nano ZS (Malvern Instruments, Malvern, UK),maintained at 1.33 and 0.89 cp for refractive index and viscosity respectively in order to mimic the value of pure water, was applied to measure the zeta potential through

electrophoretic mobility measurements. Immediately after the DS measurements, the potential was measured using the same cuvette with three successive readings for each sample, and the mean value and standard was calculated (Figure 4).

iii) Determination of viscosity and pH:

Viscosity of the developed emulsion (Formula B1-B8) was determined by using Horiba scientific SZ 100 nano particle size analyser while pH of the formulation was determined by using digital pH meter (EQ-615**).**

iv) Entrapment efficiency of PAME:

Entrapment efficiency of the emulsion (Formula B1-B8) was determined using a centrifugal filtration device (Microcon Millipore, Billerica, MA) with a 100 kDa molecular weight cut-off filter. 200mL of the emulsionwas added to the sample reservoir of the Microconsystem and then centrifuged at 1500 x g at 4°C for 45min to separate the entrapped and un-trapped components. The entrapped component in sample reservoir was washed twice with 200mL of deionized water and the whole filtrate was collected and referred to as the un-trapped component, which was evaporated and dissolved with 200mL of DMSO. Both the entrapped and un entraped components further diluted with DMSO with suitable dilutions and absorbance on UV spectrophotometer was determined at the λ max (286 nm).The concentration was determined by plotting standard calibration curve of working standard (99.9 %) pure extracts of phyllanthus amarus. The entrapment efficiency (%EE) was calculated using the following equations (Figure 5).

$$\%\ \text{entrapment efficiency} = \frac{\text{Entrapped phyllanthus amarus methanolic extract (mg)}}{\text{Initial extracts taken for formulation (mg)}} \times 100$$

Table 1: Comparative result of parameter i-iv

Formula	pH	Entrapment efficien	Droplet size (nm)	PDI	Viscosity (mPa˙s)	Zeta potential (mV)	Phase

		cy (%)					
B1 (comparative)	4.9	70.12%	2198.2	0.253	0.796	14	Monophasic
B2 (comparative)	5.1	69.22%	2196.0	0.287	0.896	11	Monophasic
B3 (comparative)	5.2	65.00%	2231.0	0.313	0.896	10	Monophasic
B4 (comparative)	4.9	71.00%	2241.0	0.316	0.797	14	Monophasic
B5 (comparative)	5.2	68.00%	2431.0	0.421	0.731	10	Bi-phasic
B6 (comparative)	4.6	69.00%	2232.0	0.317	0.710	16	Monophasic
B7 (inventive)	2.0	91.22%	1198.2	0.110	0.610	44	Monophasic
B8 (comparative)	4.8	67.00%	2200.1	0.212	0.796	14	Monophasic

Table 1 shows that Formula B5 was not at all satisfactory as this system is found as bi-phasic (i.e. phase separation) which is not desired in view of pharmaceutical drug delivery system. Zeta potential value of B2 & B3 was found to be 10 &11 respectively indicating the emulsion as an unstable system *(Mohammad Mehral et al, Preparation, characterization, viscosity, and thermal conductivity of nitrogen-doped graphene aqueous nanofluids. J Mater Sci 2014).* Zeta-potential value was slightly increased in B1, B4, B6 & B8 (14-16) but these system would also not to be considered as stable system as per *Mohammad Mehral et al***.** This may be due to equal concentration of the oil & water with non-ionic surfactant (Tween 80). On the other hand, zeta potential value of B7 was found to be 40 indicating the emulsion as highly stable *(Nidhi Bhatt et al. Stability study of O/W emulsions using zeta potential. J. Chem. Pharm. Res., 2010, 2(1): 512-527)* which may be due to 1:2 as concentration of oil and water. Also, B7 shows superior entrapment efficiency (91.22%) as compared to other formulas. Further, the safety and efficacy of pharmaceutical formulation dependent on adequate drug delivery to target tissues

with no or minimum side effects. This could be achieved by enhancing bioavailability of drug at the target tissue at lower dose. The accumulation of emulsion carrying drug to target tissue depends on the physicochemical characteristics including particle size distribution and droplet size of emulsion. It is known in art that in order to achieve maximum bioavailability at the site of action, the droplet size of emulsion should be minimum and the droplet should be homogeneous (mono-disperse).Table 1 shows the lesser droplet size in B7 while comparing to other formulas.

v) In-vitro release studies:

Aim: Comparative percentage drug release of the developed formulation (B1-B8) as to find out the faster drug release.

Method: In order to conduct in-vitro release of B1 to B8, Franz diffusion cellwas used. Receiver compartment volume of 10mL and effective diffusion area of 2.84cm^{2}were used to determine release of the active from emulsion. The dialysis membrane 0.65µm was used. The receptor compartment was filled with 60w/w ethanol and temperature was maintained at 33^{0}c. 1gm of emulsion formulation was placed in the donor compartment and 1mL of sample from receiver compartment was withdrawn at the appropriate time. The same amount of fresh sample was added and volume was kept constant. The samples were analyzed on UV spectrophotometer (Systronics AU 2701) at the wavelength of 286nm and the concentration of the active was determined of each batch from the standard curve. For standard curve, working standard of *phyllanthus amarus* with percentage purity 99.9% was used. Percentage drug release of the developed emulsion (B1-B11) is herein below:

Table 2: Comparative %drug release

Time (Min)	Batch B 1 (%) (comparative)	Batch B2 (%) (comparative)	Batch B3 (comparative) (%)	Batch B4 (%) (comparative)	Batch B5 (%) (comparative)	Batch B6 (%) (comparative)	Batch B7 (%) (**Inventive)**	Batch B8 (%) (comparative)
0	0	0	0	0	0	0	0	0
10	19.63	23.8	17.45	11.21	14.21	16.12	64.70	14.61
20	32.15	44.2	28.22	19.63	30.12	29.12	86.07	30.21
30	62.34	53.43	44.65 %	32.15	41.20	46.23	95.00	52.11

With regard to Table 2, Figure 6,faster drug release (64.70% in 10min & 95.00% in 30min)was only observed in B7 while comparing to other batches. This may be due to the higher entrapment efficiency and minimum droplet size of B7.

vi) Stability studies:

The stability is an utmost important part of the formulation called as 'emulsion', it is pharmaceutically said that "*if the emulsion is not stable then there is no sense of drug delivery and the therapeutic effect thereof"*. The stability study (up to 90 days) of developed emulsion (Formula B1-B8) was conducted and the conclusion was done on the basis of two fundamental stability parameteri.e.1) %drug content and 2) zeta potential.

With regard to point 1, negligible drug content (10% in 30 days) was observed in B1 while no active was present after 180 days in B1 (Figure 7a). On the other hand, significantly lesser % drug content was found in B2 (Figure 7b), B3 (Figure 7c), B4 (Figure 7d), B5 (Figure 7e), B6 (Figure 7f) and B8 (Figure 7h). Contrarily, 90% drug content was observed even after 180 days in B7 (Figure 7g) which may be due to 1:2 as oil and water in the emulsion.

With regard to point 2, no value of zeta potential was found on 90^{th} day for B1, B3 & B4 (Figure 7i, 7k & 7l) indicating the formulation is *"highly unstable*". On the other hand, the value *'upto 8'* or *'below 8'* was observed in B2 (Figure 7j), B5 (Figure 7m), B6 (Figure 7n) & B8 (Figure 7p) on 90^{th} day which indicates, *"the system is not stable"*. Contrarily, the value of zeta potential was remained higher (44) & constant even on 90^{th} day in B7 (Figure 7o) indicating, *"the system is highly stable"*.

<u>B) In-vivo evaluation of Formula B1-B8</u>

i) Experimental animals:

Adult male wistar rats weighing 200–340 g were used in this study. The animals were maintained under standard environmental conditions and were fed with standard diet and water ad libitum. Food and water were freely available throughout the experiments.

ii) Induction of carrageenan chronic inflammatory muscle hyperalgesia and Percentage inhibition of PGE2 concentration:

Chronic inflammation was induced by injecting 100µL of freshly prepared solution of 3% carrageenan in normal saline to the left gastrocnemius muscle belly of rats, under light ether anesthesia *(Radhakrishnana R, et al. Unilateral carrageenan injection into muscle or joint induces chronic bilateral hyperalgesia in rats. Pain, 2003,104; 567–577)*. After 24 hour of the intramuscular injection of carrageenan, spontaneous pain behavioural signs such as guarding the injected paw and weight bearing on the contra lateral paw during the first two days were observed. All the animals were divided into 9 groups as follows:

Group 1: Control

Group 2: B1

Group 3: B2

Group 4: B3

Group 5: B4

Group 5: B5

Group 6: B6

Group 7: B7

Group 8: B8

Group 9: Standard (Aceclofenac)

B1- B9 groups was treated with a dose (400mg/kg) of the drug formulation while the control group was treated without any drug.

As shown in Figure 8, B1-B6 and B8 was failed to inhibit PGE2 concentration (in view of control) which may be due to the unstable nature of B1-B6 & B8 as discussed above whereas B7 and aceclofenac both the formulation significantly reduces PGE2 level (in view of control). The Data were analyzed by one-way analysis of variance using Dunnett's multiple comparison test & $p<0.05$ was considered significant in comparison with inflammatory control.

iii) Histapathological studies:

The aim of histopathological examination herein is to find out the presence of myonecrosis, macrophages & fibrous exudates in the experimental animal tissues as these indications are known *(1. Giuliano F et al. Origins of Prostaglandin E2: Involvements of Cyclooxygenase (COX)-1 and COX-2 in Human and Rat Systems.*

Journal of Pharmacology and Experimental Therapeutics, 2002, 303; 1001–1006.; & 2. Radhakrishnana R et al. Unilateral carrageenan injection into muscle or joint induces chronic bilateral hyperalgesia in rats. Pain, 2003, 104; 567–577) as 'largely present' in a pain like condition for instance hyperalgesia.

As shown in Figure 9, normal control group (Figure 9a) was found without any above indication. Both acute & chronic inflammatory control group (Figure 9b & 9c respectively) indicates largely presence of myonecrosis, macrophages &fibrous exudates.

With regard to the treated groups, standard group (aceclofenac) indicates no macrophage and myonecrosis with very few fibrous exudates (Figure 9d). On the other hand, no significant changes was observed while comparing B1-B6 (Figure 9f-9k) & B8 (Figure 9l) with acute & chronic inflammatory control. Contrarily, B7 shows the significant changes of tissue histology i.e. no sign of myonecrosis with significantly lesser extent of macrophage and fibrous exudates (Figure 9e) which may be due to stable nature of the emulsion (B7).

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been present for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which departs from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim,

1. A pain-relief formulation comprises of

    i) methanolic extract of *Phyllanthus amarus* in an amount of 1.92% by weight;

    ii) an oil having specific gravity of 0.860-1.046 in an amount of 10% by weight;

    iii) a surfactant in an amount of 35% by weight;

    iv) a co-surfactant in an amount of 35% by weight;

    v) water in quantity sufficient.

2. The formulation as claimed in claim 1, wherein the oil is selected from a group consisting of olive oil, almond oil, castor oil, clove oil, coconut oil, rose oil or arachis oil.

3. The formulation as claimed in claim 1, wherein the surfactant is selected from a group consisting of Tween 20 or Tween 80.

4. The formulation as claimed in claim 1, wherein the co-surfactant is selected from a group consisting of polyethylene glycol 400, polyethylene glycol 200, propylene glycol, carbitol or ethanol.

5. The formulation as claimed in claim 1 is an emulsion.

6. The formulation as claimed in claim 5, wherein the emulsion is an oil-in-water (O/W) type.

7. The formulation as claimed in claim 6, wherein ratio of oil and water in said emulsion is 1:2 by weight.

8. The formulation as claimed in claim 5-7, wherein the emulsion is a micro-emulsion.

9. The formulation as claimed in claim 5-8 wherein droplet size of the said emulsion is 1100-1200nm.

10. The formulation as claimed in claim 1, wherein the pain is selected from hyperalgesia or fibromyalgia.

11. A process for preparing the formulation as claimed in claim 1 comprising the steps of

iv) preparing a mixture containing the methanolic extract of *Phyllanthus amarus*, oil & surfactant & co-surfactant;

v) adding the mixture as obtained in step (i) to water;

vi) subjecting the mixture as obtained in step (ii) to ultra-sonication for 45 minutes at 28°C;

wherein the ratio of oil & water is 1:2 by weight.

Dated this day 02nd day of February, 2020

ArghyaAshis Roy
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant

ABSTRACT

“A PAIN-RELIEF FORMULATION AND THE METHOD THEREOF”

Disclosed is a pain-relief formulation comprises of i) methanolic extract of *Phyllanthus amarus*in an amount of 1.92% by weight; ii) an oil having specific gravity of 0.860-1.046 in an amount of 10% by weight; iii) a surfactant in an amount of 35% by weight; iv) a co-surfactant in an amount of 35% by weight;v) water in quantity sufficient. Also provided a method of manufacturing the formulation.

FORM 2
THE PATENTS ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
COMPLETE SPECIFICATION
(See section 10 and rule 13)

TITLE OF THE INVENTION

MOISTURE SENSITIVE RESISTANCE BASED NANOCOMPOSITE (SEMICONDUCTOR NPS/AGAR) CHEMICAL NANOSENSOR AND A METHOD FOR FABRICATION THEREOF

1. APPLICANT(S)

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2. PREAMBLE TO THE DESCRIPTION

The following specification particularly describes the invention and the manner in which it is to be processed

MOISTURE SENSITIVE RESISTANCE BASED NANOCOMPOSITE (SEMICONDUCTOR NPS/AGAR) CHEMICAL NANOSENSOR AND A METHOD FOR FABRICATION THEREOF.

FIELD OF THE INVENTION

The present invention relates to a moisture sensitive resistance based nanocomposite (semiconductor NPs/Agar) chemical Nanosensor and a method for fabrication thereof.

BACKGROUND OF THE INVENTION

Moisture sensitive product stability and shelf life can be predetermined by the manufacturers based on a number of assumptions. Standardized storage/ transportation parameters like temperature, moisture, exposure to sunlight etc. are considered. Compliance to these conditions is independent of the control of manufacturer. Any deviation from meeting these requirements can cause huge economic loss, for instance, foodstuffs to either spoil or become unpalatable if it exposed to such conditions. Among all these parameters, moisture alone can cause deterioration in food products either by enhancing the growth of microorganisms or by chemical degradation (Steele PH and Cooper JE, 2004) if transported and stored without proper packaging.

For instance, coffee/tea undergoes oxidation if moisture seeped into package and leads to deterioration (Steele PH and Cooper JE, 2004). Therefore, detection of such deviations in moisture during transport and storage of moisture sensitive product is the need of the day; however, the detection methods must be fast, reliable, easy to use, cost effective and requiring less incubation and expertise outside the laboratory. The unique chemical, physical, electrical and optical properties of nanoscale sensing materials offer solution to these problems.

The nanosensors devised through bottom- up approach may be able to respond to environmental change like temperature, moisture etc. (Baltić MŽ et al. 2013). This is not only beneficial for the consumers to purchase good products but it also improves product safety and reduces the probability of economic loss during transport and storage. Principle of nanosensors to detect alarming changes in product is based on optical, chemical or electrical attributes such as colour of polymer, chemical stability of polymer, electric conductance, capacitance, resistance, impedance etc to alert consumers and provide real-time status of products (Liao F et al. 2005). For instance, if determination of food quality by nanosensors at low cost achieved, then laboratory analysis of products for their acceptability and prior protection will be by-passed. Therefore, such nanosensor can be the best moisture detector to check the real-time status of products during storage and transportation.

Nowadays, diverse humidity and moisture sensors available for assorted applications (Matko Vand Donlagic D, 1997, Rittersma ZM, 2002, Huang TH et al, 2008). Many moisture and humidity sensors have developed were used comb-type finger copper electrodes pattern on

printed circuit board (PCB) (Dokmeci 2001, Huang 2008, Chetpattananondh, 2014, Rukavina, 2015). The sensor structure is similar to conventional liquid crystal display, i.e. sandwich configuration with the material confined between a pair of comb-type finger electrodes. Most of them provide output in the form of change in capacitance between electrodes (Chetpattananondh, 2014). Capacitance measurement setup is not relatively simple as resistance measurement and it is more susceptible to the external environment as atmospheric air acts as dielectric between two electrodes. Resistive moisture sensors are devices that transduce moisture into a change in impedance and can measure by a current, a voltage or a resistance [Rittersma, 2002].

Despite the numerous advantages offered by conventional sensing devices, the present scenario of industry demands the path breaking approach where sensors not only perform the active role of moisture detection, but also they must intelligently participate in real time detection of moisture seepage into packaged products. Therefore, the development of such moisture sensing assembly on IoT platform for continuous monitoring is mandatory.

The developed nanosensor has several advantages over conventional silicon sensors such as, low power requirements, easy implementation, improved efficiency, and higher precision. However, its miniaturization cost could prove to be a restraining factor; though, increase in demand by various industries and investments by key players in the market could facilitate its cost reduction and boost the overall market. Ethical and social impact of nanosensor is ambiguous because of its properties and functionalities. However, the use of nanosensor in healthcare and food sector is violating safety norms. Currently, there are few sensors

available that support consumer electronics but not in other domains yet.

In this context, the ZnO nanomaterials synthesized by semi-solvo thermal method (Pawar J et al, 2017) agar gel have used for fabrication of present chemical nanosensor to detect the moisture. The Agar/NPs nanocomposite based chemical nanosensors are particularly desirable due to its reliability, hygroscopic possessions and improved electronic properties can impart by various nanofillers. Nanoparticles found to be more advantageous than any other conducting filler due to their easy dispersion into the agar matrix to form functional Agar/NPs nanocomposite, which may remain as sensing material for a long period. However, it also observed that the dispersal of nanofillers at higher loading percentage in polymer matrix leads to agglomeration of material, which ultimately loses its strength, transparency and activity. Moisture/humidity sensing is dependent on active material; sensed and measured parameter, interchangeability, linearity, reliability and stability. The improvements in sensing layer can achieved through easy implementation, improved efficiency, low power requirements and higher precision.

Although nanoscale materials have numerous beneficial potentials, it also imposes various adverse health and environmental issues brought by interaction of nanomaterials through various application areas like food sector. Therefore, it is important to develop recycling procedures and/or toxicity analysis by in vitro and in vivo methods for nanomaterials (Pathakoti K et al. 2013; He X et al. 2014; He X et al. 2016). Recently, He X et al. have attempted to address some of these issues pertaining to direct exposure of nanomaterials to humans due to leakage from packaging material in their review article (He X et al. 2016). A

critical concern about nanomaterials is because of its rapid potential of uptake by biological systems, unknown distribution pathways and potential interaction with various components of the living system (Liang et al. 2008). They have superior reactivity, tiny size, can easily penetrate skin or cell, can rapidly distributed into the human body, and even can directly interact with cellular organelles. However, Agar/NPs nanocomposite based nanosensor can minimize the adverse effect of nanoparticle by their immobilization into agar matrix, which would improve its chances for reusability and decrease the possibility of migration into surrounding.

Hence, there is need to develop nanogizmos (nanomaterials and polymer nanocomposites) for fabrication of chemical nanosensor, which may bring a paradigm shift in the product security during transport and storage.

OBJECTS OF THE INVENTION

The principal object of the present invention is to overcome the disadvantages of the prior art.

An object of the present disclosure is to improve the performance of moisture sensing layer made of agar by the incorporation of semiconductor nanomaterials into agar matrix.

Another object of the present disclosure is to provide resistance based nanocomposite (Agar/semiconducting NPs) moisture sensing layer and fabrication of chemical nanosensor for determining moisture seepage into products.

Another objective of this invention is that polymer- nanofiller interactions tend to change with changing size and type of fillers, which subsequently affect performance of resulting nanocomposites

Still another objective of the present invention is to provide moisture sensitive resistance based nanocomposite (semiconductor NPS/agar) chemical nanosensor that provides the advantages of uniform distribution of metal oxide nanoparticles into the agar matrix; absorption of water by agar matrix; displaying superior electronic property , which allows the determination of small change in electronic attributes.; real time detection by Agar/NP nanocomposite mounted on PCB with the help of embedded system; replaceable Agar/NPS nanocomposite allows device to put on use repeatedly; usage of cheap and easily available materials; and biocompatible semiconductor nanoparticles are used making the process environmental friendly.

The objects of the present invention will become readily apparent upon further review of the following detailed description of the preferred embodiment as illustrated in the accompanying drawings.

SUMMARY OF THE INVENTION

The present invention is directed to a moisture sensitive resistance based nanocomposite (semiconductor NPs/Agar) chemical nanosensor and a method for fabrication thereof. The nanosensor is highly moisture sensitive, low cost, reliable, robust, compact, reusable platform with replaceable sensing layer and nanomaterial incorporated in organic solid support.

According to an embodiment of the present invention, the sensitive resistive chemical NPs/Agar hybrid nanosensor, comprises of chemical nanosensor PCB, single core wire, NPs nanoparticles and about 2% Agar.

According to another embodiment of the present invention, the method of fabrication of resistance based chemical nanosensor, using printed circuit board (PCB) technology, comprises the steps of;

a. preparing a design and arrangement of electrodes on PCB that consisted of four fingers with cross section area of 0.07mm for each electrode;
b. amalgamating NPs/Agar nanocomposite by indirect method, wherein NPs nanoparticles (1mg/mL) were synthesized by semi-solve thermal method mixed with 2 % agar gel;
c. transferring NPs/Agar nanocomposite coated PCB on PCB with laser-iron technology;
d. performing etching process to remove unwanted copper from PCB and tinning made on electrode to avoid oxidation of copper;
e. coating of NPs/Agar nanocomposite applied on PCB with soldered wires; and
f. testing of moisture sensitive resistive chemical nanosensor, wherein a particular amount of water was applied on to the surface of nanosensor PCB and change in resistance values measured by digital multimeter.

Additional aspects, advantages, features and objects of the present disclosure would be made apparent from the drawings and the detailed description of the illustrative embodiments construed in conjunction with the appended claims that follow.

It will be appreciated that features of the present disclosure are susceptible to being combined in various combinations without departing from the scope of the present disclosure as defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings where:

Figure 1 illustrates the prototype design and arrangement of electrodes on PCB;

Figure 2 illustrates the PCB fabrication steps (a) Etching, (b) Tinning, (c) Coated with NPs/Agar Nanocomposite; and

Figure 3 illustrates a graphical representation between resistance and water volume.

DETAILED DESCRIPTION OF THE INVENTION

As required, detailed embodiments of the present disclosure are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the disclosure which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the

claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

Various other objects, advantages, and features of the disclosure will become more readily apparent to those skilled in the art from the following detailed description when read in conjunction with the accompanying drawing.

In any embodiment described herein, the open-ended terms "comprising," "comprises," and the like (which are synonymous with "including," "having" and "characterized by") may be replaced by the respective partially closed phrases "consisting essentially of," consists essentially of," and the like or the respective closed phrases "consisting of," "consists of, the like.

As used herein, the singular forms "a," "an," and "the" designate both the singular and the plural, unless expressly stated to designate the singular only.

The present invention is directed to a moisture sensitive resistance based nanocomposite (semiconductor NPs/Agar) chemical nanosensor and a method for fabrication thereof. The nanosensor is highly moisture sensitive, low cost, reliable, robust, compact, reusable platform with replaceable sensing layer and nanomaterial incorporated in organic solid support.

The sensitive resistive chemical NPs/Agar hybrid nanosensor, comprises of chemical nanosensor PCB, single core wire, NPs nanoparticles and about 2% Agar.

The method of fabrication of resistance based chemical nanosensor, using printed circuit board (PCB) technology, comprises the steps of ; preparing a design and arrangement of electrodes on PCB that consisted of four fingers with cross section area of 0.07mm for each electrode; amalgamating NPs/Agar nanocomposite by indirect method, wherein NPs nanoparticles (1mg/mL) were synthesized by semi-solvo thermal method mixed with 2 % agar gel; transferring NPs/Agar nanocomposite coated PCB on PCB with laser-iron technology; performing etching process to remove unwanted copper from PCB and tinning made on electrode to avoid oxidation of copper; coating of NPs/Agar nanocomposite applied on PCB with soldered wires; and testing of moisture sensitive resistive chemical nanosensor, wherein a particular amount of water was applied on to the surface of nanosensor PCB and change in resistance values measured by digital multimeter.

Resistance based chemical nanosensor prototype was fabricated using printed circuit board (PCB) technology. The overall dimension of sensor PCB was 30mm X 30mm with 0.35µm copper thickness. The electrode pattern made on copper-coated FR4 fiberglass substrates, which then etched with $FeCl_2$. Prototype of design and arrangement of electrodes on PCB showed in figure 1. This arrangement consists of four fingers with cross section area of 0.07mm for each electrode. Each electrode has 33.117mm length & minimal resistance of 8.13mΩ. Copper pattern created on fiberglass substrate can react with oxygen present in atmosphere, water etc. hence, tinning process performed to avoid copper oxidation.

Amalgamation of NPs/Agar nanocomposite by indirect method

NPs/Agar nanocomposite was successfully formed by indirect method in which NPs nanoparticles (1mg/mL) synthesized by semi-solvo thermal method mixed with 2 % agar gel to get homogeneous composite. Initially, NPs nanoparticles dispersed in DI water by ultra-sonication to make colloidal solution, which, then embedded in hot agar gel prepared using a microwave oven and poured into petri dish. The prepared nanocomposites applied on to the surface of PCB and form a thin layer followed by drying at room temperature.

NPs/Agar nanocomposite coated PCB

Designing of comb-type finger pattern copper electrode on PCB performed using KiCAD software. Copper pattern transferred on PCB with laser-iron technology. Etching performed to remove unwanted copper from PCB and tinning made on electrode to avoid oxidation of copper. Followed by tinning process two multi-strand 0.5mm2 copper wires were soldered on electrodes. Finally, coating of NPs/Agar nanocomposite applied on PCB with soldered wires. PCB fabrication process.

Testing of moisture sensitive resistive chemical nanosensor

Particular amount of water applied on to the surface of nanosensor PCB and change in resistance values measured by digital multimeter. The testing carried out at optimum room temperature and pressure in a closed chamber. The sensitivity of sensor tested for both tap water and distilled water.

Different water samples tested on NPs/Agar chemical nanosensor to determine its sensitivity towards moisture (Table 2). The nanosensor showed negative moisture sensing pattern, since

resistance reduced as moisture level increases. It observed that, NPs/Agar Coated sensor was more sensitive than the Agar coated sensor (Figure 3).

Many moisture and humidity sensors have developed were used comb-type finger copper electrodes pattern on printed circuit board (PCB) (Dokmeci 2001, Huang 2008, Chetpattananondh, 2014, Rukavina, 2015). The sensor structure is similar to conventional liquid crystal display, i.e. sandwich configuration with the material confined between a pair of comb-type finger electrodes. Most of them provide output in the form of change in capacitance between electrodes (Chetpattananondh, 2014). Capacitance measurement setup is not relatively simple as resistance measurement and it is more susceptible to the external environment as atmospheric air acts as dielectric between two electrodes. Resistive moisture sensors are devices that transduce moisture into a change in impedance and can measure by a current, a voltage or a resistance [Rittersma, 2002].

The present study introduces intuitive method in which PCB electrode pattern covered by layer of NPs/Agar nanocomposite and provides changes equivalent resistance according to change in moisture. Therefore, this type of nanosensors can make remarkable breakthrough in food sector, especially in moisture detection in food packages during transport and storage, which eventually protect the food from spoilage due to moisture seepage into the package.

TABLE 2: SENSITIVITY OF RESISTANCE BASED NPS/AGAR HYBRID CHEMICAL NANOSENSOR FOR ESTIMATION OF MOISTURE

Resistance (kΩ)	Agar Coated PCB		NPs/Agar Coated PCB	
Water Volume (µL)	Deionized Water	Tap Water	Deionized Water	Tap Water
Blank	28500		23300	
20	23400	21200	12260	10300
30	22150	19260	11340	8920
40	17610	15260	9650	7300
50	13200	11320	8260	2650
60	9260	7650	5340	950
70	7650	5620	1530	520

The present invention can provide effective alternatives for the conventional moisture sensing system used in various commodities for overall protection of moisture sensitive products. The nanosensor can place on to and/or near tertiary packages during transport and storage to determine moisture/humidity. The present invention can use with almost all types of products where moisture/humidity is responsible for deterioration.

In India, many people are working in the synthesis of conductor materials for solar cell application however to the best of our knowledge; currently no one is working on agar based resistive chemical hybrid nanosensors for detection of humidity. However, there is huge

demand for real time detection of moisture and relative humidity in the packaging system of food, medicine and construction materials and currently these demands are being fulfilled by the import. If the manufacturers get the indigenous source, this could be drastic step to reduce the cost and saving in the foreign currency. There are other semi-conductor nanomaterials can introduce into the polymer matrix to get similar output. Instead, amalgamation other methods like direct synthesis of Agar/NPs nanocomposites, surface coating, spraying etc. can used to incorporate nanoparticles with agar.

While the disclosure has been presented with respect to certain specific embodiments, it will be appreciated that many modifications and changes may be made by those skilled in the art without departing from the spirit and scope of the disclosure. It is intended, therefore, by the appended claims to cover all such modifications and changes as fall within the true spirit and scope of the disclosure.

Signature: Digitally signed using the e-filing portal
Dr. Kumari Lipi
Regd. Patent Agent [IN/PA-2542]
Dated: March 9, 2020

WE CLAIM:

1. A sensitive resistive chemical NPs/Agar hybrid nanosensor, comprising of chemical nanosensor PCB, a single core wire, plurality of NPs nanoparticles and about 2% Agar.

2. The nanosensor as claimed in Claim 1, wherein said sensor uniformly distributes metal oxide nanoparticles into the agar matrix and a real time detection by Agar/NP nanocomposite mounted on PCB with the help of embedded system.

3. A method of fabrication of resistance based chemical nanosensor, using printed circuit board (PCB) technology, comprises the steps of ;

a. preparing a design and arrangement of electrodes on PCB that consisted of four fingers with cross section area of 0.07mm for each electrode;
b. amalgamating NPs/Agar nanocomposite by indirect method, wherein NPs nanoparticles (1mg/mL) were synthesized by semi-solvo thermal method mixed with 2 % agar gel;
c. transferring NPs/Agar nanocomposite coated PCB on PCB with laser-iron technology;
d. performing etching process to remove unwanted copper from PCB and tinning made on electrode to avoid oxidation of copper;
e. coating of NPs/Agar nanocomposite applied on PCB with soldered wires; and

f. testing of moisture sensitive resistive chemical nanosensor, wherein a particular amount of water was applied on to the surface of nanosensor PCB and change in resistance values measured by digital multimeter.

4. The method as claimed in Claim 1, wherein the dimension of sensor PCB was 30mm X 30mm with 0.35µm copper thickness.

5. The method as claimed in Claim 1, wherein the sensitivity of the sensor was tested for both tap water and distilled water.

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Dated: March 9, 2020

ABSTRACT

Moisture Sensitive Resistance Based Nanocomposite (Semiconductor NPs/Agar) Chemical Nanosensor and a Method for fabrication thereof.

A sensitive resistive chemical NPs/Agar hybrid nanosensor, comprising of chemical nanosensor PCB, a single core wire, plurality of NPs nanoparticles and about 2% Agar and method of fabrication of resistance based chemical nanosensor, using printed circuit board (PCB) technology, comprises the steps of preparing a design and arrangement of electrodes on PCB; amalgamating NPs/Agar nanocomposite by indirect method, transferring NPs/Agar nanocomposite coated PCB on PCB; performing etching process to remove unwanted copper from PCB coating of NPs/Agar nanocomposite applied on PCB with soldered wires; and testing of moisture sensitive resistive chemical nanosensor

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Dated: March 9, 2020

FORM 2
THE PATENTS ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
COMPLETE SPECIFICATION
(See section 10 and rule 13)

TITLE OF THE INVENTION

MULTIMODAL SUSTAINED PRESSURE TRIGGER POINT RELEASE PROCESS

1. APPLICANT(S)

(a) Name: Dr. Prasannajeet Pramod Nikam
(b) Nationality: Indian
(c) Address: Krishna College of Physiotherapy, Krishna Institute of Medical Sciences "Deemed to be University", Karad, Malkapur, Karad-415339, Maharashtra, India.

2. PREAMBLE TO THE DESCRIPTION

The following specification particularly describes the invention and the manner in which it is to be processed

MULTIMODAL SUSTAINED PRESSURE TRIGGER POINT RELEASE PROCESS

FIELD OF THE INVENTION

The present invention relates to a multimodal sustained pressure trigger point release process intended to treat myofascial trigger points (MTrP's) in both static as well as dynamic ways.

BACKGROUND OF THE INVENTION

Myofascial pain syndrome is defined as sensory, motor, and autonomic symptoms resulting from painful spots in the fascia surrounding skeletal muscle known as myofascial trigger points (MTrP's).

This syndrome presents clinically as referred pain, a limited range of motion in joints, and a local twitch response following mechanical stimulation of MTrP's and is associated with motor endplates.

MTrP's may be classified as Active Trigger point and Latent Trigger point. Active Trigger point is an area of extreme tenderness that is typically found within the muscles and may cause weakness or restriction in movement.

Latent Trigger point are inactive and cause no pain during activities but are tender when touched. These points can be activated when the muscle is strained, fatigued or injured.

Positional Release Technique or Strain Counter-strain technique is a passive intervention aimed to relieve musculoskeletal pain and related dysfunction.

Post-isometric Relaxation Therapy (Karel Lewit;1991) consists of placing the patient in a comfortable position and passively extending the affected muscle to it's maximum pain-free length. While holding this position, the patient is asked to tense the muscle with little force (10-25%). After 10 seconds, he/she is asked to inhale deeply, then exhale and release the muscle tension.

The reliability of Post-isometric relaxation technique has been questionable as it has failed to establish statistically significant results in most of the control trials conducted.

Spray and Stretch Therapy (Travell & Simons;2002) is one of the intervention used for treating MTrP's. In this particular therapy, the patient is placed in a comfortable position, either sitting or lying. The skin at the site of MTrP as well as the area of the referred pain were sprayed with chlorethyl in parallel lines. Then the affected muscle is stretched carefully.

The Spray and Stretch Therapy focuses more on the utilization of drug (chlorethyl) and thus the role of physiotherapy intervention is very less.

As far as conventional PRT is concerned, the treatment part is taken in a position of ease and maintained for a period of 90 seconds. It is very exhausting for the therapist as well as the patient. Also to keep the thumb pressed for 90 long seconds is ergonomically not good as it

may lead to compressive over-load on the therapist's thumb. In this technique, the treatment duration has been divided into three sessions of 30 seconds each with a rest period of 10 seconds between each step.

Studies have shown that low pressure and a long duration, or high compression and short duration, may be more effective for immediate pain reduction. In this technique, the reduced treatment time has been compensated by the application of high compressive pressure over the MTrP's.

Various conventional manual therapy techniques which are intended to treat MTrP's are generally administered by keeping the muscle either in shortened position or position of ease. But for functional activities and for improving the overall quality of life, it is very important to train a muscle dynamically which has been addressed in this innovative technique.

OBJECTS OF THE INVENTION

The principal object of the present invention is to overcome the disadvantages of the prior art.

An object of the present disclosure is to provide a multimodal sustained pressure trigger point release process intended to treat myofascial trigger points (MTrP's) in both static as well as dynamic ways.

Another object of the present disclosure is to provide a multimodal sustained pressure trigger point release process that is less fatiguing and ergonomically less burdening for the Physiotherapist.

Another objective of this invention is to provide a multimodal sustained pressure trigger point release process, wherein there is no use of drug and thus there are no side effects of this technique.

Yet another objective of this invention is provide a multimodal sustained pressure trigger point release process that is easy to administer and there is no need of any specialised device or setup.

Still another objective of this invention is provide a multimodal sustained pressure trigger point release process that can be given for acute as well as chronic MTrP's.

The objects of the present invention will become readily apparent upon further review of the following detailed description of the preferred embodiment as illustrated in the accompanying drawings.

SUMMARY OF THE INVENTION

The present invention is directed to a multimodal sustained pressure trigger point release process intended to treat myofascial trigger points (MTrP's) in both static as well as dynamic ways, wherein the muscle is treated for static component in complete flexion & complete extension and for the dynamic component which involves treating throughout the available Active Range of Motion (AROM).

According to an embodiment of the present invention, the multimodal sustained pressure trigger point release process, comprises the steps of;

a. keeping the muscle in shortened or contracted position and applying apply gradual pressure over the MTrP using the thumb pad of the dominant side;
b. increasing the pressure till it reaches the tolerance level of the patient\ and moving to next step;
c. treating the starting position of the muscle in lengthened or stretched position and further applying pressure over the MTrP using the thumb pad of the dominant side;
d. increasing the pressure till it reaches the tolerance level of the patient and moving to the next step,
e. treating the muscle in dynamic position, wherein sustained pressure is applied and increased gradually till it reaches the patient's threshold; and
f. administering each of steps a, c and e for a period of 30 seconds with a rest period or break of 10 seconds between the steps.

Additional aspects, advantages, features and objects of the present disclosure would be made apparent from the drawings and the detailed description of the illustrative embodiments construed in conjunction with the appended claims that follow.

It will be appreciated that features of the present disclosure are susceptible to being combined in various combinations without departing from the scope of the present disclosure as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

As required, detailed embodiments of the present disclosure are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the disclosure which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

Various other objects, advantages, and features of the disclosure will become more readily apparent to those skilled in the art from the following detailed description when read in conjunction with the accompanying drawing.

In any embodiment described herein, the open-ended terms "comprising," "comprises," and the like (which are synonymous with "including," "having" and "characterized by") may be replaced by the respective partially closed phrases "consisting essentially of," consists essentially of," and the like or the respective closed phrases "consisting of," "consists of, the like.

As used herein, the singular forms "a," "an," and "the" designate both the singular and the plural, unless expressly stated to designate the singular only.

The present invention is directed to a multimodal sustained pressure trigger point release process intended to treat myofascial trigger points (MTrP's) in both static as well as dynamic ways, wherein the muscle is treated for static component in complete flexion &

complete extension and for the dynamic component which involves treating throughout the available Active Range of Motion (AROM).

The sensitive resistive chemical NPs/Agar hybrid nanosensor, comprises of chemical nanosensor PCB, single core wire, NPs nanoparticles and about 2% Agar.

The multimodal sustained pressure trigger point release process, comprises the steps of ;keeping the muscle in shortened or contracted position and applying apply gradual pressure over the MTrP using the thumb pad of the dominant side; increasing the pressure till it reaches the tolerance level of the patient\ and moving to next step; treating the starting position of the muscle in lengthened or stretched position and further applying pressure over the MTrP using the thumb pad of the dominant side; increasing the pressure till it reaches the tolerance level of the patient and moving to the next step treating the muscle in dynamic position, wherein sustained pressure is applied and increased gradually till it reaches the patient's threshold; and administering each of steps a, c and e for a period of 30 seconds with a rest period or break of 10 seconds between the steps.

Each step has to be administered for a period of 30 seconds with a rest period or break of 10 seconds between the steps.

Overall duration of the treatment duration is 90 seconds and rest duration is 30 sec. (Total=**120 seconds**)

The patient is asked to lie on the plinth in such a position that the part to be treated is easily accessible by the physiotherapist. The MTrP is located by superficial palpation throughout the length of the muscle. Local palpatory examination should be carried out according to the

alignment of the muscle fibre of the muscle to be treated. Once the MTrP's have been identified, they should be marked by putting a small dot on it with the help of black or blue marker pen. Treatment approach should be proximal to distal in case of multiple MTrP's. Pressure applied has to be high compressive force in nature within the patient's tolerance.

While the disclosure has been presented with respect to certain specific embodiments, it will be appreciated that many modifications and changes may be made by those skilled in the art without departing from the spirit and scope of the disclosure. It is intended, therefore, by the appended claims to cover all such modifications and changes as fall within the true spirit and scope of the disclosure.

Signature: Digitally signed using the e-filing portal
Dr. Kumari Lipi
Regd. Patent Agent [IN/PA-2542]
Dated: March 17, 2020

WE CLAIM:

1. A multimodal sustained pressure trigger point release process, comprising the steps of;

   a. keeping the muscle in shortened or contracted position and applying apply gradual pressure over the MTrP using the thumb pad of the dominant side;

   b. increasing the pressure till it reaches the tolerance level of the patient and moving to next step;

   c. treating the starting position of the muscle in lengthened or stretched position and further applying pressure over the MTrP using the thumb pad of the dominant side;

   d. increasing the pressure till it reaches the tolerance level of the patient and moving to the next step;

   e. treating the muscle in dynamic position, wherein sustained pressure is applied and increased gradually till it reaches the patient's threshold; and

   f. administering each of steps a, c and e for a period of 30 seconds with a rest period or break of 10 seconds between the steps

2. The process as claimed in Claim 1, wherein the rest period or break is of about 10 seconds between the steps of said process;

3. The process as claimed in Claim 1, wherein said process is easy to administer and there is no need of any specialized device or setup.

4. The process as claimed in Claim 1, wherein said process can be given for acute as well as chronic MTrP's.

5. The process as claimed in Claim 1, wherein the muscle is treated for static component in complete flexion & complete extension and for the dynamic component which involves treating throughout the available Active Range of Motion (AROM).

6. The process as claimed in Claim 1, wherein the muscle to treated in 3 sessions of 30 seconds each in various positions.

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Dated: March 17, 2020

ABSTRACT

MULTIMODAL SUSTAINED PRESSURE TRIGGER POINT RELEASE PROCESS

A multimodal sustained pressure trigger point release process, comprising the steps of ; keeping the muscle in shortened or contracted position and applying apply gradual pressure over the MTrP using the thumb pad of the dominant side; increasing the pressure till it reaches the tolerance level of the patient and moving to next step; treating the starting position of the muscle in lengthened or stretched position and further applying pressure over the MTrP using the thumb pad of the dominant side; increasing the pressure till it reaches the tolerance level of the patient and moving to the next step; treating the muscle in dynamic position, wherein sustained pressure is applied and increased gradually till it reaches the patient's threshold; and administering each of steps a, c and e for a period of 30 seconds with a rest period or break of 10 seconds between the steps.

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Dr. Kumari Lipi
Regd. Patent Agent [IN/PA-2542]
Dated: March 17, 2020

FORM 2

THE PATENT ACT 1970

&

The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

1. TITLE OF THE INVENTION:

"A Device for Holding a Mini Implant Placement Guide"

2. APPLICANT(s):

Name	Nationality	Address
PHAPHE, Sandesh	Indian	Krishna Institute of Medical Sciences "Deemed to be University", Karad, NH 4, Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra
SATHE, Tanuja Tanaji		Krishna Institute of Medical Sciences "Deemed to be University", Karad, NH 4, Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra

3. PREAMBLE TO THE DESCRIPTION:

~~PROVISIONAL~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed.

Field of the invention

[0001] The present invention relates to a mini implant placement guide. More particularly, the present invention relates to a device for holding a mini implant placement guide.

Background of the invention

[0002] Generally, a mini implant can be defined as a device that is temporarily fixed to the bone for the purpose of enhancing orthodontic anchorage either by supporting the teeth of the reactive unit (indirect anchorage) or by obviating the need for the reactive unit altogether (Direct Anchorage), which is subsequently removed after use. The uses of the mini implant placement guides are for proper placement of mini implants. The proper positioning of implants avoids any interferences with the surrounding dentoalveolar structures. Also, the stability of the implant is a major important factor for an Orthodontist. The orthodontist should also take into consideration for any intervention of the adjacent anatomical structures, such as dental roots, nasomaxillary cavities, and neurovascular tissues.

[0003] The currently available devices for the mini implant are a periapical radiograph which needs to be at hand to check root positioning and the amount of interradicular space available for insertion of the mini-screw. Use infiltration anesthesia. Identify the site of the insertion of the mini screw using a graduated probe, guided by the periapical radiograph. Make a punch incision in the

keratinized gingiva with a gingival punch. In the case when the cortical plate is thick, it may be advisable to make a small notch in the bone with round bur or drill. Hold the mini-screw with pliers and insert it using pliers, carefully checking the direction of insertion. The hands need to be kept steady, and rotational movement applied with no change in the insertion path. In the maxilla, the mini-screw should be inserted perpendicular to the alveolar bone or at an angle of approximately eighty degrees to the occlusal plane.

[0004] But the existing device is not having proper angulation and insertion technique that may lead to mini-implant failure. Also, determining a proper vertical height for placement is difficult and an accurate mesiodistal placement point is difficult between the two adjacent roots. Also, as it is an arbitrary method there are chances of deviating from the path of insertion. Also, the existing devices are not having provision for measuring horizontal and vertical distances or accurate placement of mini implants. And the placement of mini implants without any proper stents or guides can be dangerous and orthodontists may be dealing with unnecessary risk factors.

[0005] To overcome one or all drawbacks of the existing device, there is a need for a device for holding a mini implant placement guide, the device is configured on a dental brace.

Object of the invention

[0006] An object of the present invention is to provide a device for holding a mini implant placement guide.

[0007] Another object of the present invention is to provide a device for holding a mini implant placement guide, which provides accurate placement of a mini implant in three planes of space, namely, sagittal, vertical and transverse.

[0008] Yet another object of the present invention is to provide a device for holding a mini implant placement guide, which helps in the placement site decision mesiodistally, as well as the vertical positions of the crown-to-root areas can be determined.

[0009] Further object of the present invention is to provide a device for holding a mini implant placement guide, which is accurate, easy, reliable, and stable.

[0010] Further one more object of the present invention is to provide a device for holding a mini implant placement guide, which is compact and economical.

[0011] Still one more object of the present invention is to provide a device for holding a mini implant placement guide, which is robust in operation.

Summary of the invention

[0012] According to the present invention, there is provided with a device for holding a mini implant placement guide. The device is configured on a dental brace. The device is provided with an engaging member, an operating member, a vertical arm and a horizontal arm. The engaging member is having two engaging legs. The two engaging legs are connected by the horizontal arm. The engaging member is removably arranged on the dental braces with a substantial distance between the two engaging legs. The engaging member is provided for placing the device in the mouth of a patient for holding the mini-implant placement guide on the teeth of the patient who is undertaking the orthodontic dental treatment.

[0013] The operating member is operably connected to the horizontal arm of the engaging member. Specifically, the operating member is slidably arranged on the horizontal arm. The operating member is linearly movable along the horizontal arm. Similarly, the vertical arm is operably connected to the operating member. The vertical arm is slidably arranged on the operating member. The vertical arm is having the mini-implant placement guide arranged at a distal end. More specifically, upon operating the operating member, the vertical arm moves translationally, thereby guiding the mini-implant placement guide. In the

present embodiment, the vertical arm is calibrated in terms of millimeters thereby providing the exact location for placement of a mini implant.

[0014] Further, the operating member is having two operating knobs such as a first operating knob and a second operating knob. The first operating knob is arranged on the horizontal arm and the second operating knob is arranged on the vertical arm. The first operating knob is provided for operating the linear movement of the operating member on the horizontal arm and the second operating knob is provided for operating the translational movement of the vertical arm.

[0015] Further, the horizontal arm is a rack arrangement with a pinion configured inside the operating member. Upon operating the first operating knob, the pinion engages with the rack enabling the movement of the operating member along the horizontal arm. Similarly, the vertical arm is also a rack arrangement with a pinion configured inside the operating member. Upon operating the second operating knob, the pinion engages with the rack enabling the translational movement of the vertical arm. Thereby guiding the implant placement guide for placement at an accurate position to avoid damaging of dental roots.

Brief Description of the Drawings

[0016] The advantages and features of the present invention will become better understood with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0017] Figure 1 illustrates a perspective view of a device for holding a mini implant placement guide in accordance with the present invention;

[0018] Figure 2 illustrates the perspective view of the device for holding the mini-implant placement guide in accordance with the figure 1;

[0019] Figure 3 illustrates a side view of the device for holding the mini-implant placement guide; and

[0020] Figure 4 illustrates a top view of the device.

Detail Description of the Invention

[0021] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising," having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not

meant to be an exhaustive listing such item or items or meant to be limited to only the listed item or items.

[0022] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0023] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0024] The present invention provides a device which is used in an orthodontics treatment. The orthodontics is a dental specialty that aids in the correction of the alignment of teeth, with respect to the skeletal form, and a soft-tissue relationship of a patient undertaking the treatment. The field of orthodontic treatment is associated with various types of fixed appliances which may include brackets that are attached to the teeth by adhesive, and an archwire that is attached to the brackets. Specifically, in the orthodontics treatment, the brackets are passive components of fixed orthodontic appliance, bonded to the enamel which provides the means to transfer the force applied by the activated archwire to the tooth.

[0025] The archwire is made of stainless steel, cobalt-chromium alloy, titanium–nickel alloy, and titanium–molybdenum alloy and used to provide

the required force to move improperly aligned teeth to their proper positions. The orthodontic archwire is connected to the slots of the brackets (orthodontic the brackets) adhered to each tooth. Specifically, the main aim of the orthodontist treatment is to maximize the desired tooth movement and minimize undesirable effects with three-dimensional control. For achieving this, a mini implant (not shown) is used, to gain maximum anchorage for each tooth.

[0026] In the present embodiment, the mini implant is used in orthodontics as a temporary anchorage device which is temporarily fixed to the bone to enhance the anchorage either by supporting the teeth of the reactive units or by obviating the need for the reactive unit altogether, and the mini implant is subsequently removed after use. The mini implant is used for delivery of differentiated force systems for posterior tooth movement or extrusion of impacted canines where mini-screws are used as anchorage for tooth movements in cases to achieve class one molar relationship by molar distalization. Also, the mini implants are used as an orthodontic anchorage for maxillary expansion, maxillary protraction.

[0027] In another embodiment, the mini implant may also be used in some cases as an alternative to orthognathic surgery. A critical step that determines the success of the mini implant is the atraumatic surgical placement of the mini implant. Precise pre-surgical planning is very important to avoid damaging dental roots and to provide an estimation of bone quantity and allow for careful

selection of diameter and length of micro-implants, placement site and direction of placement. In the present embodiment, the device 100 provides accurate placement of the mini implant in three planes of space, namely, sagittal, vertical and transverse.

[0028] Referring now to figures 1, 2, 3 and 4, a various view of a device 100 for holding a mini implant placement guide 200 in accordance with the present invention is illustrated. In the present embodiment, the mini implant placement guide 200 is slidably and adjustably arranged on the device 100. The device 100 is configurable on a dental brace 400 of the patient. It may be obvious to a person skilled in the art to configure the device 100 on teeth of the patient. The mini implant placement guide 200 is used in orthodontics dental for measuring accurate location for placing the mini implant. Specifically, in the orthodontics dental treatment, the mini implant is used as a support for retraction of the teeth 320.

[0029] Further, the device 100 is having an engaging member 110, an operating member 120, a vertical arm 130 and a horizontal arm 140. The engaging member 110 is having two engaging legs 112 and 114. The two engaging legs 112 and 114 are connected by the horizontal arm 140. The engaging member 110 is removably arranged on the dental brace 400 with a substantial distance between the two engaging legs 112, 114. In the present embodiment, the difference between both engaging legs is around 15-25 mm. The two engaging legs 112and

114 are connected on both ends of the horizontal arm 140. In the present embodiment, the engaging member 110 is provided for placing the device 100 in the mouth of a patient. Specifically, the engaging member 110 is provided for placing the device 100 for holding the mini-implant placement guide 200 on the teeth of the patient who is undertaking the orthodontic dental treatment. In the present embodiment, the two engaging legs 112and 114 are in a capsule shape. It may be obvious to a person skilled in the art to configure any geometry (shape and dimensions) of the engaging legs 112 and 114 around the engaging member 110.

[0030] The two engaging legs 112 and 114 are configured with a slit 116. The slit 116 is adapted to engage with the archwire 310. Specifically, the slit 116 is engaged with the arc wire 310, where the mini implant is required to place. More specifically, the one engaging leg 112 of the engaging member 110 may be engaged with one side of teeth where the implant need to be placed and the other engaging leg 114 is engaged with the other side of the teeth.

[0031] Further, the operating member 120 is operably connected to the horizontal arm 140 of the engaging member 110. Specifically, the operating member 120 is slidably arranged on the horizontal arm 140. In the present embodiment, the operating member 120 is linearly movable along the horizontal arm 140. Similarly, the vertical arm 130 is operably connected to the operating member 120. In the present embodiment, the vertical arm 130 is slidably arranged on the operating member 120. The vertical arm 130 is having the mini-implant

placement guide 200 arranged at a distal end. More specifically, upon operating the operating member 120, the vertical arm 130 moves translationally, thereby guiding the mini-implant placement guide 200. In the present embodiment, the vertical arm 130 is calibrated in terms of millimeters thereby providing the exact location for placement of a mini implant.

[0032] The operating member 120 is having two operating knobs 122 and 124. The first operating knob 122 is arranged on the horizontal arm 140 and the second operating knob 124 is arranged on the vertical arm 130. The first operating knob 122 is provided for operating the linear movement of the operating member 120 on the horizontal arm 140 and the second operating knob 124 is provided for operating the translational movement of the vertical arm 130.

[0033] The mini implant placement guide 200 is placed with a ring 210. In the present embodiment, the ring 210 is a nut shaped ring. It may be obvious to a person skilled in the art to use a square or a circular ring. The ring 210 acts as a guide for placing the mini implant thereon. Specifically, the cavity of the ring 210 acts as a guide for placing the mini implant. In the present embodiment, the mini implant placement guide 200 is rotatably placed on the vertical arm 130 for rotating and adjusting the ring 210 according to the requirement.

[0034] Referring again to figure 2, in the present embodiment, the horizontal arm 140 is a rack arrangement (not shown) with a pinion 142

configured inside the operating member 120. Upon operating the first operating knob 122, the pinion 142 engages with the rack enabling the movement of the operating member 120 along the horizontal arm 140. Similarly, the vertical arm 130 is also a rack arrangement (not shown) with a pinion 132 configured inside the operating member 120. Upon operating the second operating knob 124, the pinion 132 engages with the rack enabling the translational movement of the vertical arm 130, thereby guiding the implant placement guide 200 for placement at an accurate position to avoid damaging of dental roots.

[0035] Therefore, the advantage of the present invention is to provide a device 100 for holding a mini implant placement guide. Also, the device 100 provides accurate placement of a mini implant in three planes of space, namely, sagittal, vertical and transverse. Further, the device 100 help in the placement site decision mesiodistally, as well as the vertical positions of the crown-to-root areas can be determined. Furthermore, the device 100 is accurate, easy, reliable, and stable. Moreover, the device 100 is compact, economical and robust in operation.

[0036] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously, many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to explain the principles of the present invention best and its

practical application, to thereby enable others skilled in the art to best utilize the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omission and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such are intended to cover the application or implementation without departing from the spirit or scope of the present invention.

We Claim:

1. A device 100 for holding a mini implant placement guide 200, the device 100 is being configurable on a dental brace 400, the device 100 comprising:

an engaging member 110 having two engaging legs 112and 114 connected by a horizontal arm 140, the engaging member 110 is removably arranged on the dental brace with a substantial distance between the two engaging legs 112 and 114;

an operating member 120 operably connected to the horizontal arm 140 of the engaging member 110, the operating member 120 is linearly movable along the horizontal arm 140;

a vertical arm 130 operably connected to the operating member 120, the vertical arm 130 having the mini-implant placement guide 200 arranged at a distal end;

wherein the vertical arm 130 moves translationally upon operating the operating member 120 thereby guiding the implant placement guide.

2. The device 100 for holding a mini implant placement guide 200 as claimed in claim 1, wherein the operating member 120 includes two operating knobs 122 and 124 for operating the linear movement of the operating member 120 and the translational movement of the vertical arm 130 respectively.

3. The device 100 for holding a mini implant placement guide 200 as claimed in claim 1, wherein the horizontal arm 140 is a rack arrangement with a pinion 142 configured inside the operating member 120, upon operating the operating knob, the pinion 142 engages with the rack enabling the movement of the operating member 120 along the horizontal arm 140.

4. The device 100 for holding a mini implant placement guide 200 as claimed in claim 1, wherein the vertical arm 130 is a rack arrangement with a pinion 132 configured inside the operating member 120, upon operating the operating knob, the pinion 132 engages with the rack enabling the translational movement of the vertical arm 130 and thereby the implant placement guide.

5. The device 100 for holding a mini implant placement guide 200 as claimed in claim 1, wherein the vertical arm 130 is calibrated in terms of millimeters, thereby providing the exact location for placement of a mini implant.

Dated this April 22, 2020

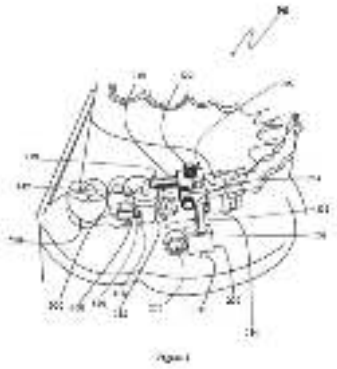
Suneet Baliram Sabale
(Agent for Applicant)
Reg. No.: IN/PA-1773

Abstract

Title: A device for holding a mini implant placement guide

The present invention provides a device 100 for holding a mini implant placement guide 200. The device 100 is being configurable on a dental brace. The device 100 is having an engaging member 110, an operating member 120, a vertical arm and a horizontal arm 140. The engaging member 110 is having two engaging legs 112, 114 connected by a horizontal arm 140. The engaging member 110 is removably arranged on the dental brace 400 with a substantial distance between the two engaging legs 112, 114. The operating member operably connected to the horizontal arm 140. The operating member 120 is linearly movable along the horizontal arm 140. The vertical arm 130 operably connected to the operating member 120. The vertical arm 130 having the mini-implant placement guide 200 arranged at a distal end. The vertical arm 130 moves translationally upon operating the operating member 120 thereby guiding the mini-implant placement guide 200.

Figure 1



FORM 2

THE PATENT ACT 1970

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(SEE SECTION 10 AND RULE 13)

1. TITLE OF THE INVENTION: "A Belt for Treating Symphysis Pubis Dysfunction"

2. APPLICANT(s):

Name	Nationality	Address
PATIL, Vinaya Rajendra	Indian National	Krishna Institute of Medical Sciences "Deemed to be University", Karad, Krishna College of Phsiotheraphy, NH 4, Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra
SAHOO, Kashinath Dharmu	Indian National	Krishna Institute of Medical Sciences "Deemed to be University", Karad, Dept of Prosthetics & Orthotics, NH 4, Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed

Field of the Invention

[0001] The present invention relates to a wearable arrangement. More particularly, the present invention relates to a belt for treating symphysis pubis dysfunction and low back pain.

Background of the Invention

[0002] A vast majority of back pain experienced by the general population occurs in the lower portion of the back, generally referred to as the lumbar area. Lower back pain affects the spine's stability, flexibility, and strength, as a result, cause pain, discomfort and stiffness during daily living activities such as sitting, driving or sleeping. In most cases, some form of a support garment is a common expedient for reducing the back pain. One of the well-known garments for this purpose is the wrap-around corset or waist-bands of a non-flexible material. Waistbands and or belts are typical wearable arrangement for providing back support of the human body. These arrangements are shown to embrace the abdominal area and the lumbar area for supporting the back region, including the lumbar, spinal, abdominal, and pelvic and the other related joints. These belts may have a rigid element for supporting the human body.

[0003] Further, the existing belt supports only pubis symphysis due to its less coverage which leads to less stability to the Sacro-Iliac (SI) joint.

Also, no provision is made to support the lower back region, which eventually leads to an increase in low back pain. As the belt has less width, i.e. the belt covers less body surface area, the probability of slipping the belt upwards (towards the abdomen) is high, leading to less therapeutic effect. The cause of SPD can be attributed to hormonal changes, lengthening of pelvic ligaments and muscles. Treatment for SPD has to cover all above-said components by the help of orthosis, positioning and physical therapy to prevent functional disability.

[0004] Hence, there is a requirement of a wearable arrangement like a belt which overcomes few or all the drawbacks of the existing wearable arrangements.

Objects of the Invention

[0005] An object of the present invention is to provide a belt for treating symphysis pubis dysfunction.

[0006] Another object of the present invention is to provide a belt for treating symphysis pubis dysfunction which gives stability in all pelvic joints and lumbosacral joints that minimizes the three degrees of movements including sagittal, frontal and transverse planes.

[0007] Yet another object of the present invention is to provide a belt for treating symphysis pubis dysfunction which treats and prevents the symphysis pubis dysfunction (SPD) for postnatal women.

[0008] One more object of the present invention is to provide a belt for treating symphysis pubis dysfunction which supports lower back with pubis symphysis that helps in reducing associated low back pain and reduces SPD complications.

[0009] Still, one more object of the present invention is to provide a belt for treating symphysis pubis dysfunction which covers a more substantial body surface area, thereby minimizing the chances to slip or displacement from the applied position.

Summary of the invention

[0010] According to the present invention, a belt for treating symphysis pubis dysfunction is provided. The belt has to be wrapped around the body of the user. The belt facilitates supporting the lower back region of the human body. The belt includes an abdominal corset and a posterior support. The abdominal corset embraces the abdominal portion of the body and the posterior support embracing the lumbar area of the human body. The abdominal corset and the

posterior support are integral such that the adjoining of the abdominal corset and the posterior support enables the user to wear around the user body.

[0011] In the present embodiment, one end of the abdominal corset is provided with a suspension system which can be fastened with one end of the posterior support. The suspension system enables the belt to prevent the slipping or movement of the belt from the abdominal and lumbar area. The suspension system can be fasteners. Specifically, in this embodiment one end of the abdominal corset is arranged with the fasteners for attaching the abdominal corset with the posterior support to prevent the slipping or dislocation of the belt from the abdominal and lumbar area. The fasteners can be a hook and loop arrangement.

[0012] Further, a reinforcement strap is arranged on the posterior support for providing additional support to the belt. The reinforcement strap extends from an outer periphery of the posterior support and is adapted to encircle the torso along with the abdominal corset. The reinforcement strap is fastened with the posterior support allowing the belt to provide stability in pelvic joints and lumbosacral joints that minimizes the degree of movements including sagittal, frontal and transverse planes.

[0013] Further, one end of the reinforcement strap is connected to a portion of the posterior support, and the other end is detachably connected to a locking end of the posterior support. Further, the posterior support is provided with

a lumbar supporting member. The lumbar supporting member includes two elongated elements which support the lumbar region of the body. Specifically, the elongated members extend vertically across the length of the posterior support for supporting the lumbar region of the body. In the present embodiment, a plurality of vertical elements is arranged across the posterior support and the abdominal corset for retaining the structure of the belt.

[0014] The material of abdominal corset and posterior support can be replaced by soft leather. The reinforcement strap may be made of nylon. Elastic material can replace the nylon reinforcement strap. The suspension system can be replaced by a leather strap and buckle.

Brief Description of the Drawings

[0015] The advantages and features of the present invention will be understood better with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0016] Figure 1 illustrates a schematic representation of an anterior view of a belt for treating symphysis pubis dysfunction; and

[0017] Figure 2 illustrates a schematic representation of a posterior view of the belt for treating symphysis pubis dysfunction.

Detailed Description of the Invention

[0018] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising, "having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items or meant to be limited to only the listed item or items.

[0019] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0020] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0021] The present invention provides a belt for treating symphysis pubis dysfunction. The belt gives stability in all pelvic joints and lumbosacral joints that minimizes the three degrees of movements including

sagittal, frontal and transverse planes. It also treats and prevents the symphysis pubis dysfunction (SPD) for postnatal women. The cause of pubis symphysis disorder (SPD) can be attributed to hormonal changes, lengthening of pelvic ligaments and muscles. Treatment for the SPD has to cover by the help of orthosis, positioning and physical therapy to prevent functional disability. This belt can overcome the sign & symptoms caused by symphysis pubis dysfunction (SPD) for postnatal women with the help of high pelvic support devices.

[0022] Referring now to figures 1a and 1b, a belt 100 for treating symphysis pubis dysfunction in accordance with the present invention is illustrated. The belt 100 has to be wrapped around the body of the user. The belt 100 facilitates in supporting the lower back region of the human body. The belt 100 includes an abdominal corset 200 and a posterior support 300. The abdominal corset 200 embraces the abdominal portion of the body and the posterior support 300 embracing the lumbar area of the human body. The abdominal corset 200 and the posterior support 300 are integral such that the adjoining of the abdominal corset 200 and the posterior support 300 enables the user to wear around the user body.

[0023] In the present embodiment, one end of the abdominal corset 200 is provided with a suspension system 210, which can be fastened with one end of the posterior support 300. The suspension system 210 enables the belt 100 to prevent the slipping or movement or dislocation of the belt 100 from the abdominal and lumbar area. The suspension system 210 can be fasteners.

Specifically, in this embodiment one end of the abdominal corset, 200 is arranged with the fasteners for attaching the abdominal corset 200 with the posterior support 200 to prevent the slipping or displacement or movement of the belt 100 from the abdominal and lumbar area. The fasteners can be a hook and loop arrangement.

[0024] Further, a reinforcement strap 310 is arranged on the posterior support 300 for providing additional support to the belt 100. The reinforcement strap 310 extends from an outer periphery of the posterior support 300 and is adapted to encircle the torso along with the abdominal corset 200. The reinforcement strap 310 is fastened with the abdominal corset 200allowing the belt 100 to provide stability in pelvic joints and lumbosacral joints that minimizes the degree of movements including sagittal, frontal and transverse planes.

[0025] Further, one end of the reinforcement strap 310 is connected to a portion of the posterior support 300, and the other end is detachably connected to a locking end of the posterior support 300. The reinforcement strap 310 includes two strap members connected to the posterior support 300 which elongates in an almost parallelly along with the posterior support 300 and adjoins at a proximal end of the posterior support 300 and extends as a single strap from the proximal end. The posterior support 300 has a ring arrangement 320 for inserting and latching a free end of the reinforcement strap 310 and fasten with the posterior support 300 for additional support. In an alternative embodiment, the reinforcement strap may be fastened with the abdominal corset 200.

[0026] Further, the posterior support 300 is provided with a lumbar supporting member 330, as shown in figure 1b. The lumbar supporting member 330 includes two elongated elements which support the lumbar region of the body. Specifically, the elongated members extend vertically across the length of the posterior support 300 for supporting the lumbar region of the body. In the present embodiment, a plurality of vertical elements 400 is arranged across the posterior support 300 and the abdominal corset 300 for retaining the structure of the belt 100. For example, the vertical elements 400 ensures to retain the structure of the belt 100when the user changes the posture, such as while sitting, moving around or sleeping.

[0027] The material of abdominal corset 200 and posterior support 300 can be replaced by soft leather. In the present embodiment, the reinforcement strap 310 may be made of nylon. The reinforcement strap 310 can be replaced by elastic material. The suspension system 210 can be replaced by leather strap and buckle.

[0028] Further, the belt 100 ensures directing force laterally making the pubic symphysis closer. This increases the stability leading to expected therapeutic effect. Further, the belt 100 can transfer the axial load & muscle activation and recruitment is possible. The belt 100 restricts trunk motion in all three planes of motion, i.e. lateral bending, flexion and extension. Due to lumbar and abdominal bracing by the corresponding posterior support 300 and the abdominal

corset 200, the increased intra-abdominal pressure reduces the low back pain. Also, the belt 100 helps to reduce the gap between two pubis bones. Due to the decrease in trunk motion, it is beneficial in the prevention of low back pain. Lumbar bracing increases intra-abdominal pressure. The pressure within the abdominal cavity is believed to influence a load of the spine by supporting the trunk anteriorly. Increased Intra-abdominal pressure also helps in reducing abdominal girth.

[0029] Therefore the present invention has the advantage of providing a belt 100 for treating symphysis pubis dysfunction. The belt gives stability in all pelvic joints and lumbosacral joints that minimizes the three degrees of movements including sagittal, frontal and transverse planes. It also treats and prevents the symphysis pubis dysfunction (SPD) for postnatal women. Further, the belt supports lower back with pubis symphysis that helps in reducing associated low back pain and reduces SPD complications. Also, it covers a more substantial body surface area, thereby minimizing the chances to slip from the applied position.

[0030] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the present invention and its practical application, and to thereby enable others skilled in the art to best utilize the present invention

and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omissions and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such omissions and substitutions are intended to cover the application or implementation without departing from the scope of the claims of the present invention.

We Claim:

1. A belt 100 for treating symphysis pubis dysfunction, the belt 100 being wrapped around the body of a user, characterized in that the belt 100 comprising:

an abdominal corset 200 for bracing the abdominal portion of the user; and

a posterior support 300 for bracing the lumbar area, the abdominal corset 200 and the posterior support 300 are integral to wrap around the body of the user;

wherein a reinforcement strap 310 extends from an outer periphery of the posterior support 300 and is adapted to encircle the torso along the abdominal corset 200, and the reinforcement strap 310 is fastened with the posterior support 300 allowing the belt 100 to provide stability in pelvic joints and lumbosacral joints that minimizes the degree of movements including sagittal, frontal and transverse planes.

2. The belt 100 as claimed in claim 1, wherein one end of the reinforcement strap 310 is connected to a portion of the posterior support 200, and the other end is detachably connected to a locking end of the posterior support 300.

3. The belt 100 as claimed in claim 1, wherein one end of the abdominal corset 200 is provided with a suspension system 210, which can be fastened with one end of the posterior support 300.

4. The belt 100 as claimed in claim 1, wherein the suspension system 210 enables the belt 100 to prevent the slipping or movement or dislocation of the belt 100 from the abdominal and lumbar area.

5. The belt 100 as claimed in claim 1, wherein the posterior support 300 is provided with a lumbar supporting member 320, the lumbar supporting member 330 includes two elongated elements which support the lumbar region of the body.

6. The belt 100 as claimed in claim 1, wherein the belt 100 ensures directing force laterally making the pubic symphysis closer.

7. The belt 100 as claimed in claim 1, wherein a plurality of vertical elements 400 are arranged across the posterior support 300 and the abdominal corset 200 for retaining the structure of the belt 100.

Dated this March 30, 2020

Suneet Baliram Sabale
(Agent for Applicant)
Reg. No.: IN/PA-1773

Abstract

Title: A belt for treating symphysis pubis dysfunction

The present invention provides a belt 100 for treating symphysis pubis dysfunction. The belt 100 being wrapped around the body of a user. The belt 100 includes an abdominal corset 200 and a posterior support 300. The abdominal corset 200 braces the abdominal portion and the posterior support 300 braces the lumbar area. The abdominal corset 200 and the posterior support 300 are integral to wrap around the user body. Further, a reinforcement strap 310 extends from an outer periphery of the posterior support 300 and is adapted to encircle the torso along with the abdominal corset 200. The reinforcement strap 310 is fastened with the posterior support 300 allowing the belt 100 to provide stability in pelvic joints and lumbosacral joints that minimizes the degree of movements including sagittal, frontal and transverse planes.

Figure 1b

FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A METHOD FOR DEPOSITING LAYER OF ZINC OXIDE NANOPARTICLES OVER A SUBSTRATE OF HYGROSCOPIC MATERIAL AS A DIELECTRIC SUBSTRATE AND A SENSOR CONTAINING THE SUBSTRATE FOR DETECTING MOISTURE"

APPLICANT

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Maharashtra, India

The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to a method for depositing layer of zinc oxide nanoparticles (hereinafter referred ZnO-NP) over a substrate of hygroscopic material. More particularly the present invention relates to a method for depositing layer of ZnO-NP over a substrate of hygroscopic material as a dielectric substrate and a sensor containing such dielectric substrate for detecting moisture seepage in packets of industrial products during transport and storage. The ZnONP deposited dielectric substrate based sensor of the present invention is highly sensitive towards moisture.

BACKGROUND ART

The safe transport and storage of moisture sensitive products is mandatory to avoid huge economic losses due to unnoticed moisture seepage into packets more particularly tertiary packaging system. Nowadays, diverse humidity and moisture sensors available for assorted applications *(Matko, V. and Donlagic, D., 1997. Sensor for high-air-humidity measurement. Sensors and Actuators A: Physical, 61(1), pp.331-334.; Rittersma, Z.M., 2002. Recent achievements in miniaturised humidity sensors—a review of transduction techniques. Sensors and Actuators A: Physical, 96(2), pp.196-210.;* Huang, T.H., Chou, J.C., Sun, T.P. and Hsiung, S.K., 2008. A device for skin moisture and environment humidity detection. Sensors and Actuators B: Chemical, 134(1), pp.206-212*).*

Many moisture and humidity sensors have followed comb-type finger copper electrodes pattern on printed circuit board (PCB) *(Dokmeci, M. and Najafi, K., 2001. A high-sensitivity polyimide capacitive relative humidity sensor for monitoring anodically bonded hermetic micropackages. Journal of Microelectromechanical Systems, 10(2), pp.197-204.; Huang, T.H., Chou, J.C., Sun, T.P. and Hsiung, S.K., 2008. A device for skin moisture and environment humidity detection. Sensors and Actuators B: Chemical, 134(1),*

pp.206-212.; Chetpattananondh, K., Tapoanoi, T., Phukpattaranont, P. and Jindapetch, N., 2014. A self-calibration water level measurement using an interdigital capacitive sensor. Sensors and Actuators A: Physical, 209, pp.175-182.; & Rukavina, A.V., 2015. Non-invasive liquid recognition based on interdigital capacitor. Sensors and Actuators A: Physical, 228, pp.145-150). However, these existing sensors are not sensitive towards absolute moisture in the industrial packets, in particular tertiary packets.

In environmental science, there is a difference between relative humidity and absolute humidity. The term *"Relative moisture or humidity"* is the measure of water vapor relative to the temperature of the air. It is expressed as the amount of water vapor in the air as a percentage of the total amount that could be held at its current temperature. It does not give the exact quantity of water vapor in the air whereas the term *"Absolute moisture or humidity"* is the measure of water vapor or moisture in the air, regardless of the temperature which is usually expressed in amount of moisture per cubic meter (g/m^3) of air and could also be converted to µL using the standard conversion known in the art.

In existing art, few capacitive sensors are working on the principle of parallelly arranged metal electrode, for instance Chetpattananondh K et al, 2014 *(Chetpattananondh, K., Tapoanoi, T., Phukpattaranont, P. and Jindapetch, N., 2014. A self-calibration water level measurement using an interdigital capacitive sensor. Sensors and Actuators A: Physical, 209, pp.175-182*; and Homayoonnai S. et al, 2016 *(Homayoonnia et al., Design and Fabrication of Capacitive Nanosensor based on MOF Nanoparticles as Sensing Layer for VOCs Detection, Sensors and Antuators B. Chemical, 2016, Vol. 237, Page No. 776-786).*

However, the existing sensors are not sensitive towards absolute moisture determination (µL) which might be due to the sensing material as used, the

arrangement of the sensing material in the device and size of the electrodes. In the existing art, also, as the second plate of the sensor has been made by Ag paste, it is not possible for the complete plate to sandwitch the dielectric material and therefore difficult to achieve the moisture sensitivity. Further, Due to second electrode of the sensor of Homayoonnai et al, the surface area of the electrodes may be decreased; the distance between the electrodes may be increased; dielectric constant of the sensing material may be decreased. These conditions are not suitable in order to increase the sensitivity of the sensor. In Homayoonnai et al, as the entire nanosensor assembly requires closed cabinet to execute the testing of various compounds at specific temperature and humidity, this sensor may not be worked in open atmosphere (regardless of the temperature). If this kind of sensor is placed in open atmosphere then air interference may create the noise in signal and thus affects the sensitivity.

Also, in the existing art, the metal nanoparticles as used in this sensor needs ultrasonic generator which is the costlier step. Further, raw materials Cu and 1,3,5-benzenetricarboxylic acid for preparing the nanomaterial (sensing material) are the costlier products as compared to the raw materials of present invention. Further, the existing tecchnology uses the costly silver based material to fabricate the nanosensor.

The earlier disclosures of the inventor [*Application of semi-solvo thermally synthesized zinc oxide (ZnO) nanoparticles in food technology and their characterization International Journal of Nanotechnology and Applications, Volume 11, Number 1 (2017), pp. 75-80]* teaches urea and ethylene glycol based zinc oxide nanoparticles. However, as the nanoparticles shows the nugget like morphology the same may not be effective in determing the moisture sensitivity.

Patent Document *202021010152* (Earlier disclosure of the inventor) relates to a resistance based chemical nanosensor includes a nanocomposite comprises of a metal nanoparticles and agar. However, this prior art does not suggest capacitance based sensor. Also, as the entired printed circuit board (PCB) is coated with the sensing material in IN'152' there is a chance to dislocate the sensing material from the functional area which might be due to the adhesion problem between the electrodes and the sensing materials which affects the moisture sensing. Futher limitation is corrosion of the electrode of this type of sensor which can occur after 5 times of it's usage. Additional limitations of this prior art are i) continuous monitoring of moisture seepage may not be possible as moisture may not be uniformly distributed over the sensing material and also the sensor is mostly used for storage purpose so it is expected to deliver data for longer duration and hence, it is not used for continuous monitoring; ii) stability is upto one year only as the composite may be deformed by dehydration iii) reliability and linearity.

Therefore, there is a need to overcome the aforesaid problems.

OBJECT OF THE INVENTION

It is an objective of the invention is to prepare low cost ZnO-NP deposited dielectric substrate which is highly sensitive towards moisture.

It is another objective of the invention is to provide a capacitor includes ZnO-NP deposited dielectric substrate.

It is another objective of the invention is to provide a ZnO-NP deposited dieletric substrate based sensor device for detecting moisture in packets of industrial products during transport and storage in particular tertiary packaging system.

It is yet another objective of the invention is to provide a sensor by which a continuous monitoring of moisture seepage into a packaged products of the industry can be feasible where moisture imposed is a major issue in stability and safety of the products in particular food processing, printing, textile, cement or mining.

It is yet another objective of the invention is to provide a sensor which requires less current, could provide an uniform result, is more sensitive and accurate.

It is yet another objective of the invention is to provide a sensor which could solve the existing corrosion problem.

It is yet another objective of the invention is to provide a sensor which could work in open atmosphere i.e. independent of the temperature.

It is yet another objective of the invention is to provide a sensing material that can be stable for a longer duration.

It is yet another objective of the invention is to provide a sensor having more reliability and linearity.

It is further objective of the invention is to provide a method for measuring the moisture of a tertiary packaging system employing the aforesaid sensor.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided a method for depositing layer of zinc oxide nanoparticles over a substrate of hygroscopic material as dielectric substrate comprising the steps of

i) seperately preparing two liquid mixture by dissolving 0.2M of zinc acetate in 50mL of water and 0.8M of urea in 50mL of aqueous ethylene glycol;

ii) adding the said mixtures as obtained in step (i) and stirring the said mixtures to prepare a homogeneous solution;

iii) subjecting the said solution as obtained in step (ii) to autoclaving process at 200°C for 30 hours to obtain a precipitate product;

iv) subjecting the said product as obtained in step (iii) to centrifugation process at 5000rpm for 15 minute twice with water and once with ethanol to romove the water soluble and water insoluble impurities respectively;

v) subjecting the product as obtained in step (iv) to calcination process at 600°C for 8 hours to remove the volatile impurities;

vi) preparing a suspension comprises of the product as obtained in step (v) and ethanol;

vii) dipping a hygroscopic substrate in the suspension as prepared in step (vi) so as to obtain an uniform distribution of the said product onto the substrate.

viii) drying the substrate as obtained in step (vii) at room temperature;

wherein shape of the product as obtained in step (v) is flake having pores; and

wherein diameter of the pores is 10-50nm.

According to second aspect of the invention, there is provided a zinc oxide nanoparticles deposited dielectric substrate sandwitched between two conducting metal electrodes forming a capacitor configured for altering capacitance based on presence of moisture level, wherein the said deposition of the nanoparticles includes

means for extracting zinc nanoparticles from a uniform mixture of solution of 0.2M of zinc acetate in 50mL of water and 0.8M of urea in 50mL of aqeous ethylene glycol;

means for preparing a suspension of the extracted zinc oxide nanoparticles in ethyl alcohol with concentration 1mg/mL; and

means for dipping the substrate of cellulose paper in the said nanoparticle solution for 5 minute for depositing the said nanoparticles over the said substrate.

According to third aspect of the invention, there is provided a capacitor including a zinc oxide nanoparticles deposited dielectric substrate sandwitched between two metal electrodes configured for use with a sensor device configured for detecting moisture comprising of :

a circuitry for sensing the change in the capacitance of the said capacitor due to the absorption of atmospheric moisture and output an amplified signal;

a microcontroller for receiving the said amplified signal and displaying the corresponding real time moisture content values as complared from a look up table.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 schematically illustrates the process steps for preparing ZnO-NP deposited cellulose paper as dielectric substrate in accordance with the present invention;

Figure 2 illustrates the FESEM images of ZnO-NP in accordance with the present invention;

Figure 3 illustrates the TEM images of ZnO-NP nanoparticles in accordance with the present invention;

Figure 4 illustrates the sensor device in accordance with the present invention;

Figure 5 illustretes the working of sensor device in accordance with the present invention;

Figure 6 illustrates an arrangement of the capacitor plate electrodes and the sensing material in which Fig. 6a shows sandwitch arrangement of the sensing material between two electrode plates & Fig. 6b shows parallal arrangement of the electrodes in accordance with the present invention;

Figure 7 illustrates sensitivity of the sensor with or without ZnO-NP towards moisture seepage in accordance with the present invention; &

Figure 8 illustrates the application of sensor in accordance with the present invention;

Figure 9 illustrates comparative moisture sensitivity studies with regard to length of the electrode in which Fig. 9a, 9b & & 9c shows the sensitivity graph of 1cm x 1cm, 3cm x 3cm, 5cm x 5cm respectively in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Fig. 1, the present invention provides a method for depositing layer of zinc oxide nanoparticles over a substrate of hygroscopic material as a dielectric substrate for detection of moisture as hereinbelow:

Method: Two liquid mixtures are prepared seperately by dissolving 0.2M zinc acetate in 50 mL and 0.8M urea in 50 mL solution of aqueous ethylene glycol (35 mL ethylene glycol and 15 mL deionized water) on a magnetic stirrer. Both the liquid mixture are added with continuous stirring to form a homogenous solutions. The homogeneous solution is then transferred to Teflon-lined stainless steel autoclaveing process at 200°C for 30 hours to obtain the precipitate. The resultant precipitate as obtained is subjected to a centrifugation process at 5000 rpm for 15 minute twice with DI water and once with absolute ethanol to remove water soluble and insoluble impurities respectively. The the product is subjected to calcination process at 600°C for 8 hours to remove volatile impurities.

The following according to present invention is the chemical reaction when the homogeneous solution containing zinc acetate and urea mixture is subjected under the elevated temperature:

$$NH_2 + H_2O \xrightarrow{\Delta} NH_4^+ + OH^-$$

$$Zn^{2+} + 2OH^- \xrightarrow{\Delta} Zn(OH)_2$$

$$(CH_3COO)_2Zn + (CH_2OH)_2 + CO(NH_2)_2 \xrightarrow{\Delta} Zn(OH)_2 + 2(CH_3COO(CH_2)_2OH) + NH_3 + CO_2\uparrow$$

$$Zn(OH)_2 \xrightarrow{\Delta} ZnO + H_2O\uparrow$$

As shown in Fig. 2 and Fig. 3, the characterization of ZnO particles as above obtained are performed. FESEM examination (Fig. 2) is conducted for obtaining size and surface morphological information of ZnO particles whereas, topography and morphology of the nanoparticles is observed by TEM microscopy (Fig. 3). Figure 2 shows the formation of perforated flakes like particles wherein each flake is having thickness of 20-40 nm. The length of the nano flake is 500 nm to 1μm while width is 200-500 nm. Due

to such perforated nano flake like structures, the specific surface area of said nanoparticle increases. TEM image (Fig. 3) also shows a representative flake having the pores wherein the diameter of the pores is 10-50nm which come into view that the said nanoparticles is a good mesoporous material indicating present ZnO-NP as advantageous over the existing ZnO-NP as the pores may hold more water and provide more number of active sites, which overall can enhance the dielectic behaviour of a sensing material and conduction.

In preferred embodiment of the invention, the hygroscopic substrate is a cellulose material which would be an advantageous matrix over agar as it is observed by the present inventors that the dispersal of nanoparticles at higher loading percentage in agar matrix would lead to agglomeration of material which ultimately loses its strength, transparency and activity.

In an embodiment of the invention, suitable method for depositing ZnO-NP onto the cellulose paper is either coating or spraying. In preferred embodiment, the method is coating.

Briefly, the deposition method is that a suspension is prepared by adding ZnO-NP in absolute ethanol and the cellulose paper (0.8 mm Whatman Cellulose Blotting Paper, Grade GB005) is dipped in the suspension of ZnO-NP for 5 minute to obtain an uniform distribution of ZnO-NP onto the paper.

In an embodiment of the invention, concentration of the nanoparticles is upto to 1mg/mL, beyond that it affects surface roughness and porosity of cellulose paper, which leads to desorption of water molecule subsequently affects the moisture sensitivity. Preferably, the concentration is 0.5-1.0mg/mL. Most preferably, the concentration is 1.0mg/mL.

In preferred embodiment of the invention, the moisture is an absolute moisture.

As shown in Fig. 4 & 5, the present invention provides also a sensor (9) for detecting moisture in packets of industrial products during transport and storage comprising

i) sensing material (6)

ii) insulated plate electrodes (5);

iii) plate holder (4);

iv) microcontroller system (1);

v) data cable (2);

vi) single core wire (3);

vii) serial port (7); &

viii) a Display unit (8)

In an embodiment, the present invention provides a capacitor (5) which comprises two parallel metal plates and ZnO-NP deposited dielectric substrate wherein the ZnO-NP deposited dielectric substrate is sandwitched between two conducting metal plates for altering capacitance based on presence of moisture level. Briefly, the design of sensor (9) according to present invention includes ZnO-NP deposited dielectric substrate (6) is placed between the two parallel aluminium plate electrodes (5) which is covered by an insulating plastic material to avoid the corrosion. The device also comprises a holder to hold the plates so as to close enough to avoid air interference and keep the sensing material at an appropriate place to achieve the desired capacitance. The device further comprises a microcontroller

system (1) which provides the output signal in a digital form into the display unit (8) through the data cable (2) while moisture seepage is occured.

In preferred embodiment, the sensing material consist of ZnO-NP deposited dielectric substrate.

As shown in Figure 6(a) & (b), the capacitor plates according to present invention is parallelly arranged under which the sensenting material is placed for changing the capacitance while the moisture is present. In preferred embodiment, the plate is made up of aluminium.

In preferred embodiment of the invention, the capacitor plates 3cm x 3cm in dimension cut in 2 pieces which further attached to single core wire (3). These plates are then placed vertically in an insulating plastic material in such a way that they are parallel to each other. In preferred embodiment, the space between the two electrodes is 0.5mm and the insulating plastic material is polyethylene (PE). In order to meeting the sentivity requirements such as i) increase the surface of the electrodes; ii) decreases the distance between the same & iii) increase the dielectric constant of the sensing material, 3cm x 3cm as the size of the plates is found as a surprising feature of the invention. It has also been found by the present inventors that the overall less current requirement, high sensitivity and good response time is observed using the plate size of 3cm x 3cm only which otherwise is not possible.

In an embodiment of the invention, present device includes a plate holder. Capacitance measurement setup is not relatively simple as resistance measurement and it is more susceptible to the external environment as atmospheric air acts as dielectric between two electrodes. Therefore, in conventional capacitors the dielectric material and electrodes enclosed

within metallic cylinder to achieve desired performance of capacitor. However, in the present invention such metallic cylinders are not feasible to use due to flat shape of the electrodes and the device requirement to absorb external moisture into the capacitor. Therefore, a holder is designed to hold the plate so as to close enough to avoid air interference and keeping sensing material at the proper place to achieve suitable capacitance. The plate holder according to present invention is made up of poly-lactic acid polymer.

In an embodiment of the invention, the present invention includes a circuitry for sensing the change in the capacitance of the said capacitor due to the absorption of atmospheric moisture and output an amplified signal. The circuitry according to present invention is connected to the capacitor (5) through either in series or in parallel.

In an embodiment of the invention, the present invention also includes a microcontroller (1) for receiving the said amplified signal and displaying the corresponding real time moisture content values as complared from a look up table (Table 1). The operating voltage and frequency of the microcontroller according to present invention are 5V DC and 16MHz respectively. In-built oscillator circuit & binary ripple counter of the system converts analog data collected by the sensing material into a digital data with resolution of 10 bits and the data transmitted to USB of computer at baudrate of 9600 bauds/sec. In the context of microcontroller system, which was programmed to execute measurements of the frequency signals at intervals of 10 ms. This testing enables to get quantitative analysis of change in capacitance with change in frequency. The in-built oscillator circuit has set frequency at 16 MHz. As the amount of moisture seeped inside the capacitor, the capacitance values are changed; this changed the frequency of output signal, which was analysed by microcontroller to sense the amount of moisture. After signal conditioning done by the

microcontroller, the signal referred to the display unit by either USB cable or Wi-Fi module.

The formula used to calculate the capacitance value is;

$$C = \in^{0} \in^{r} \frac{A}{d} \qquad \text{..... 1}$$

where,

C = capacitance (F);

A = overlap area of the two plates (m^2);

ε_0 = dielectric constant ($\varepsilon_0 \approx 8.854 \times 10^{-12}$ F·m^{-1});

ε_r = dielectric constant of the material between the plates;

d = distance between the plates (m)

Table 1: Look up Table

Moisture (µL)	Capacitance (pF)
100	48
200	54
300	62
400	76
500	82
600	86
700	94

In the present invention, changing the capacitance is developed after seepage of deionised (DI) or tap water into the sensing layer (Table 2, Figure 7). Since ZnO nanomaterials have higher dielectric constant (2.7) than cellulose (2.3) use of such nanomaterials to develop chemical sensor would be a good choice for higher sensitivity and accuracy. Change in composition of dielectric medium between conducting plates changes the capacitance value. The dielectric constant of ZnONPs is 2.7 and that of water is 80. So, as the moisture seeped into the capacitor, the capacitance value is changed accordingly. Since, water molecules have high polarity the dielectric value of the sensing layer changes significantly with respect to water content seeped into the capacitor and subsequently the capacitance of the sensor.

Additionally, zinc oxide retains semiconductor behaviour where it can show dielectric property at low temperature and conductor at high temperature. Therefore, water seepage into the ZnONPs-Cellulose sensor keeps the temperature low of the system and maintains its dielectric property rather; dielectric constant of the sensor increases with moisture level and so the capacitance. Consequently, capacitance is directly proportional to the moisture seeped into the sensor.

Table 2: Sensitivity of the nanosensor

Capacitance (pF)	Blank cellulose paper		Flake shaped ZnONP deposited cellulose paper			
			P1 (0.5 mg/mL)		P2 (1 mg/mL)	
Moisture Seepage (μL)	Deionized Water	Tap Water	Deionized Water	Tap Water	Deionized Water	Tap Water
100	18	19	22	25	40	48
200	20	21	26	28	47	54

300	23	24	30	33	55	62
400	24	27	34	39	60	76
500	26	28	41	46	75	82
600	29	32	53	58	79	86
700	32	35	58	62	81	94

Table 2 and Figure 7 shows that the sensor containing flaked shaped ZnONP deposited cellulose paper is more sensitive towards moisture seepage as compared to plain cellulose paper in tap water. Also, greater capacitance is observed for concentration 1mg/mL compared to 0.5mg/mL (in tap water).

In preferred embodiment of the invention, packets of industrial products includes a tertiary packaging system.

In preferred embodiment of the invention, the tertiary packaging system is paperboard cartons of moisture sensitive goods.

In an embodiment of the invention, the moisture sensitive good is selected from a group consisting of food processing, printing, textile, cement or mining goods.

In an embodiment of the invention, the food processing good is selected from a group consisting of wheat flour, milk powder, biscuits, grains or sugar.

In preferred embodiment of the invention, the food processing good is milk-powder.

The invention is now illustrated by non-limiting examples:

Example 1 (inventive example):

Application of the sensor device onto a paperboard cartons of milk powder:

As shown in Fig. 2 & Fig. 3, a ZnO-NP deposited dielectric cellulose paper (6) sandwitched between two conducting aluminium electrodes (5) was used with a sensor device (1) for detecting moisture, wherein the deposition of method is hereinbelow:

Method: Two liquid mixtures were prepared seperately by dissolving 0.2M zinc acetate in 50 mL and 0.8M urea in 50 mL solution of aqueous ethylene glycol (35 mL ethylene glycol and 15 mL deionized water) on a magnetic stirrer. Both the liquid mixture were added with continuous stirring to form a homogenous solutions. The homogeneous solution was then transferred to Teflon-lined stainless steel autoclaveing process at 200°C for 30 hours to obtain the precipitate. The resultant precipitate as obtained was subjected to a centrifugation process at 5000 rpm for 15 minute twice with DI water and once with absolute ethanol to remove water soluble and insoluble impurities respectively. The the product was subjected to calcination process at 600°C for 8 hours to remove volatile impurities (Fig. 1).

As shown in Fig. 8, the sensor device was applied to a paperboard cartons (10) of milk powder to detect moisture seepage during transport. The perishable or semi-perishable foodstuffs were initially packaged in primary packet (direct interaction with food) then all primary packages into one secondary packet and finally enclosed all secondary packages in one big tertiary packet made of paperboard cartons. The present device (9) was placed on two vertical sides of the tertiary packets with the hygroscopic sensing assembly (6) between the capacitive plates (5) to absorb the moisture and monitored by microcontroller system (1) wherein the size of the plates is 3cm x 3cm.

The operating voltage and frequency of the microcontroller system (1) were 5V DC and 16MHz respectively. In-built oscillator circuit & binary ripple counter of the system converts the analog data collected by the sensing assembly (6) into a digital data with resolution of 10 bits and the data transmitted to USB of computer at baudrate of 9600 bauds/sec. In this trail, the microcontroller was programmed to execute measurements of the frequency signals at intervals of 10 ms which enables to get quantitative analysis of change in capacitance with change in frequency. As the amount of moisture seeped inside the capacitor, the capacitance values are changed; this changed the frequency of output signal, which was analysed by microcontroller to sense the amount of moisture. After signal conditioning done by the microcontroller, the signal referred to the display unit by either USB cable or Wi-Fi module.

Example 2 (Comparative example):

The same application method was followed onto a paperboard cartons of milk powder as in Example 1 except the size of the plates which herein was 1cm x 1cm.

Example 3 (Comparative example):

The same application method was followed onto a paperboard cartons of milk powder as in Example 1 except the size of the plates which herein was 5cm x 5cm.

Table 3: Comparative moisture sensitivity with respect to the size of electrodes

Size of the electrode	Voltage (Volts)	Current (mA)	Moisture seepage*	Response time (ms)	Sensitivity for moisture (µL)
1cm X 1cm	5	09.75	Flooded	6	100 µL
3cm X 3cm	5	21.00	Uniform	10	100 µL

5cm X 5cm	5	38.50	Non-uniform	30	300 µL

*Moisture seepage with respect to sensitive amount of moisture taken was 100 µL

It is observed by the present inventors that flooded result (Figure 9a) in view of the moisture seepage was found while the electrode size is 1cm x 1cm. It was also found that as the small size electrode plates only managed the moisture seepage upto 100µL, more water seepage can not give quantitative results as sensing material is saturated with moisture and also damage the capacitor by short circuit. For large size electrode (5cm x 5cm), moisture seepage was not found as uniform (Figure 9c) which may be due to the large surface area and less signal to noise ratio for the electrode. Surprisingly, uniform moisture seepage and more sensitivity with good response time was found in 3cm x 3cm as size of the electrodes (Figure 9b).

It is also found by the present inventors that the size of the electrode greatly affects the current input required by the circuit. Table 3 shows that the plate having size of 5cm X 5cm needs more current than 3cm X 3cm, consequently, the overall power consumption would be increased, which greatly reduces the battery life of the device.

Comparative stability studies:

The stability of both the sensing material viz. ZnONP-agar and ZnONP-celulose paper were studied at room temperature for 12 months in open atmosphere. During the study both the materials was analysed for their polymeric degradation and fragmentation. It is observed that the ZnONP-agar composite was fragmented and damaged due to moisture loss over a period of 12 months whereas ZnONP-celulose paper was found to be intact even after 30 months (Table 4).

Table 4: Stability study

Sensing material consist of ZnONP-agar material	Sensing material consist of flake shaped ZnONP-celulose paper material
12 months	30 months

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim,

1. A method for depositing layer of zinc oxide nanoparticles over a substrate of hygroscopic material as dielectric substrate, comprising the steps of
   i) preparing two liquid mixture by dissolving 0.2M of zinc acetate in 50mL of water and 0.8M of urea in 50mL of aqueous ethylene glycol seperately;
   ii) adding the said mixtures as obtained in step (i) and stirring the said mixtures to prepare a homogeneous solution;
   iii) subjecting the said solution as obtained in step (ii) to autoclaving process at 200°C for 30 hours to obtain a precipitate product;
   iv) subjecting the said product as obtained in step (iii) to centrifugation process at 5000rpm for 15 minute twice with water and once with ethanol to romove the water soluble and water insoluble impurities respectively;
   v) subjecting the product as obtained in step (iv) to calcination process at 600°C for 8 hours to remove the volatile impurities;
   vi) preparing a suspension comprises of the product as obtained in step (v) and ethanol;
   vii) dipping a hygroscopic substrate in the suspension as prepared in step (vi) so as to obtain an uniform distribution of the said product onto the substrate.
   viii) drying the substrate as obtained in step (vii) at room temperature;

   wherein shape of the product as obtained in step (v) is flake having pores; and

   wherein diameter of the pores is 10-50nm.
2. The method as claimed in claim 1, wherein the hygroscopic material is a cellulose paper.
3. The method as claimed in claim 1, wherein concentration of the suspension in step (vi) is 0.5-1.0 mg/mL.

4. The method as claimed in claim 1, wherein the dipping step in step (viii) is carried out for 5 minutes.
5. The method as claimed in claim 1, wherein length of the flake is 500nm-1μm.
6. The method as claimed in claim 1, wherein width of the flake is 200-500nm.
7. A zinc oxide nanoparticles deposited dielectric substrate (6) sandwitched between two conducting metal electrodes (5) forming a capacitor configured for altering capacitance based on presence of moisture level, wherein the said deposition of the nanoparticles includes

   means for extracting zinc oxide nanoparticles from a uniform mixture of solution of 0.2M of zinc acetate in 50mL of water and 0.8M of urea in 50mL of aqeous ethylene glycol;

   means for preparing a suspension of the extracted zinc oxide nanoparticles in ethyl alcohol with concentration 1mg/mL; and

   means for dipping the substrate of cellulose paper in the said nanoparticle solution for 5 minute for depositing the said nanoparticles over the said substrate.

8. A zinc oxide nanoparticles deposited dielectric substrate (6) sandwitched between two conducting metal electrodes (5) forming a capacitor as claimed in claim 7, wherein the means for extracting zinc oxide nanoparticles further includes

   means for dissolving 0.2M of zinc acetate in 50mL of water and 0.8M of urea in 50mL of ethylene glycol in order to obtain two liquid mixtures;

   means for mixing the liquid mixtures obtained in step (i) in order to prepare a homogeneous solution;

means for autoclaving at 200°C upto 30 hours the said solution as obtained in step (ii) in order to obtain a precipitate product;

means for centrifugation process at 5000rpm for 15 minute subjecting the said product obtained in step (iii) twice with water and once with ethanol in order to romove the water soluble and water insoluble impurities respectively from the said product;

means for calcination at 600°C for 8 hours subjecting the product as obtained in step (v) in order to obtain zinc oxide nanoparticles; and

wherein shape of the nanoparticles is flake having pores; and

wherein diameter of the pores is 10-50nm.

9. A zinc oxide nanoparticles deposited dielectric substrate sandwitched between two conducting metal electrodes forming a capacitor as claimed in claim 8, wherein length of the flake is 500nm-1μm.

10. A zinc oxide nanoparticles deposited dielectric substrate sandwitched between two conducting metal electrodes forming a capacitor as claimed in claim 8, wherein the width of the flake is 200-500nm.

11. A capacitor including a zinc oxide nanoparticles deposited dielectric substrate sandwitched between two metal electrodes (5) as claimed in claim 7 configured for use with a sensor device (9) configured for detecting moisture comprising of :

a circuitry for sensing the change in the capacitance of the said capacitor due to the absorption of atmospheric moisture and output an amplified signal;

a microcontroller (1) for receiving the said amplified signal and displaying the corresponding real time moisture content values as complared from a look up table.

12. The capacitor including a zinc oxide nanoparticles deposited dielectric substrate sandwitched between two metal electrodes as claimed in claim 11, wherein the size of the electrode is 3cm x 3cm.

13. The capacitor including a zinc oxide nanoparticles deposited dielectric substrate sandwitched between two metal electrodes as claimed in claim 11, wherein the electrode is made up of aluminium.
14. The sensor device as claimed in claim 11, wherein the circuitry includes a plurality of said capacitors (5) connected in series or in parallel.
15. The sensor device as claimed in claim 11, wherein the said sensor is configured for detecting the absolute moisture of a tertiary packaging system.

Dated this 12th day of June, 2020

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
of
Lex-Regia
For the Applicant

To,
The Controller of Patents,
The Patent Office
At Mumbai

ABSTRACT

"A METHOD FOR DEPOSITING LAYER OF ZINC OXIDE NANOPARTICLES OVER A SUBSTRATE OF HYGROSCOPIC MATERIAL AS A DIELECTRIC SUBSTRATE AND A SENSOR CONTAINING THE SUBSTRATE FOR DETECTING MOISTURE"

Disclosed is a method of depositing layer of zinc oxide nanoparticles over a substrate of hygroscopic material as a dielectric substrate. Also, provided a sensor (9) containing the zinc oxide nanoparticles deposited dielectric substrate for detecting moisture of a tertiary packaging system. Figure 1

FORM 2

THE PATENT ACT 1970

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The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

1. TITLE OF THE INVENTION:

"A Twin Wire Tucker"

2. APPLICANT(s):

Name	Nationality	Address
SARODE, Karishma Rajiv	Indian	Krishna Institute of Medical Sciences "Deemed to be University", Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra
PAWAR, Renuka Lalit	Indian	Krishna Institute of Medical Sciences "Deemed to be University", Near Dhebewadi Road, Malkapur, Karad - 415539, Maharashtra

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~ ~~The following specification describes the invention.~~	**COMPLETE** The following specification particularly describes the invention and the manner in which it is to be performed

Field of the invention

[0001] The present invention relates to a twin wire tucker. More particularly, the present invention relates toa twin wire tucker for tucking the wire in the bracket slot to provide ligature ties.

Background of the invention

[0002] Generally, for giving ligature ties around the bracket slot, the traditional dental instruments have a single slot at the end of a single vertical arm of the instrument, which lacks the stability while bonding of bracket on the tooth surface. Also, it provides lesser stability to the ligature ties due to the single arm. The existing dental instruments provide lesser convenience to insert the wire when brackets are bonded lingually.

[0003] Further, with the presence of only a single-arm, it becomes very difficult for the person to hold the instrument while treating the patients. Also, there is no grip provided on the instruments, which prevents the slippage of fingers. Furthermore, it requires a lot of force while tucking the wire and keeping the instrument stable.

[0004] Till today, there is no such dental instrument which can be a multi-utility instrument and can overcome the drawback of the existing dental instruments.

[0005] Therefore, there is a need for a dental instrument which can overcome the drawbacks of the existing prior art.

Objects of the invention

[0006] Object of the present invention is to provide a twin wire tucker.

[0007] Another object of the present invention is to provide a twin wire tucker, which prevents de-bonding of the bracket from the tooth surface.

[0008] Further object of the present invention is to provide a twin wire tucker, which requires less force while tucking the wire, thereby making providing more stability.

[0009] One more object of the present invention is to provide a twin wire tucker having more convenience to hold the device.

[0010] Yet another object of the present invention is to provide a twin wire tucker, having a good grip, thereby preventing the slippage of fingers.

[0011] Further one object of the present invention is to provide a twin wire tucker, which is economical and simple in operation.

Summary of the invention

[0012] According to the present invention, there is provided a twin wire tucker. The twin wire tucker are having a pair of arms attached together at a proximal end. Each of the arms has a bend at a distal portion. A locking arrangement is configured between the pair of arms for locking the pair of arms at a desired angle therebetween. Also, a slot is configured at the distal end of each of the arm for holding the wire while performing dental treatment. A gripping surface is configured on an outer surface of each of the arms. In the present embodiment, the grip is a combination of depression or cut-outs or vertical serrations configured on the outer surface of each of the arm.

Brief Description of the invention

[0013] Figure1showsaschematic diagram of a twin wire tucker in accordance with the present invention; and

[0014] Figure 2 shows a top view of figure 1;

Details description of the invention

[0015] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising," "having," "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items, or meant to be limited to only the listed item or items.

[0016] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “a” and “an” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0017] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0018] The present invention provides a twin wire tucker. The twin wire tucker prevents the de-bonding of the bracket from the tooth surface. Also, the twin wire tucker is more stable. Further, the twin wire tucker is convenient to hold. Further, the twin wire tucker have a good grip, thereby prevents the slippage of fingers. Moreover, the twin wire tucker are economical and simple in operation.

[0019] Referring now to figures 1 and 2, a twin wire tucker 100 in accordance with the present invention is illustrated. The twin wire tucker 100 includes a pair of arms 10a and 10b and a locking arrangement40. The pair of arms 10a and 10b are attached together at a proximal end 20 to configure a forked structure. Each of the arms 10a and 10b has a bend 30a and 30b at a distal portion. Specifically, the arms 10a has the bend 30a and the arm 10b has the 30b. The pair of arms 10a and 10b is used for tucking a wire in a bracket slot to provide ligature ties while performing dental treatment. In the present embodiment, the length of the pair of arms 10a and 10b ranges from 10 centimetres to 20 centimetres. It may be obvious to a person skilled in the art to configure a pair of arms of any geometry (shape, size, and dimensions).

[0020] Also, a slot 50a and 50b are configured at a distal end of each of the arms 10a and 10b for holding the wire while performing dental treatment. Specifically, the slot 50a is configured at the distal end of the arms 10a and the slot 50b is configured at the distal end of the arm 10b. The slots 50a and 50b are made to stabilize the wire while doing dental treatment. In the present embodiment, the width of the slots 50a and 50b is 1mm(approximately) and the depth of the slots 50a and 50b are 1.5mm (approximately). It may be obvious to a person skilled in the art to configure the slots of any geometry (shape, size, and dimensions). In the present embodiment, the wire is fixed in the slots 50a and 50bfrom both sides, thereby giving ligature ties around the braces.

[0021] Further, a gripping surface 60 is configured on an outer surface of each of the arm10a and 10b as shown in figure 1. Specifically, in the present invention, the grip is a combination of depression or cut-outs or vertical serrations configured on the outer surface of each of the arms 10a and 10b.

[0022] Referring again to figures 1and 2, the locking arrangement 40 is configured between the pair of arms 10a and 10b for locking the pair of arms 10a and 10b at a desired angle therebetween. Specifically, the locking arrangement 40 is having a locking arm 40a and 40b. The locking arm 40a and 40b is extending towards each other from the pair of arms 10a and 10b respectively. The locking arm 40a has a serrated tooth in one direction and the locking arm 40b has a serrated

tooth in opposite direction, thereby getting locked with other and thereby permitting the pair of arms 10a and 10b at different angles therebetween as per the requirement of the user. The pair of arms 10a and 10b is in locked condition when pressed towards each other and the pair of arms 10a and 10b is in unlocked condition when the pressures are released from the pair of arms 10a and 10b.

[0023] Therefore, the present invention provides an advantage of providing the twin wire tucker 100.The twin wire tucker 100 prevents the debonding of the bracket from the tooth surface. Also, the twin wire tucker 100 is more stable. Further, the twin wire tucker 100 are convenient to hold. Further, the twin wire tucker 100 have a good grip, thereby prevents the slippage of fingers. Moreover, the twin wire tucker 100 is economical and simple in operation.

[0024] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously, many modifications and variations are possible considering the above teaching. The embodiments were chosen and described to best explain the principles of the present invention and its practical application, to thereby enable others skilled in the art to best utilize the present invention and various embodiments with various modifications as are suited to the use contemplated. It is understood that various omission and substitutions of equivalents are contemplated as circumstances may suggest or render expedient,

but such are intended to cover the application or implementation without departing from the scope of the description of the present invention.

FORM 2

THE PATENT ACT 1970

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

(SEE SECTION 10 AND RULE 13)

1. TITLE OF THE INVENTION: "A Wearable Device for Orthopaedic Treatment"

2. APPLICANT(s):

(a) NAME: **NIKAM, Prasannajeet Pramod**

(b) NATIONALITY: Indian

(c) ADDRESS: Krishna Institute of Medical Sciences "Deemed to be University", Karad, Krishna College of Physiotherapy, NH 4, Near Dhebewadi Road, Malkapur, Karad - 415539, Maharashtra

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed

Field of the Invention

[0001] The present invention relates to an orthopaedic treatment device. More particularly, the present invention relates to a wearable device for orthopaedic treatment, especially for treating lower back pain.

Background of the Invention

[0002] Back pain affects persons despite all ages for a variety of reasons. A vast majority of back pain experienced by the general population occurs in the lower portion of the back, generally referred to as the lumbar area. Lower back pain affects the spine's stability, flexibility, and strength, as a result, cause pain, discomfort and stiffness during daily living activities such as sitting, driving or sleeping. In most cases, some form of a support garment is a common expedient for reducing the back pain. One of the well-known garments for this purpose is the wrap-around corset of a non-flexible material. Physical therapy treatments are also widely used as a useful measure of pain relief.

[0003] Typical stretching and other conventional physical therapy treatments may not alleviate pain caused by radiculopathy and acute lower back pain. Till now; as a part of conventional physiotherapy, the first choice of treatment modality used for treating low back pain was ‘Transcutaneous Electrical Nerve

Stimulation" (TENS) which is also called as "Neuro-muscular Electrical Stimulation" (NMES).

[0004] If LBP (low back pain) was accompanied with radiculopathy, then the modality used is "Interferential Therapy" (IFT). Both TENS/NMES and IFT work on the principle of "pain control" or "pain gate theory". Further, to correct posture, ergonomic advice is given to the patients. Advances like biofeedback are rarely used as it is not available on a global basis. For LBP cases secondary to PIVD (prolapsed intervertebral disc), spondylolisthesis, spondylitis, etc., exercise protocol like Mckenzie's Extension Regime is advised.

[0005] Soft-tissue decompression therapy, posture correction technique and TENS/NMES have been effective to some extent when given separately. Though all of the above mentioned therapeutic techniques and modalities are known to affect individually, still there is no evidence of any modality working on the combined principle of the above mentioned three techniques. While administering modalities like TENS/NMES or IFT, it is not always taken into consideration that the patient is in anatomically and biomechanically correct posture. The management strategies are available for LBP focus only on the pain-relieving component.

[0006] Therefore there is a need for a concrete physiotherapy treatment option for low back pain based on medically explained mechanism of action which can partially or completely overcome few or all the drawbacks of the existing devices.

Objects of the Invention

[0007] An object of the present invention is to provide a wearable device for orthopaedic treatment, especially for treating lower back pain.

[0008] Another object of the present invention is to provide a wearable device which will not only focus on the pain relief component but also target posture-correction as well as soft-tissue off-loading simultaneously.

[0009] Yet another object of the present invention is to provide a wearable device, which provides soft-tissue decompression by lifting and off-loading the muscles of the back.

[0010] One more object of the present invention is to provide a wearable device, which facilitates removal of waste-products like lactic-acid and thus help to improve the physiological properties of the muscle like flexibility, contractibility etc.

[0011] Further object of the present invention is to provide a wearable device, which is simple and economical in construction.

Summary of the invention

[0012] According to the present invention, a wearable device for orthopaedic treatment in accordance with the present invention is provided. The wearable device has to be wore by the user. The wearable device includes a support member which is adapted to wear around the torso of the user. The support member has an adjustable arm-strap and an adjustable lumbar belt to ensure fitting over the body of the user.

[0013] Further, the support member is a jacket like an arrangement to wear around the body of the user. The support member varies in size, shape and aesthetics according to the requirement of the user. In an embodiment, the device is configured in such a way that an inner circumferential area of the support member contacts with the back region of the user for providing body treatment. The support member is configured with rubber pad electrodes and vacuum suction cups. Specifically, the vacuum suction cups are operably mounted in between the rubber pad electrodes. The vacuum suction cups are removably configured from the support member such that the user can wear the support member for correcting the posture.

[0014] The device provides soft-tissue decompression by lifting and off-loading the muscles of the body through the vacuum suction cups. In the present embodiment, the vacuum suction cups are operated manually.

[0015] Further, a neuromuscular electrical stimulation machine is arranged on the support member for providing neuromuscular electrical stimulation through the rubber pad electrodes. The neuromuscular electrical stimulation is provided through the rubber pad electrodes to facilitate passive contraction and relaxation of the muscles. The rubber pad electrodes are controlled by a battery-operated controlling unit arranged inside a pocket over the lumbar belt. The device provides neuromuscular electrical stimulation along with soft-tissue decompression therapy in anatomically and biomechanically to correct the posture of the user.

Brief Description of the Drawings

[0016] The advantages and features of the present invention will be understood better with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0017] Figure 1 illustrates a schematic representation of a wearable device for orthopaedic treatment in accordance with the present invention.

Detailed Description of the Invention

[0018] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising, "having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items or meant to be limited to only the listed item or items.

[0019] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0020] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0021] Lower back pain affects the spine's stability, flexibility, and strength, as a result, cause pain, discomfort and stiffness during daily living activities such as sitting, driving or sleeping. In most cases, some form of a support garment is a common expedient for reducing the back pain. In general cases, a wrap-around corset of non-flexible material serves this purpose. The wearable device in the present invention provides a concrete physiotherapy

treatment option for low back pain based on medically explained mechanism of action. The wearable device is a combination of electrical as well as mechanical components. The wearable device has to be wear as a jacket over the trunk region by the user (patient).

[0022] Referring now to figure 1, a wearable device, hereinafter referred to as a device 100 for orthopaedic treatment in accordance with the present invention is illustrated. The device 100 has to be wear by the user. The wearable device 100 includes a support member 200 which is adapted to wear around the torso of the user. The support member 200 has an adjustable arm-strap 210 and an adjustable lumbar belt 220 to ensure fitting over the body of the user. The arm strap 210 and the lumbar belt 220 enables the user to properly fit the wearable device 100 around the body despite the size and shape of the user.

[0023] In the present embodiment, two such arm straps 210 are provided for holding the support member 200, each arm straps 210 being wear around both the shoulders of the user. The arm strap 210 has a locking member 212 to be fastened with a corresponding locking element 214 configured on the support member 200 to hold the support member 200 around the body, particularly around the shoulder of the user. Similarly, the lumbar belt 220 is fastened around the waist or lumbar region of the body to hold the support member 200. It may be obvious to a person skilled in the art to fasten the arm strap 210 and the lumbar belt 220 using hook and loop arrangement and the like.

[0024] Referring again to figure 1, the support member 200 is a jacket like an arrangement to wear around the body of the user. The support member 200 varies in size, shape and aesthetics according to the requirement of the user. This helps the device 100 to be easy to fit for a variety of individuals with diverse anatomical and physical variations. In the present embodiment, the device 100 is configured in such a way that an inner circumferential area of the support member 200 contacts with the back region of the user for providing body treatment. The support member 200 ensures that the user maintains good posture throughout the treatment.

[0025] The support member 200 is configured with rubber pad electrodes 110 and vacuum suction cups 120. In the present embodiment, one or more rubber pad electrodes 110 and respective vacuum suction cups 120 has to be arranged on the support member 200. Specifically, the vacuum suction cups 120 are operably mounted in between the rubber pad electrodes 110. The vacuum suction cups 120 are removably configured from the support member 200. By way of non-limiting example, the support member 200 can wore by the user after removing the vacuum suction cups 120 for correcting the posture.

[0026] The device 100 also provides soft-tissue decompression by lifting and off-loading the muscles of the body through the vacuum suction cups 120. In the present embodiment, the vacuum suction cups 120 are operated

manually. By way of non-limiting example, the vacuum suction cups 120 can be inflated manually both by the user (patient) as well as the therapist.

[0027] Further, a neuromuscular electrical stimulation machine 130 is arranged on the support member 200 for providing neuromuscular electrical stimulation through the rubber pad electrodes 110. The neuromuscular electrical stimulation is provided through the rubber pad electrodes 110 to facilitate passive contraction and relaxation of the muscles. The rubber pad electrodes 110 are controlled by a battery-operated controlling unit arranged inside a pocket 222 over the lumbar belt 220. The rubber pad electrodes 110 are operated through a cable of electrodes 140 connected between the neuromuscular electrical stimulation machine 130 and the rubber pad electrodes 110. The device 100 provides neuromuscular electrical stimulation along with soft-tissue decompression therapy in anatomically and biomechanically to correct the posture of the user. This will help in reducing pain as well as facilitate removal of waste-products like lactic-acid and thus help to improve the physiological properties of the muscle like flexibility, contractibility etc.

[0028] Therefore the present invention has the advantage of providing a wearable device 100 for orthopaedic treatment, especially for treating lower back pain. The device 100 will not only focus on the pain relief component but also target posture-correction as well as soft-tissue off-loading simultaneously. Further, the device 100 provides soft-tissue decompression by

lifting and off-loading the muscles of the back. The device 100 facilitates in removal of waste-products like lactic-acid and thus help to improve the physiological properties of the muscle like flexibility, contractibility etc. Also, the device 100 is simple and economical in construction.

[0029] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the present invention and its practical application, and to thereby enable others skilled in the art to best utilize the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omissions and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such omissions and substitutions are intended to cover the application or implementation without departing from the scope of the claims of the present invention.

I Claim:

1. A wearable device 100 for orthopaedic treatment, the wearable device 100 comprising:

a support member 200 adapted to wear around the body of the user, the support member 200 having an arm-strap 210 and a lumbar belt 220 to ensure fitting over the body of the user, characterized in that;

the support member 200 is configured with rubber pad electrodes 110 and vacuum suction cups 120, wherein neuromuscular electrical stimulation is provided through the rubber pad electrodes 110 facilitating passive contraction and relaxation of the muscles.

2. The wearable device 100 as claimed in claim 1, wherein a neuromuscular electrical stimulation machine 130 is arranged on the support member 200 for providing neuromuscular electrical stimulation through the rubber pad electrodes 110.

3. The wearable device 100 as claimed in claim 1, wherein the vacuum suction cups 120 are operably mounted in between the rubber pad electrodes 110.

4. The wearable device 100 as claimed in claim 1, wherein the support member 200 is a jacket to wear around the body of the user, the support member 200 varies in size, shape and aesthetics according to the requirement of the user.

5. The wearable device 100 as claimed in claim 1, wherein the rubber pad electrodes 120 are controlled by a battery-operated controlling unit arranged inside a pocket 222 over the lumbar belt 220.

6. The wearable device 100 as claimed in claim 1, wherein the device 100 provides neuromuscular electrical stimulation along with soft-tissue decompression therapy in anatomically and biomechanically to correct the posture of the user.

7. The wearable device 100 as claimed in claim 1, wherein the device 100 provides soft-tissue decompression by lifting and off-loading the muscles of the body through the vacuum suction cups 120.

8. The wearable device 100 as claimed in claim 1, wherein the device 100 is configured in such a way that an inner circumferential area of the support member 200 contacts with the back region of the user for providing body treatment.

9. The wearable device 100 as claimed in claim 1, wherein the vacuum suction cups 120 are operated manually.

10. The wearable device 100 as claimed in claim 1, wherein the vacuum suction cups 120 are removably configured from the support member 200 such that the user can wear 200 the support member for correcting the posture.

Dated this April 06, 2020

Suneet Baliram Sabale

(Agent or Applicant)

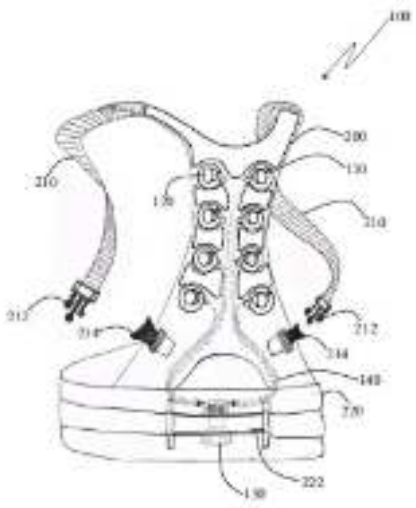
5 **Reg. No.: IN/PA-1773**

Abstract

Title: A wearable device for orthopaedic treatment

The present invention provides a wearable device 100 for orthopaedic treatment. The wearable device 100 includes a support member 200 adapted to wear around the body of the user. The support member 200 has an arm-strap 210 and a lumbar belt 220 to ensure fitting over the body of the user. Further, the support member 200 is configured with rubber pad electrodes 110 and vacuum suction cups 120. Neuromuscular electrical stimulation is provided through the rubber pad electrodes 110, facilitating passive contraction and relaxation of the muscles. The device 100 is especially for treating lower back pain. It also facilitates in removal of waste-products like lactic-acid and thus helps to improve the physiological properties of the muscle like flexibility, contractibility etc.

Figure 1



FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A LIPOSOMAL COMPOSITION OF *PTEROCARPUS SANTALINUS* AND THE PROCESS THEREOF"

APPLICANT

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to herbal plant *Pterocarpus santalinus.* More particularly, the present invention relates to a liposomal composition of *Pterocarpus santalinus* for acute inflammation and a process for preparing the composition.

BACKGROUND OF THE INVENTION

Acute inflammation induced by PGE2 (prostaglandin E2) through mast cell activation via EP3 receptor, is an indication of pain in major diseases including cancer, Parkinson's or HIV. Controlled release (CR) system may be better option than immediate-release (IR) and sustain release (SR) in these conditions as it delivers the drug in controlled manner (pre-determined) such that lesser dosage of the drugs are required in order to achieve the therapeutic effect and thereby reduce the side effects.

In view of processing cost and side effects of the synthetic anti-inflammatory drug for instance non-steroidal anti-inflammatory drugs, currently the focus of researcher has been turned into the herbal moiety. Nevertheless the controlled-release system of any therapeutic compound is a challenging task and that too when it is an herbal moiety as the behavior of such moieties is mostly unstable which may be due to the physical instability or the enzymatic degradation or the chemical reactions *(Thakur et al., Novel Approaches For Stability Improvement in Natural Medicines, Pharmacognosy Reviews, 2011, Vol 5(9), 48-54).*

In existing art, the herb *Pterocarpus santalinus* which contains glycoside and flavonoids is used in acute inflammation *(Dinesh Kumar, 2011).* However, glycoside and flavonoids are poorly absorbed molecules to skin due to their large molecular size to act on the inflammatory receptor (PGE2). Also due to their polar nature these molecules may not cross the lipid-rich biological membranes consequently affects bioavailability of the drug. On the other hand, accumulation of these molecules at the site of action may offer side effects such as skin irritation, drying scaling and the related problems.

Dinesh Kumar, 2011(Anti-inflammatory, analgesic, and antioxidant activities of methanolic wood extract of Pterocarpus santalinusL. Journal of Pharmacology and Pharmacotherapeutics, 2011, Vol 2, Issue 3), discloses the use of methanolic wood extract of *Pterocarpus santalinus* L. in inflammation. However, oral dose of the methanolic wood extract is very high (500mg/kg) which also is not economical. Further, this prior art shows that the lower dose (100mg/kg) is not significantly effective in acute inflammation (i.e. reduced paw volume of 100mg/kg is 0.33mL in 60 minute and 0.52mL in 120 minute). Moreover, in this prior art, the paw volume is enhanced as compared to control in first 30 minutes of using the drug (100mg/kg) which is not at all desired.

S. Majumdar et al. *(Shivprasad Majumdar et al., Formulation study of gel containing pterocarpus santalinus extract for its anti-inflammatory activity, World Journal of Pharmacy and Pharmaceutical Sciences, 2013, volume 2, issue 6, 4951-4964)* discloses a topical anti-inflammatory formulation containing methanolic extract of *Pterocarpus santalinus.* However, the formulation of this prior art is a conventional matrix type (i.e. not an encapsulation) hence high amount (0.5g) of the drug is required which is not desired. Also, paw volume value is again more (more than 0.5mL in 90 minutes) in this prior art. Further, the pH (more than 7) of the formulation is beyond the limit of pH (4.7-5.7) of skin therefore releases of the drug onto the targeted organ is under question. Also, as the spreadability of the formulation is less in this prior art the formulation may be less-consistent. Further, as the viscosity of the formulation is less, the drug may not retain at the site of action for a longer period.

Therefore, there is a need to overcome the aforesaid drawbacks.

OBJECTIVE OF THE INVENTION

It is objective of the invention is to provide a liposomal composition of *Pterocarpus santalinus* for acute inflammation.

It is another objective of the invention is to provide a topical controlled release formulation of *Pterocarpus santalinus* for acute inflammation occurred in a disease in particular cancer, Parkinson's or HIV.

It is yet another objective of the invention is to provide a topical formulation of *Pterocarpus santalinus* with the desired pH such that the drug could be released from the formulation to a targeted organ.

It is yet another objective of the invention is to provide a topical formulation of *Pterocarpus santalinus*with higher spreadibility such that the drug would be consistently spread onto the affected area.

It is yet another objective of the invention is to provide a topical formulation of *Pterocarpus santalinus* with higher viscosity such that the drug could be retained onto the targeted organ for a longer period.

It is yet another objective of the invention is to provide a topical formulation of *Pterocarpus santalinus* for acute inflammation with no side effect of the drug.

It is yet another objective of the invention is to provide a stable herbal liposomal formulation of *Pterocarpus santalinus.*

It is yet another objective of the invention is to provide a process for preparing the composition.

It is further objective of the invention is to provide a process for preparing the formulation.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided a liposomal composition of *Pterocarpus santalinus*comprisesof

i) an encapsulation system includes 100mg of methanolic extract of *Pterocarpus santalinus* and synthetically processed lipid mixture of 400mg of phospholipid and 410mg of sterol wherein said extract being encapsulated within the said lipid mixture;

ii) phosphate buffer.

According to second aspect of the invention, there is provided a topical controlled release formulation of *Pterocarpus santalinus* comprises of

i) 100mg of methanolic extract of *Pterocarpus santalinus;*

ii) synthetically processed lipid mixture of 400mg of phospholipid and 410mg of sterol;

iii) phosphate buffer;

iv) gelling agent: 50 mg

v) penetration enhancer: 0.2 mL;

vi) preservative: 0.75 mg.

According to third aspect of the invention, there is provided a process for preparing liposomal composition of *Pterocarpus santalinus* comprising the steps of:

i) dissolving phosphatidylcholine and cholesterol in a solvent mixture consist of equivalent concentration of methanol and chloroform to obtain a liquid mixture;

ii) adding methanolic extract of *Pterocarpus santalinus* into the mixture as obtained in step (i) and subjecting the said mixture into vortexing for 15 minute;

iii) subjecting the mixture as obtained in step (ii)into a rotary evaporator at 60°C to obtain a thin film;

iv) hydrating the thin film as obtained in step (iii) with a phosphate buffer to obtain an aqueous suspension;

v) agitating the suspension as obtained in step (iv) for 30 minute;

vi) sonicating the suspension as obtained in step (v) for 1 hour;

wherein the evaporation process in step (iii) is carrying out at 30rpm;

wherein pH of the buffer in step (iv) is 7.4.

According to fourth aspect of the invention, there is a process for preparing controlled release formulation of *Pterocarpus santalinus* comprising the steps of

i) dissolving phosphatidylcholine and cholesterol in a solvent mixture consist of equivalent concentration of methanol and chloroform;

ii) adding methanolic extract of *Pterocarpus santalinus* into the mixture as obtained in step (i) and subjecting the said mixture into vortexing for 15 minute;

iii) subjecting the mixture as obtained in step (ii) into a rotary evaporator at 60°C to obtain a thin film;

iv) hydrating the thin film as obtained in step (iii) with a phosphate buffer to obtain a suspension;

v) agitating the suspension as obtained in step (iv) for 30 minute;

vi) sonicating the suspension as obtained in step (v) for 1 hour;

vii) adding the suspension as obtained in step (vi) to an aqueous solution of cross-linked polyacrylic acid and stirring the said addition at 30°C to obtain a mono-disperse viscous product;

viii) adding the penetration enhancer and preservative to the said product as obtained in step (vii);

ix) neutralizing the product as obtained in step (viii) by using 0.1N NaOH;

wherein the stirring process in step (vii) is carrying out at 1200 rpm.

In accordance with these and other objects, which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 schematically illustrates the SEM image of liposomal composition in accordance with the present invention;

Figure 2 illustrates block diagram of preparation method of liposomal composition in accordance with the present invention;

Figure 3 illustrates comparative % inhibition of the liposomal compositions and the reference drug (methanolic extract of *Pterocarpus santalinus*) in accordance with the present invention;

Figure 4 illustrates comparative drug release of the liposomal formulations in accordance with the present invention;

Figure 5 illustrates comparative stability study (in view of pH) of the liposomal formulations wherein Fig. 5a shows the stability at 25°C/65±5%RH & Figure 5b shows the stability at 40°C/75±5%RH in accordance with the present invention;

Figure 6 illustrates comparative in-vivo paw volume in accordance with the present invention; &

Figure 7 illustrates comparative in-vivo percentage inhibition in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Expression:

'*Pterocarpus santalinus*' herein is methanolic extracts of *Pterocarpus santalinus* which according to present invention is a drug for the treatment of acute inflammation.

"Liposome" herein is a thin film which comprises an encapsulation system includes methanolic extracts of *Pterocarpus santalinus* and synthetically processed lipid mixture in which the said extract being encapsulated within the said lipid mixture.

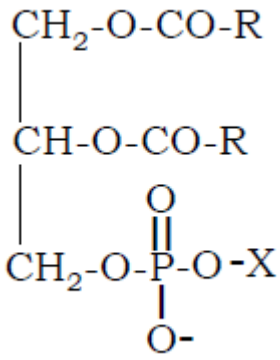
'Liposomal composition' herein is a combination of the aforesaid liposome and phosphate buffer in which the drug is in solid-in-liquid system.

"Synthetically processed lipid mixture" herein is a combination of two lipids which is prepared using a synthetic route and is commercially available in the market.

'Controlled release formulation' herein is a gel that can deliver the drug at predetermined rate for specific period of time topically.

The present invention provides a liposomal composition of *Pterocarpus santalinus* for acute inflammation comprises of i) an encapsulation system includes methanolic extract of *Pterocarpus santalinus* and synthetically processed lipid mixture wherein the said extract is encapsulated within the said lipid mixture and ii) a buffer.

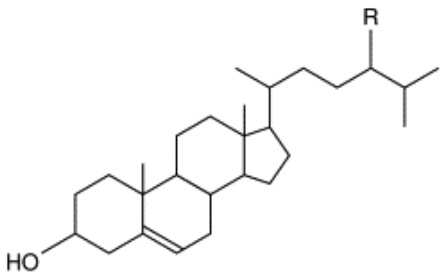
In preferred embodiment of the invention, the synthetic processed lipid mixture is a combination of phospholipid of Formula (I) and sterol compound of Formula (II).



Formula (I)

+

In preferred embodiment of the invention, X is $–CH_2-CH_2-N(CH_3)_3$



Formula(II)

In an embodiment R is selected from a group consisting of H, $-C_2H_5$, $-CH_3$, or $CH-CH_3$.

In preferred embodiment of the invention, R is H.

In preferred embodiment of the invention, the phospholipid is phosphatidylcholine.

In preferred embodiment of the invention, the sterol is cholesterol.

In preferred embodiment of the invention, the buffer is phosphate buffer.

In preferred embodiment of the invention, amount of the drug is 100mg.

In preferred embodiment of the invention, amount of the phospholipid and the sterol is 400mg and 410mg respectively. The desired effect i.e. % maximum inhibition and controlled release of the drug would not be possible if the amount of the lipids is not within this range.

In preferred embodiment of the invention, particle size of the liposomal composition is 495.9nm (Figure 1).

In another embodiment of the invention, the liposomal composition of *Pterocarpus santalinus* is prepared by a process comprising the steps of:

i) dissolving the phospholipid and the sterol compound in a solvent mixture consist of equivalent concentration of methanol and chloroform;

ii) adding methanolic extract of *Pterocarpus santalinus* into the mixture as obtained in step (i) and subjecting the said mixture into vortexing;

iii) subjecting the mixture as obtained in step (ii) into a rotary evaporator to obtain a thin film;

iv) hydrating the said film as obtained in step (iii) with a phosphate buffer to obtain an aqueous suspension;

v) agitating the suspension as obtained in step (iv); &

vi) sonicating the suspension as obtained in step (v).

According to present invention, the vortexing time of step (ii) is preferably more than 5 minute, most preferably more than 10 minutes, most preferably 15 minutes.

In preferred embodiment, amount of phosphate buffer in step (iv) is 10mL.

In yet another embodiment, the present invention provides a formulation comprises of aforesaid liposomal composition and a pharmaceutical excipient selected from a group consisting of gelling agent, penetration enhancer, preservative or a combination thereof, would be used topically for the purpose of acute inflammation.

In an embodiment of the invention, the gelling agent is cross-linked polyacrylic acid. In preferred embodiment, the gelling agent is Carbopol 940.

In preferred embodiment of the invention, the penetration enhancer is eucalyptus oil.

In preferred embodiment of the invention, the preservative is methyl paraben.

In preferred embodiment of the invention, amount of the gelling agent is 50mg while amount of the penetration enhancer & the preservative is 0.2mL and 0.75mg respectively.

In an embodiment of the invention, the formulation is gel.

In preferred embodiment of the invention, the formulation is liposomal gel.

In another embodiment of the invention, pH of the gel is 5.5-5.7.

In yet another embodiment of the invention, the aforesaid formulation is prepared by a process comprising the steps of:

i) adding the aforesaid suspension to an aqueous solution of the gelling agent to obtain and stirring the said addition at 30°C to obtain a mono-disperse viscous product;
ii) adding the penetration enhancer and preservative to the product as obtained in step (i);
iii) neutralizing the product as obtained in step (ii) using 0.1N NaOH;

In preferred embodiment of the invention, speed of the stirring process of step (ii) is 1200 rpm.

In preferred embodiment of the invention, the inflammation is acute inflammation selected from a group consisting of cancer, parkinson's or HIV.

The invention is now illustrated by non-limiting examples:

EXAMPLE 1:

Materials: Methanolic extract of *Pterocarpus santalinus*in the form of amorphous powder was obtained from YUCCA ENTERPRISE MUMBAI, INDIA.Phosphatidylcholine, cholesterol, methanol, chloroform, eucalyptus

oil, methyl paraben, Carbopol 940were purchased from RL FINE CHEMPVT. LTD. MUMBAI, INDIA.

Preparation of phosphate buffer (pH 7.4):

50mL of 0.2M potassium dihydrogen phosphate was placed in 200mL volumetric flask, 39.1mL of 0.2M sodium hydroxide was added to it and finally 200 ml volume make up was done with distilled water.

Preparation of liposomal composition (inventive example 1):

Referring to Figure 2, 400mg of Phosphatidylcholine and 410mg of cholesterol were dissolved in chloroform-methanol (1:1) mixture. 100mg of methanolic extract of *Pterocarpus santalinus* was added into it and the said mixture was then subjected into vortexing for 15 minutes. The mixture was then subjected into an evaporation step using Super-lift rotary evaporator at 60°C and 30rpmto obtain a thin film (liposome). The film was then hydrated with a phosphate buffer (pH 7.4) to obtain aqueous suspension and then the suspension was agitated at 85 rpm for 30 minutes first and then was sonicated for 1 hour to obtain the nano-size particles as shown in Figure 1.

Preparation of liposomal composition (comparative liposomal composition):

The liposome and liposomal compositions were prepared as per the method described in Example 1 except the amount of Phosphatidylcholine and cholesterol. In this method,the amount of Phosphatidylcholine and cholesterol were:

Phosphatidylcholine and cholesterol = 195mg : 615mg (comparative example 1)

Phosphatidylcholine and cholesterol = 615mg : 195mg (comparative example 2)

Phosphatidylcholine and cholesterol = 405mg: 405mg (comparative example 3)

i) Drug encapsulation efficiency of the liposome

Entrapment capacity of the extract within the liposome was determined by ultracentrifuge (Remi) equipped with a TLA-45 rotor at 15,000 rpm at 4^0C for 3h. After separation of *Pterocarpus santalinus* entrapped liposome vesicles, the amount of un-entrapped was determined using UV/Visible spectrophotometry at 247 nm. Each sample was analyzed in triplicate. The amount of drug entrapped in vesicles was calculated by the equation given below:

Entrapment efficiency % = amount of free drug/ total amount of drug x100

Table 1: % encapsulation efficiency

Parameter	Liposome			
	Inventive example 1	Comparative example 1	Comparative example 2	Comparative example 3
% encapsulation efficiency	92.7±2.08	70.91±1.2	65.78±3.31	61.9±1.67

The liposomal composition of Example 1 (inventive example) shows highest drug encapsulation efficiency as compared to the other examples (Table 1)thereby absorbing more amount of the drug at the site of action and therefore improves the bioavailability.

ii) Particle size and poly-dispersity index analysis of the liposomal composition:

The aforesaid liposomal composition was separately subjected to Zeta Sizer 1000 HS_A, (Malvern Instrument, UK)at 25°C to measure the particle size and polydispersity index of the liposome.

Table 1: Particle size and Poly-dispersity index

	Liposomal composition

Parameter	Inventive example 1	Comparative example 1	Comparative example 2	Comparative example 3
Particle size (in nm)	495.9nm	820 nm	689 nm	780 nm
Poly-dispersity index	0.1	0.902	0.958	0.982

It is observed that Example 1 (inventive example) shows smaller particles as compare to other comparative example which facilitates in enhancing the drug penetration into the site of action and therefore improves the bioavailability.

It is also observed that the polydispersity index value of the liposomal composition of Example 1 (inventive example) is low as compared to other comparative examples concluding that the liposomal composition of Example 1ishighly mono-disperse and is therefore stable.

iii: Anti-inflammatory activity of the liposomal compositions:

Anti-inflammatory activity of the aforesaid liposomal composition was performed by Protein Denaturation method *(In-vitro anti-inflammatory activity of methanolic extract of enicostemma axillare G Leelaprakash , S.Mohan Dass International Journal of Drug Development & Research, July-September 2011 Vol. 3 Issue 3)* in which a reaction mixture (10 mL) consist of 0.4mL of egg albumin (from fresh hen's egg), 5.6 mL of phosphate buffered saline (PBS, pH 6.4) and 4mL of the liposomal composition (each mL consist of 200, 400, 600, 800 or 1000 µg of the drug). Then the mixtures were incubated at 37^0c ±2 in an incubator for 15 min and were then heated at 70^oC for 5 min. After cooling, the absorbance was measured at 660 nm. Similarly, different concentration (200, 400, 600, 800 or 1000 µg/mL) of methanolic extract of *Pterocarpus santalinus* was prepared as reference drug and the absorbance was taken in same way as above. The percentage inhibition of protein denaturation was calculated by using the following formula,

% inhibition = absorbance of control - absorbance of test / absorbance of control x 100

Table 3: % inhibition

Parameter	Liposomal composition				Reference drug
	Inventive example 1	Comparative example 1	Comparative example 2	Comparative example 3	
200µg/mL	70%	35%	33.6%	42%	28%
400 µg/mL	75%	36 %	37 %	44 %	40 %
600 µg/mL	80%	40 %	41 %	46 %	50 %
800 µg/mL	85%	42 %	43 %	47 %	60 %
1000 µg/mL	90%	49 %	48 %	48.5 %	64%

As shown in Table 3 and Fig. 3 the liposomal composition of Example 1 (inventive example) shows superior anti-inflammatory activity as compared to other examples and reference drug (methanolic extract of *Pterocarpus santalinus*) which might be due to i) smallest particle size of the liposomal composition of Example 1 so that the active constituent flavonoid and glycoside are fully penetrated; ii) highly mono-disperse nature of the liposomal composition of Example 1so that the active constituents are stable at the time of delivery and iii) highest encapsulating nature of the liposomal composition of Example 1 so that the maximum amount of the active constituents can be absorbed. On the other hand as the active constituents are wholly penetrated throughout the biological membrane there may be any hardly chance of its adverse effect.

Preparation of liposomal gel):

Formula F1 (inventive formula):

Sr. No.	Ingredient	Quantity
Liposomal composition		
1	methanolic extract of *Pterocarpus santalinus*	100mg
2	Phosphatidylcholine	400mg
3	cholesterol	410mg
Excipients		
4	Carbopol 940	50mg
5	Eucalyptus oil	0.2 mL
6	Methyl paraben	0.75mg

Method 'A':50 mg of Carbopol 940 was soaked into 10 ml of water for an hour. The swelled mass of Carbopol 940 was stirred till Carbopol 940 completely dissolved in the distilled water. The aforesaid liposomal composition was added to Carbopol 940 solution and the said solution was further subjected into continuous stirring at 1200rpm and 30^0Cto obtain a viscous product.0.2 ml of eucalyptus oil and 0.75mg of methyl paraben were then added into it to increase the penetration of the drug and to inhibit the microbial growth respectively. pH of the gel was adjusted by using 0.1N NaOH. The liposomal gel was stored at room temperature (25 ± 1^0c).

Formula F2 (Comparative formula):

Sr. No.	Ingredient	Quantity
Liposomal composition		
1	methanolic extract of *Pterocarpus santalinus*	100mg
2	Phosphatidylcholine	195mg
3	cholesterol	615mg
Excipients		

4	Carbopol 940	50mg
5	Eucalyptus oil	0.2 mL
6	Methyl paraben	0.75mg

Method 'B': The liposomal gel was prepared as per the method described in Method 'A' except the amount of the lipids.

Formula F3 (Comparative formula):

Sr. No.	Ingredient	Quantity
Liposomal composition		
1	methanolic extract of *Pterocarpus santalinus*	100mg
2	Phosphatidylcholine	615mg
3	cholesterol	195mg
Excipients		
4	Carbopol 940	50mg
5	Eucalyptus oil	0.2 mL
6	Methyl paraben	0.75mg

5

Method 'C': The liposomal gel was prepared as per the method described in Method 'A' except the amount of the lipids.

Formula F4 (Comparative formula):

Sr. No.	Ingredient	Quantity
Liposomal composition		
1	methanolic extract of *Pterocarpus santalinus*	100mg
2	Phosphatidylcholine	405mg
3	cholesterol	405mg
Excipients		
4	Carbopol 940	50mg

5	Eucalyptus oil	0.2 mL
6	Methyl paraben	0.75mg

Method 'C': The liposomal gel was prepared as per the method described in Method 'A' except the amount of the lipids.

Evaluation of the liposomal gels:

i. pH:

The pH of developed gels was determined by digital pH meter (Make Lab India) wherein one gram of aforesaid gel was dissolved in 100 ml of distilled water and stored at 4°C for two hours. The measurement of pH of each formulation was in triplicate and the average values are presented**.**

ii. Spreadability:

Spreadability was calculated by taking two glass slides having 7.8 cm length and then the aforesaid gel was sandwiched in-between them. A weight of 50gm was placed over the upper slide of glass for uniform spreading of the gel and the takeoff that applied weight of 50 mg, and then the spreadability of the gel was measured with respect to a known applied weight of 20 gm with the help of a pulley, and the time taken to roll down the glass slide was noted. Subsequently, the procedure was repeated thrice to take an average of the total spreadability achieved by placing 20 gm of weight over it. Further, spreadability was calculated by the following formula:

$S = M \times L/T$

where S is the spreadability of the liposomal gel,

M is the weight tied on the upper slide (20 gm),

L is the length of the slide (7.8 cm) and t is the time taken by the upper slide to roll down.

iii. Viscosity:

A Brookfield Rotational Digital Viscometer DV II RVTDV-II was used to determine the viscosity (in cps) of the aforesaid gels wherein the spindle

No.63 was rotated at 200 rpm. Samples of the gels were permitted to settle over 30 min at room temperature (25 ± 1°C).

iv. Extrudability test:

In this study, the amount of gelin percentage and gel extruded from lacquered aluminum collapsible tube on application of weight in grams required to extrude at least 0.5 cm strip of gel in 10 seconds. More extruded amountis equal to better extrudability. The measurement of extrudability of formulation was in triplicate and the average values are presented. The extrudability was then calculated by using the following formula:

Extrudability = Applied weight to extrude gel from tube (in gm)/ Area in cm^2

Table 4: Evaluation of liposomal gels

Parameters	F1 (inventive gel)	F2 (comparative gel)	F3 (comparative gel)	F4 (comparative gel)
pH	5.5±0.05	6.5±0.05	7.5±0.04	6.4±0.09
Viscosity	6728±0.59	4520±0.75	5685± 0.47	6225±0.098
Spreadability (gcm/sec)	14.3±0.46	10.12±0.23	10.20±0.87	11.8±0.36
Extrudability	Excellent	Good	poor	poor

Table 4 shows that pH of F1 formula 5.5 which is within the range of human skin pH (4.7 to 5.75)therefore would be compatible for topical application. On the other hand, pH of F2-F4 is not within the range of human skin and therefore would not be compatible for topical application.

With regard to the parameter viscosity and spreadability, F1 was found as superior as compared to other comparative formulas (F2-F4) and accordingly it can be interpreted that F1 would be retain at the site of action for a longer period and would also be more consistent while applying at the

site of action. The extrudability of the liposomal gel (F1) was also found as better than the other examples.

v) In-vitro release studies:

To study the release of the drug from liposomal gel (Formula F1-F4), Franz diffusion cell was used in which volume of receiver compartment is 10mL, effective diffusion area is 2.84cm^2 and the dialysis membrane is 0.65µm. The receiver compartment was filled with 60% w/w ethanol and temperature was maintained at 33^{0}C. 1g of the liposomal gel was placed in the donor compartment and 1ml of sample from receiver compartment was withdrawn at the interval of 20 mints. The same amount of fresh sample (60% w/w ethanol)was added and volume was kept constant. The samples were analysed on UV-Spectrophotometer (Systronics AU 2701) at the wavelength of 247nm using standard curve (*Pterocarpus santalinus* with percentage purity 99.9 %).

Table 5: % drug release of Formula F1

Time in minutes	% drug released
0	0
20	44.3 %
40	54.2 %
60	64.2 %
80	74.1 %
100	84.2 %
120	94.2 %

Table 6: % drug release of Formula F2

Time in minutes	% drug released
0	0
20	36.22 %
40	39.11 %
60	50.32 %
80	58.12 %

100	60.11 %
120	76.12 %

Table 7: % drug release of Formula F3

Time in minutes	% drug released
0	0 %
20	31.12 %
40	51.12 %
60	65.11 %
80	69.21 %
100	70.12 %
120	91.65 %

Table 8: % drug release of Formula F4

Time in minutes	% drug released
0	0 %
20	29.21 %
40	38.12 %
60	54 .21 %
80	58.21 %
100	61.23 %
120	83.46 %

As shown in Table 5-8 and Figure 4, F1 releases maximum amount of the drug (44.3%) at first 20 minutes and accordingly the patient could get the immediate relief from the pain. On the other hand, as compared to other formulas, F1 provides the drug release in so controlled manner as to attainthe uniform concentration (10%) of drug to the absorption site and thus may allow the maintenance of plasma concentration within the therapeutic range which minimizes not only the side effects but also the frequency of administration of the drug whereas uniform concentration of the drug cannot be observed in F2-F4.

vi) Stability studies:

The stability study was performed as per ICH guidelines in which thedeveloped gel (Formula F1-F4) was filled in collapsible tubes and stored at different temperatures and humidity viz,25°C±2°C/60%RH±5%RH, 30°C±2°C/65%RH±5%RH&40°C±2°C/75%RH±5%RH for 6 months. The tests carried out as the stability indicator were pH,appearance, viscosity drug content uniformity, spreadabilityand extrudability. The data related to pH, appearance and viscosity is hereinbelow:

Table 9: Stability data

F1 (Inventive gel):

Liposomal gel	25±2°/65±5% RH					40±2°/75±5% RH			
	0 Month	1 month	2 month	3 month	6 month	1 month	2 month	3 month	6 month
pH	5.5± 0.05	5.5± 0.07	5.5± 0.08	5.52± 0.02	5.57± 0.03	5.53± 0.05	5.55± 0.06	5.56± 0.06	5.56± 0.08
Appearanc	Smooth	smooth	smooth	smooth	smooth	smooth	smooth	smooth	smooth
Viscosity	6728 ± 0.59	6734 ± 0.04	6742 ± 0.02	6757 ± 0.02	6759 ± 0.09	6762 ± 0.08	6769 ± 0.09	6777 ± 0.03	6781 ± 0.09

F2 (comparative gel):

Liposomal gel	25±2°/65±5% RH					40±2°/75±5% RH			
	0 Month	1 month	2 month	3 month	6 month	1 month	2 month	3 month	6 month
pH	6.5± 0.05	7.4± 0.04	7.9± 0.01	8.2±0 .02	8.6±0 .03	8.9±0 .05	9.1±0 .06	9.6±0 .07	9.8±0 .08
Appearanc	Smooth	smooth	smooth	graininess	graininess	graininess	graininess	graininess	graininess

Viscosity	4520 ± 0.75	4712 ± 0.04	5187 ± 0.02	6039± 0.02	7257± 0.06	8742± 0.08	8953± 0.05	9558± 0.09	9860± 0.07

F3 (comparative gel):

Liposomal gel	25±2°/65±5% RH					40±2°/75±5% RH			
	0 Month	1 month	2 month	3 month	6 month	1 month	2 month	3 month	6 month
pH	7.5± 0.04	8.3± 0.02	8.9± 0.02	9.2± 0.03	9.6±0.04	8.4±0.05	8.9±0.04	9.8±0.09	10.3± 0.02
Appearanc	Smooth	smooth	smooth	smooth	graininess	graininess	graininess	graininess	graininess
Viscosity	5685 ± 0.47	6238 ± 0.04	7085 ± 0.02	7864 ± 0.02	8765± 0.07	8943± 0.02	9353± 0.05	9458± 0.06	9963± 0.08

F4 (comparative gel):

Liposomal gel	25±2°/65±5% RH					40±2°/75±5% RH			
	0 Month	1 month	2 month	3 month	6 month	1 month	2 month	3 month	6 month
pH	6.4± 0.09	6.7± 0.05	8.7± 0.04	9.5± 0.08	9.6±0.08	8.2±0.02	9.3±0.03	9.5±0.07	10.2± 0.03
Appearanc	Smooth	smooth	smooth	smooth	graininess	graininess	graininess	graininess	graininess
Viscosity	6225 ± 0.098	6938 ± 0.058	7295 ± 0.02	7994 ± 0.03	8965± 0.06	9683± 0.06	9823± 0.04	9918± 0.05	9989± 0.07

Referring to Figure 5a and 5b, it is found that comparative formulas (F2-F4)do not qualify the test of stability mainly in view of pH and appearance as these formulas showed the pH above 6 over the extended period which is not at all compatible with the skin (pH 4.7 - 5.75) and also, appearance of these formulas (F2-F4)was found as graininess(which is not at all smooth) over the extended period. On the other hand, the pH of F1 was found as 5.5-5.57 over the extended period indicating the compatibility of the formulation with the skin (Figure 5). Further, the appearance of F1 was found as smooth over the extended period.

It is also observed that the viscosity of F2-F4 was not consistent over the extended period indicating instability of the formulation. Contrarily, the viscosity of F1 was found as consistent over the extended period.

vii) In-vivo acute anti-inflammatory activity of F1-F4:

Paw oedema was induced by injecting 0.1ml of 1% carrageenan in physiological saline into the subplantar tissues of the left hind paw of Albino rat. The gel (F1-F4) was applied to the paw by gentle rubbing. The paw volume was measured at 1hour, 2hour, 3hour & 4hour by using a plethysmometer. Total increase in paw volume was noted after applying the gel and the technical effect was judged on the basis of reduction of paw volume.

Table 10: Total increase in paw volume Vs time

Treatment	Total increase in paw volume (ml)			
	1 Hour	2 Hour	3 Hour	4 Hour
Control	0.94	1.31	1.24	1.12
F1	0.09	0.09	0.12	0.11
F2	0.23	0.40	0.83	0.88
F3	0.26	0.38	0.78	0.81
F4	0.31	0.48	0.90	0.88

As shown in Table 10 and Figure 6, F1 possess the superior effect in reduction of paw volume as compared to F2-F4 in acute inflammation which might be due to unique combination of Phosphatidylcholine and cholesterol (1:1.1) of F1. It is also surprising that the combination of Phosphatidylcholine and cholesterol 1:1 (F4) even cannot significantly reduce the paw volume as F1.

The result of paw volume (Table 10, Figure 6) also addresses the significant advantage of the present invention over *Dinesh Kumar, 2011* as reduction of paw volume in present invention was 0.09mL (100mg) in 60minutes and 0.09mL (100mg) in 120minutes whereas in Dinesh Kumar, 2011 it was 0.33mL (100mg) and 0.52mL (100mg) in 60minutes and 120minutes respectively. Accordingly it could be interpreted that the present invention reduces the paw volume (in-vivo) more than 3-5 times than the extract of *Dinesh Kumar, 2011* in the acute condition.

% inhibition of acute inflammation:

The percentage inhibition of inflammation of F1-F4 was observed using following equation applied to Table 10:

Formula for % inhibition = $\frac{\text{paw volume of control - Paw volume of sample}}{\text{Paw volume of control}}$ x100

Table 11: % inhibition of inflammation

Treatment	Percentage inhibition of paw volume			
	1 Hour	2 Hour	3 Hour	4 Hour
Control	0.94	1.31	1.24	1.12
F1	90.42	93.12	90.32	90.17
F2	7.55	6.94	3.12	2.14
F3	7.23	7.09	3.70	2.76
F4	6.70	6.33	2.74	2.14

As shown in Table 10 and Figure 7, F1 shows the significant effect in inhibition of inflammation (acute) as compared to F2-F4 which might be due to the unique combination of Phosphatidylcholine and cholesterol 1:1.1that may be responsible for substantial penetration of the therapeutic compounds (glycoside and flavonoids) into the biological membrane.

Findings of the invention:

1) lower amount (100mg) of the herbal drug could significantly reduce the inflammation (acute) provided it should be under an encapsulation system of a phospholipid and sterol compound wherein ratio of the phospholipid and sterol is 1:1.1 and thus the said composition of present invention would provide a significant edge over the existing product in a medical condition like cancer or HIV or Parkinson's where other drugs and sometimes that too with higher amount is already prescribed;
2) The present invention could reduce the paw volume more than 3-5 times than the extract of *Dinesh Kumar, 2011* in acute inflammation therefore the present invention is significantly efficacious with regard to the existing technology.
3) phospholipid and sterol 1:1 (F4) would not be effective for achieving anti-inflammatory activity of the herbal drug (100mg) in acute condition;
4) Compatible pH could only be achieved at the ratio of phospholipid and sterol 1:1.1 for this drug;
5) Controlled release of the drug couldn't be achieved even if the ratio of phospholipid and sterol is 1:1;
6) The higher range of phospholipid and the lower range of sterol or vice-versa, would not be effective for achieving anti-inflammatory activity of the drug wherein the drug is in lesser amount (100mg);
7) The ratio of phospholipid and sterol 1:1.1 may inhibit the drug accumulation at the site of action and thus side effects of the drug can be prevented;
8) For achieving a stable controlled release anti-inflammatory gel of *Pterocarpus santalinus*, the phospholipid and sterol 1:1.1 must be

combined with 50mg of the gelling agent, 0.2mL of the penetration enhancer and 0.75mg of the preservative (F1).

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been present for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which departs from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim,

1. A liposomal composition of *Pterocarpus santalinus* comprises of
    i) an encapsulation system includes 100mg of methanolic extract of *Pterocarpus santalinus* and synthetically processed lipid mixture of 400mg of phospholipid and 410mg of sterol; and
    ii) phosphate buffer.

2. The liposomal composition as claimed in claim 1, wherein amount of phosphate buffer is 10mL.

3. The liposomal composition as claimed in claim 1, wherein the phospholipid is phosphatidylcholine.

3. The liposomal composition as claimed in claim 1, wherein the sterol is cholesterol.

4. The liposomal composition as claimed in claim 1, wherein particle size of the said composition is 495.9nm.

5. A topical controlled release formulation comprises of
    i) 100mg of methanolic extract of *Pterocarpus santalinus;*
    ii) synthetically processed lipid mixture of 400mg of phospholipid and 410mg of sterol;
    iii) phosphate buffer;
    iv) gelling agent: 50 mg
    v) penetration enhancer: 0.2 mL;
    vi) preservative: 0.75 mg.

6. The formulation as claimed in claim 5, wherein the phospholipid and the sterol is phosphatidylcholine and cholesterol respectively.

7. The formulation as claimed in claim 5, wherein the gelling agent is cross-linked polyacrylic acid.

8. The formulation as claimed in claim 5, wherein the penetration enhancer is eucalyptus oil.

9. The formulation as claimed in claim 5, wherein the preservative is methyl paraben.

10. The formulation as claimed in claim 5, wherein pH of the formulation is 5.5-5.7.

11. A process for preparing liposomal composition of *Pterocarpus santalinus* comprising the steps of

    i) dissolving phosphatidylcholine and cholesterol in a solvent mixture consist of equivalent concentration of methanol and chloroform to obtain a liquid mixture;

    ii) adding methanolic extract of *Pterocarpus santalinus* into the mixture as obtained in step (i) and subjecting the said mixture into vortexing for 15 minute;

    iii) subjecting the mixture as obtained in step (ii) into a rotary evaporator at 60°C to obtain a film;

    iv) hydrating the thin film as obtained in step (iii) with a phosphate buffer to obtain an aqueous suspension;

    v) agitating the suspension as obtained in step (iv) for 30 minute; and

    vi) sonicating the suspension as obtained in step (v) for 1 hour;

    wherein the evaporation process in step (iii) is carrying out at 30 rpm;

    wherein pH of the buffer in step (iv) is 7.4

12. The process for preparing the controlled release formulation as claimed in claim 5 comprising the steps of

i) dissolving phosphatidylcholine and cholesterol in a solvent mixture consist of equivalent concentration of methanol and chloroform;

ii) adding methanolic extract of *Pterocarpus santalinus* into the mixture as obtained in step (i) and subjecting the said mixture into vortexing for 15 minute;

iii) subjecting the mixture as obtained in step (ii) into a rotary evaporator at 60°C to obtain a thin film;

iv) hydrating the thin film as obtained in step (iii) with a phosphate buffer to obtain a suspension;

v) agitating the suspension as obtained in step (iv) for 30 minute;

vi) sonicating the suspension as obtained in step (v) for 1 hour;

vii) adding the suspension as obtained in step (vi) to an aqueous solution of cross-linked polyacrylic acid and stirring the said addition at 30°C to obtain a mono-disperse viscous product;

viii) adding the penetration enhancer and preservative to the said product as obtained in step (vii);

ix) neutralizing the productas obtained in step (viii) by using 0.1N NaOH;

wherein the stirring process in step (vii) is carrying out at 1200 rpm.

13. The liposomal composition as claimed in claim 1 for treatment of acute inflammation selected from a group consisting of cancer, parkinson's or HIV.

Dated this 26th day of June, 2020

ArghyaAshis Roy
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant

ABSTRACT

"A LIPOSOMAL COMPOSITION OF *PTEROCARPUS SANTALINUS* AND THE PROCESS THEREOF"

Disclosed is a liposomal composition of *Pterocarpus santalinus* comprises of a stable encapsulation system comprises of 100mg of methanolic extract of *Pterocarpus santalinus* and synthetically processed lipid mixture composed of 400mg of phospholipid and 410mg of sterol wherein the said extract being capsulated within the said lipid mixture. Also provided is method of manufacturing the composition. Figure 1

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FORM 2

THE PATENT ACT 1970

&

The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

1. TITLE OF THE INVENTION:

"A Measuring Device for Assessing and Measuring a Dentoalveolar Asymmetry"

2. APPLICANT(s):

Name	Nationality	Address
RONAD, Yusuf Ahammed A.	Indian National	Krishna Institute of Medical Sciences "Deemed to be University", Karad, Dept of Orthodontics & Dentofacial Orthopaedics, School of Dental Sciences, NH 4, Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra.

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed.

Field of the invention

[0001] The present invention relates to a measuring device. More particularly, the present invention relates to a measuring device for assessing and measuring a dentoalveolar asymmetry.

Background of the invention

[0002] Generally, variations in the facial size, shape, skeletal, and facial structures are important in providing each individual with their own identity. The teeth play a vital role in defining the facial structure of each individual. The dental asymmetries and a variety of functional deviations can be treated orthodontically to improve the facial structure of each individual. But, significant structural facial asymmetries are not easily amenable to orthodontic treatment. These problems may require orthopedic correction during the growth period and or surgical management after cessation of growth.

[0003] Also, for orthodontics, it is most important to analyze a skeletal and a dentoalveolar asymmetry for treating dental prostheses of a patient. Especially, analyzing the upper jaw, the lower jaw of the patient is equally important for a dentist to treat a patient’s dental prostheses. Also, measuring and analyzing from the center of a patient's face to the respective occlusal plane vertically downwards that helps a dentist to measure the discrepancy between right and left maxillae which are crucial data for treating a patient’s dental prostheses.

The analyzed data helps a dentist in treatment planning and diagnosis of the dental asymmetries.

[0004] There are some existing devices for measuring the facial data, where either a dentist manually places a millimeter scale for the facial data or a single device is not capable of measuring all the dentoalveolar asymmetry and skeleton details.

[0005] To overcome one or all drawbacks of the existing device, there is a need for a measuring device for assessing and measuring a dentoalveolar asymmetry.

List of elements and their reference numbers:

Measuring Device- 100

Vertical support 110

Vertical millimeter-scale- 115

First member- 120

Second member- 122

Guiding members -124a, 124b

First guiding member- 124a

Second guiding member- 124b

Slider- 126

First set of bows- 130a, 130b

Inner bow- 130a

Outer bow- 130b

Second bow- 140

Object of the invention

[0006] An object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry.

[0007] Another object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry, which is used for measuring dental asymmetries for treating a variety of functional deviations orthodontically.

[0008] Yet another object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry, which facilitates in assessing and measuring the dentoalveolar asymmetries numerically

which help a dentist in treatment planning, diagnosis of a dental asymmetry of a patient.

[0009] Further object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry, which has graduated scales in all three planes of space such as vertical, transverse, and sagittal for measurement.

[0010] Further one more object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry, which measures facial data from the center of pupils to the respective occlusal plane vertically downwards hat help to measure the discrepancy between right and left maxillae.

[0011] Still one object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry, which is compact and robust.

[0012] Still one more object of the present invention is to provide a measuring device for assessing and measuring a dentoalveolar asymmetry, which assessed and measured the dentoalveolar asymmetries data numerically that helps in diagnosis, treatment planning, and aid in the treatment of asymmetries.

Summary of the invention

[0013] According to the present invention, there is provided with a measuring device for assessing and measuring a dentoalveolar asymmetry. The measuring device is provided with a vertical support, a first member, a second member, and two guiding members. The vertical support is engraved with a vertical millimeter scale. The vertical millimeter scale is provided for measuring the vertical discrepancy such as the discrepancy between right and left maxilla or maxillary dentition. Further, the first member is arranged to a distal end of the vertical support. The first member extends perpendicularly on both sides equally of the vertical support. The first member is also engraved with a horizontal millimeter scale.

[0014] Further, the second member is also arranged on the distal end of the vertical support. The second member is extending perpendicularly from the vertical member and the first member toward a face of a patient. The second member is adapted to move an anterior and posterior direction in contact with the skin over and between eyebrows. Specifically, the second member is arranged in contact over a glabella for providing stability for measuring the distance from the glabella to the mandible.

[0015] Further, the two guiding members are slidably arranged on the first member. Specifically, the two guiding members are slidably arranged on both sides of the vertical support. A slider is placed on the first member for sliding the guiding members. The guiding members are provided for measuring a pupillary distance of a person by the horizontal millimeter scale of the first member.

[0016] Further, a first set of bows and a second bow are slidably placed on the vertical support. The first set of bows and the second bow is engraved with a millimeter-scale to assess the dentoalveolar asymmetry therein. The first set of bows are extending outwards symmetrically on both sides. In the present embodiment, the first set of bows is having an inner bow and an outer bow. Specifically, the first set of bows is provided for measuring a discrepancy between right and left maxilla or maxillary dentition which is reflected onto the second member. Specifically, the discrepancy between right and left maxilla or maxillary dentition is reflected on the horizontal millimeter scale of the first member.

[0017] Further, a second bow is slidably placed on the vertical support. Specifically, the second bow is placed below the first set of bows. In the present embodiment, the second bow is placed on the lower border of the mandible. The second bow is provided to assess the skeletal and the mandibular asymmetry. Also, the second bow assesses a vertical discrepancy by assessing from a lower border to an occlusal plane and from a lower border to the interpupillary plane.

Brief Description of the Drawings

[0018] The advantages and features of the present invention will become better understood with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0019] Figure 1 illustrates a perspective view of a measuring device for assessing and measuring a dentoalveolar asymmetry in accordance with the present invention;

[0020] Figure 2 illustrates a top view of the measuring device for assessing and measuring a dentoalveolar asymmetry in accordance with the figure 1; and

[0021] Figure 3 illustrates a front view of the measuring device for assessing and measuring a dentoalveolar asymmetry.

Detail Description of the Invention

[0022] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising," having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not meant to be an exhaustive listing such item or items or meant to be limited to only the listed item or items.

[0023] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one

element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0024] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0025] The present invention provides a measuring device which is used in orthodontics treatment. The measuring device is a clinical acumen that is used in the dental field, specifically used in an orthodontics dental treatment. The measuring device is used for assessing and measuring an asymmetry of a skeleton and a dentoalveolar. Also, the measuring device is used to measure the discrepancy between right and left maxillae. The significant structural facial asymmetries are not easily amenable to orthodontic treatment. These problems may require orthopedic correction during the growth period and or surgical management after cessation of growth.

[0026] Referring now to figures 1, 2, and 3, various views of a measuring device for assessing and measuring a dentoalveolar asymmetry in accordance with the present invention is illustrated. The measuring device 100, hereinafter is referred to as the device 100. The device 100 is provided with a vertical support 110, a first member 120, a second member 122, and two guiding members like a first guiding member 124a, and a second guiding member 124b. The vertical support 110 is like an “I” shaped strip or stick, engraved with a vertical

millimeter-scale 115. The vertical millimeter-scale 115 is provided for measuring the vertical discrepancy such as a discrepancy between right and left maxilla or maxillary dentition.

[0027] Further, the first member 120 is arranged to a top portion of the vertical support 110. The first member 120 is an elongated member extending transversely across the longitudinal axis of the vertical support 110 with an intersection in between forming a “T” shape structure. The first member 120 is also engraved with a horizontal millimeter scale (not shown). Further, the second member 122 is also arranged on the top portion of the vertical support 110 intersecting the first member perpendicularly. The second member 122 extends perpendicularly from the vertical member 110 in an axis facing towards a face of a user/patient. The second member 122 is a rod-shaped element, which is adapted to move an anterior and posterior direction in contact with the skin over and between eyebrows. Specifically, the second member 122 is arranged in contact over a glabella for providing stability for measuring the distance from the glabella to the mandible.

[0028] Further, the two guiding members 124a, 124b are slidably arranged on a lower portion of the first member 120 such that both the guiding members 124a, 124b hangs from the first member 120. In the present embodiment, the guiding members 124a, 124b is an eye-piece in a circular shape. Specifically, the two guiding members 124a, 124b are slidably arranged on both sides of the first

member and either side to the vertical support 110. More specifically, the first guiding member 124a is placed on the left side lower portion of the first member 120 and the second guiding member 124b is placed on the right side lower portion of the first member 120 and is adapted to configure in front of both eyes. A slider 126 is placed on a top portion of the first member 120 for sliding the guiding members 124a, 124b, as shown in figures 1, 2.

[0029] The guiding members 124a, 124b are slid in the left direction and the right direction to configure a desire position to positively fit on the eyes of the user/patient. Specifically, the eyes are considered as a standard reference point for medial or lateral deviation of maxillae because eyes are equidistant from mid-sagittal plane eyes and also derived embryologically directly from a brain and meant to be symmetrical always, thus the guiding members 124a, 124b is placed therein, as shown in figure 3. In this embodiment, by sliding, the first guiding member 124a slides in the left direction and the second guiding member 124b slides in the right direction respectively away from the vertical support 110. The guiding members 124a, 124b is for measuring a pupillary distance of a person by the horizontal millimeter scale of the first member 120. Specifically, a right maxilla and the left maxilla are assessed separately on the first member 120 connecting the guiding members 124a, 124b.

[0030] Referring again to figure 1, a first set of bows and a second bow 140 is slidably placed on a substantially middle portion of the vertical

support 110. The first set of bows includes an inner bow 130a and an outer bow 130b. The first set of bows 130a, 130b and the second bow 140 are made of a flexible material to adjust it according to the shape of the mouth of the patient. In the present embodiment, the first set of bows 130a, 130b and the second bow 140 are removably placed on the vertical support 110. The first set of bows 130a, 130b and the second bow 140 are in a horseshoe-shaped structure. Further, the first set of bows 130a, 130b and the second bow 140 are engraved with a millimeter scale (not shown) to assess the dentoalveolar asymmetry therein.

[0031] The first set of bows 130a, 130b extend outwards symmetrically on both sides of the vertical support 110. Further, the inner bow 130a and the outer bow 130b are attached to each other and are configured on the vertical support 110. Specifically, the inner bow 130a is adapted to place in an inside periphery of the user/patient's mouth and the outer bow 130b is adapted to place on an outside periphery of the patient's mouth. In the present embodiment, the first set of bows 130a, 130b are provided for measuring a discrepancy between right and left maxilla or maxillary dentition which is reflected onto the second member 122. Specifically, the discrepancy between right and left maxilla or maxillary dentition is reflected onto the horizontal millimeter scale of the first member 120. In another embodiment, the discrepancy between right and left maxilla or maxillary dentition may be measured by using an external millimeter scale.

[0032] Further, the second bow 140 is slidably placed on the vertical support 110. Specifically, the second bow 140 is placed below the first set of bows 130a, 130b. In the present embodiment, the second bow 140 is placed on the lower border of the mandible. It may be obvious to a person skilled in the art to slide the second bow and maxilla or upper jaw to measure asymmetry therein. The second bow 140 is provided to assess the skeletal and the mandibular asymmetry. Also, the second bow 140 assesses a vertical discrepancy by assessing from lower border to occlusal plane and from lower border to the interpupillary plane. Specifically, the vertical discrepancy is assessed over from a lower border to an occlusal plane and from a lower border to the interpupillary plane.

[0033] By way of non-limiting example, the three-dimensional discrepancy such as vertical, transverse and sagittal is measured by using the device 100, in an exemplary embodiment of the device for measuring the three-dimensional discrepancy is explained below respectively:

[0034] The vertical discrepancy such as the discrepancy between right and left maxilla or maxillary dentition is done by the vertical support 110 and that is reflected onto the vertical millimeter-scale 115 placed thereon. Also, the vertical discrepancy is assessed over from lower border to occlusal plane and from lower border to the interpupillary plane using the first set of bow 130a, 130b and the second bow 140. Further, the transverse discrepancy is measured from the center of a pupil to the respective occlusal plane vertically downwards that will help

us to measure the discrepancy between right and left maxillae using the first set of bow 130a, 130b and the second bow 140. The pupil to the occlusal plane is measured vertically of the left side and the right side separately. Both the data are compared to fin the asymmetry therein. Further, for measuring the sagittal discrepancy, horizontal interdental measurements can be done with a scale measuring the distance between teeth transversely and an anterior-posterior measurement is done with an external millimeter scale.

[0035] Therefore, the device 100 is measuring all the discrepancy in all the three dimensions of space that gives the orthodontist an analyzed data to decide and treat the area of a patient's face need to be treated.

[0036] Therefore, the advantage of the present invention is to provide a measuring device 100 for assessing and measuring a dentoalveolar asymmetry. The measuring device 100 is used for measuring dental asymmetries for treating a variety of functional deviations orthodontically. Further, the measuring device 100 assessed and measured the dentoalveolar asymmetries numerically which help a dentist in treatment planning, diagnosis of the dental asymmetries of a patient. Also, the measuring device 100 has graduated scales in all three planes of space namely vertical, transverse, and sagittal. The measuring device 100 measures from the center of the pupil to the respective occlusal plane vertically downwards that help to measure the discrepancy between right and left maxillae. Further, the measuring device 100 is compact and robust.

[0037] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously, many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to explain the principles of the present invention best and its practical application, to thereby enable others skilled in the art to best utilize the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omission and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such are intended to cover the application or implementation without departing from the spirit or scope of the present invention.

I Claim:

1. A measuring device 100 for assessing and measuring a dentoalveolar asymmetry, the measuring device 100 having a vertical support 110 with a vertical millimeter-scale 115 engraved thereon, the measuring device 100 comprising:

a first member 120 arranged to a top portion of the vertical support 110 and is an elongated member extending transversely across the longitudinal axis of the vertical support 110, the first member 120 is having a horizontal millimeter-scale thereon;

a second member 122 arranged on the top portion of the vertical support 110 intersecting the first member perpendicularly and extends perpendicularly from the vertical member in an axis facing towards a face of a user/patient, the second member 122 is adapted to place in contact over glabella for providing stability for measuring the distance from the glabella to the mandible;

a two guiding members 124a, 124b slidably arranged on a lower portion of the first member 120 and configured either side to the vertical support 110 for measures a pupillary distance of a person by the vertical millimeter-scale 115 of the first member 120;

a first set of bows 130a, 130b is slidably placed on the vertical support 110 extending outwards symmetrically on both sides thereof, the first set of bows 130a, 130b is having an inner bow and an outer bow which is placed in left and right side in the mouth to measure a discrepancy between right and left maxilla or maxillary dentition which is reflected onto the second member 122;

a second bow 140 is slidably placed below the first set of bows 130a, 130b on the vertical support 110, the second bow 140 placed on the lower border of the mandible to assess a skeletal, a mandibular asymmetry.

2. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the first set of bow 130a, 130b, and the second bow 140 is in a horseshoe-shaped structure.

3. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the second bow 140 assesses a vertical discrepancy by assessing from lower border to an occlusal plane and from lower border to the interpupillary plane.

4. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the first member 120 is an elongated member extending transversely across the longitudinal axis of the vertical support 110.

5. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the second member 122 is also arranged on the top portion of the vertical support 110 intersecting the first member perpendicularly.

6. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the second member 122 extends perpendicularly from the vertical member 110 in an axis facing towards a face of a user/patient.

7. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the two guiding members 124a, 124b are an eye-piece in a circular shape.

8. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the two guiding members 124a, 124b are slidably arranged on both sides of the first member and either side to the vertical support 110.

9. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the first set of bows includes an inner bow 130a and an outer bow 130b and the second bow 140 is removably placed on the vertical support 110.

10. The dental measuring device 100 for assessing and measuring a facial information as claimed in claim 1, wherein the first set of bows 130a, 130b and the second bow140 are made of by a flexible material to adjust according to the of a person.

Dated this May 29, 2020

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Reg. No.: IN/PA-1773

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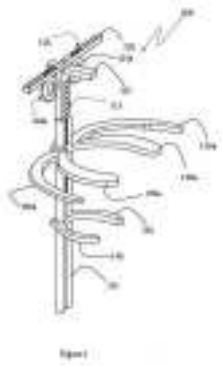
Abstract

Title: A Measuring Device for Assessing and Measuring a Dentoalveolar Asymmetry

The present invention is to provide a measuring device 100 for assessing and measuring a dentoalveolar asymmetry. The measuring device 100 having a vertical support 110 engraved with a vertical millimeter-scale 115. A first member 120 is arranged to a distal end of the vertical support 110 and extends perpendicularly on both sides equally, a second member 122 is also arranged on the distal end of the vertical support 110 and extends perpendicularly from the vertical member and the first member 120 toward a face. Further, two guiding members 124a, 124b are slidably arranged on the first member 120 to measures a pupillary distance of a person. A first set of bows 130a, 130b, and a second bow 140 is slidably placed on the vertical support 110 for measuring a discrepancy between right and left maxilla or maxillary dentition and to assess a skeletal and a mandibular asymmetry respectively.

Figure 1



FORM-2

THE PATENTS ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

COMPLETE SPECIFICATION

(SECTION 10, RULE 13)

TITLE

"A PROCESS FOR PREPARING IMMEDIATE RELEASE TOPICAL FORMULATION OF *PTEROCARPUS MARSUPIUM ROXB"*

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The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF THE INVENTION

The present invention relates to a *Pterocarpus marsupium Roxb.* More particularly, the present invention relates to a process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb*.

BACKGROUND OF THE INVENTION

Inflammation is a normal protective response to tissue injury caused by physical trauma, noxious chemical or microbial agents. The commonly used drug for management of inflammatory conditions are non-steroidal anti-inflammatory drugs, which have several adverse effects especially gastric irritation leading to formation of gastric ulcers, Natural products of plant extracts administered through topical route may be a better alternative in inflammation.

Pterocarpus marsupium Roxb (Family Leguminoceae) commonly known as Bijasar, is widely cultivated in India. The plantis a source of polyphenolic compounds such as stilbene, pterostilbenecatechin, epicatechin, flavonoids, pseudobaptigenin, liquiritigenin, chalcone, isoliquiritigenin *(R.MAURYA, A.B. RAY,F.K. DCAH, D.J. SLATKIN, and P.L. SCHIFF, JR. CONSTITUENTS OF PTEROCARPUS MARSUPIUM, Journal of Natural Products Vol. 47, No. 1,pp. 179-181. Jan-Feb 1984)*. The plant is usefulas anti-hyperlipidemic *(MA. FARBOODNIAY JAHROMI, ANE B. RAY and J.P.N. CHANSOUR.ANTIHYPERLIPIDEMIC EFFECT OF FLAVONOIDS FROM PTEROCARPUS MARSUPIUM, Jouml of Natural Products Val. 56, NO. 7, pp. 989-994, July 1993)*, anti-inflammatory *(Mohammed Rageeb, Mohammedusman,PathanEkbalkhaH,JainbhratV,PawarSandeep R,Invitro anti-inflammatory activity of PterocarpusmarsupiumRoxb on albino rat,Journal of pharmaceutical and scientific innovation,2012.)*, anti-oxidant *(RadhikaTippani,MahendarPorika,VenkateshamAllenki,R. N. R. Anreddy,Narsimha Reddy Yellu, Antioxidant and Analgesic Activities of Pterocarpusmarsupium Roxb,Journal of Herbs, Spices & Medicinal Plants , Volume 16, 2010 - Issue 1)*and also useful in the treatment of liver damage (Jadhav Anil G., DhikaleRupali S., PatilMrutyunjay B, HEPATOPROTECTIVE

ACTIVITY OF PTEROCARPUS MARSUPIUM HEARTWOOD AGAINST CARBON TETRACHLORIDE INDUCED HEPATOTOXICITY IN FEMALE ALBINO WISTAR RATS, Int. J. Res. Ayurveda Pharm. 10 (4), 2019).

Chitosan (polymer) based sustained release formulation of *Pterocarpus marsupium Roxb* & process for preparing such sustained release formulationis available in existing art (**1.**Anupama Ammulu Manne et al, *Pterocarpus marsupium Roxb. Heartwood extracts synthesized chitosan nanoparticles and its biomedical applications, 2020, Journal of Genetic Engineering and Biotechnology, 18:19, Pg No. 1-13*& **2.***SK Patil et al., Comparative Studies on Anti-Inflammatory Activity of Hydrogels Containing Herbal Extracts, IJPCBS 2012, 2(4), 612-616*). However, the acute inflammation requires an immediate effect of the drug that can only be possible when the maximum amount of the drug released in lesser time and these documents failed to suggest how to prepare the immediate release topical formulation of *Pterocarpus marsupium Roxb.*

The other drawbacks/limitation associated with *Anupama Ammulu Manne et al* (Document 1) & *SK Patil et al* (Document 2) are:

i) Document1 shows 676± 2.76 nm as the particle size of the formulation is large (676± 2.76 nm) which may not be suitable for achieving quick onset of the action for the drug;

ii) According to Document 1, the entrapment efficiency is dependent on the concentration of drug, in other words higher the drug concentration higher the entrapment efficiency. Hence the amount of the drug to be used is more (15% in Document 1 and 1g in Document 2) which is not desired;

iii) The pH of the formulation in Document 2 is 6 whereas the pH of skin is 4.7-5.75 and no in-vitro/ in-vivo release study is discussed in this prior art which may raise a very valid question for authenticity of the results;

iv) As nature of the formulation is hydrogel type in Document 2, mechanical strength of the formulation may be weak;

v) No in-vivo or in-vitro study is disclosed in Document 1 upon which a person-skilled-in-art would understand the route of administration;

vi) pH of the final formulation is not disclosed in Document 1 therefore the target organ on which the drug is to be released is not clear;

vii) For achieving the desired effect, pH of the formulation must be stable over extended period of time. Document 1 & 2 failed to suggest such extended effect;

viii) As Document 2 uses ethanol as penetration enhancer for achieving the final effect, it enhances cost of the formulation;&

ix) The hydrogel is known *(Shailesh Kumar Singh, ArchanaDhyani and DivyaJuyal, Hydrogel: Preparation, Characterization and Applications, The Pharma Innovation Journal 2017; 6(6): 25-32)* to be difficult in handling and loading as they are very spongy, highly flexible and contain about 90% of water. &

x) Hydrogels are non-adherent to the skin and needs secondary dressing for the application.

In existing technology, Gaikwad DD. et al *(Dr. Gaikwad DD et al, Formulation and Evaluation of the Herbal Tablets of Pterocarpus marsupium, IJIPSR, 2016, 732-743)* discloses the immediate release oral solid unit dosage form (Tablet) of *Pterocarpus marsupium* for free-radical scavenging activity. Immediate release topical formulation of *Pterocarpus marsupium* & the method for manufacturing the same is not disclosed in this prior art.

Therefore there is a need to overcome the aforesaid drawbacks and accordingly provide a process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb*.

OBJECTIVE OF THE INVENTION

It is objective of the invention is to overcome the aforementioned drawbacks.

It is another objective of the invention is to provide a simple process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb.*

It is yet another objective of the invention is to provide a process which can be ended into a formulation of *Pterocarpus marsupium Roxb* with lesser droplet size thereby achieved faster absorption of the drug.

It is yet another objective of the invention is to provide a process which can result a formulation with lesser amount of the drug for achieving the therapeutic effect.

It is yet another objective of the invention is to provide a process which can be ended into a formulation of *Pterocarpus Marsupium Roxb* with suitable pH.

It is yet another objective of the invention is to provide a process for preparing formulation of *Pterocarpus Marsupium Roxb* in which the said formulation can be stable over the extended period of time.

It is yet another objective of the invention is to provide a process for preparing formulation of *Pterocarpus Marsupium Roxb*in which no penetration enhancer is used for achieving the therapeutic effect.

It is yet another objective of the invention is to provide a process for preparing formulation of *Pterocarpus Marsupium Roxb* in which the said formulation is viscous such that it could retain onto the skin for a longer period.

It is yet another objective of the invention is to providea process that results an easy to handle topical formulation of *Pterocarpus Marsupium Roxb*.

It is yet another objective of the invention is to prepare a formulation of *Pterocarpus Marsupium Roxb* with commonly available pharmaceutical excipient such as oil, water, surfactant, co-surfactant & preservative and without any polymer.

It is yet another objective of the invention is to provide the immediate release stable anti-inflammatory topical formulation of *Pterocarpus marsupium Roxb.*

SUMMARY OF THE INVENTION

According to one aspect, there is provided a process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb* comprises of

i) preparing an oil phase by mixing an oil having specific gravity of 0.860-1.046 and first preservative and heating the mixture at 60°C until the preservative melts in the said oil;

ii) stirring the oil phase as obtained in step (i) for 30 minutes;

iii) preparing an aqueous phase by mixing aqueous extract of *Psterocarpus marsupium,* surfactant, co-surfactant, buffer and second preservative at 60°C;

iv) dispersing the oil phase of step (ii) into the aqueous phase of step (iii) to form an oil-in-water mixture and stirring the said dispersion for 30 minutes;

v) adding a rheological modifier to the mixture as obtained in step (iv) and heating the said mixture at 70°C for 5 minutes;&

vi) stirring the mixture as obtained in step (v) for 30 minute to form a homogeneous mixture as the immediate release topical formulation;

wherein the stirring speed in step (i) and step (ii) is 910rpm; and

wherein the stirring speed in step (iv) and step (vi) is 1500rpm.

According to another aspect of the invention, there is provided a stable immediate release topical formulation of *Pterocarpus marsupium Roxb* includes an oil-in-water emulsion typed cream, said cream comprises of:

i) aqueous extract of *Pterocarpus marsupium Roxb* in an amount of 5% by weight;
ii) coconut oil in an amount of 10.95% by weight;
iii) polyoxyethylene sorbitanmonooleate in an amount of 17.5% by weight;
iv) polyethylene glycol 400 in an amount of 5.9% by weight; &
v) aqueous phosphate buffer in an amount of 55.5% by weight;
vi) cetostearyl alcohol in an amount of 5% by weight;
vii) propyl paraben in an amount of 0.05% by weight; and
viii) methylparaben in an amount of 0.1% by weight.

In accordance with these and other objects, this will become apparent herein after, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 is a flow chart of the process in accordance with the present invention;

Figure 2 illustrates comparative polydispersity index in accordance with the present invention;

Figure 3 illustrates comparative drug entrapment efficiency in accordance with the present invention;

Figure 4 illustrates comparative droplet size in accordance with the present invention;

Figure 5 illustrates comparative %drug release in accordance with the present invention;

Figure 6 illustrates comparative stability studies (6 months pH study of the formulation) in accordance with the present invention; &

Figure 7 illustrates comparative anti-inflammatory activity in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Expression:

"The drug" herein is aqueous extracts of *Pterocarpus marsupium Roxb.*

"Immediate release" herein is maximum drug release in lesser time from the formulation.

"Stable formulation" herein is the formulation whose pH is equilibrium to the pH of skin (targeted organ) at the time of delivery and over the extended period of time.

"Entrapment efficiency" herein is the ratio/amount of the components which is capable to load maximum amount of the drug into the formulation and is not related to the concentration of drug per se.

"Poly-dispersity index (PDI)" herein is related to homogeneity of the formulation. If the PDI value is greater than 1 then the formulation cannot be said as homogeneous. On the other hand, lowest value of PDI denotes the highest or superior homogeneity.

"Rheological modifier" herein means to enhance the viscosity of the formulation.

Referring to Figure 1, the present invention provides a process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb* comprising the steps of:

i) preparing an oil phase by mixing an oil and first preservative and heating the mixture at 60°C until the preservative melts in the said oil;

ii) stirring the oil phase as obtained in step (i) for 30 minutes;

iii) preparing an aqueous phase by mixing aqueous extract of *Psterocarpus marsupium,* surfactant, co-surfactant, buffer and second preservative at 60°C;

iv) dispersing the oil phase of step (ii) into the aqueous phase of step (iii) to form an oil-in-water mixture and stirring the said mixture for 30 minutes;

v) adding a rheological modifier to the mixture as obtained in step (iv) and heating the said mixture at 70°C for 5 minutes;&

vi) stirring the mixture as obtained in step (v) for 30 minute to form a homogeneous mixture as the immediate release topical formulation.

In an embodiment of the invention, the oil is selected from a group having specific gravity of 0.860-1.046 includes coconut oil, rose oil, arachis oil, castor oil, clove oil, olive oil and almond oil. In preferred embodiment of the invention, the oil is coconut oil.

In an embodiment of the invention, the surfactant is selected from a group consisting of Tween 80 (polyoxyethylene sorbitanmonooleate), Tween 20 (Polyoxyethylene sorbitanmonolaurate), Labrafil or Labrasol. In preferred embodiment, the surfactant is Tween 80.

In an embodiment of the invention, the co-surfactant is selected from a group consisting of polyethylene glycol 400 (PEG 400) or polyethylene glycol 200 (PEG 200). In preferred embodiment, the co-surfactant is PEG400.

In preferred embodiment of the invention, the buffer is aqueous phosphate buffer (pH = 5.5).

In preferred embodiment of the invention, the rheological modifier is cetostrearyl alcohol.

In preferred embodiment of the invention, the first preservative is propyl paraben while the second preservative is methyl paraben.

In preferred embodiment of the invention, amount of the drug is 5% by weight. On the other hand, amount of the oil is 10.95% while the amount of surfactant and co-surfactant is 17.5% and 5.9% by weight. The amount of the aqueous phosphate buffer according to present invention is 55.5% by weight while amount of the rheological modifier is 5% by weight. The amount of the first preservative and second preservative is 0.05% and 0.1% respectively. The immediate release effect of the drug would not be achieved if the aforesaid ranges are varied.

In preferred embodiment of the invention, speed of the stirring in step (i) & is(ii) is 910rpm while in step (iv) and step (vi) is 1500rpm respectively. The desired consistency, uniformity and particle size would not be possible if the aforesaid stirring condition is varied.

In an embodiment of the present invention, present invention provides a viscous, stable immediate release topical formulation of *Pterocarpus marsupium Roxb* comprises of:

i) aqueous extract of *Pterocarpus marsupium Roxb* in an amount of 5% by weight;
ii) oil in an amount of 10.95% by weight;
iii) surfactant in an amount of 17.5% by weight;
iv) co-surfactant in an amount of 5.9% by weight; &
v) aqueous phosphate buffer in an amount of 55.5% by weight;
vi) rheological modifier in an amount of 5% by weight;
vii) first preservative in an amount of 0.05% by weight; &
viii) second preservative in an amount of 0.1% by weight.

In an embodiment of the invention, the oil is selected from a group consisting of Coconut oil, rose oil, arachis oil, castor oil, clove oil, olive oil or almond oil. In preferred embodiment of the invention, the oil is coconut oil.

In an embodiment of the invention, the surfactant is selected from a group consisting of Tween 80 (polyoxyethylene sorbitanmonooleate), Tween 20 (Polyoxyethylene sorbitanmonolaurate), Labrafil or Labrasol. In preferred embodiment, the surfactant is Tween 80.

In an embodiment of the invention, the co-surfactant is selected from a group consisting of polyethylene glycol 400 (PEG 400) or polyethylene glycol 200 (PEG 200). In preferred embodiment, the co-surfactant is PEG400.

In preferred embodiment of the invention, the buffer is aqueous phosphate buffer (pH = 5.5).

In preferred embodiment of the invention, the rheological modifier is cetostrearyl alcohol.

In preferred embodiment of the invention, the first preservative is propyl paraben while the second preservative is methyl paraben.

In preferred embodiment of the invention, the topical formulation is cream.

In an embodiment of the invention, the cream is oil-in-water (O/W) type emulsion.

In preferred embodiment of the invention, droplet of the emulsion is 100nm.

In preferred embodiment of the invention, polydispersity index of the formulation is less than 0.2.

In preferred embodiment of the invention, pH of the formulation is 5.5-5.7.

In an embodiment of the invention, no penetration enhancer is used for preparing the formulation.

In an embodiment of the invention, the topical formulation can be applied for the faster treatment of acute inflammation.

The invention is now illustrated by the non-limiting examples:

Materials: Aqueous extract *Pterocarpus Marsupium* (Amorphous Powder form) was obtained from YUCCA ENTERPRISE MUMBAI, India. The other excipients were purchased from RL Fine Chem Pvt. Ltd. Mumbai India.

EXAMPLE 1(INVENTIVE EXAMPLE):

Preparation of Aqueous phosphate buffer (pH 5.5):13.61g of potassium dihydrogen phosphate was dissolved in distill water and dilute to 1000mL with the same solvent (solution A). 35.81g of disodium hydrogen phosphate was dissolved in distill water and dilute to 1000mL with the same solvent (solution B). 96.4 mL of solution A and 3.6 mL of solution B were mixed.

Preparation of Cream:

Method: An oil phase was prepared by mixing 0.05wt% of propyleparaben and 10.95wt% of coconut oil and said mixture was heated at water bath (60°C). Then the oil phase was stirred at 910rpm for 30minutes. The aqueous phase was prepared by mixing 5wt% of aqueous extract of *Psterocarpus marsupium*, 17.5wt% of Tween 80, 5.9wt% of PEG400, 55wt% of aqueous phosphate buffer (pH 5.5) and 0.1wt% of methyl paraben at 60°C. The aforesaid oil phase was dispersed into the aqueous phase and the said mixture was then stirred at 1500rpm for 15minute to form O/W emulsion.Cetostrearyl alcohol was added into the emulsion and the said product was heated at 70°C using water bath. Then the product was stirred at 1500rpm for 30minutes using T25 Ultra-Turrax (IKA, USA) homogenizer(Make & Model) to obtain a homogeneous mixture as cream.

Formula F1:

Ingredients	Quantity (% Wt)

Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	10.95%
Tween 80	17.5%
PEG400	5.9%
Aqueous Phosphate Buffer	55%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	5.0%

EXAMPLE 2 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components and the first stirring condition. In this method, the amount of the components is used as follows and stirring speed and time is 800rpm and 20minute respectively.

Formula F2:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpus marsupium*	5.0%
Coconut oil	14.45%
Tween 80	17.5%
PEG400	6.0%
Aqueous Phosphate Buffer	46.9%

Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	10.0%

EXAMPLE 3 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components and the second stirring condition. In this method, the amount of the components is used as follows and stirring speed and time is 1000rpm and 40minute respectively.

Formula F3:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	17.5%
Tween 80	17.5%
PEG400	16.5%
Aqueous Phosphate Buffer	35.85%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	7.5%

EXAMPLE 4 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components and the third stirring condition. In this

method, the amount of the components is used as follows and stirring speed and time is 1200rpm and 50minute respectively.

Formula F4:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	17.5%
Tween 80	30.0%
PEG400	5.0%
Aqueous Phosphate Buffer	32.35%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	10.0%

EXAMPLE 5 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components. In this method, the amount of the components is used as follows:

Formula F5:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	10.0%
Tween 80	30.0%

PEG400	5.0%
Aqueous Phosphate Buffer	42.35%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	7.5%

EXAMPLE 6 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components. In this method, the amount of the components is used as follows:

Formula F6:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	10.15%
Tween 80	23.75%
PEG400	10.1%
Aqueous Phosphate Buffer	40.85%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	10.0%

EXAMPLE 7 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components. In this method, the amount of the components is used as follows:

Formula F7:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	11.8%
Tween 80	23.75%
PEG400	8.95%
Aqueous Phosphate Buffer	42.85%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	7.5%

EXAMPLE 8 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components. In this method, the amount of the components is used as follows:

Formula F8:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	7.25%

Tween 80	30.0%
PEG400	5.5%
Aqueous Phosphate Buffer	47.1%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	5.0%

EXAMPLE 9 (Comparative Example):

Method: Cream was prepared as per the method described in Example 1 except amount of the components. In this method, the amount of the components is used as follows:

Formula F9:

Ingredients	Quantity (% Wt)
Aqueous extract of *Psterocarpusmarsupium*	5.0%
Coconut oil	10.0%
Tween 80	23.75%
PEG400	10.5%
Aqueous Phosphate Buffer	45.6%
Methyl Paraben	0.1%
Propyl Paraben	0.05%
Cetostrearyl alcohol	5.0%

EVALUATION OF THE CREAM (F1-F9):

a.OrganolepticChracterization:

The developed cream (F1-F9) was tested for physical appearance, color, texture, phase separation and homogeneity. Homogeneity and texture were tested by pressing a small quantity of the cream between the thumb and index finger.

b.pH:

pH of the cream (F1-F9) was determined by using Digital pH meter(Equiptronics). One gram of cream was added in 100 ml of distilled water and stored for two hours. The pH of the cream was determined at 27°C using digital pH meter.

c.TubeExtrudability:

It is usual empirical test to measure the force required to extrude the material from tube. More quantity extruded signifies better Extrudability. The cream (F1-F9) was filled in clean, lacquered aluminum collapsible tube with nozzle tube of 5mm opening and applies pressure on tube by the help of finger. Tube extrudability was then determined by measuring amount of the formulation extruded.

e.Spreadability:

Spreadability of the formulations was determined by measuring the spreading diameter of 1g of sample between two horizontal glass plates (10 cm × 20 cm) after one minute. The standard weight applied to the upper plate was 500 g.

$S = M \times L / T$

Where, S= Spreadability, M= weight in the pan (tied to upper slide), L= Length moved by the slide, T= Time (in sec).

f.Viscosity Measurement:

The viscosity of the formulation (F1-F9) was measured using Malvern zeta sizer at room temperature (28°C±20°C).

g.Dropletsize measurement:

The droplet size of the formulation (F1-F9)was measured using Zeta Sizer 1000 HS_A, (Malvern Instrument, UK). In this test, the sample(1mg) was diluted with the phosphate bufferto determine the Z average value.

h. Drug entrapment efficiency:

Drug entrapment efficiency of the formulation (F1-F9) was determined using a centrifugal filtration device (Microcon Millipore, Billerica, MA) with a 100 kDa molecular weight cut-off filter. 200mL of the formulation was added to the sample reservoir of the Microconsystem and then was centrifuged at 1500rpmfor 50min to separate the entrapped and untrapped components. The entrapped component was washed twice with 200mL of distilled water and weighed.The whole filtrate was collected and referred to as the untrapped component, which was evaporated and dissolved with 200 mL of DMSOThe entrapment efficiency (%EE) was calculated using the following equations:

$$\% EE = \frac{\text{weight of entrapped drug}}{\text{initial weight of drug}} \times 100$$

Table 1: Comparative evaluation of cream

Parameter	F1**(inventive)**	F2	F3	F4	F5	F6	F7	F8	F9
Colour	white	white	White	white	white	white	white	white	white
Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
Appearance	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
Spreadability (gcm/sec)	32.1±0.87	10.12 ±0.23	11.8±0.36	13.3± 0.58	14.3±0.46	12.6 ±0.52	12.0± 0.98	12.5± 0.34	13.1± 0.21
Viscosity(cp)	10625± 0.45	26075 ± 0.78	26070± 0.09	27072 ± 0..98	26073± 0.96	2608 0± 0.48	26972 ± 0.54	26026 ± 0.76	25082 ± 0.56
Extruda	Good	Good	Good	Good	Good	Good	Good	Good	Good

bility									
pH	5.5±0.04	6.5±0.05	6.4±0.09	7±0.05	7.5±0.05	6.8±0.05	6.5±0.06	6.2±0.04	5.2±0.04
Polydispersity index	0.1	0.922	0.925	0.940	0.821	0.920	0.935	0.932	0.942
%EE	91.22%	70%	76%	75%	70%	72%	77%	69%	78%
Droplet size(nm)	100±0.9	325±0.93	319±0.93	340±0.93	314±0.57	336±0.57	348±0.93	356±0.57	357±0.57

Table 1 shows that the colour of the cream (Formula F1-F9) was found as white while the appearance was observed as smooth. The extrudability of all the formulas was found as good. As the viscosity of all the formulas was found more than 10000cp the cream would retain onto the targeted organ for longer time. As the polydispersity index of all the formulas was found below 1 therefore the cream is homogeneous. With regard to homogeneity, F1 was found as better formulation as it shows lowest value (Fig. 2) as compared to other formulas (F2-F9).With regard to pH, F1 and F9 were found as only formulas suitable for skin application (pH 4.7-5.75)whereaspH of other formulas (F2, F3, F4, F5, F6, F7, F8) was found beyond the pH of skin (4.7-5.75) [Table 1] and therefore not suitable for skin application. With regard to %encapsulation efficiency,F1 was found as superior formula (Fig. 3) over F2-F9 therefore better drug absorption would be possible. As compared to F2-F9, F1 was also found as the better formula in view of spreadability.With regard to the droplet size, lowest droplet size (Fig. 4) was found in F1 (Table 1) so higher surface area and therefore better drug absorption may be possible in F1 as compared to F2-F9.

i. Drug release study:

To study the release of *Pterocarpusmarsupium*fromformulation (F1 to F9) Franz diffusion cell was used in which volume of Receivercompartmentis 10mL and effective diffusion area is 2.84cm^2. The dialysis membrane is 0.65 micrometer.The receptor compartment was filled with 60% w/w ethanol and temperature was maintained at 33°C. 1gm of the formulation was placed in

the donor compartment and 1ml of sample from receiver compartment was withdrawn at the appropriate time. The same amount of fresh ample was added and volume was kept constant. The samples were analyzed byUV-Spectrophotometer (Systronics AU 2701) at the wavelength of 266nm and drug concentration was determined using the standard curve. *Pterocarpusmarsupium* with percentage purity 99.9% was used as standard curve.

Table 2: Comparative percentage drug release at 10 min

Sr. no	Formula	% drug release at 10 min
1	F1	71.12%
2	F2	35.67%
3	F 3	38.6%
4	F4	38.16%
5	F5	38.16%
6	F6	36.21%
7	F7	39.21%
8	F8	33.71%
9	F9	18.21%

Table 3: Comparative percentage drug release at 20 min

Sr. no	Formula	% drug release at 20 min
1	F1	88.71%
2	F2	41.61 %
3	F 3	51.61 %
4	F4	44.12 %

5	F5	43.13%
6	F6	39.61%
7	F7	41.12 %
8	F8	40.21%
9	F9	41.61%

Table 4:Comparative percentage drug release at 30 min

Sr. no	Formula	% drug release at 30 min
1	F1	96.12 %
2	F2	56.39 %
3	F3	55.21%
4	F4	56.17 %
5	F5	57.16 %
6	F6	56.32 %
7	F7	56.13%
8	F8	45.21%
9	F9	58.16 %

The immediate drug release (71.12% in 10 minute, Table 1) was observed in F1 whereas F2-F9 shows the delayed drug release (Table 2-4, and Figure 5). Hence F1 may be the suitable formulation for the condition like acute inflammation where the immediate effect of the drug is needed.

j) Stability studies:

Stability study of the formulation (F1-F9) was conducted at 40±2°/75±5% RH as per the ICH guidelines. The samples were placedat temperature 40±2°/75±5% RH in a stability chamber.At periodic intervals of 1, 2, 3 and 6

months, all the samples which were stored at 40±2°/75±5% RH were studied for pH, appearance and viscosity.

F1:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	5.5±0.04	5.5±0.04	5.5±0.04	5.5±0.04	5.5±0.04
Appearance	smooth	smooth	smooth	smooth	smooth
Viscosity	10625± 0.45	10625± 0.45	10625± 0.45	10625± 0.45	10625± 0.45

F2:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	6.5±0.05	6.5±0.05	6.6±0.06	6.7±0.04	6.7±0.02
Appearance	smooth	smooth	smooth	smooth	graininess
Viscosity(cp)	26075± 0.78	31207± 0.34	41008± 0.25	49805± 0.64	58076± 0.56

F3:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	6.4±0.09	7.4±0.03	7.8±0.07	8.4±0.02	8.9±0.03
Appearance	smooth	smooth	smooth	graininess	graininess
Viscosity	26070± 0.09	37090± 0.03	`46054± 0.02	51121± 0.01	54770± 0.09

F4:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	7±0.05	7± 0.02	8.48± 0.08	87.6± 0.05	89.3± 0.02
Appearance	smooth	smooth	smooth	smooth	graininess
Viscosity	27072± 0..98	38073± 0.5	45043± 0.56	46035± 0.23	54043± 0.21

F5:

5

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	7.5±0.05	7.8± 0.02	7.98± 0.04	8.6± 0.02	8.43± 0.01
Appearance	smooth	smooth	smooth	graininess	graininess
Viscosity	26073± 0.96	37073± 0.34	39083± 0.25	45053± 0.64	53076± 0.56

F6:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	6.8±0.05	8.0± 0.12	8.1± 0.02	8.7± 0.03	8.8± 0.023
Appearance	smooth	smooth	smooth	graininess	graininess
Viscosity	26080± 0.48	38072± 0.14	39181± 0.11	42143± 0.4	51471± 0.16

F7:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	6.5±0.06	7.3± 0.023	7.21± 0.012	8.21± 0.01	8.42± 0.02
Appearance	smooth	smooth	smooth	graininess	graininess
Viscosity	26972± 0.54	37023± 0.53	40000± 0.12	44052± 0.13	45540± 0.13

F8:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	6.5±0.06	7.2± 0.01	7.6± 0.02	8.8± 0.01	8.93± 0.03
Appearance	smooth	smooth	smooth	graininess	graininess
Viscosity	26026± 0.76	37056± 0.54	47089± 0.02	49083± 0.43	50047± 0.78

F9:

Parameter	40±2°/75±5% RH				
	0 Month	1 month	2 month	3 month	6 month
pH	5.2±0.04	6.2± 0.01	6.28± 0.03	8.2± 0.01	8.41± 0.01
Appearance	smooth	smooth	smooth	graininess	graininess
Viscosity	25082± 0.56	36073± 0.14	47021± 0.23	51013± 0.24	53016± 0.34

pH is main indicator of the stability study as if pH of the formulation is not within the limit (4.7-5.75) over extended period of time then the formulation

is of no use. pH of F2-F8 was found as more than 6.0 at very initial stage (0 month) therefore these formulation is of no use for skin application. pH of F9 was found as 5.2 at 0 month but later on it was found as more than 6 months therefore can't be used anymore. Surprisingly, the desired effect was found in F1 only as this formulation shows the suitable pH (5.5.) over the extended period of time i.e. 6 months (Figure 6).

With regard to the appearance, F2 & F4 was found as graininess after 6 months while the same was found for formula F3, F5-F9 after 3 months. Contrary to this, the appearance of F1 was found as smooth over 6 months. In view of the viscosity parameter, F1 was also found as consistent formula over the extended period of time with regard to F2-F9. Hence F1 was found as most stable formulation for skin use.

k) Anti-inflammatory Activity of the Extracts & the Formulation (F1-F9):

Denaturation of proteins is a well-documented cause of inflammation and rheumatoid arthritis *[Ishaku Leo Elisha1, Jean-Paul Dzoyem, Lyndy Joy McGaw, Francien S. Botha and Jacobus Nicolaas Eloff, The anti-arthritic, anti-inflammatory, antioxidant activity and relationships with total phenolics and total flavonoids of nine South African plants used traditionally to treat arthritis, BMC Complementary and Alternative Medicine (2016) 16:307 DOI 10.1186/s12906-016-1301-z*]. In present invention, the anti-inflammatory activity of aqueous extract of *Psterocarpus marsupium* (50 - 200 µg/ml) and the formulation F1-F9 (5.0%) was evaluated in view of percentage inhibition of protein denaturation. The procedure for protein denaturation activity of the aqueous extract of *Psterocarpus marsupium* and formulation (F1 –F9) was as follows:

Test solution of (1ml) containing different concentrations (50 - 200 µg/ml) of aqueous extract of *Psterocarpus marsupium* which was mixed with 1ml of egg albumin solution (1mM) and then incubated at 27 ±1 °C for 15 min.

Denaturation was induced by keeping the reaction mixture at 70^0C in a water bath for 10 min. After cooling, the turbidity was measured spectrophotometrically at 660nm. Percentage inhibition of denaturation was calculated from the control where no drug was added. Each experiment was carried out in triplicate and the average was taken.

Similarly, the formulation (F1-F9) containing 5.0% of aqueous extract *Psterocarpus marsupium* was evaluated. F1 was found as superior formulation as compared to F2-F9 in view of % inhibition of protein denaturation activity (Table 5 & Figure 7).

Table 5: % Inhibition of Protein Denaturation

Extracts/Formulation	Concentration (%)	% Inhibition of protein denaturation
Aqueous extract of *Psterocarpus marsupium*	50 (µg/ml)	43.31
	100 (µg/ml)	68.88
	200 (µg/ml)	85.11
F1	5%	94.73
F2	5%	57.89
F3	5%	55.63
F4	5%	65.73
F5	5%	52.63
F6	5%	44.73
F7	5%	48.26
F8	5%	47.36
F9	5%	55.26

Values are mean n=6

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been present for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which departs from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

I Claim:

1. A process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb* comprising the steps of:

   i) preparing an oil phase by mixing an oil having specific gravity of 0.860-1.046 and first preservative and heating the mixture at 60°C until the preservative melts in the said oil;

   ii) stirring the oil phase as obtained in step (i) for 30 minutes;

   iii) preparing an aqueous phase by mixing aqueous extract of *Psterocarpus marsupium,* surfactant, co-surfactant, buffer and second preservative at 60°C;

   iv) dispersing the oil phase of step (ii) into the aqueous phase of step (iii) to form an oil-in-water mixture and stirring the said mixture for 30 minutes;

   v) adding a rheological modifier to the mixture as obtained in step (iv) and heating the said mixture at 70°C for 5 minutes;&

   vi) stirring the mixture as obtained in step (v) for 30 minute to form a homogeneous mixture as the immediate release topical formulation;

   wherein the stirring speed in step (i) and step (ii) is 910rpm; and

   wherein the stirring speed in step (iv) and step (vi) is 1500rpm.

2. The process as claimed in claim 1 wherein the oil is selected from a group consisting of coconut oil, rose oil, arachis oil, castor oil, clove oil, olive oil or almond oil.

3. The process as claimed in claim 1, wherein the first preservative is propyl paraben.

4. The process as claimed in claim 1, wherein the second preservative is methyl paraben.

5. The process as claimed in claim 1, wherein the surfactant is selected from group consisting of polyoxyethylene sorbitan monooleate, Polyoxyethylene sorbitanmonolaurate, Labrafil or Labrasol.

6. The process as claimed in claim 1, wherein the co-surfactant is selected from a group consisting of polyethylene glycol 400 or polyethylene glycol 200.

7. The process as claimed in claim 1, wherein the buffer is aqueous phosphate buffer of pH 5.5.

8. The process as claimed in claim 1, wherein the rheological modifier is cetostearyl alcohol.

9. The process as claimed in claim 1, wherein amount of the oil is 10.95% by weight.

10. The process as claimed in claim 1, wherein amount of the first preservative is 0.05% by weight.

11. The process as claimed in claim 1, wherein amount of the second preservative is 0.05% by weight.

12. The process as claimed in claim 1, wherein amount of the surfactant is 17.5% by weight.

13. The process as claimed in claim 1, wherein amount of the co-surfactant is 5.9% by weight.

14. The process as claimed in claim 1, wherein amount of the aqueous phosphate buffer is 55.5% by weight.

15. The process as claimed in claim 1, wherein amount of aqueous *Pterocarpus marsupium Roxb* is 5% by weight.

16. The process as claimed in claim 1, wherein amount of the rheological modifier is 5% by weight.

17. A stable immediate release topical formulation of *Pterocarpus marsupium Roxb* includes an oil-in-water emulsion typed cream, said cream comprises of:

i) aqueous extract of *Pterocarpus marsupium Roxb* in an amount of 5% by weight;

ii) coconut oil in an amount of 10.95% by weight;

iii) polyoxyethylene sorbitanmonooleate in an amount of 17.5% by weight;

iv) polyethylene glycol 400 in an amount of 5.9% by weight;

v) aqueous phosphate buffer in an amount of 55.5% by weight;

vi) cetostearyl alcohol in an amount of 5% by weight;

vii) propyl paraben in an amount of 0.05% by weight; and

viii) methyl paraben in an amount of 0.1% by weight.

18. The formulation as claimed in claim 17, wherein droplet size of the emulsion is 100nm.

19. The formulation as claimed in claim 17, wherein pH of the formulation is 5.5-5.7.

20. The formulation as claimed in claim 17 is prepared without penetration enhancer.

Dated this 11th Day of August, 2020

Arghya Roy

(Arghya Ashis Roy)
Patent Agent (IN/PA 2346)
Of Lex-Regia
For the Applicant

To,
The Controller of Patents,
The Patent Office
Mumbai

ABSTRACT

"A PROCESS FOR PREPARING IMMEDIATE RELEASETOPICAL FORMULATION OF *PTEROCARPUS MARSUPIUM ROXB"*

A process for preparing immediate release topical formulation of *Pterocarpus marsupium Roxb* comprising the steps of: i) preparing an oil phase by mixing an oil having specific gravity of 0.860-1.046 and first preservative and heating the mixture at 60°C until the preservative melts in the said oil; ii) stirring the oil phase as obtained in step (i) for 30 minutes; iii) preparing an aqueous phase by mixing aqueous extract of *Psterocarpus marsupium,* surfactant, co-surfactant, buffer and second preservative at 60°C; iv) dispersing the oil phase of step (ii) into the aqueous phase of step (iii) to form an oil-in-water mixture and stirring the said mixture for 30 minutes; v) adding a rheological modifier to the mixture as obtained in step (iv) and heating the said mixture at 70°C for 5 minutes; & vi) stirring the mixture as obtained in step (v) for 30 minute to form a homogeneous mixture. Figure 1

FORM 2

THE PATENT ACT 1970

&

The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

1. TITLE OF THE INVENTION:

"A Training Device for the Treatment of Cerebral Palsy"

2. APPLICANT(s):

Name	Nationality	Address
Krishna Institute of Medical Sciences "Deemed to Be University", Karad	Indian Deemed Institute	Krishna Institute of Medical Science "Deemed to be University", Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed

Field of the invention

[0001] The present invention relates to a training device. More particularly, the present invention relates to a training device for treating cerebral palsy.

Background of the invention

[0002] Generally, various standing frames are provided for the treatment of children who are suffering from cerebral palsy. i.e. (who are unable to stand or have difficulty in standing). The available standing frames are not movable. However, there are some standing frames which are movable, but very costly to afford for the normal people. Also, the available standing frames do not provide proper support to children to stand for a longer period, which may lead to abnormal postural movement, contractures of a child. Further, the standing frames are not fully equipped with features that can train the upper limb as well as train the child to stand.

[0003] Furthermore, children suffering from cerebral palsy, have impairment of the upper limb which leads to participation restriction and difficulty in daily activities. Also, due to disturbed sensory information, the hand does not function properly. So, when a child tries to lift the object, finds it difficult in coordinating their fingers while gripping the object and releasing their grip from the object.

[0004] Till today, there is no such standing frame which can be a multi-utility training device and can overcome the drawback of the existing training devices.

[0005] Therefore, there is a need for a standing frame which can overcome the drawbacks of the existing prior art.

Objects of the invention

[0006] Object of the present invention is to provide a training device for the treatment of cerebral palsy.

[0007] Further object of the present invention is to provide a training device for the treatment of cerebral palsy, which provides proper support to a child to stand for a longer period and to train the upper limb.

[0008] One more object of the present invention is to provide a training device for the treatment of cerebral palsy, which helps in strengthening fingers and palm.

[0009] Further one object of the present invention is to provide a training device for the treatment of cerebral palsy, which is economical and simple in operation.

Summary of the invention:

[0010] According to the present invention, there is provided a training device for the treatment of cerebral palsy. The training device is having a base structure arranged on wheels. A plate is mounted on the base structure for providing a platform for standing thereon. In the present embodiment, the plate is a wood plank. Also, the base structure is having two vertical arms and two horizontal arms, thereby forming a rectangular shape therebetween.

[0011] Further, a first supporting member is extending vertically from the base structure. An ADL table is mounted on the first supporting member. Also, the ADL table is inclined, which has more than one pegboard arranged thereon to train an upper limb activity of the child. A second supporting member is arranged on the base structure opposite to the first supporting member. The second supporting member has more than one fastener for fastening the straps to the child.

Brief Description of the invention

[0012] Figure1 shows a schematic diagram of a training device for the treatment of cerebral palsy in accordance with the present invention;

[0013] Figure 2 shows a side view of figure 1;

[0014] Figure 3a shows a schematic diagram of a first fastener for anterior support to the shoulder;

[0015] Figure 3b shows a schematic diagram of the first fastener for posterior support to the shoulder;

[0016] Figure 4a shows a schematic diagram of a second fastener for anterior support to the knee;

[0017] Figure 4b shows a schematic diagram of the second fastener for posterior support to the knee;

[0018] Figure 5a shows a schematic diagram of a first fastener for anterior support to the ankle; and

[0019] Figure 5b shows a schematic diagram of the second fastener for posterior support to the ankle.

Details description of the invention

[0020] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising," "having," "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items, or meant to be limited to only the listed item or items.

[0021] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “a” and “an” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0022] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0023] The present invention provides a training device for the treatment of cerebral palsy. The training device provides proper support to a child to stand for a longer period and trains the upper limb. Also, the training device helps in strengthening fingers and palm. Further, the training device is economical and simple in operation.

[0024] Referring now to figures 1 and 2, a training device (100) for the treatment of cerebral palsy in accordance with the present invention is illustrated. The training device (100) includes a base structure (10), a plate (30), a first supporting member (40a), and a second supporting member (40b). The base structure (10) is arranged on wheels (20). In the present embodiment, four wheels are used. The wheels (20) are used to move the training device (100) in any direction. The wheels (20) have a latching arrangement (not shown in the figure) for restricting the movement of the training device (100), thereby ensuring the

safety of a child. Also, in the present embodiment, the base structure (10) is having two vertical arms (10a) and two horizontal arms (10b), thereby forming a rectangular shape therebetween. The plate (30) is mounted on the base structure (10) for providing a platform for standing thereon. In the present embodiment, the plate (30) is a wood plank. The plate (30) is mounted on the two horizontal arms (10b). In an alternate embodiment, the plate (30) can be sensory mats to improve gait(walking) or sensations of the foot. It may be obvious to a person skilled in the art to use any position sensor.

[0025] Referring again to figure 1 and 2, the first supporting member (40a) is extended vertically from the base structure (10). An ADL table (50) is mounted on the first supporting member (40a). The ADL table (50) is inclined at an angle. Also, the ADL table (50) is having more than one pegboard arranged thereon to train the upper limb activities of the child such as gripping objects, reaching to the objects, having strength and sensations in hand movements, gross motor training, fine motor training, coordination training, biofeedback training and the like. In the present embodiment, three pegboards are used. It may be obvious to a person skilled in the art to use more than three pegboards to train the upper limb activities of the child. The angle of the ADL table (50) is adjustable according to the height of the child to provide proper support to the upper limb of the child. Also, the angle of the ADL table is adjustable by 360 degrees thereby providing training to the child at various angles to improve trunk control, reduce spasticity and the like.

[0026] Further, the second supporting member (40b) is arranged on the base structure (10) opposite to the first supporting member (40a). The second supporting member (40b) is having more than one fastener (60) for fastening the straps to the child from falling. In the present embodiment, three fasteners are used. It may be obvious to a person skilled in the art to use more than three fasteners for fastening the straps. Specifically, a first fastener (60a) provides support to the shoulder of the child(as shown in figure 3a and 3b), a second fastener (60b) provides support to the knee of the child (as shown in figure 4a and 4b) and a third fastener provides support to the ankle of the child(as shown in figure 5a and 5b). Also, the height of the first supporting member (40a) and the second supporting member (40b) can be adjusted according to the height of the child to provide proper support to the upper limb and the lower limb of the child.

[0027] Therefore, the present invention provides an advantage of providing a training device (100) for the treatment of cerebral palsy. The training device (100) provides proper support to a child to stand for a longer period and trains the upper limb. Also, the training device (100) helps in strengthening fingers and palm. Further, the training device (100) is economical and simple in operation.

[0028] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and

description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously, many modifications and variations are possible considering the above teaching. The embodiments were chosen and described to best explain the principles of the present invention and its practical application, to thereby enable others skilled in the art to best utilize the present invention and various embodiments with various modifications as are suited to the use contemplated. It is understood that various omission and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such are intended to cover the application or implementation without departing from the spirit or scope of the description of the present invention.

We Claim:

1. A training device (100) for the treatment of cerebral palsy, the training device (100) comprising:

   a base structure (10) arranged on wheels (20).

   a plate (30) mounted on the base structure (10) for providing a platform for standing thereon;

   a first supporting member (40a) extending vertically from the base structure (10);

   an ADL table (50) mounted on the first supporting member (40a); and

   a second supporting member (40b) arranged on the base structure (10) opposite to the first supporting member (40a), the second supporting member (40b) has more than one fastener (60) for fastening the straps to the child, characterized in that;

   wherein the ADL table (50) is inclined and has more than one pegboard (70) arranged thereon to train an upper limb activity of the child.

2. The training device (100) for the treatment of cerebral palsy as claimed in claim 1, wherein the base structure (10) is having two vertical arms (10a) and two horizontal arms (10b), thereby forming a rectangular shape therebetween.

3. The training device (100) for the treatment of cerebral palsy as claimed in claim 1, wherein the plate (30) is a wood plank.

Dated this September 14, 2020

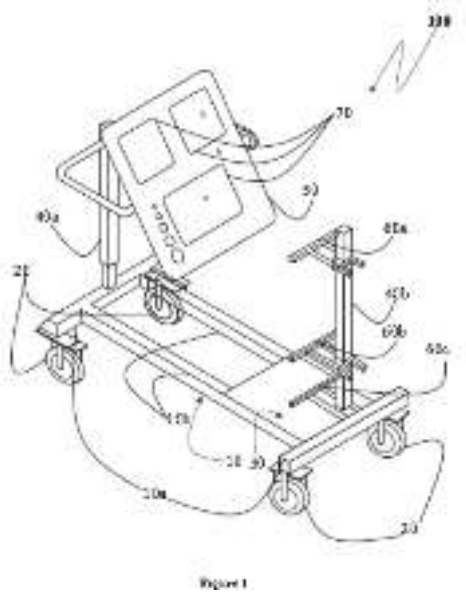
Suneet Baliram Sabale
(Agent for Applicant)
Reg. No.: IN/PA-1773

Abstract

Title: A training device for the treatment of cerebral palsy

The present invention provides a training (100) for the treatment of cerebral palsy. The training device (100) includes a base structure (10), which is arranged on wheels (20). A plate (30) is mounted on the base structure for providing a platform for standing thereon. A first supporting member (40a) is extending vertically from the base structure (10). Also, an ADL table (50) is mounted on the first supporting member (40a). Further, a second supporting member (40b) is arranged on the base structure (10) opposite to the first supporting member (40a). The second supporting member (40b) has more than one fastener (60) for fastening the straps to the child**.** Furthermore, the ADL table (50) is inclined and has more than one pegboard (70) arranged thereon to train an upper limb activity of the child.

Figure 1



FORM 2

THE PATENT ACT 1970

&

The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

1. TITLE OF THE INVENTION:

"A Manikin Device for Demonstrating Movement of a Human Body"

2. APPLICANT(s):

Name	Nationality	Address
YADAV, Trupti Saurabh	Indian	Krishna College of Physiotherapy, Krishna Institute of Medical Sciences "Deemed to be University", Karad, NH 4, Near Dhebewadi Road, Malkapur, Karad -415539, Maharashtra

3. PREAMBLE TO THE DESCRIPTION:

~~**PROVISIONAL**~~	**COMPLETE**
~~The following specification describes the invention.~~	The following specification particularly describes the invention and the manner in which it is to be performed.

Field of the invention

[0001] The present invention relates to a manikin device. More particularly, the present invention relates to a manikin device for demonstrating the movement of a human body in relation to axis and planes.

Background of the invention

[0002] Presently, there is no such equipment available for accurately demonstrating the movement of a human body in relation to axis and planes that can be used to train health practitioners or a medical professional. Currently, people use cardboard and pencils for demonstrating the movements of the human body such as axes, planes, and the like. To understand the movement of the human body in planes and axes, people turn the pencil around by placing the pencil on the cardboard as per the movement of the human body and demonstrate the movement in respective axis and plane. Therefore, it is not possible to understand the accurate movement of the human body.

[0003] To overcome the above-mentioned problem, few attempts have been made where a manikin is designed for demonstrating the movement of the human body but the design of the manikin were not portable. Also, the manikin were not able to demonstrate the movement of the human body properly.

[0004] To overcome one or all drawbacks of the existing manikin device, there is a need of a device which can accurately demonstrate the movements of the human body.

Object of the invention

[0005] An object of the present invention is to provide a manikin device for demonstrating movement of a human body.

[0006] Another object of the present invention is to provide a manikin device for demonstrating movement of a human body, which can be used as medical equipment for educational purposes or to train health practitioners.

[0007] Yet another object of the present invention is to provide a manikin device for demonstrating movement of a human body, which is useful for a practical demonstration of all the human body movements taking place in respective axes and planes in the human body.

[0008] One more object of the present invention is to provide a manikin device for demonstrating movement of a human body, which doesn't require any additional element to be placed for demonstrating axes and planes.

[0009] Further object of the present invention is to provide a manikin device for demonstrating movement of a human body, where movements can be performed easily.

[0010] Furthermore object of the present invention is to provide a manikin device for demonstrating movement of a human body, which perform all movements on the model by an individual without anybody's assistance.

[0011] Furthermore, the object of the present invention is to provide a manikin device for demonstrating movement of a human body, which is compact and easy to carry by an individual.

Summary of the invention

[0012] According to the present invention, there is provided with a manikin device for demonstrating movement of a human body. The manikin device is having a framework which comprises articulated blocks of the human body. In the present embodiment, the blocks are a hollow housing provided to configure the parts of the human body. Specifically, the blocks are articulated to configure the human's body part such as legs, hands, thorax region, pelvis region, and head. For making a hand, two blocks are cascaded together using a biasing member. One block acts as an arm and the other block acts as a forearm. The cascaded region of the biasing member acts as an elbow joint. Further, the forearm is cascaded with a block using the biasing member for making a palm region. In the

present embodiment, the cascaded region between the forearm and the palm region act as a wrist joint. The hand block is further cascaded with the fingers using the biasing member.

[0013] Similarly, for creating legs two blocks are cascaded together by using the biasing member. The one block is used for making the thigh region and another block is for creating a shank region. The cascaded region of the biasing member acts as a knee joint. The shank region is further cascaded with a block using the biasing member for making the foot of the manikin device. In the present embodiment, the cascaded region between the shank region and the foot is acting as an ankle joint. Further, the foot is cascaded with toes using the biasing member.

[0014] In the present embodiment, the biasing member is used for cascading the blocks as per joints of the human body for providing joints movement such as elbow joint, knee joint, wrist joint, ankle joint, cervical joint, leg, foot, fingers, toe, lumbar, and hip of the manikin device in accordance with the movement of the human body . The biasing member is having a spring and a connecting wire. The size and stiffness of the spring and the connecting wire vary as per required flexibility of the joints such as the spring and the connecting wire used for cascading fingers and toes are way thinner than the spring and connecting wire is used for the cervical joint and lumbar region. In the present embodiment,

the connecting wire is arranged on the joint to articulate the blocks and the spring provides flexible movement upon applying force thereon.

[0015] Further, two more blocks are cascaded together by the biasing member for making the thorax region and the pelvis region. The cascaded region between the thorax region and the pelvis region is for providing the lumbar region movement. In the present embodiment, further one more block is cascaded to the thorax region for making the head region part of the manikin device. The cascaded region between the thorax region and the head region acts as a cervical joint of the manikin device.

[0016] Further, the hands are cascaded with the thorax region using the biasing member as per the human body. The cascaded region between the hands and the thorax region acts as a shoulder joint of the human body. Similarly, the thigh regions are cascaded with the pelvis region, especially in the pelvis region of the manikin device. The cascaded region herein between the thigh region and the pelvis region acts as a hip movement.

[0017] Two cavities are configured on the front side of the thorax region. Both cavities are configured in a plus-shaped and flat plates are configured on the cavities. In the present embodiment, both cavities are like a slit configured adjacent to the chest portion for holding the flat plates. Both flat plates are perpendicular to each other to configure a plus-shaped to get inside the plus shaped

cavities. Both flat plates are configured for demonstrating the sagittal plane and transverse plane.

[0018] The block of the head region is configured with a plurality of cavities for securing rods, each of the rod extending from the head region directs left to right and front to back and on top for demonstrating the transvers axis, sagittal axis and vertical axis respectively.

Brief Description of the Drawings

[0019] The advantages and features of the present invention will become better understood with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0020] Figure 1 illustrates a perspective view of a manikin device for demonstrating movement of a human body in accordance with the present invention;

[0021] Figure 2 illustrates a backside view of the manikin device in accordance with the figure 1;

[0022] Figure 3 illustrates a front view of the manikin device in accordance with the figure 1;

[0023] Figures 4 & 5 illustrate left and a right side view of the manikin device in accordance with the figure 1; and

[0024] Figures 6 & 7 illustrate a top and a bottom view of the manikin device in accordance with the figure 1.

Detail Description of the Invention

[0025] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising," having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open-ended in that an item or items following any one of these words is not meant to be an exhaustive listing such item or items or meant to be limited to only the listed item or items.

[0026] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0027] A manikin device is provided for demonstrating a human body. Specifically, the manikin device is made to demonstrate axes and planes in the body. The body movement occurs in different axes and different planes as per

the body joints movement. The manikin device is provided with a provision to perform movements in the axes as well as planes according to the joint movement. In the present embodiment, the manikin device is used for the practical demonstration of all the body movements taking place in the respective axis and planes. Further, in the present embodiment, the manikin device is made of wood. It may be obvious to a person skilled in the art to make the manikin device using a plastic, celluloid, cardboard, or the like.

[0028] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0029] Referring now to figures 1, 2, 3, 4, 5, 6 and 7, various view of a manikin device 100 for demonstrating a human body in accordance with the present invention is illustrated. The manikin device 100 is having a framework which comprises articulated blocks of the human body. In the present embodiment, the blocks are a hollow housing provided to configure the parts of the human body. Specifically, the blocks are articulated to configure the human's body part such as legs, hands, thorax region, pelvis region, and head. For making a hand 110, two blocks 112, 114 are cascaded together using a biasing member 200. One block acts as an arm 112 and the other block acts as a forearm 114. The cascaded region of the biasing member 200 acts as an elbow joint 115. Further, the forearm 114 is cascaded with a block using the biasing member 200 for making a palm region 117. In the present embodiment, the cascaded region between the forearm 114 and the palm

region 117 act as wrist joint 118. The hand 110 block is further cascaded with the fingers 119 using the biasing member 200.

[0030] Similarly, for creating legs 120 two blocks 122, 124 are cascaded together by using the biasing member 200. The one block is used for making thigh region 122 and another block is for creating a shank region 124. The cascaded region of the biasing member 200 acts as a knee joint 125. The shank region 124 is further cascaded with a block using the biasing member 200 for making the foot 126 of the manikin device 100. In the present embodiment, the cascaded region between the shank region 124 and the foot 126 is acting as an ankle joint 127. Further, the foot 126 is cascaded with toes 128 using the biasing member 200.

[0031] In the present embodiment, the biasing member 200 is used for cascading the blocks as per joints of the human body for providing joints movement such as elbow joint, knee joint, wrist joint, ankle joint, cervical joint, leg, foot, fingers, toe, lumbar, and hip of the manikin device 100 in accordance with the human body. The biasing member 200 is having a spring 210 and a connecting wire 220. The size and stiffness of the spring 210 and the connecting wire 220 vary as per required flexibility of the joints such as the spring 210 and the connecting wire 220 used for cascading fingers 119 and toes 128 are way thinner than the spring 210 and connecting wire 220 is used for cervical and lumbar region 145. In the present embodiment, the connecting wire 220 is arranged on the joint to articulate

the blocks and the spring 210 provides flexible movement upon applying force thereon.

[0032] Referring again to figure 1, further two more blocks are cascaded together by the biasing member 200 for making the thorax region 130 and the pelvis region 140. The cascaded region between the thorax region 130 and the pelvis region 140 is for providing the lumbar region 145 movements. In the present embodiment, further one more block is cascaded to the thorax region 130 for making the head region 150 part of the manikin device 100. The cascaded region between the thorax region 130 and the head region 150 acts as a cervical region 134 of the manikin device 100. The cervical region 134 is also made using a biasing member 212 which is thicker in size.

[0033] Further, the hands 110 are cascaded with the thorax region 130 using the biasing member 200 as per the human body. The cascaded region between the hands 110 and the thorax region 130 acts as a shoulder joint 132 of the human body. Similarly, the thigh regions 122 are cascaded with the pelvis region 140, especially in the pelvis region 146 of the manikin device 100. The cascaded region herein between the thigh region 122 and the pelvis region 140 acts as a hip 148 movement.

[0034] Referring again to figures 1 and 3, two cavities 160 are configured on the front side of the thorax region 130. Both cavities 160 are

configured in such a way that it creates a plus-shaped cavity. A flat plate 165, 165' are configured on the cavities 160. In the present embodiment, both cavities 160 are like a slit configured adjacent to the chest portion for holding the flat plates 165, 165'. Both flat plates 165, 165' are perpendicular to each other to configure a plus-shaped to get inside the plus shaped cavities 160. Both flat plates 165, 165' are configured for demonstrating the sagittal plane and transverse plane. Specifically, the vertical flat plate 165 is adapted to demonstrate the sagittal plane and the horizontal flat plate 165' is adapted to demonstrate the transverse plane.

[0035] Further referring again to the figures 1, 2, 3, 4, 5 and 6, the block of the head region 150 is configured with a plurality of cavities 170, 172, 174, 176, and 178 for securing rods 180, 182, and 184. Each of the rod 180, 182 and 184 extending from the head region 150 directs left to right and front to back and on top for representing frontal axis, sagittal axis, and vertical axis respectively. Specifically, the rod 180 is representing frontal axis. The rod 182 sagittal axis and the rod 184 represents vertical axis.

[0036] Each of the rod 180, 182 and 184 is extending from the head region 150 directs left to right which represents the frontal axis, front to back which represents the sagittal axis and on top represents vertical axis respectively. More specifically, one rod 180 passes from a left cavity 170 to a right cavity 172, and another rod 182 passes from the front side cavity 174 of the head region 150 which is known as forehead to the backside cavity 176. Further, one another rod

184 is arranged on the cavity 178 which is on the top side of the head region 150. The head region 150 is configured with a flat plate 190 which represents frontal plane. The flat plate 190 is arranged adjacent to the rod 184 configured on the upper portion of the head region 150 to represent frontal plane.

[0037] Therefore the advantage of the present invention is to provide a manikin device 100 for demonstrating the human body. The manikin device 100 can be used as medical equipment for educational purposes or for training health practitioners. Especially, the manikin device 100 is useful for a practical demonstration of all the body movements taking place in the respective axis and planes in the human body. Further, the manikin device 100 doesn't require any additional element to be placed for demonstrating axes and planes. Also, movements in the manikin device 100 can be performed easily. The manikin device 100 performs all movements on the model by an individual without the need for anybody's assistance. Also, the manikin device 100 is compact and portable.

[0038] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously, many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to explain the principles of the present invention best and its practical application, to thereby enable others skilled in the art to best utilize the

present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omission and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such are intended to cover the application or implementation without departing from the spirit or scope of the present invention.

We Claim:

1. A manikin device 100 for demonstrating movement of a human body, the manikin device 100 having a framework which comprises articulated blocks of the human body, characterized in that:

a biasing member 200 connecting the blocks as per joints of the human body;

wherein two cavities 160 are configured on a front side of a thorax region 130 and flat plates 165, 165' are configured thereon, the flat plates 165, 165' are perpendicular to each other to configure plus-shaped for demonstrating sagittal plane and transverse plane, the block of the head region 150 is configured with a plurality of cavities 170, 172, 174, 176 and 178 for securing rods 180, 182 and 184, each of the rod 180, 182 and 184 extending from the head region 150 directs left to right and front to back and on top for demonstrating transverse axis, sagittal axis and vertical axis, respectively.

2. The manikin device 100 as claimed in claim 1, wherein each of the hands 110 and the legs 120 comprises two blocks cascaded together with the biasing member 200 for creating an elbow joint 115 to provide the elbow joint 115 movements.

3. The manikin device 100 as claimed in claim 1, wherein a block for thorax region 130 and a block for a pelvis region 140 is cascaded together with the biasing member 200 for providing lumbar movement.

4. The manikin device 100 as claimed in claim 1, wherein a block is cascaded with the block of the thorax region 130 using the biasing member 200 to represent head region 150.

5. The manikin device 100 as claimed in claim 1, wherein the biasing member 200 is having a spring 210 and a connecting wire 220.

6. The manikin device 100 as claimed in claim 5, wherein the connecting wire 220 is arranged on the joint to articulate the blocks and the spring 210 provides flexible movement upon applying force thereon.

7. The manikin device 100 as claimed in claim 1, wherein the head region 150 is configured with a flat plate 190 to represent frontal plane, the flat plate 190 is arranged adjacent to the rod 184 configured on the upper portion of the head region 150 to represents vertical axis.

8. The manikin device 100 as claimed in claim 1, wherein the rods 180, 182, and 184 configured on the head region 150 is protruded outside of a surface of the head region 150.

Dated this September 21, 2020

Suneet Baliram Sabale

(Agent for Applicant)

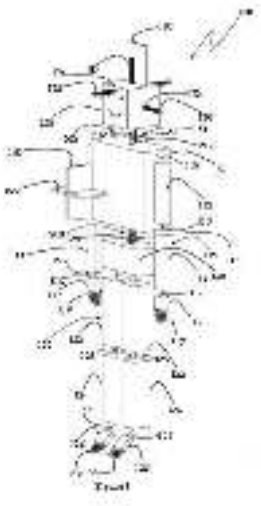
5 **Reg. No.: IN/PA-1773**

Abstract

Title: A manikin device for demonstrating movement of a human body

The present invention is to provide a manikin device 100 for demonstrating movement of a human body. The manikin device 100 is having a framework which comprises articulated blocks of the human body. A biasing member 210 connecting the blocks as per joints of the human body. Two cavities 160 are configured on a front side of a thorax region 130 and flat plates 165, 165' are configured thereon. The flat plates 165, 165' are perpendicular to each other to configure plus-shaped for demonstrating the sagittal and transverse plane. The block of the head region 150 is configured with a plurality of cavities 170, 172, 174, 176, and 178 for securing rods 180, 182, and 184. Each of the rod 180, 182, and 184 is extending from the head region 150 directs left to right, front to back and on top for representing the transverse, sagittal and vertical axis respectively.

Figure 1



FORM 2
THE PATENTS ACT 1970
(39 of 1970)
&
THE PATENTS RULES, 2003
COMPLETE SPECIFICATION
(See section 10 and rule 13)

1. TITLE OF THE INVENTION
PORTABLE AIR CONDITIONING APPARATUS

2. APPLICANT

(i) NAME : Dr. Suhas P. Deshmukh
(ii) NATIONALITY : IN
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(ii) NATIONALITY : IN
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2. PREAMBLE TO THE DESCRIPTION

COMPLETE

The following specification particularly describes the invention and the manner in which it is to be performed.

FIELD OF INVENTION

The present invention generally relates to the field of mechanical engineering and particularly to the field of thermal engineering. The present invention specifically relates to an air cooling inside a suit or shirt by using Peltier effect.

BACKGROUND OF THE INVENTION

In the global pandemic of corona, social distancing plays vital role. The spread of corona virus causing fatal diseases can be due to a room air conditioning system.The environmental temperature across the globe is increasing due to effect of climate change. The working condition of the labors and other professionals working outdoor is getting worse day by day and eventually leading to fatal diseases. Aiming of this problem and to control high temperature of human body, an air cooler or an air conditioning system is much needed. The application of the room air conditioning devices in the pandemic times becomes difficult as it might enhance the spread and growth of virus. A number of researches had been done on the air conditioning system with different applications for different users. Such as EP1388444A1 which discloses an air conditioning system comprising at least one Peltier type cell comprising at least one exothermic face and at least one endothermic face supply means electric of said cell, suction means of said air, exchange means between the sucked air and a first face of said cell located in extension of said suction means, means guide of the air flow leaving said exchange means. According to the invention, the system further comprises a device for transporting the thermal production of a second face of said cell outside the space where said air flow will be directed by said guide means to allow depending on the polarity of said supply means to selectively cool or reheat said space using said aspirated air.

US8613200B2 also suggests systems for heating and cooling the interior climate of a vehicle. In some embodiments, the system comprises a conduit having a first fluid channel, a second fluid channel, a fluid diversion channel configured to divert fluid flow between the first and second channels, and a thermoelectric device operatively connected to the fluid conduit. In certain embodiments, the thermoelectric device comprises a plurality of thermal zones. In some embodiments, the plurality of thermal zones comprises a first thermal zone connected to a first electric circuit switchable between a first polarity and a second polarity and a second thermal zone connected to a second electric circuit switchable between the first polarity and the second polarity independent of the polarity of the first electric circuit.

A number of other inventions disclose air conditioning systems and methods for heating and cooling an enclosed space. However none of the existing technologies provide a portable air conditioning system for a user working in outdoor hot temperatures and especially for the individuals in pandemic

situations of airborne diseases where social distancing becomes a primary factor of saving lives. The inventions provide different cooling systems for different phases, however during the need of the hour a system is need which can provide a cooling to individual persons separately. The limitations and need are overcome by the technical advancements of the present invention.

BRIEF SUMMARY OF THE INVENTION

The present invention relates to an application of the air conditioning system to provide cooling and heating to an individual users separately inside the suits. The system employs the application of Peltier effect to provide suitable temperature to the individual body. The system comprises a thermoelectric device/Peltier module, a plurality of fans, an air duct,a heat sink, a plurality of fins, a power unit with a plurality of rechargeable batteries, a controlling unit and a plurality of filters. The Peltier module is placed inside the air duct. The heat sink is attached to hot side of Peltier module while a fin is attached to cold side of Peltier module.At inlet port, the filter is attached with fan while another filter is placed at outlet port. The fan and Peltier module is operated by using controlling unit having knob for manual operation of device. The controlling unitis supplied with battery. The whole unit is mounted on belt. When the electric current through battery is passed through Peltier module, due to Peltier effect heating and cooling effect is generated. Whenever fan is started to rotate due to battery supply, the suction or low pressure area is generated at inlet port due to which air is sucked inside the duct. To avoid turbulence and proper direction of sucked air, the air foil shape plate inside provided at inlet. This sucked air passes through fin. As the fin become cool and again passed to filter.As the Peltier module also generate heating effect on other side. To control unwanted heating, heat sink with fan is attached. The cooling effect in Peltier module is the function of electric current. This electric current is controlled by using controlling unit while the variable mass flow rate of air is achieved by varying speed of fan.

In an embodiment of the present invention a portable air conditioning apparatus is disclosed. The apparatus comprising: a housing enclosing an air duct, wherein the housing is attached to the air cooling suit by means of a belt with a plurality of adjustable fasteners, wherein the air duct comprises an inlet port and an outlet port, wherein the inlet port is a suction port and the outlet port is an exhaust port; a thermoelectric module coupled to the air duct, wherein the thermoelectric module comprises a upper hot section and a lower cold section, wherein the thermoelectric module is fixed normal to the air duct along the diameter of the air duct, wherein the thermoelectric module is configured to generate cooling at the cold section and heating at the hot section; a heat sink is coupled to the upper hot section of the thermoelectric module to conduct heat from the hot section of the module and transmit the heat to surroundings; a first fan secured with the heat sink by means of bolts, wherein the first fan is configured to cool down the heat sink by directing air towards the heat sink, wherein the

heat sink absorbs the heat from the upper hot section of the thermoelectric module; a plurality of fins hinged to the lower cold section of the thermoelectric module, wherein the fins are configured to absorb heat from flowing air from the inlet port to the outlet port of the air duct; a second fan fixed at the inlet port of the air duct, wherein the second fan is configured to suck air from the surroundings and transmit the suctioned air to the air duct; a plurality of adjustable filters coupled to the air duct, wherein the filters are configured to receive clean air inside the duct, wherein a first filter is hinged with the second fan at the inlet port of the duct and a second filter is attached at the outlet port of the air duct; a controlling unit coupled with the air duct to control movement of air flowing inside the air duct from the second fan, wherein the control unit comprises a circuitry arrangement with an input port and a plurality of output ports, wherein the output ports are coupled to the thermoelectric module and the first and second fan; and a power unit is coupled to the input port of the controlling unit, wherein the power unit is configured to supply electric charge to the circuitry of the controlling unit and the output ports of the controlling unit supply the received electric charge to control the movement of the fans and the thermoelectric module.

Another embodiment is that the controlling unit comprises: a knob switch to control the movement of the first and the second fan by rotating the knob switch clockwise and counter clockwise in order to achieve variable mass flow rate of air, wherein the knob switch is rotated clockwise to increase the movement of the second fan to receive flow of air incoming the air duct, wherein the counter clockwise rotation of knob switch reduces the movement of the second fan and thereby incoming air.

Another embodiment is that the thermoelectric module generates heating and cooling at the upper hot section and lower cold section respectively when the electric charge from the power unit is fed through controlling unit, wherein the first fan rotates by the electric charge received from the power unit and cools down the heat sink of the thermoelectric module.

Another embodiment is that the second fan rotates when received electric charge of the power unit through controlling unit and due to the rotation of said fan, a suction or low pressure area is generated at the inlet port of the air duct due to which air is sucked inside the air duct.

Another embodiment of the present invention is that the portable air conditioning apparatus comprises: an air foil shape plate fixed at the inlet port of the air duct, wherein the air foil plate is configured to reduce turbulence of the air sucked by the second fan at the inlet port and to direct the air towards the fins and the thermoelectric module, wherein the sucked air is passed through the duct in order to cool the fins, wherein the air passed over the fins is then directed towards the filter at the outlet port of the air duct.

Another embodiment of the present invention is that the thermoelectric module comprises: a thermoelectric element configured to heat at least a portion of an air flowing inside the duct upon the application of electric charge from the power unit in a first polarity over the upper hot section of the

thermoelectric module and to cool at least a portion of air flowing inside the duct in a second polarity. The thermoelectric module is subdivided into a plurality of thermal zones, wherein the plurality of thermal zones comprises: a first thermal zone operatively connected to a first output port of the controlling unit and switchable between the first polarity and the second polarity; and a second thermal zone operatively connected to a second output port of the controlling unit and switchable between the first polarity and the second polarity independent of the polarity of the first output port of the controlling unit.

Another embodiment is that the air cooling apparatus comprises: a switch interface coupled to the controlling unit for turning the portable air conditioning suit ON and OFF, wherein the switch interface comprises a two pin push button being configured to reverse the polarity of the thermoelectric module from the first thermal zone to the second thermal zone and vice versa.

Another embodiment is that the apparatus comprises: a plurality of thermoelectric modules with a control unit being capable of operating the plurality of thermoelectric modules based on one or more operational instructions received from a user.

Another embodiment of the present invention states a method of operation of a portable air conditioning apparatus. The method comprising steps: receiving an input electric charge from a power unit, by turning a switch interface ON, wherein the power unit is coupled to a controlling unit, wherein the controlling unit comprises a circuitry arrangement with an input port and a plurality of output ports; creating a suction area at an inlet port of an air duct, wherein a second fan fixed at the inlet port of the air duct, wherein the second fan is configured to suck air from the surroundings; wherein a plurality of adjustable filters coupled to the air duct, wherein the filters are configured to receive clean air inside the duct, wherein a first filter is hinged with the second fan at the inlet port of the duct and a second filter is attached at the outlet port of the air duct; directing the suctioned air from the surrounding inside the air duct by an air foil shape plate, wherein the air foil shape plate fixed at the inlet port of the air duct, wherein the air foil plate is configured to reduce turbulence of the air sucked by the second fan at the inlet port; directing a first section of the air inside the duct towards a thermoelectric module, wherein the thermoelectric module coupled to the air duct, wherein the thermoelectric module comprises a upper hot section and a lower cold section, wherein the thermoelectric module is fixed normal to the air duct along the diameter of the air duct, wherein the thermoelectric module is configured to generate cooling at the cold section and heating at the hot section; wherein the controlling unit is coupled with the air duct to control movement of air flowing inside the air duct from the second fan, wherein the controlling unit comprises a circuitry arrangement with an input port and a plurality of output ports, wherein the output ports are coupled to the thermoelectric module and the first and second fan; directing a second of the air inside the duct towards a plurality of fins hinged to the lower cold section of the thermoelectric module, wherein the

fins are configured to absorb heat from flowing air from the inlet suction port; transmitting a heat generated at the upper hot section of the thermoelectric module towards a heat sink, wherein the heat sink is coupled to the upper hot section of the thermoelectric module to conduct heat from the hot section of the thermoelectric module and transmit the heat to surroundings by a first fan secured with the heat sink by means of bolts, wherein the first fan is configured to cool down the heat sink by directing air towards the heat sink; and directing the suctioned air flowing inside the duct over the thermoelectric module and the fins towards the exhaust port of the duct.

To further clarify advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof, which is illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail with the accompanying drawings

BRIEF DESCRIPTION OF FIGURES

These and other features, aspects, and advantages of the present invention will become better understood when the following detailed description is read with reference to the accompanying drawings in which like characters represent like parts throughout the drawings, wherein:

Figure 1 illustrates a block diagram of components installed in a portable air conditioning apparatus.

Figure 2a-d illustrates a front view, top view, a side view and a three dimensional view of the portable apparatus.

Figure 3 illustrates an operational view of the portable suit affixed with a belt.

Figure 4 illustrates another view of the portable device fastened to the belt.

Figure 5 illustrates an isometric view of the portable device.

Figure 6 illustrates an exploded view of the portable suit device.

Figure 7 illustrates a prototype model of the portable device.

Figure 8 illustrates the portable device fastened to the belt in operational condition.

Figure 9 illustrates the portable device suctioning air from the surrounding and delivering the exhaust air.

Figure 10 illustrates a circuitry diagram of a controlling unit of the portable device.

Figure 11-12 illustrate a performance of the portable device with respect to application of energy or current.

Figure 13 illustrates the portable device fastened by a belt on a user waist.

Figure 14 illustrates a sectional diagram of the portable device.

Figure 15 illustrates another sectional diagram of the components of the portable device.

Figure 16 illustrates a flow diagram of operations of the portable device.

Further, skilled artisans will appreciate that elements in the drawings are illustrated for simplicity and may not have been necessarily been drawn to scale. For example, the flow charts illustrate the method in terms of the most prominent steps involved to help to improve understanding of aspects of the present invention. Furthermore, in terms of the construction of the device, one or more components of the device may have been represented in the drawings by conventional symbols, and the drawings may show only those specific details that are pertinent to understanding the embodiments of the present invention so as not to obscure the drawings with details that will be readily apparent to those of ordinary skill in the art having benefit of the description herein.

DETAILED DESCRIPTION

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated system, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

It will be understood by those skilled in the art that the foregoing general description and the following detailed description are exemplary and explanatory of the invention and are not intended to be restrictive thereof.

Reference throughout this specification to “an aspect”, “another aspect” or similar language means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrase “in an embodiment”, “in another embodiment” and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment.

The terms "comprises", "comprising", or any other variations thereof, are intended to cover a non-exclusive inclusion, such that a process or method that comprises a list of steps does not include only those steps but may include other steps not expressly listed or inherent to such process or method.

Similarly, one or more devices or sub-systems or elements or structures or components proceeded by "comprises...a" does not, without more constraints, preclude the existence of other devices or other sub-systems or other elements or other structures or other components or additional devices or additional sub-systems or additional elements or additional structures or additional components.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The system, methods, and examples provided herein are illustrative only and not intended to be limiting.

Embodiments of the present invention will be described below in detail with reference to the accompanying drawings.

The following specification particularly describes the manner in which device work.

The components of the present invention along with the working operations of the system is described in a detailed manner. The main components of device are thermoelectric devices or Peltier module, fans, duct, heat sink, fins, energy source or battery, controlling unit and filters. The thermoelectric device/Peltier module is placed inside the air duct. The heat sink is attached to hot side of Peltier module while the finsare attached to cold side of Peltier module.

Figure 1 illustrates a block diagram of components installed in a portable air conditioning apparatus. A housing is provided which encloses an air duct (106). The housing is attached to the portable air conditioning suit by means of a belt with a plurality of adjustable fasteners. The air duct (106) comprises an inlet port (110) and an outlet port (108), wherein the inlet port is a suction port and the outlet port is an exhaust port. A thermoelectric module (112) is coupled to the air duct (106). The thermoelectric module (112) comprises an upper hot section and a lower cold section. The thermoelectric module is fixed normal to the air duct (106) along the diameter of the air duct. The thermoelectric module (112) is configured to generate cooling at the cold section and heating at the hot section. A heat sink (118) is coupled to the upper hot section of the thermoelectric module (112) to conduct heat from the hot section of the module and transmit the heat to surroundings. A first fan or an exhaust fan (116) is secured with the heat sink (118) by means of bolts, wherein the first fan (116) is configured to cool down the heat sink (118) by directing air towards the heat sink. The heat sink absorbs the heat from the upper hot section of the thermoelectric module (112). A plurality of fins (120) are hinged to the lower cold section of the thermoelectric module (112). The fins are configured to absorb heat from flowing air from the inlet port to the outlet port of the air duct.

A suction or second fan (114) is fixed at the inlet port of the air duct (106). The second fan is configured to suck air from the surroundings and transmit the suctioned air to the air duct. A plurality of adjustable filters are coupled to the air duct (106). The filters are configured to receive clean air

inside the duct (106) and a first filter is hinged with the second fan at the inlet port (110) of the duct and a second filter is attached at the outlet port (108) of the air duct.

A controlling unit (104) is coupled with the air duct (106) to control movement of air flowing inside the air duct (106) from the second fan, wherein the controlling unit (104) comprises a circuitry arrangement with an input port and a plurality of output ports. The output ports are coupled to the thermoelectric module and the first (116) and second fan (114). A power unit (102) is coupled to the input port of the controlling unit (104). The power unit (102) is configured to supply electric charge to the circuitry of the controlling unit (104) and the output ports of the controlling unit supply the received electric charge to control the movement of the fans and the thermoelectric module (112).

The controlling unit comprises a knob switch to control the movement of the first and the second fan by rotating the knob switch clockwise and counterclockwise in order to achieve variable mass flow rate of air, wherein the knob switch is rotated clockwise to increase the movement of the second fan to receive flow of air incoming the air duct, wherein the counterclockwise rotation of knob switch reduces the movement of the second fan and thereby incoming air. The thermoelectric module generates heating and cooling at the upper hot section and lower cold section respectively when the electric charge from the power unit is fed through controlling unit, wherein the first fan rotates by the electric charge received from the power unit and cools down the heat sink of the thermoelectric module. The second fan rotates when received electric charge of the power unit through controlling unit and due to the rotation of said fan, a suction or low pressure area is generated at the inlet port of the air duct due to which air is sucked inside the air duct.The knob switch, in operational connection with the controlling unit, controls the heating and cooling generated by the thermoelectric module according to the rotation of the switch in clockwise and counterclockwise directions.

The portable air conditioning apparatus also includes an air foil shape plate fixed at the inlet port of the air duct, wherein the air foil plate is configured to reduce turbulence of the air sucked by the second fan at the inlet port and to direct the air towards the fins and the thermoelectric module, wherein the sucked air is passed through the duct in order to cool the fins, wherein the air passed over the fins is then directed towards the filter at the outlet port of the air duct.

The thermoelectric module includes a thermoelectric element configured to heat at least a portion of an air flowing inside the duct upon the application of electric charge from the power unit in a first polarity over the upper hot section of the thermoelectric module and to cool at least a portion of air flowing inside the duct in a second polarity. The thermoelectric module is subdivided into a plurality of thermal zones, wherein the plurality of thermal zones comprises: a first thermal zone operatively connected to a first output port of the controlling unit and switchable between the first polarity and the second polarity; and a second thermal zone operatively connected to a second output port of the

controlling unit and switchable between the first polarity and the second polarity independent of the polarity of the first output port of the controlling unit.

The suit comprises a switch interface coupled to the controlling unit for turning the portable air conditioning suit ON and OFF, wherein the switch interface comprises a two pin push button being configured to reverse the polarity of the thermoelectric module from the first thermal zone to the second thermal zone and vice versa. The device can also include a plurality of thermoelectric modules with a control unit being capable of operating the plurality of thermoelectric modules based on one or more operational instructions received from a user.

Figure 2a-d illustrates a front view, top view, a side view and a three dimensional view of the portable apparatus. A thermoelectric module (204) is enclosed inside an air duct (218). The module can be Peltier module or any other device employed for heating and cooling of devices. The module includes two sections one hot section and one cold section. These sections are also called as thermal zones. A heat sink (202) is placed above the hot section and a fan or blower (208) is placed above the heat sink (202) such that the fan cools down the heat sink by blowing surrounding ambient air over it. A filter (210) is placed above a suction fan (212) such that when the fan rotates only clean air is sucked into the air duct (218). A controlling unit (214) is provided in connection with a power source unit. The suction fan (212), thermoelectric module (204) and all other arrangements are coupled to the controlling unit (214). A knob switch (216) is provided at the controlling unit (214) to control the movement of the suction fan by increasing and decreasing the speed of the fan according to the ease of a user. An air foil plate is provided inside the duct (218) to direct the air towards the fins (220) placed below the thermoelectric module in order to avoid turbulence of incoming air. A filter (206) is placed at the exhaust port of the air duct (218).The controlling unit is configured to supply hot and/or cold air from the thermoelectric module (112) towards the outlet port (108) of the air duct, wherein the outlet port receives hot and cold air from the thermoelectric module (112) through the air duct (106) and supplies the received hot and/or cold air to a suit of a user.

Figure 3 illustrates an operational view of the portable suit affixed with a belt. The device is attached to a belt (312)and fastened by adjustable fasteners. The adjustable fasteners can be hook and loop fasteners, Velcro buttons and the like. An exhaust port (310) directs the hot air or used air from the module and the fins to the ambient air. A knob switch (314) is provided so that the user can manually operate the device depending upon the comfort of the user. A suction fan (316) creates a low pressure area near the inlet port of the duct when the switch is rotated clockwise or counter-clockwise.

Figure 4 illustrates another view of the portable device fastened to the belt. The device can be used by all the labors and professional workers. The belt can be any conventional belt worn by the user around the waist. Adjustable fasteners are provided to adjust the size of the device on the belt and around the waist of the user.

Figure 5 illustrates an isometric view of the portable device, and **Figure 6** illustrates an exploded view of the portable suit device. A filter (610) is provided or hinged or fastened over a suction fan (612). A controlling unit (614) is provided with a connection to a power source. The power source can be any kind of rechargeable batteries such as lithium ion batteries or any kind of other cells to supply a DC to the controlling unit (614). A heat sink (616) is provided with a blower fan above it. The heat sink is coupled to a hot thermal zone of a thermoelectric module (618). A number of fins (620) are provided and coupled with a cold thermal zone of the thermoelectric module (618). The air duct (624) is placed in a housing with a base (626). A filter (622) is also hinged to an exhaust port of the air duct (624).

Figure 7 illustrates a prototype model of the portable device. The size of the device can vary according to the need of the user. The components such as fans blowers, heat sink and fins are bolted to the duct or welded.

Figure 8 illustrates the portable device fastened to the belt in operational condition, and **Figure 9** illustrates the portable device suctioning air from the surrounding and delivering the exhaust air. The operation of the device is such that when a main interface switch is turned ON and the controlling unit starts transferring electric charge to the components. The suction fan sucks air from the surrounding air by rotating and creating a suction or low pressure air at the suction or inlet port of the duct. The air foil plate reduces turbulence of the air sucked and directs the air towards the thermoelectric modules. The air gets hot due to the hot section of the module, the air is then passed to the fins as the fins are connected to the cold section of the modules. The air flows over the fins and is directed towards the exhaust port. The heat sink connected to the hot section is cooled down by the blowing fan.

Figure 10 illustrates a circuitry diagram of a controlling unit of the portable device. The controlling unit comprises of different circuitry arrangements on a PCB with a plurality of relays and capacitors and resistors to control and smooth the flow of current from the power source. The unit have a number of outlet ports to connect to the fans and modules. The controlling switch also includes a main interface switch to turn ON and OFF the whole device. A knob switch is also provided to control the movement of the suction fan.

Figure 11-12 illustrate a performance of the portable device with respect to application of energy or current. From the graphs it can be concluded that the performance of the device or the device functions at low power consumption. Therefore a light weight batteries as the power source can be employed rather than charging and discharging the device. The batteries are rechargeable and can be removed when empty and then charged again. An example of the system can be illustrated as follows;

Density of air (ρ) = 1.164 kg/m^3

- Mass (m) = ρ x q = 1.164 x 0.01 = 0.01164 kg/s

- For temperature difference (ΔT) = 10℃ and Cp (specific heat) = 1KJ/kg
    - Total Heat (Q) = m x Cp x ΔT

      = 0.01164 x 1 x 10

      = 0.1164 KW ~ 116 watt

Total heat = Latent Heat + Sensible Heat = Q_l + Qs

= 75.4 + 40.6 = 116 watt

- The concerned of sensible heat is only change in the temperature of gas or material but not the phase shift. The phase shift between the solid, liquid and gas is relevant to the latent heat. Hence, we take only sensible heat for calculation.
- Considering sensible heat for calculation with all losses

Q = 50 watt

- Thermo-electric cooler (TEC) Selection
    - Heat supplied (Qs) = 12V x 4A (Battery parameters)

      = 48 watt
    - Coefficient of performance (COP) = $\frac{Q}{Qs}$ = $\frac{50}{48}$ = 1.04
    - Required temperature
        1. Cool side temperature (Tc) = 25℃
        2. Ambient temperature (Ta) = 30℃
        3. Hot side temperature (Th) = 35℃
        4. ΔT = 35℃ - 25℃ = 10 K

With reference to Peltier module data sheet,

For COP (Coefficient of performance) = 1.04 and

ΔT(Temperature difference) = 10 K

$\frac{I}{Imax}$ = 0.6

With reference to Peltier module data sheet,

For $\frac{I}{Imax}$ = 0.6, I_{max} = maximum current

$\frac{Q}{Qmax}$ = 0.67

- Q_{max}(maximum heat) = 83.33 watt

- According to above data,
  - For TEC 12706,
    1. Q_{max} = 92 watt
    2. Voltage = 12V
    3. Current = 0-6 A
    4. Size = 40 x40 x 4 mm

Operating Current = I = $I_{max\ (peltier)}$ x $\frac{I}{Imax}$ = 6 x 0.6

I (operating current) = 3.6A

- For heat sink,
  - From graph, for $\frac{I}{Imax}$ = 0.6 and ΔT = 10 K
  - $\frac{Qh}{Qmax}$ = 1.2
  - Q_h(heat in heat sink) = 1.2 x 83.33 = 99.99 ~ 100 watt
  - R (resistance in heat sink) = $\frac{Th-Ta}{Qh}$ = $\frac{5}{100}$ = 0.05 k/w

- Power supply
  - Capacity = 20000mAh
  - Output = 12V 4A
  - Size: - Length = 80 mm

Width = 60 mm

Height = 120 mm

- Fan Speed

Voltage = 12V Current = 4A

Figure 13 illustrates the portable device fastened by a belt on a user waist. The device can be worn by the user around the waist. The device is fitted to the belt at the back of the user, such that user can feel free handed while working.

Figure 14 illustrates a sectional diagram of the portable device, and **Figure 15** illustrates another sectional diagram of the components of the portable device. The duct (1010) comprises a suction port (1014) and an exhaust port. An air foil plate (1016) is provided to direct the flow of fluid (air) inside the duct without turbulence. A heat sink (1012) is coupled to the hot thermal zone of the thermoelectric element and a plurality of fins are connected to the cold zone of the module/element. At inlet port filter is attached with fan while another filter placed at outlet port. The fan and Peltier module is operated by using controlling unit having knob for manual operation of device. The controlling unit is supplied with battery. The whole unit is mounted on belt. When the electric current through battery is passed through Peltier module, due to Peltier effect heating and cooling effect is generated. When fan is starts to rotate due to battery supply, the suction or low pressure area is generated at inlet port due to which air is sucked inside the duct. To avoid turbulence and proper direction of sucked air, the airfoil shape plate inside provided at inlet. This sucked air passes through fin. As the fin become cool and again passed to filter.As the Peltier module also generate heating effect on other side. To control unwanted heating, heat sink with fan is attached. The cooling effect in Peltier module is the function of electric current. This electric current is controlled by using controlling unit while the variable mass flow rate of air is achieved by varying speed of fan.The heat conduction and convection are the function of surface area. More the surface area, more will be conduction and convection. Aluminum material has good thermal conductivity. For effective cooling, aluminum material sheet is arranged in manner that more surface area contacted with flowing air. The results from the reading calculated are; Temperature range to be achieved by using knob = 24℃-33℃; Mass flow rate of air = 0-10 liter/min (varying by using knob); Surrounding temperature = 30℃

Figure 16 illustrates a flow diagram of operations of the portable device. A method of operation of a portable air conditioning apparatus is disclosed. The method comprising steps as; the first step states (1002) receiving an input electric charge from a power unit, by turning a switch interface ON, wherein the power unit is coupled to a controlling unit, wherein the controlling unit comprises a circuitry arrangement with an input port and a plurality of output ports; second step (1004) involves creating a suction area at an inlet port of an air duct, wherein a second fan fixed at the inlet port of the air duct, wherein the second fan is configured to suck air from the surroundings; wherein a plurality of adjustable filters coupled to the air duct, wherein the filters are configured to receive clean air inside the duct, wherein a first filter is hinged with the second fan at the inlet port of the duct and a second filter is attached at the outlet port of the air duct; third step (1006) involves directing the suctioned air from the surrounding inside the air duct by an air foil shape plate, wherein the air foil shape plate fixed at the inlet port of the air duct, wherein the air foil plate is configured to reduce turbulence of the

air sucked by the second fan at the inlet port; fourth step (1008) involves directing a first section of the air inside the duct towards a thermoelectric module, wherein the thermoelectric module coupled to the air duct, wherein the thermoelectric module comprises a upper hot section and a lower cold section, wherein the thermoelectric module is fixed normal to the air duct along the diameter of the air duct, wherein the thermoelectric module is configured to generate cooling at the cold section and heating at the hot section; wherein the controlling unit is coupled with the air duct to control movement of air flowing inside the air duct from the second fan, wherein the controlling unit comprises a circuitry arrangement with an input port and a plurality of output ports, wherein the output ports are coupled to the thermoelectric module and the first and second fan; fifth step (1010) involves directing a second of the air inside the duct towards a plurality of fins hinged to the lower cold section of the thermoelectric module, wherein the fins are configured to absorb heat from flowing air from the inlet suction port; sixth step (1012) involves transmitting a heat generated at the upper hot section of the thermoelectric module towards a heat sink, wherein the heat sink is coupled to the upper hot section of the thermoelectric module to conduct heat from the hot section of the thermoelectric module and transmit the heat to surroundings by a first fan secured with the heat sink by means of bolts, wherein the first fan is configured to cool down the heat sink by directing air towards the heat sink; and a final step (1014) involves directing the suctioned air flowing inside the duct over the thermoelectric module and the fins towards the exhaust port of the duct.

The present invention is advantageous and can be applied to a number of system. The features such as that by the application of the present device the temperature can be varying as per the comfort; Flow rate of air can be varying as per comfort of person; less weight; having long battery backup; Work for more time; Less noise; Proper circulation inside suit or shirt; Low cost.From figure 13, it is shown that the purposed product can be mounted inside shirt with closed member or can placed inside suit.Also the purposed product can be easily wearable on belt.This proposed model useful for worker and medical staffs to control this temperature in summer as well as winter season. In this proposed model, we use Peltier effect principle to achieve cooling effect.

The drawings and the forgoing description give examples of embodiments. Those skilled in the art will appreciate that one or more of the described elements may well be combined into a single functional element. Alternatively, certain elements may be split into multiple functional elements. Elements from one embodiment may be added to another embodiment. For example, orders of processes described herein may be changed and are not limited to the manner described herein. Moreover, the actions of any flow diagram need not be implemented in the order shown; nor do all of the acts necessarily need to be performed. Also, those acts that are not dependent on other acts may be performed in parallel with the other acts. The scope of embodiments is by no means limited by these specific examples. Numerous variations, whether explicitly given in the specification or not, such as

differences in structure, dimension, and use of material, are possible. The scope of embodiments is at least as broad as given by the following claims.

Benefits, other advantages, and solutions to problems have been described above with regard to specific embodiments. However, the benefits, advantages, solutions to problems, and any component(s) that may cause any benefit, advantage, or solution to occur or become more pronounced are not to be construed as a critical, required, or essential feature or component of any or all the claims.

WE CLAIM:

1. A portable air conditioning apparatus comprising

a housing enclosing an air duct (106), wherein the housing is attached to the portable air conditioning suit by means of a belt with a plurality of adjustable fasteners, wherein the air duct (106) comprises an inlet port (110) and an outlet port (108), wherein the inlet port is a suction port and the outlet port is an exhaust port;

a thermoelectric module (112) coupled to the air duct (106), wherein the thermoelectric module (112) comprises a upper hot section and a lower cold section, wherein the thermoelectric module is fixed normal to the air duct (106) along the diameter of the air duct, wherein the thermoelectric module (112) is configured to generate cooling at the cold section and heating at the hot section;

a heat sink (118) is coupled to the upper hot section of the thermoelectric module (112) to conduct heat from the hot section of the module and transmit the heat to surroundings;

a first fan (116) secured with the heat sink (118) by means of bolts, wherein the first fan (116) is configured to cool down the heat sink (118) by directing air towards the heat sink, wherein the heat sink absorbs the heat from the upper hot section of the thermoelectric module (112);

a plurality of fins (120) hinged to the lower cold section of the thermoelectric module (112), wherein the fins are configured to absorb heat from flowing air from the inlet port to the outlet port of the air duct;

a second fan (114) fixed at the inlet port of the air duct (106), wherein the second fan is configured to suck air from the surroundings and transmit the suctioned air to the air duct;

a plurality of adjustable filters coupled to the air duct (106), wherein the filters are configured to receive clean air inside the duct (106), wherein a first filter is hinged with the second fan at the inlet port (110) of the duct and a second filter is attached at the outlet port (108) of the air duct;

a controlling unit (104) coupled with the air duct (106) to control movement of air flowing inside the air duct (106) from the second fan, wherein the controlling unit (104) comprises a circuitry arrangement with an input port and a plurality of output ports, wherein the output ports are coupled to the thermoelectric module and the first (116) and second fan (114), wherein the controlling unit is configured to supply hot and/or cold air from the thermoelectric module (112) towards the outlet port (108) of the air duct, wherein the outlet port receives hot and cold air from the thermoelectric module (112) through the air duct (106) and supplies the received hot and/or cold air to a suit of a user; and

a power unit (102) is coupled to the input port of the controlling unit (104), wherein the power unit (102) is configured to supply electric charge to the circuitry of the controlling unit (104) and the output ports of the controlling unit supply the received electric charge to control the movement of the fans and the thermoelectric module (112).

2. The portable air conditioning apparatus as claimed in claim 1, wherein the controlling unit comprises:

a knob switch to control the movement of the first and the second fan by rotating the knob switch clockwise and counterclockwise in order to achieve variable mass flow rate of air, wherein the knob switch is rotated clockwise to increase the movement of the second fan to receive flow of air incoming the air duct, wherein the counterclockwise rotation of knob switch reduces the movement of the second fan and thereby incoming air, wherein the knob switch, in operational connection with the controlling unit, controls the heating and cooling generated by the thermoelectric module according to the rotation of the switch in clockwise and counterclockwise directions.

3. The portable air conditioning apparatus as claimed in claim 1, wherein the thermoelectric module generates heating and cooling at the upper hot section and lower cold section respectively when the electric charge from the power unit is fed through controlling unit, wherein the first fan rotates by the electric charge received from the power unit and cools down the heat sink of the thermoelectric module.

4. The portable air conditioning apparatus as claimed in claim 1, wherein the second fan rotates when received electric charge of the power unit through controlling unit and due to the rotation of said fan, a suction or low pressure area is generated at the inlet port of the air duct due to which air is sucked inside the air duct.

5. The portable air conditioning apparatus as claimed in claim 1, wherein the portable apparatus comprises:

an air foil shape plate fixed at the inlet port of the air duct, wherein the air foil plate is configured to reduce turbulence of the air sucked by the second fan at the inlet port and to direct the air towards the fins and the thermoelectric module, wherein the sucked air is passed through the duct in order to cool the fins, wherein the air passed over the fins is then directed towards the filter at the outlet port of the air duct.

6. The portable air conditioning apparatus as claimed in claim 1, wherein the thermoelectric module comprises:

a thermoelectric element configured to heat at least a portion of an air flowing inside the duct upon the application of electric charge from the power unit in a first polarity over the upper hot section of the thermoelectric module and to cool at least a portion of air flowing inside the duct in a second polarity.

7. The portable air conditioning apparatus as claimed in claim 1, wherein the thermoelectric module is subdivided into a plurality of thermal zones, wherein the plurality of thermal zones comprises:

a first thermal zone operatively connected to a first output port of the controlling unit and switchable between the first polarity and the second polarity; and

a second thermal zone operatively connected to a second output port of the controlling unit and switchable between the first polarity and the second polarity independent of the polarity of the first output port of the controlling unit.

8. The portable air conditioning apparatus as claimed in claim 1, wherein the apparatus comprises:

a switch interface coupled to the controlling unit for turning the portable air conditioning suit ON and OFF, wherein the switch interface comprises a two pin push button being configured to reverse the polarity of the thermoelectric module from the first thermal zone to the second thermal zone and vice versa.

9. The portable air conditioning apparatus as claimed in claim 1, wherein the apparatus comprises:

a plurality of thermoelectric modules with a control unit being capable of operating the plurality of thermoelectric modules based on one or more operational instructions received from a user, wherein the thermoelectric modules are configured to generate cold and/or hot air according to the operational instructions set by the user.

10. A method of operation of a portable air conditioning apparatus, the method comprising steps:

receiving an input electric charge from a power unit, by turning a switch interface ON, wherein the power unit is coupled to a controlling unit, wherein the controlling unit comprises a circuitry arrangement with an input port and a plurality of output ports;

creating a suction area at an inlet port of an air duct, wherein a second fan fixed at the inlet port of the air duct, wherein the second fan is configured to suck air from the surroundings; wherein a plurality of adjustable filters coupled to the air duct, wherein the filters are configured to receive clean air inside the duct, wherein a first filter is hinged with the second fan at the inlet port of the duct and a second filter is attached at the outlet port of the air duct;

directing the suctioned air from the surrounding inside the air duct by an air foil shape plate, wherein the air foil shape plate fixed at the inlet port of the air duct, wherein the air foil plate is configured to reduce turbulence of the air sucked by the second fan at the inlet port;

directing a first section of the air inside the duct towards a thermoelectric module, wherein the thermoelectric module coupled to the air duct, wherein the thermoelectric module comprises a upper hot section and a lower cold section, wherein the thermoelectric module is fixed normal to the air duct along the diameter of the air duct, wherein the thermoelectric module is configured to generate cooling at the cold section and heating at the hot section; wherein the controlling unit is coupled with the air duct to control movement of air flowing inside the air duct from the second fan, wherein the controlling unit comprises a circuitry arrangement with an input port and a plurality of output ports, wherein the output ports are coupled to the thermoelectric module and the first and second fan;

directing a second of the air inside the duct towards a plurality of fins hinged to the lower cold section of the thermoelectric module, wherein the fins are configured to absorb heat from flowing air from the inlet suction port;

transmitting a heat generated at the upper hot section of the thermoelectric module towards a heat sink, wherein the heat sink is coupled to the upper hot section of the thermoelectric module to conduct heat from the hot section of the thermoelectric module and transmit the heat to surroundings by a first fan secured with the heat sink by means of bolts, wherein the first fan is configured to cool down the heat sink by directing air towards the heat sink; and

directing the suctioned air flowing inside the duct over the thermoelectric module and the fins towards the exhaust port of the duct.

Dated this 23rd day of October, 2020

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ABSTRACT

PORTABLE AIR CONDITIONING APPARATUS

A portable air conditioning apparatus is disclosed. A housing enclosing an air duct (106). A thermoelectric module (112) coupled to the air duct (106), configured to generate cooling at the cold section and heating at the hot section. A heat sink (118) is coupled to the upper hot section of the thermoelectric module (112) to conduct heat from the hot section of the module and transmit the heat to surroundings. A plurality of fins (120) hinged to the lower cold section of the thermoelectric module (112). A suction fan (114) is configured to suck air from the surroundings and transmit the suctioned air to the air duct. A controlling unit (104) coupled with the air duct (106) to control movement of air flowing inside the air duct (106) from the second fan.

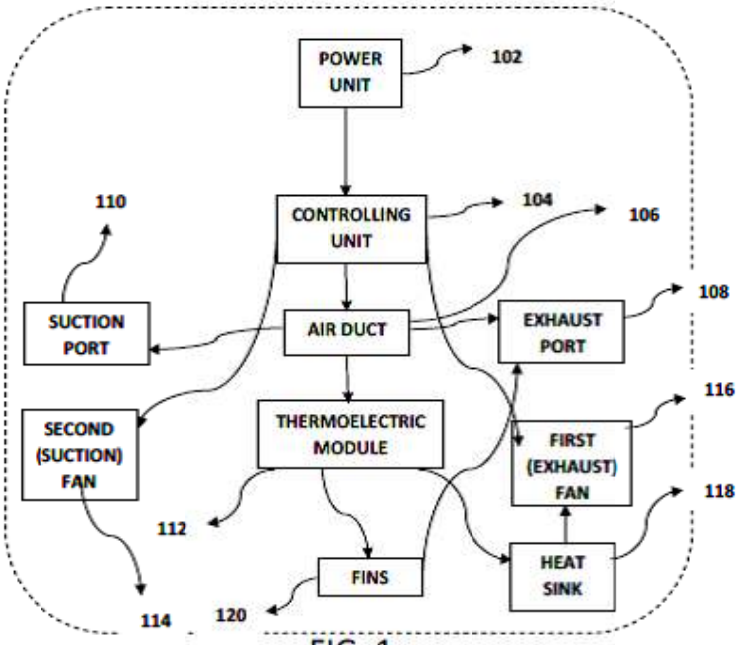

FIG. 1

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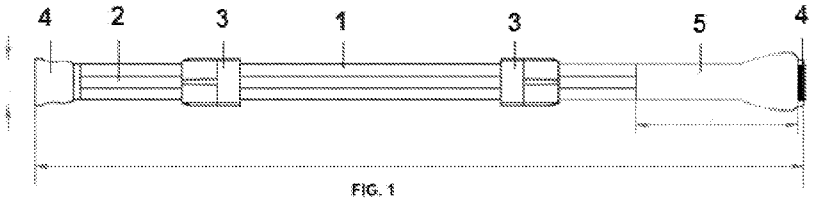

FIG. 1

(57) **Abstract:** Disclosed is a device for physically restraining movement comprising first strap (1) and second strap (2); the second trap being placed within the first strap; plurality of buckles (3,4) having a slide release mechanism; the said buckle being made up of polypropylene derivative; a padding unit (5) being made of the sheet which consists of polyethylene vinyl acetate; wherein the first strap being made up a polymer selected from a combination of polyamide: polystyrene: polyacrylamide; wherein polyamide: polystyrene: polyacrylamide is 1.0:0.7:0.5 by weight.

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A DEVICE FOR PHYSICALLY RESTRAING MOVEMENT

FIELD OF THE INVENTION

The present invention relates to a medical device. More particularly, the present invention relates to a device which can physically restrain the movement of a patient who is non-cooperative.

BACKGROUND OF THE INVENTION

In medical field, the restraints are often used to help ensure patient and staff safety for example physical restraint, mechanical restraint, chemical restraint, psychological restraint. Out of this the more suitable restraint in medical science is physical restraint. The physical restraint has many uses for instance physically restraining a patient during surgical procedures is utilized to place the patient in a proper surgical position, and to avoid sudden involuntary movements during surgery. Restraining devices are also used in psychological facilities to help restrict patients from injuring themselves or the others. It can be also used to control difficult or unpredictable patients during transport. In short physical restraints are used for patients who are assessed to be in extreme danger of injury to themselves and others.

Mechanical appliances, material or equipment attached to the patient's body that he/she cannot easily remove themselves, restricting movement or normal access to one's body. There are a Restraint standards, Regulations and policies (Hospital Restraint Policies, Dr. Richard Griffiths and Dr. Nicholas Love, Imperial College Healthcare, AAGBI Position Statement, September 2013) to be followed, as the use of Restraint has been found to be sometimes unnecessary or many a times used inappropriately and often found to be the cause of injury or even death. The guidelines are restraints are medical appliances used as a last resort, when alternatives have been failed to prevent harm from violent or non violent behavior; It is also mandatory to provide a safe environment for the patient, who is in restraint; Patients and families must be provided with information on restraint to allow for an informed decision; Patient should be monitored every 15 minutes, Patient restraint management flow chart sheet should be maintained every two hours, Physician is responsible for writing and reviewing the restraint order, Nurse is responsible for assessment and documentation, New order is required after 24

hours, Modify the environment, provide companionship and supervision; Give attention to patient's hydration, nutrition, elimination and range of motion; Keep record of patient's vital signs; Regular checks should be carried out that the restraint appliance does not restrict the circulation; Restraints are not to be used for discipline or staff convenience; Restraints should be applied by the trained staff.

The prior art US5546962 disclose a device for restraining movement without completely prohibiting movement is disclosed. Two coupling devices connected by a extensible material form the physical restraint device. One of the coupling devices may be coupled to a patient while the other may be coupled to a fixed object. The length and extensibility of the extensible material connecting the coupling devices determines the amount of movement allowed between the user and the fixed object. A variety of lengths and strengths of the extensible material may be used and interchanged. Because of the flexibility and extensibility of the material, the physical restraint device may also be used as an exerciser for the person being restrained. A recessed pin locking device is located within each coupling device. Access to each pin locking device is through a hole located in the coupling device. An object such as a pen or a pin must be inserted into the hole in order to release the locking device. When the locking device is released, the coupling device is opened so that it can be connected to or disconnected from the user or fixed object. Because the lock is recessed, access is quick and easy for the person applying the restraint, but is unavailable to the person being restrained. This device might work like handcuff and is difficult to prevent the movement of violent patients (like alcoholic, psychotic or the patients who consume poison) as the device of US'692' is restricted to specific movement only. Further, as the metal is used as a component US'962', this device would not suitable for performing certain important medical procedure such as MRI or CT scan.

Another disclosure US4414969 relates to wrist restraint which is a device especially for restraining the movements of the limb of a patient during a medical procedure is disclosed. The device includes a generally long rectangular flexible member which encircles the limb. The outside surface of this member is a Velcro loop pile. A strap having a Velcro hook fiber surface is attached at one of its ends to the encircling

member. The strap is wrapped around the encircling member in the direction toward the end closest to which the strap is attached such that the Velcro hook fiber surface of the strap is brought into contact and locking engagement with the Velcro pile surface of the encircling member. The strap is routed through a small ring attached to the outside surface of the encircling member and proceeds to a support structure to which it is releasably attached by fastening means located at or near said end. Because of the locking engagement of the Velcro surfaces of the encircling member and the strap and the small size of the ring, the encircling member cannot be substantially tightened by a pulling force exerted on or by the encircled limb in a direction away from the support structure. As the patient's movement as concerned, US'969' is limited to particular part only, moreover the prior art is silent how the device is applicable to the violent patients.

Accordingly, there is a need to provide a solution for physically restraining the movement of a patient.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a medical device for physically restraining the movement of a patient.

It is another objective of the invention is to provide a device for physically restraining the movement of a patient who is non-cooperative.

It is another objective of the invention is to provide a novel polymer based physical restraint device.

It is yet another objective of the invention is to provide a device to ensure the immediate physical safety of the patients, staff members and others in emergency situation.

It is yet another objective of the invention is to provide a device to conduct certain procedures smoothly for instance inserting/securing important tubes, intravenous line etc.

It is yet another objective of the invention is to provide a device to prevent disoriented/alcoholic patient from self-extubation, oxygen cannulae, Ryle's tube, drains, naso-tracheal tube, urinary catheter etc.

It is yet another objective of the invention is to provide a physical restraint device with minimum discomfort.

It is yet another objective of the invention is to provide a device which does not cause ulcers or trauma to the wrist, ankles and skin.

It is further objective of the invention is to provide a device which can be used to prevent the movement of the patients who have undergo MRI or CT scan.

SUMMARY OF THE INVENTION

There is provided A device for physically restraining movement of a patient comprising

first strap and second strap; the second trap being placed within the first strap;

plurality of buckles having a slide release mechanism; the said buckle being made up of polypropylene derivative;

a padding unit being made of the sheet which consists of polyethylene vinyl acetate;

wherein the first strap being made up a polymer selected from a combination of polyamide: polystyrene: polyacrylamide;
wherein polyamide: polystyrene: polyacrylamide is 1.0:0.7:0.5 by weight.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates schematically a physical restraint device in accordance with present invention;

Figure 2 illustrates schematically an outer view of the device in accordance with the present invention;

Figure 3 illustrates schematically a top view (closed manner) of the device in accordance with present invention;

Figure 4 illustrates a flow chart of working of the device in accordance with the present invention;

Figure 5 is an image of working of the device in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to Figure 1 (inside view) and Figure 2 (outside view), the present invention provides a novel polymer based physical restraint device, the said device consists of:

i) first strap (1);

ii) second strap (2);

iii) plastic buckles (3,4); &

iv) padding unit (5)

i) <u>First strap (denoting as symbol "1" in Figure 1):</u>

The first strap (1) which could be considered as a base, used to fix with the cot/bed framework. The strap according to present invention is made up of a polymer which is selected from a group consisting of polyamide (nylon), polystyrene, polyacryl amide and the combination thereof. The ratio of the polymers polyamide, polystyrene and polyacrylamide as used in present invention is 0.5:0.5:0.5 to 1:1:1

by weight. All the polymers are commonly available in market. The suitable method known in the art is referred for making the strap.

The length of the first strap according to present invention is 38inch, while the width is 1.5inch. The thickness of the strap is 0.07inch.

ii) second strap (denoting as symbol "2" in Figure 1);

A second strap (2) is placed in between the first strap which is used as a support for first strap. The second strap according to present invention is made up of rexin and the suitable process known in art is used to prepare the second strap.

The length of the second strap according to present invention is 38inch and while the width is 0.05-1.5inch.

iii) plastic buckles (denoting as symbol "3,4" in Figure 1);

According to present invention, there are 3 buckles (3,4) having male (3)-female (4) system for ease of locking and un-locking. The buckles also have a sliding release mechanism. The buckle according to present invention is made up of high density polypropylene which is also commonly available in market. The size of the buckle according to present invention is 1.5inch.

iv) padding unit (denoting as symbol "5" in Figure 1):

The padding unit (5) is used as cushioning purpose for the device, is made up of polyethylene-vinyl-acetate sheet, which is secured at patient's wrist or ankles or both. The length of the padding unit according to present invention is 7inch, while the width is 2inch. The thickness of the padding unit is 2mm. Polyethylene-vinyl-acetate as used in the invention is commonly available in market.

As shown in Figure 3, present inventor illustrates the top view (close) of the physical restraint device.

The working of the device to establish the advantageous effect of the present invention is demonstrated in Figure 4 and 5. The studies were performed at

Krishna Institute of Medical Sciences and Krishna Hospital, Karad and10 patients is selected from each group as follows:

Cooperative: 10 NOS

Alcoholic: 10 NOS

Psychotic: 10 NOS } NON-COOPERATIVE

Poison consuming: 10 NOS

As shown in the flow chart (Figure 4), a patient who is sleeping on the bed and the device whose one end is secured to wrist and ankle of the patient (Figure 5) and another end is fixed to a bed framework. A system is attached to the bed framework so that it can be worked as an alarm when the patient gets detached from the device.

First strap of the physical restraint device is having the following ratio:

1) Polyamide: Polystyrene: Polyacrylamide = 0.5:0.5:0.5 by weight
2) Polyamide: Polystyrene: Polyacrylamide = 0.5:0.7:1.0 by weight
3) Polyamide: Polystyrene: Polyacrylamide = 1.0:0.7:0.5 by weight

The efficacy of the device is evaluated by the alarm system as above i.e. the alarm is ON if the patient gets unlocked any time after securing the device.

Table 1: Efficacy of physical restraint device (in hours)

Sr. No.	Patients			
	Co-operative	Alcoholic	Psychotic	Poison consuming
Polyamide: Polystyrene: Polyacrylamide	Alarm on after 5 hour	Alarm on after 1 hour	Alarm on after 0.5 hour	Alarm on after 1 hour

= 0.5:0.5:0.5				
Polyamide: Polystyrene: Polyacrylamide = 0.5:0.7:1.0	Alarm on after 5.5 hour	Alarm on after 1.2 hour	Alarm on after 0.5 hour	Alarm on after 1.1 hour
Polyamide: Polystyrene: Polyacrylamide = 1.0:0.7:0.5	Alarm on after 10 hour	Alarm on after 6 hour	Alarm on after 5 hour	Alarm on after 6.5 hour

Table 1 shows the superior effect of the first strap which is made up of Polyamide: Polystyrene: Polyacrylamide = 1.0:0.7:0.5. Accordingly the present device is not a mere admixture.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

Claims:

1. A device for physically restraining movement comprising

   first strap (1) and second strap (2); the second trap being placed within the first strap;

   plurality of buckles (3,4) having a slide release mechanism; the said buckle being made up of polypropylene derivative;

   a padding unit (5) being made of the sheet which consists of polyethylene vinyl acetate;

   wherein the first strap being made up a polymer selected from a combination of polyamide, polystyrene and polyacrylamide;
   wherein polyamide: polystyrene: polyacrylamide is 1.0:0.7:0.5 by weight.

2. The device as claimed in claim 1, wherein length of the first strap is 38inch.

3. The device as claimed in claim 1, wherein width of the first strap is 1.5inch.

4. The device as claimed in claim 1, wherein thickness of the first strap is 0.07inch.

5. The device as claimed in claim 1, wherein length of the second strap is 38inch.

6. The device as claimed in claim 1, wherein width of the second strap is 1.5inch.

7. The device as claimed in claim 1, wherein length of the padding unit is 7inch.

8. The device as claimed in claim 1, wherein width of the padding unit is 2inch.

9. The device as claimed in claim 1, wherein thickness of the padding unit is 2mm.

10. The device as claimed in claim 1, wherein the buckle is 15 inch-buckles.

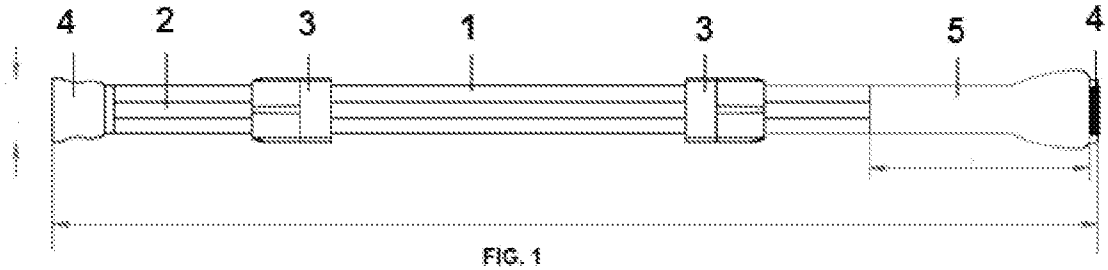

FIG. 1

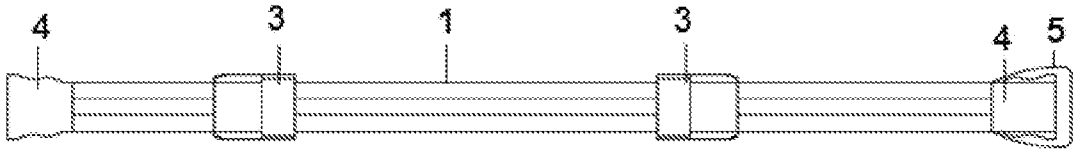

FIG. 2

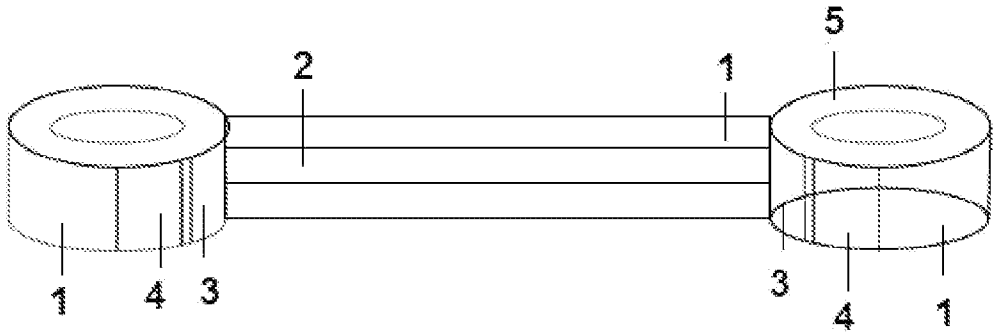

FIG. 3

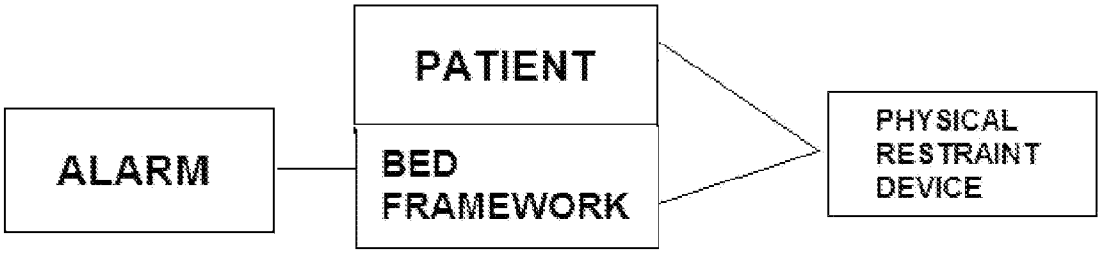

FIG. 4

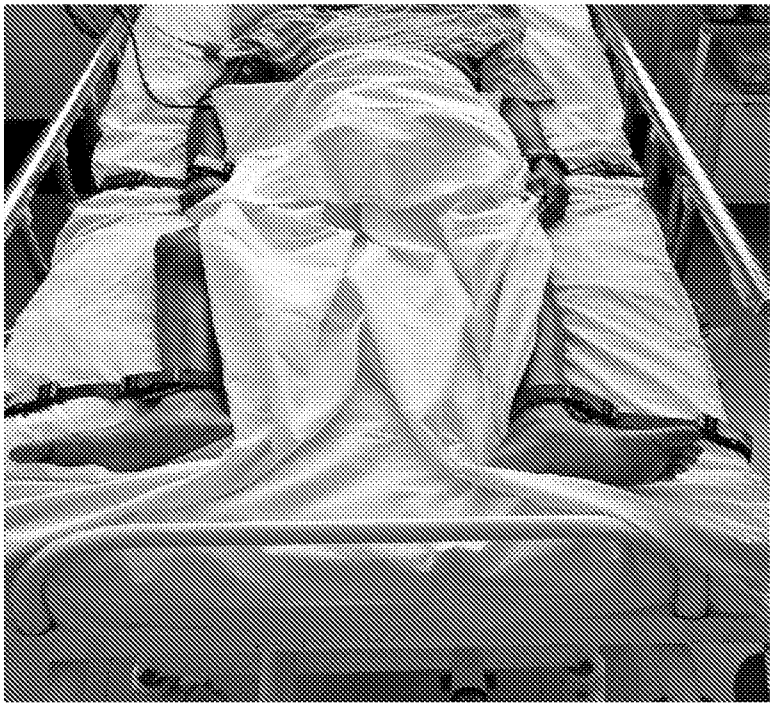

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2018/050720

A. CLASSIFICATION OF SUBJECT MATTER
A61F5/37 Version=2019.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Databases: TotalPatent One, IPO Internal Database
Keywords: Patient restraining, belt, strap, bed

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2848993 A (TERRELL, CHARM G), 26-08-1958 (26 August 1958) claims 1, 3, 7, figures 2, 3	1-10
Y	US 5360019 A (HOLLISTER INC),01-11-1994 (01 November 1994) claim 1, figures 1, 8, 9	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26-03-2019	26-03-2019

Name and mailing address of the ISA/	Authorized officer
Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Shivam Verma Telephone No. +91-1125300200

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:
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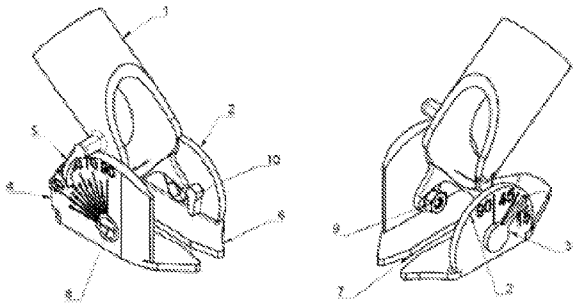


(a) (b)

Fig. 1

(57) **Abstract:** Disclosed is an injection guide comprises a holder (1) being cylindrical shape, said holder is having a provision for insertion of a syringe; a base frame (6) means to support for the syringe holder; primary angle unit (2) and secondary angle unit (4), said units having a predetermined degree of angle varying from 10° to 90°; a primary pointer (3) and a secondary pointer (5);the primary pointer and the secondary pointer being connected to primary angle unit (2) and secondary angle unit (4) respectively; a slit (7) being oval shape means to insert the needle; said slit being centrally placed in the said injection guide; wherein the syringe holder (1) being fixed to the primary unit system (2,3) or the secondary unit system (4, 5) such that the needle of the syringe can attain an angle varying from 10° to 90°; wherein the length of the syringe holder is 46.92mm. The said device is used for intravenous, intramuscular, subcutaneous or intradermal injection.

WO 2020/044358 A1

AN INJECTION GUIDE

FIELD OF THE INVENTION

The present invention relates to an injection guide. More particularly, the present invention relates to an injection guide that provides the delivery process of intravenous, intramuscular, intradermal, subcutaneous etc more accurately and safely.

BACKGROUND OF THE INVENTION

Injections are administered in various angles. Intramuscular injection is administered at 90°, subcutaneous injection at 45°, intravenous injection administered at 20° and intradermal injection at 10 to15°.

Currently, what are the practices to determine these angles:

i) At present injections angles are decided manually;
ii) Devices are available for insertion of Jelcos/scalp veins for administration of Intravenous (IV) fluids/transfusions. Other devices are available to hold syringe i.e. Infusion pumps for intravenous infusion of micro-dose or IV fluids;
iii) charts/Figures of various angles of administration of injections are available.

Many times errors in administration of injections were noted by health care professionals and as a result patient suffers from the complications which sometimes very severe and even in the case, the death might be happened due to this error.

PRIOR ART

US3063449 discloses a syringe holder for supporting a syringe in a desired position such as an inclined position or location. According to US'449' the syringe can be moved from the remote location so a medical professional will be protected from a harmful drug. US'449' may be effective for intravenous process only. Also, the mechanism of US'449' is electrically operated. Further, overall process of the administration is costlier.

US4332248 discloses an apparatus or guide to aid in inserting the needle of syringes and the like into body conduits such as veins. The apparatus includes a pair of

members which are placed on the opposite sides of a vein, parallel to the longitudinal axis thereof, thereby preventing lateral movement of the vein while it is being pierced by the needle. A guide of US'248' is provided to aid in inserting the needle to the desired depth. US'248' is silent how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process.

US2008/0269671 relates to a volume-adjustable micro-injection device. The device includes a base structure having a syringe positioning structure and a grip, in which the syringe positioning structure can flexibly accommodate injection syringes with different volumes; a holding structure capable of flexibly adjusting an injection angle of syringe content for easier operation; a qualitative controller capable of accurately controlling injection volume; a pressure pushing structure to hold and push a plunger; an injection controller interlinked with the qualitative controller and the pressure pushing structure; and an eject structure facilitating the operation and replacement of injection syringes. US'671' states in abstract that *"In contrast to conventional structures, the present invention provides advantages that control injection volume more accurately, address better injection angle control, allow for the syringe contents to be free from air exposure, require no special syringes, and allow for single-handed replacement of the injection syringe"*. However, how such better angle control is done is not disclosed in US'671'. Also, US'248' is silent on how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process. Further, the mechanism of US'671' is electrically operated and overall process of the administration is costlier.

US2007/0232999 relates to an artery stabilizer device, with a slide over which a technician can guide a syringe, is provided for restraining a targeted artery while the technician inserts the needle of the syringe into the artery. A pair of stabilizer fingers holds the artery in place while the syringe is maneuvered over the slide of a shaft which is connected to a base above the stabilizer fingers. US'999' discloses a finger-hold platform emanates from the bottom of the shaft, and a gauze dressing member with a gauze pad is removably attached to the bottom of the platform, allowing the technician to quickly apply a dressing over the wound created by the needle insertion procedure. An artery stabilizer adjustment track allows the technician to alter the width between

each stabilizer finger. US'999' is silent on how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process.

US2012/0000571 discloses a holding devices and methods for using the same. The holding device configured to hold a container having a dose or multiple doses of a liquid medicine with a needle-piercable cap. The holding device includes a holder for the container, a base, and an angular adjustment linkage between the base and the holder. Another aspect of the invention provides a method of loading a syringe with a liquid medicament held in a container. The method includes: providing a holding device including a holder for the container, a base, and an angular adjustment linkage between the base and the holder; placing the holding device on a surface; placing the container into the holder; and using two hands to draw the liquid medicament from the container into the syringe. The purpose of US'571' is to hold the vial only, not to administer into any route of injection.

WO2009047512 discloses an intravenous injection guide and a method of using such a guide which comprising a supporting base frame and one or more guider arms connected to the base frame whereby the guider arm or arms can be used so as to engage with a protrusion from a transfusion set in such a way that the contour of the guider arm or arms helps guide the trajectory of the transfusion needle into the vein of the patient during the act by a user of attempting veni-puncture access for medicinal infusion or blood sampling. It is basically a guiding apparatus for winged type infusion set where the needle of the latter can be assisted to follow a fixed or adjustable or feel enhanced injection tranjectory path aided by guide thus enabling IV process made easier safe. The apparatus assists only for insertion of shaft of venous accesses needles/iv cannulas to superficial and deeper veins, not helps for vein identification/stabilization. The prior art doesn't point how to pierce the vein at 20° (which is the exact angle for intravenous injection) to give single dose of IV injection by simple manner i.e. injection needle attached with syringe. Also, WO'512' is winged type infusion set to which an additional syringe can be attached to give IV injection. The process is therefore is not cost-effective. Further, WO'512' is required transfusion set in conjunction with the specially G-transfusion set (wing type transfusion set) to locate the

injection site. WO'512' is silent on how the device is effective for other route of administration such as intramuscular, subcutaneous and intradermal process.

Prior art findings limited to intravenous process only. Existing devices are not accurate and safe for other route of injection such as intramuscular, subcutaneous and intradermal with addition to intravenous process as there is no provision of determining the exact angle for the injection. Further, the existing devices are electrically operated and costlier in view of construction and overall mode of the treatment.

Accordingly, there is a need to provide an injection guide that could facilitate to determine the exact angle of an injection includes intravenous, intramuscular, subcutaneous and intradermal process.

OBJECT OF THE INVENTION

It is an objective of the invention is to overcome the aforesaid drawbacks and accordingly provide an injection guide.

It is another objective of the invention is to provide an injection guide that provides the delivery process of intravenous, intramuscular, intradermal, subcutaneous more accurately and safely.

It is yet another objective of the invention is to provide an injection guide which facilities intravenous process without use of jelcos/scalpel.

It is yet another objective of the invention is to provide a manually operated injection guide.

It is yet another objective of the invention is to provide injection process that can be carried out accurately with single needle.

It is yet another objective of the invention is to provide an injection guide which can be operated without any uncertainty and fear.

It is yet another objective of the invention is to provide an injection guide which can be operated by one who is under healthcare training.

It is yet another objective of the invention is to provide a cost effective injection process.

It is further objective of the invention is to provide an easy to handle injection guide.

SUMMARY OF THE INVENTION

There is provided an injection guide comprises

a holder (1) being cylindrical shape, said holder is having a provision for insertion of a syringe;

a base frame (6) means to support for the syringe holder;

primary angle unit (2) and secondary angle unit (4), said units having a predetermined degree of angle varying from 10° to 90°;

a primary pointer (3) and a secondary pointer (5);the primary pointer and the secondary pointer being connected to primary angle unit (2) and secondary angle unit (4) respectively;

a slit (7) being oval shape means to insert the needle; said slit being centrally placed in the said injection guide;

wherein the syringe holder (1) being fixed to the primary unit system (2,3) or the secondary unit system (4, 5) such that the needle of the syringe can attain an angle varying from 10° to 90°;

wherein length of the syringe holder is 46.92mm.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1a and 1b illustrates an injection guide in accordance with present invention;

Figure 2 illustrates a cylindrical shape of syringe holder in accordance with present invention;

Figure 3 illustrates the oval slit in accordance with present invention;

Figure 4 illustrates a side view (4a) and front view (4b) of the device in accordance with present invention; &

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

Present invention provides an injection guide for safe and accurate delivery process of the drug through the route selected from intravenous, intramuscular, intradermal and subcutaneous.

Referring now to Figure 1 (a & b), the injection guide according to present invention consists of:

a syringe holder (1);

a primary angle unit (2);

a primary pointer (3);

a secondary angle unit (4):

a secondary pointer (5);

a base (6);

a central slit (7);

a screw (8);

a nut (9);

a stopper (10);

Syringe holder:

The syringe holder (1) according to present invention is cylindrical shape (Figure 2) in which there is a provision of insertion of a syringe of 1cc (for 1mL), 2cc (for 2mL), 5cc (for 5mL) and 10cc (for 10mL) which is as per the need. The internal and external diameter of the syringe holder is as per the width of the syringe. The length of the syringe holder according to present invention is so as to adjust the syringe to get the desired angle for the injection. The critical length of the syringe holder according to present invention is 46.96mm.

Base:

The present invention includes a base (6) for stability while the injection is administered. The length of base according to present invention is as per the type of injection. In preferred embodiment, the length of the base is 26.83-54.5mm while the width is 16-28.8mm.

Primary and secondary angle unit:

According to present invention, left side on the base, there is primary angle unit (2) which presents a chart of 15°, 45° and 90°. One could select 45° for subcutaneous injection and 90° for intramuscular injection. The primary pointer (3) on the primary angle chart shows the current degree on chart.

On the other hand, at right side on the base, there is secondary angle unit (4) which presents a chart of 10° divisions up to 90°. One could select 10°-15° for intradermal injection and 20° for intravenous injection. The secondary pointer (5) on the secondary angle chart shows the current degree on chart. Primary angle unit along with primary pointer and secondary angle unit along with secondary here is primary unit system and secondary unit system respectively.

Other components:

The present invention also comprises an oval slit (7) which is centrally located in the design [Figure 3] means to insert the needle into the skin layer. The width of the slit is 4mm while the length is 45mm. The present device includes a screw with nut to attach syringe holder to the angle charts such as herein described. The present invention also includes a stopper to limit the injection holder to move above 90°. The syringe holder, the base and the other major components as used in the said injection guider is made of plastic known in art.

As shown in Figure 4a and 4b, the present inventor illustrates a side view and front view respectively of the device

Now, the invention is illustrated by non-limiting examples:

Example 1:

Injection guide for subcutaneous injection:

Insulin injection (1cc syringe along with needle, 1mL dose) through subcutaneous route (45° as standard angle) was performed on diabetic patient at **Krishna Institute of Nursing Sciences and Krishna Hospital, Karad** wherein

i) Syringe holder:

Length of the syringe holder: 25mm, 35mm, 46.92mm and 55mm

External diameter of the syringe holder: 10mm

Internal diameter of the syringe holder: 7mm

ii) Base:

Length of the base: 26.83mm

Width of the base: 16mm

iii) Primary and secondary unit angle along with pointer and other component as above

For intravenous (20° angle), intramuscular (90° angle) and intradermal (10° angle) injection, except length of the syringe holder, the dimension of other components was varied and it was selected as per the type of the injection.

Table 1: Observation (Relation between length of the syringe holder and angle of the injection)

Length of syringe holder of the injection guide	Injection route (angle)			
	10° (intradermal)	20° (intravenous)	45° (subcutaneous)	90° (intramuscular)
25mm (comparative example)	unstable syringe	unstable syringe	unstable syringe	unstable syringe
35mm (comparative example)	unstable syringe	unstable syringe	unstable syringe	unstable syringe
46.92mm **(inventive example)**	stable syringe	stable syringe	stable syringe	stable syringe
55mm (comparative example)	Syringe is not moved	Syringe is not moved	Syringe is not moved	Syringe is not moved

Accordingly, the present inventor concludes that not only primary and secondary angle unit of the device but also length of the syringe holder is critical in order to achieve the desired angle for the injection.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

Claims:

1. An injection guide comprises

   a holder (1) being cylindrical shape, said holder is having a provision for insertion of a syringe;

   a base frame (6) means to support for the syringe holder;

   primary angle unit (2) and secondary angle unit (4), said units having a predetermined degree of angle varying from 10° to 90°;

   a primary pointer (3) and a secondary pointer (5);the primary pointer and the secondary pointer being connected to primary angle unit (2) and secondary angle unit (4) respectively;

   a slit (7) being oval shape means to insert the needle; said slit being centrally placed in the said injection guide;

   wherein the syringe holder (1) being fixed to the primary unit system (2,3) or the secondary unit system (4, 5) such that the needle of the syringe can attain an angle varying from 10° to 90°;

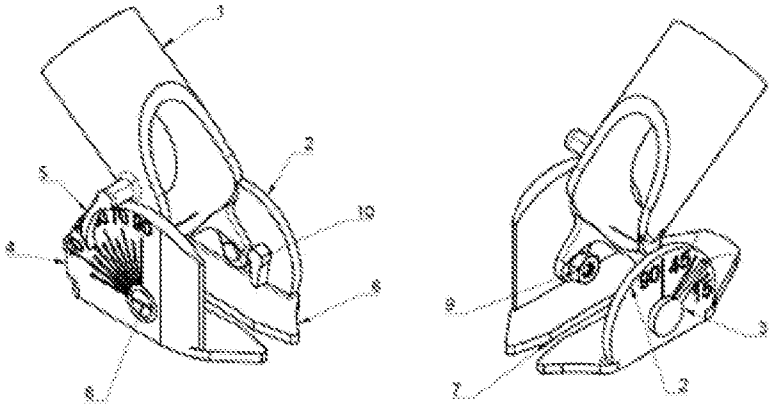
   wherein length of the syringe holder is 46.92mm.

2. The guide as claimed in claim 1, wherein the syringe is 1cc syringe, 2cc syringe, 5cc syringe or 10cc syringe.

3. The guide as claimed in claim 1, wherein length of the base is 26.83-54.5mm.

4. The guide as claimed in claim 1, wherein width of the base is 16-28.8mm.
5. The guide as claimed in claim 1 is made up of a plastic known to person-skilled-in-art.

6. The device as claimed in claim 1 is for an injection selected from a group consisting of intravenous, intramuscular, subcutaneous or intradermal.



(a) (b)

Fig. 1

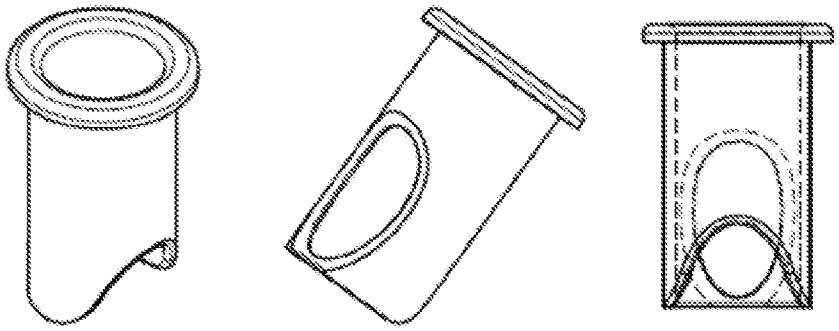


Fig. 2

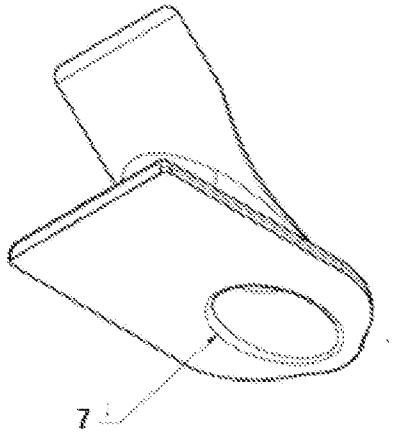


Fig. 3

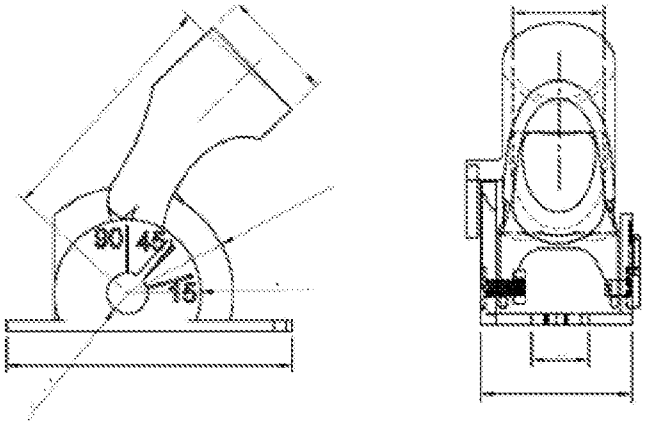


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2018/050721

A. CLASSIFICATION OF SUBJECT MATTER
A61M5/00 Version=2018.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

TotalPatent One, IPO Internal Database
Keywords: syringe holder, angle, guide

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN105473173A (UNION MEDICO APS) 06 APRIL 2016 (06-04-2016) paras [0055]-[0058], para [0336]	1-6
Y	US20080269671A1 (DERMATO-PLASTICA-BEAUTY CO., LTD.) 30 OCTOBER 2008 (30-10-2008) abstract, claim 7	1-6
Y	US2525398A (ARTHUR L. COLLINS) 10 OCTOBER 1950 (10-10-1950) figs.1,2	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10-12-2018	10-12-2018
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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2018/050721

Citation	Pub.Date	Family	Pub.Date
CN 105473173 A	06-04-2016	KR 20160040600 A	14-04-2016
		EP 3027251 A2	08-06-2016
US 20080269671 A1	30-10-2008	TW 200841894 A	01-11-2008

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(54) **Title:** CUSTOMISED ANKLE FOOT ORTHOTIC DEVICE

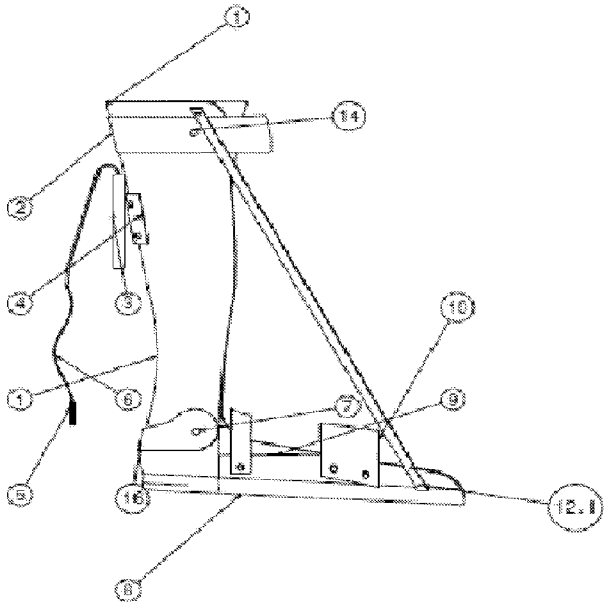

Figure 1a

(57) **Abstract:** A customised ankle foot orthotic device consist of calf piece (1); calf strap (2); a muscle stimulator (3); stimulator suspension (4) includes a press button with nylon strap; two adhesive electrodes (5); electrical wires (6); hinge joint (7); JBR outsole (8); foot piece (9); snkle strap (10); forefoot strap (11); ring (12.2 and 12.3); adjustable strap (13); press button (14); cold and hot pack pouch (15); a means to provide upward projection (16); & shank (17); charecterized in that the adhesive strap being mounted on the the rings (12.2 and 12.3) so as to keep the plantar section of the foot piece (9) in straight position and wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight; wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5wt% ammonium nitrate, 4wt% hydropropylmethyl cellulose and 15wt% propylene glycol; and wherein the said electrode being made up of a hydrogel

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[Continued on next page]

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CUSTOMISED ANKLE FOOT ORTHOTIC DEVICE

FIELD OF THE INVENTION

The present invention relates to an orthotics and physiotherapy field. More particularly, the present invention relates to an orthotic device which can be useful in foot drop problem of a patient suffering from strokes, multiple sclerosis, cerebral palsy patients, and in common peroneal nerve injury.

BACKGROUND OF THE INVENTION

Foot drop is common problem in stroke, multiple sclerosis, cerebral palsy patients, and in common peroneal nerve injury patient. Electrical stimulation and ankle foot orthosis (AFO) have been routinely used in individuals with foot drop to re-educate muscles which are weak and to keep ankle in neutral position. It is known that electrical stimulation is useful in treating individuals with foot drop. Studies (**Freeha Sharif, Samina Ghulam, Arshad Nawaz Malik and Quratulain Saeed, Effectiveness of Functional Electrical Stimulation (FES) versus Conventional Electrical Stimulation in Gait Rehabilitation of Patients with Stroke, Journal of the College of Physicians and Surgeons Pakistan 2017, Vol. 27 (11): 703-706)** showed that the functional electrical stimulation (FES) is better in foot drop than conventional electrical stimulation (EMS) in stroke patients.

Existing ankle foot orthosis and its drawback:

An ankle-foot orthosis, or AFO, is an orthotic device which is a support intended to control the position and motion of the ankle, compensate for weakness, or correct deformities of foot and ankle. AFOs can be used to support weak limbs, or to position a limb with contracted muscles into a more normal position. In addition, AFOs are used to control foot drop caused by a variety of neurologic and musculoskeletal disorders. Due to the common use for addressing foot drop, AFO has become synonymous with the term "foot-drop brace AFO are easy to wear, and can be easily available at orthotics.

Drawbacks:

i) AFO limits mobility and range of motion of joint as it is not movable.

ii) Movements is usually limited to certain direction..

iii) There is restriction of rotation around a joint.

iv) The aforesaid technologies failed to suggest the combined effect of AFO and cold & hot pack pouch in food drop.

Prior art:

A document **(https://www.braceworks.ca/2018/09/20/devices/lower-limbs/afo/ankle-foot-orthoses-and-functional-electrical-stimulation-for-foot-drop-in-ms/)** discloses that the people with multiple sclerosis (MS) have difficulty walking: Gait impairment, including the reduced ankle dorsiflexion of foot drop, is one of the most common indicators of disability early in the course of this progressive autoimmune disease of the central nervous system, affecting approximately 75% of people with MS. Assistive technology, such as ankle–foot orthosis (AFO) and functional electrical stimulation (FES), increases the safety of walking and the speed of ambulation (even then, only about one half of patients remain ambulatory 15 years after disease onset).Assistive technology also reduces the risk of injury to the knee and ankle and reduces the effort of ambulation.

Another document **(https://www.resna.org/sites/default/files/legacy/conference/proceedings/2008/SDC2008/Hadley.html)** discloses that “Cerebral Palsy (CP) is a non-progressive neurological disorder which develops in-utero or after birth. Current treatment for CP includes physical therapy and braces used to increase ambulation. Ankle-Foot Orthoses (AFOs) are lightweight plastic braces that secure the lower leg, ankle, and foot in a predetermined position, commonly used to aide dorsiflexion in CP patients. another common treatment, Functional Electrode Stimulation (FES), is administered by physical therapists in order to build muscle tone and improve dorsiflexion. FES

uses low energy electrical stimulation to excite either the common peroneal nerve or the tibialis anterior muscle, causing the patient to actively dorsiflex, increasing foot-ground clearance. Our device integrates an FES unit with a hinged AFO, to automate and improve the current physical therapy processes used to treat CP patients. This allows for the rapid and accurate placement of FES electrodes, which removes the major barrier to at-home administration of this therapy.

A literature **(Walbran et al., *Cogent Engineering* (2016), 3: 1227022 http://dx.doi.org/10.1080/23311916.2016.1227022)** discloses neuromuscular disorders and injuries such as cerebral palsy and stroke often result in foot-drop which can result in a person having great difficulty walking. Ankle foot orthoses (AFOs) or splints have been prescribed for many years now to limit the range of motion of the ankle, provide the patients with support and assist with rehabilitation. However the majority of AFOs require a long, labour-intensive manufacturing process which results in unacceptable waiting times for children that are rapidly growing and patients with varying conditions. This research proposes a new approach to AFO manufacturing that utilizes digital and additive manufacturing technologies to customise the fit and form to an individual. By implementing an interchangeable carbon fibre spring at the ankle joint the design will result in a stronger, more comfortable, more flexible AFO that can adaptively constrain ankle movement for various different activities. Three iterations of AFO design have been developed and tested to validate their efficacy. A custom machine has been designed and constructed in order to empirically test stiffness values for the AFO and allow for optimal AFO geometry based on input parameters. This machine has proven the structural integrity of the final AFO design. Progress has been made in automating parts of the design process which will significantly reduce labour requirements and hence manufacturing delay times.

Another literature **(Mario C. Faustini, Richard R. Neptune*, Richard H. Crawford, and Steven J. Stanhope, Manufacture of Passive Dynamic Ankle–Foot Orthoses Using Selective Laser Sintering, IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, VOL. 55, NO. 2, FEBRUARY 2008)** discloses AFO designs vary in size, shape, and functional characteristics depending on the desired clinical application. Passive Dynamic (PD) Response ankle–foot orthoses (PD-AFOs) constitute a design that seeks to improve walking ability for persons with various neuromuscular disorders by passively (like a spring) providing variable levels of support during the stance phase of gait. Current PD-AFO manufacturing technology is either labor intensive or not well suited for the detailed refinement of PD-AFO bending stiffness characteristics. The study was to explore the feasibility of using a rapid freeform prototyping technique, selective laser sintering (SLS), as a PD-AFO manufacturing process. Feasibility was determined by replicating the shape and functional characteristics of a carbon fiber AFO (CF-AFO). The study showed that a SLS-based framework is ideally suited for this application. A second objective was to determine the optimal SLS material for PD-AFOs to store and release elastic energy; considering minimizing energy dissipation through internal friction is a desired material characteristic. This study compared the mechanical damping of the CF-AFO to PD-AFOs manufactured by SLS using three different materials. Mechanical damping evaluation ranked the materials as Rilsan™ D80 (best), followed by DuraForm™ PA and DuraForm™ GF. In addition, Rilsan™ D80 was the only SLS material able to withstand large deformations.

US8512415 discloses a powered ankle-foot prosthesis, capable of providing human-like power at terminal stance that increase amputees metabolic walking economy compared to a conventional passive-elastic prosthesis. The powered prosthesis comprises a unidirectional spring, configured in parallel with a force-controllable actuator with series elasticity. The prosthesis is controlled to deliver the high mechanical power and net positive work observed in normal human walking.

US8808214 discloses an Active Ankle Foot Orthosis (AAFO) is provided where the impedance of an orthotic joint is modulated throughout the walking cycle to treat ankle foot gait pathology, such as drop foot gait. During controlled plantar flexion, a biomimetic torsional spring control is applied where orthotic joint stiffness is actively adjusted to minimize forefoot collisions with the ground. Throughout late stance, joint impedance is minimized so as not to impede powered plantar flexion movements, and during the swing phase, a torsional spring-damper (PD) control lifts the foot to provide toe clearance. To assess the clinical effects of variable-impedance control, kinetic and kinematic gait data were collected on two drop foot participants wearing the AAFO. It has been found that actively adjusting joint impedance reduces the occurrence of slap foot, allows greater powered plantar flexion, and provides for less kinematic difference during swing when compared to normal.

US8838263 discloses a computer-controlled fabrication of a patient-specific orthotic device using an automated fabrication machine capable of following computer instructions to create 3D surface contours and new developments in non-invasive three-dimensional (3D) scanning have made it possible to acquire digital models of freeform surfaces such as the surface anatomy of the human body and to then fabricate such a patient-specific device with high precision. Such a patient-specific device brings significant improvement in patient-specific fit, comfort, and function of medical devices (and, in particular, to orthoses that require a close fit to the wearer's body to act effectively). The combination of these two technologies is ideally suited for the development of patient-specific orthotic devices. A patient specific ankle-foot orthotic device using this technology is disclosed. This exemplary device is used to help stabilize the ankle-foot region, for example, in patients with impaired gait.

None of the document suggests a hot and cold pouch unit in AFO and FES system for improving foot drop of strokes, multiple sclerosis, cerebral palsy patients, and common peroneal nerve injury patients.

The existing document failed to suggest the adhesive electrode in AFO and FES system for improving foot drop of strokes, multiple sclerosis, cerebral palsy patients, and common peroneal nerve injury patients.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a customised ankle foot orthotic device with an effective hot and cold pouch unit for improving foot drop of a patient selected from strokes, multiple sclerosis, cerebral palsy patients and common peroneal nerve injury.

It is another objective of the invention is to provide a customised ankle foot orthotic device with novel adhesive electrode for the treatment of foot drop.

It is yet another objective of the invention is to provide a customised ankle foot orthotic device with novel adjustable strap for the treatment of foot drop.

It is yet another objective of the invention is to provide a novel customised foot orthotic device for improving gait and rehabilitation.

It is yet another objective of the invention is to provide a cost effective and easy to use orthotic device for foot drop problem.

It is yet another objective of the invention is to provide a device that could reduce the pain as compared to conventional AFO while treating foot drop.

It is further objective of the invention is to increase the speed of a foot drop patient in treadmill using the device.

SUMMARY OF THE INVENTION

According to first aspect of the invention, there is provided a customised ankle foot orthotic device consist of

calf piece (1);
calf strap (2);
a muscle stimulator (3);
stimulator suspension (4) includes a press button with nylon strap;
two adhesive electrodes (5);
electrical wires (6);
hinge joint (7);
JBR outsole (8);
foot piece (9);
ankle strap (10);
forefoot strap (11);
ring (12.2 and 12.3);
adjustable strap (13);
press button (14);
cold and hot pack pouch (15)
a means to provide upward projection (16); &
shank (17);

charecterized in that the adhesive strap being mounted on the the rings (12.2 and 12.3) so as to keep the plantar section of the foot piece (9) in straight position and

wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene

wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight;

wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5 wt% ammonium nitrate, 4 wt% hydropropylmethyl cellulose and 15 wt% propylene glycol; and

wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1a schematically illustrates the customised ankle foot orthotic device in accordance with the present invention;

Figure 1b schematically illustrates the side view of the device in accordance with the present invention;

Figure 1c schematically illustrates the front view of the device in accordance with the present invention;

Figure 1d schematically illustrates the rear view of the device in accordance with present invention; &

Figure 2 is the visual analogue scale for the measure of pain in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:

Expression:

The following term as used in the invention is defined:

Ankle Foot Orthosis (AFO): It is a device applied to the ankle for modifying functional characteristics of neuromuscular conditions.

Electrical Stimulator: It is an electrical device which is used for stimulating impaired structures in neuromuscular conditions and for improving strength in weak muscles.

Range Of Motion (ROM): It is a linear or angular distance that a moving object normally travels while properly attached to other. Usually it ranges or flexion and extension. Alternatively, the range of motion is defined as it is the measurement of movement around a specific joint. The range of motion is denoted by “degree”.

Foot Drop: It is the neuromuscular condition in which the muscles or nerve which are supplying to the foot are paralysed and is unable to lift the foot while walking it is called as Foot Drop.

Spasticity: It is the condition in which muscles get stiff and tight.

Stroke: It is medical condition in which there is poor blood supply to brain which may result in cell death due to interruption of blood flow there is damage to brain. Stroke caused by blocked artery or bursting of blood vessels. Due to this, brain is not functioning properly which may lead to improper body functioning.

Multiple Sclerosis: It is potentially disabling disease of brain and spinal cord. In multiple sclerosis the immune system attacks the protective sheath (myelin) that covers nerve fiber and causes communicating problem between the brain and rest of body.

Cerebral Palsy: It is a congenital disorder of movement muscle tone and posture that appear in early childhood.

Visual analog scale (VAS): It is a psychometric response scale which can be used in questionnaires. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points.

The present invention provides a customised ankle foot orthotic device for improving foot drop of a patient selected from strokes, multiple sclerosis, cerebral palsy patients and common peroneal nerve injury. The device (Figure 1a-1d) of the present invention consist of

1. Calf piece;
2. Calf strap;
3. Portable Muscle stimulator;
4. Stimulator suspension consisting of press button with nylon strap;
5. Adhesive electrode;
6. Electrical wires;
7. 2D hinge joint consisting of 4mm MS nut and bolt;
8. JBR outsole;
9. Foot piece;
10. Ankle strap;
11. Forefoot strap;
12. Ring;
13. Adjustable strap;
14. Press button;
15. Cold and Hot pack pouch;
16. Upward projection; &
17. Shank;

Referring to Figure 1a-1d, the orthosis of the present invention mainly consists of two sections: a Calf piece (1) and a Foot (9) which are articulately joined on each side of the ankle by two hinge joint of MS nuts and Bolts (7). The calf piece comprises a calf strap with an upper portion which may be wrapped around the patient's calf and secured by a velcro strap (2). The strap is attached to one side of the greave while the other end is free and is designed to loop around the calf. Below the strap (2), there is a stimulator suspension (4) which consists of press buttons in which portable muscle stimulator (3) is mounted. The greave extends downward from the calf area (1) to forward narrow shank (17) below which the greave broadens at ankle area to match the contour of the ankle. The plantar section (9) has a JBR (Johnson bros rubber) outsole (8) and an upward project on (16) which intimately wraps around heel & ankle areas of the patient. The hinge joints (7) are mounted loosely so that a plantar section (9) can rotate upward around the axis delineated by the two hinge (7). This movement of plantar section (9) provides for dorsiflexion of foot during the swing phase of gait cycle. The downward movement of plantar section (9) is stopped when the upper edge of the projection (16) comes in contact with the on the inner side of greave (2) thus, preventing the foot drop. The two sections (1) and (9) of the present device are made from thin-sheeted polypropylene material which are designed so as to counter the shape of the objects leg and foot. Ankle strap (10) is looped around the ring ankle (12.1) so as to fasten the strap tightly around the ankle. Forefoot strap (11) which is looped around the forefoot so as to fasten the strap tightly around the forefoot. Adjustable straps (13) is mounted on respective side by a ring (12.2) & (12.3) for keeping plantar section (9) in a stretched position.

Electrical muscle stimulator (3) consist of two adhesive electrodes (5) attached by electrical wire (6). Pouch (15) which is the inner aspect of calf piece of AFO includes cold and hot pack. All the straps herein are embedded by press buttons

All straps are embedded by press buttons (14).

Adhhesive electrode:

The self-adhesive hydrogel electrodes (5) according to present invention is prepared by the method as given in **Keller et al., Electrodes for transcutaneous (surface) electrical stimulation, JOURNAL OF AUTOMATIC CONTROL, UNIVERSITY OF BELGRADE, VOL. 18(2):35-45, 2008** except the amount of acrylic acid and N-vinylpyrrolidone which is 1:2 by weight in the present invention. The impulses are generated by the device and are delivered through electrodes on the skin near to the muscles being stimulated. The electrodes are generally pads that adhere to the skin. The impulses mimic the action potential that comes from the central nervous system, causing the muscles to contract.

Hot and cold pouch:

The hot and cold pouch according to present invention is prepared by the method disclosed in **US4462224**:

Table 1

Formulation code	Gel formulation					
G-I	Water solvent	Solute	Gelling agent	Wetting agent	-23°C to 10°C, Time	Ambient Viscosity
G-2	35 wt. %	35 wt. % NH_4NO_3	5wt% F4M Methocel	25wt% propylene glycol	15 minutes	>1,000,000 centipoise
G-3	42.5 wt. %	42.5 wt. % NH_4NO_3	5wt% F4M Methocel	10wt% propylene glycol	31 minutes	273,000 centipoise

G-4	41,83 wt %	41.83 wt. % NH_4NO_3	5wt% F4M Methocel	12.33wt% propylene glycol	29 minutes	>1,000,000 centipoise
G-5	40.5 wt. %	40.5 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% propylene glycol	25.6 minutes	563,000 centipoise
G-6	40 wt. %	40 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% propylene glycol	21 minutes	>1,000,000 centipoise
G-7	37.5 wt. %	37.5 wt. % NH_4NO_3	5wt% F4M Methocel	20wt% propylene glycol	13.5 minutes	>1,000,000 centipoise
G-8	40 wt. %	40 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% ethanol	17 minutes	>1,000,000 centipoise
G-9	40 wt, %	40 wt. % NH_4NO_3	5wt% SGP	15wt% propylene glycol	19 minutes	183,000 centipoise
G-10	40 wt. %	40 wt. % NH_4NO_3	5wt% gum tragacant	15wt% propylene glycol	16.5 minutes	170,000 centipoise
G-11	40 wt. %	40 wt. % NH_4NO_3	5wt% guar gum	15wt% propylene glycol	18.3 minutes	>1,000,000 centipoise
G-12	43.75 wt. %	31,25 wt. % NH_4NO_3	5wt% F4M Methocel	20wt% propylene glycol	11 minutes	>1,000,000 centipoise

G-13	51,33 wt, %	28.66 wt. % NH_4NO_3	5wt% F4M Methocel	15wt% propylene glycol	19.5 minutes	>1,000,000 centipoise
G-14	40 wt. %	28 wt.% $CO(NH_2)_2$ and 12 wt. % KCl	5wt% F4M Methocel	15wt% propylene glycol	11 minutes	>1,000,000 centipoise
G-15	37.5 wt. %	37.5 wt. % NH_4NO_3	5wt% F4M Methocel	20wt% metahnol	11.5 minutes	780,200 centipoise

Wherein Methocel: Hydroxypropyl methyl cellulose

Adjustable strap:

The self adjusted strap herein is used for stretching purposes in which specific muscle or tendon (or muscle group) is deliberately flexed or stretched in order to improve the muscle's felt elasticity and achieve comfortable muscle tone. The result is a feeling of increased muscle control, flexibility, and range of motion. A combination of polyvinyl chloride:polypropylene:polyethylene 1:1:2 by weight according to the present invention is used for making the strap. The orthotic device of the present invention improves the gait and rehabilitation ,in previously used orthosis there were not active dorsiflexion which is very important for gait training and rehabilitative purposes we just have to wear and do gait training ,thus our device is doing dorsiflexion of ankle with the help of functional electrical stimulation through adhesive pads which is fitted on tibialis anterior muscle,this will also gives feedback.

The customised ankle foot orthotic device according to the present invention increases the speed of a foot drop patient in treadmill as compared to conventional AFO.

The invention is now illustrated by non-limiting examples.

Example 1:

Preparation of the hot and cold pouch unit and the adhesive hydrogel:

All the materials like the solute, solvent, gelling agent, wetting agent & other parameters as in Table 1, was purchased from the local market, Mumbai and prepared the gel formulation following the method disclosed in US4462224. 20 g of the gel was incorporated into the pouch for the purpose of treatment.

The adhesive electrode was prepared by the method disclosed in Keller et al in which the amount of acrylic acid and N-vinylpyrrolidone which is 1:2 by weight.

Experimental trials:

The experimental trial as to evaluate the efficacy of the present device for foot drop, was conducted in **Krishna Institute of Physiotherapy, near Dhebewadi Road, Malkapur, Karad, Pin code- 415110, Maharashtra, India**.

10 NOS patient whose average weight of 40-70 either gender, was selected for the following each groups:

Goup-I: strokes;

Goup-II: multiple sclerosis;

Goup-III: cerebral palsy patients; &

Goup-III: common peroneal nerve

Following were the steps to set the device to the patient:

Turn on the intensity:

After the electrodes were placed firmly on skin and the lead wires are plugged in the socket of device, turn the ON/ OFF control clockwise.The menu will reveal on LCD.

Select mode:

There were two EMS modes of option, S (synchronous) or A (alternate) .Select a mode by pressing the mode control when a EMS mode is selected, the LCD shows EMS on the top. After a mode is selected, press SET control to enter next setting. The patient may adjust the setting only when it is flashing and then press the increment or decrement control to change the settings.

Set Ramp Time:

The ramp time controls the time of output current that increase from 0 to the setting level, and from the setting value to 0. When the ramp time was set, each contraction was ramped up and down in order that the signals come on and come off gradually and smoothly. The ramp time was adjustable from 1 to 8 seconds.

Set ON time:

The On Time controls the time of stimulation. By pressing the “SET” control, the contraction time can be adjusted. Both channels stimulation was cycled on and off by the contraction and relaxation settings. The_range is_adjustable_ from 2 seconds to 90 seconds.

As the “ON” time including the ramp up and ramp down time, the setting of it should be no less than two times of the “RAMP” time.

Set OFF time:

The off times controls the time of relaxation. By pressing the "SET" control , the relaxation time can be adjusted. Both channels stimulation is cycled on and off by the contraction and relaxation settings. The range ios adjustable from 0 second to 90 seconds.

In alternate mode, the OFF time should be equal or more than the ON time.

Set Pulse Width:

Pulse Width was adjustable from 50 us to 300 us. Press "SET" control to enter this menu, the press "Increment or Decrement" to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 us setting.

Set Pulse Rate:

Pulse rate was adjustable from 2Hz to 150Hz. Press "SET" control to enter this menu, then press "Increment or Decrement" to adjust the setting. Unless otherwise instructed, turn the pulse rate control to the 70-120 range.

Set Timer:

The treatment time was adjustable from 1 to 60 minutes or C (continuous). Press "SET" control to enter this menu, then press "Increment" or "Decrement" to adjust the setting. Press "Increment" control when the timer shows 60 minutes, it was switched to continuous stimulation.

Compliance Meter:

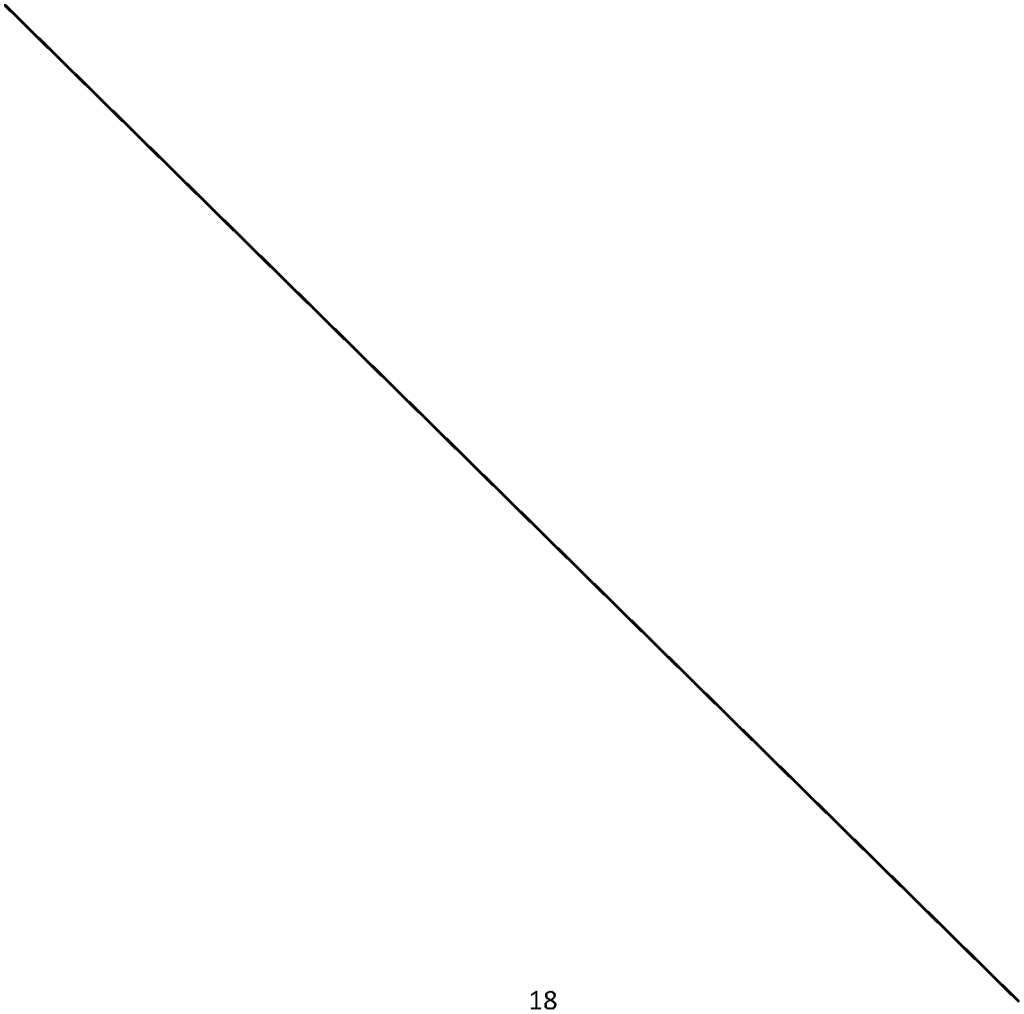
This unit can store 60 sets of operation records. Total treatment time up to 999 hours can be stored.

Check and Delete individual record:

Press “MODE” control and turn on the power simultaneously. The LCD display shows the number of records and operation time. Press the “increment” and “decrement” button to each record. After all set then train the patient on flat surface with customized dynamic orthosis, and then make him to walk on treadmill with obstacles placing between them.

Comparative study of customised ankle foot orthotic device with or without hot & cold unit and adjustable strap for range of motion:

Table 2



Sr. No.	Pre-treatment # (i.e. without customised ankle foot orthotic device) (ROM)	Post-treatment# i.e. with customised ankle foot orthotic device BUT without hot and cold unit and adjustable strap (ROM) (CE)	Post-treatment i.e. with customised ankle foot orthotic device WITH hot and cold unt (G1-G15) and the adjustable strap P:P:P 1:1:2 (ROM)															Post treatment with G4 & adjustable strap P:P:P 1:1:1 (ROM) (CE)
			G1 (CE)	G2 (CE)	G3 (CE)	G4 **(IE)**	G5 (CE)	G6 (CE)	G7 (CE)	G8 (CE)	G9 (CE)	G10 (CE)	G11 (CE)	G12 (CE)	G13 (CE)	G14 (CE)	G15 (CE)	19°
1	5°	15°	17°	19°	17°	25°	16°	15°	18°	19°	18°	17°	19°	19°	17°	15°	16°	20°
2	10°	20°	20°	20°	21°	35°	21°	19°	19°	20°	19°	19°	20°	21°	19°	18°	20°	21°
3	9°	15°	15°	16°	22°	30°	23°	18°	21°	19°	18°	17°	22°	19°	21°	21°	22°	24°

4	15°	18°	19°	18°	20°	40°	22°	17°	19°	19°	20°	19°	22°	20°	20°	18°	22°	21°
5	18°	22°	22°	21°	24°	45°	20°	21°	21°	21°	21°	20°	21°	21°	22°	19°	21°	18°
6	20°	14°	14°	16°	15°	42°	19°	19°	22°	18°	17°	19°	20°	17°	16°	21°	20°	20°
7	8°	16°	16°	20°	20°	35°	21°	16°	20°	21°	19°	16°	21°	20°	19°	19°	20°	20°
8	10°	17°	17°	19°	21°	40°	21°	19°	21°	19°	17°	19°	21°	17°	21°	20°	21°	19°
9	14°	19°	20°	20°	19°	38°	19°	20°	23°	20°	21°	21°	20°	23°	20°	21°	20°	19°
10	13°	18°	18°	20°	20°	40°	19°	18°	19°	19°	19°	21°	19°	19°	18°	17°	18°	19°

Wherein #: Measurement was done with the help of goniometer

CE: Comparetive example;

IE: Inventive example; &

P:P:P = polyvinyl chloride:polypropylene:polyethylene

Table 2 shows the superior effect of hot and cold unt made up of the gel formulation G4 (40.5% water; 40.5% NH_4NO_3, 4% F4M Methocel, 15% propylene glycol) and adjustable strap made up of a combination of polyvinyl chloride:polypropylene:polyethylene 1:1:2 while evaluating range of motion (ROM) in foot drop of a stroke patient.

Accordingly, hot & cold pack unit (15) made up of G4 (40.5% water; 40.5% NH_4NO_3, 4% F4M Methocel, 15% propylene glycol) and adjustable strap (13) made up of a combination of polyvinyl chloride:polypropylene:polyethylene 1:1:2 both were selected for further studies.

10-meter walk test:

The present device was evaluated by 10-meter walk test and the results were noted in metres/second. The individual was walked without assistance for 10 metres, with the time measured for the intermediate 6 metres to allow for acceleration and deceleration. Assistive devices may be used, but must be kept consistent and documented for each test. Count the start time when the toes pass the 2 metre mark and stoping time when the toes pass the 8 metre mark. It can be tested at either preferred walking speed or maximum walking speed (ensure to document which was tested). This test was performed for each group of disease three times and calculated te average of the same.

Visual analogue scale/Graphic rating scale:

As shown in Figure 2, the Visual Analogue Scale (VAS) or Graphic Rating Scale was first used in psychology by Freyd in 1923, consists of a straight line with the endpoints defining extreme limits such as 'no pain at all' and 'pain as bad as it could be'. The patient was asked to mark his pain level on the line between the two endpoints. The distance between 'no pain at all' and the mark then defines the subject's pain as 0-3.99 as mild; 4-6.99 as moderate and 7-10 as severe.

Table 3: Group I (Stroke patients)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive example)**	Conventional AFO# **(Comparetive example)**	Conventional AFO# **(Comparetive example)**	Customised ankle foot orthotic device **(Inventive example)**
1	40	0.97	0.71	8	2

2	45	0.99	0.68	7	2
3	55	0.97	0.73	9	1
4	60	0.99	0.65	6	2
5	58	0.98	0.73	6	1
6	59	0.99	0.69	7	4
7	53	0.94	0.72	8	4
8	54	0.98	0.76	9	1
9	55	0.98	0.70	8	3
10	45	0.92	0.68	9	4

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 4: Group II (multiple sclerosis)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive example)**	Conventional AFO# **(Comparetive example)**	Conventional AFO# **(Comparetive example)**	Customised ankle foot orthotic device **(Inventive example)**
1	55	0.98	0.69	9	1

2	45	0.96	0.70	6	2
3	56	0.89	0.73	7	4
4	95	0.99	0.75	8	1
5	58	0.96	0.68	9	3
6	65	0.98	0.78	6	2
7	40	0.97	0.77	5	1
8	42	0.94	0.71	8	3
9	49	0.96	0.77	7	4
10	54	0.94	0.74	8	2

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 5: Group III (cerebral palsy patients)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive example)**	Conventional AFO# **(Comparetive example)**	Conventional AFO# **(Comparetive example)**	Customised ankle foot orthotic device **(Inventive example)**

1	14	0.85	0.65	5	2
2	15	0.89	0.68	7	3
3	25	0.90	0.70	6	1
4	21	0.87	0.68	9	2
5	11	0.90	0.69	4	1
6	25	0.91	0.65	7	1
7	18	0.92	0.66	5	3
8	14	0.85	0.68	6	1
9	19	0.86	0.70	3	2
10	12	0.87	0.75	2	1

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 6: Group IV (common peroneal nerve)

Sr. No.	Patients age	10 meter walk test SPEED (metres/sec)		Visual analogue scale	
		Customised ankle foot orthotic device **(Inventive example)**	Conventional AFO# **(Comparetive example)**	Conventional AFO# **(Comparetive example)**	Customised ankle foot orthotic device **(Inventive**

					example)
1	25	1.02	0.85	7	3
2	18	1.05	0.89	8	2
3	42	1.50	0.90	9	2
4	35	0.99	0.78	6	3
5	28	1.23	0.91	8	1
6	45	1.7	0.86	5	2
7	54	1.56	0.87	7	3
8	52	1.22	0.83	8	2
9	70	1.23	0.92	7	1
10	22	1.11	0.89	9	2

conventional AFO was prepared with the same components as in present device but WITHOUT the adhesive electrode (5), the hot & cold pack unit (15) and adjustable strap (13). Silicone electrode was used in the conventional AFO.

Table 3-6 showed the superior effect of customized ankle foot orthotic device as compared to conventional AFO in view of both 10-meters walk test and the visual analogue scale for different diseases conditions.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of

changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

Claims:

1. A customised ankle foot orthotic device consist of

calf piece (1);

calf strap (2);

a muscle stimulator (3);

stimulator suspension (4) includes a press button with nylon strap;

two adhesive electrodes (5);

electrical wires (6);

hinge joint (7);

a rubber outsole (8);

foot piece (9);

ankle strap (10);

forefoot strap (11);

ring (12.2 and 12.3);

adjustable strap (13);

press button (14);

cold and hot pack pouch (15)

a means to provide upward projection (16); &

shank (17);

charecterized in that the adhesive strap being mounted on the the rings (12.2 and 12.3) so as to keep the plantar section of the foot piece (9) in straight position and

wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene

wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight;

wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5 wt% ammonium nitrate, 4 wt% hydropropylmethyl cellulose and 15 wt% propylene glycol; and

wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone.

2. The customised ankle foot orthotic device as claimed in claim 1, wherein the ratio of

acrylic acid and N-vinylpyrrolidone is 1:2 by weight.

3. The customised ankle foot orthotic device as claimed in claim 1, wherein the downward movement of plantar section (9) is stopped when the upper edge of the projection (16) comes in contact with the inner side of greave (2).

4. The customised ankle foot orthotic device as claimed in claim 1, wherein the calf piece (1) and foot piece (9) is made up of polypropylene material.

5. The customised ankle foot orthotic device as claimed in claim 1, wherein the straps are embedded by the press botton (14).

6. The customised ankle foot orthotic device as and when used for foot drop of the disease condition selected from a group consisting of strokes, multiple sclerosis, cerebral palsy or common peroneal nerve injury.

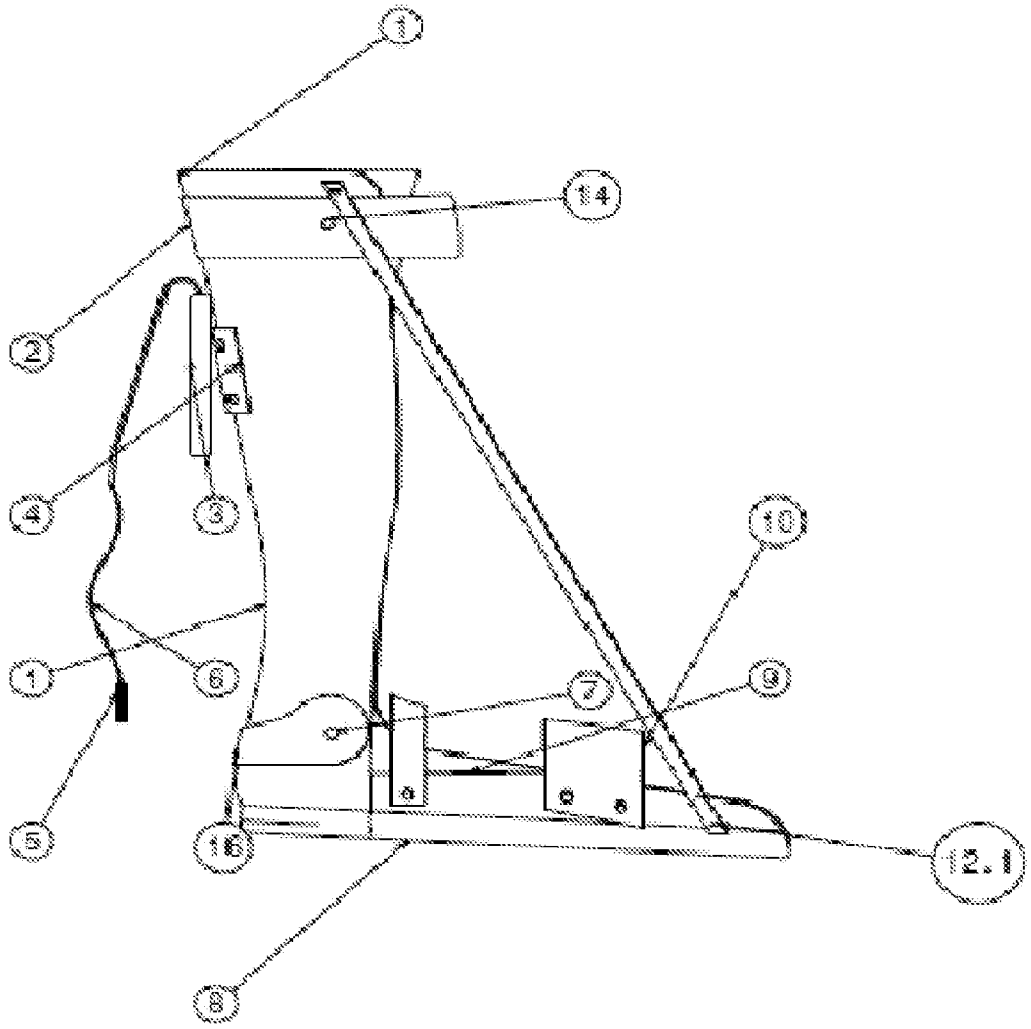


Figure 1a

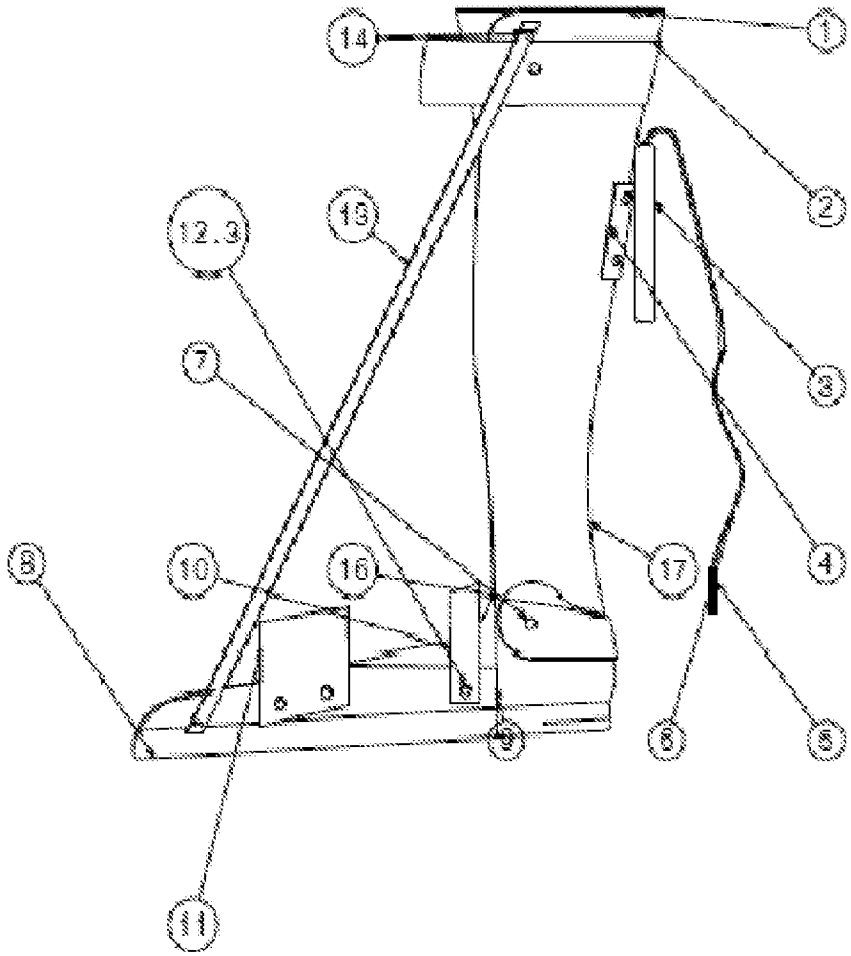


Figure 1b

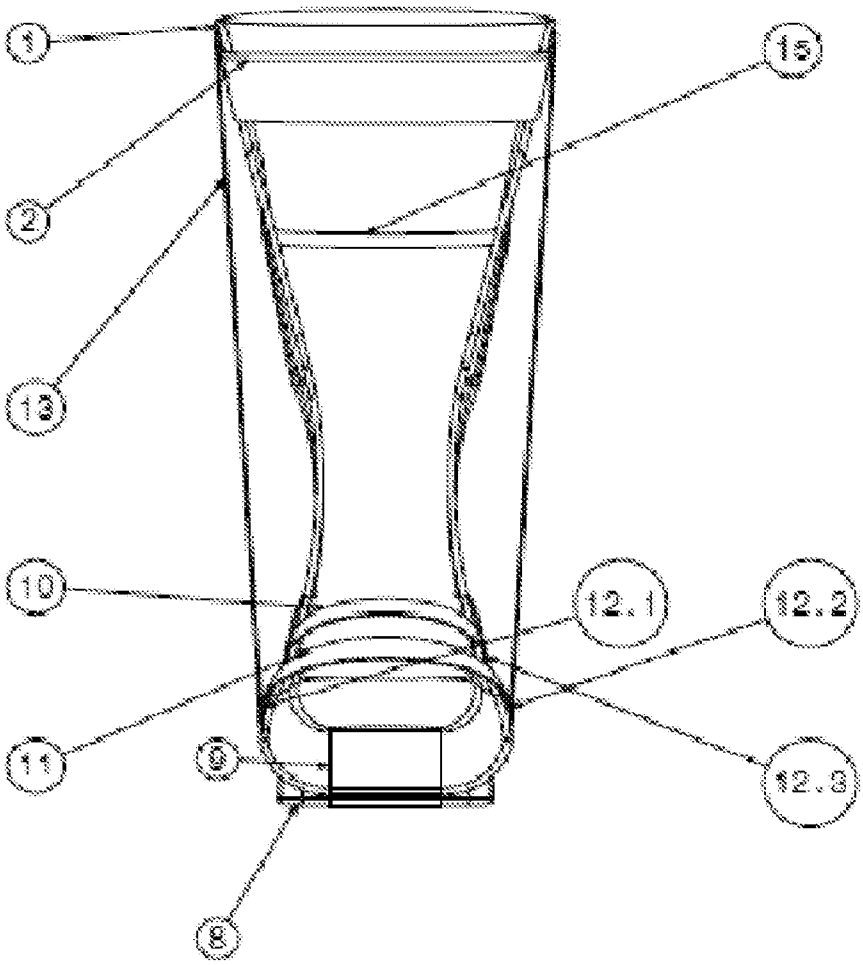


Figure 1c

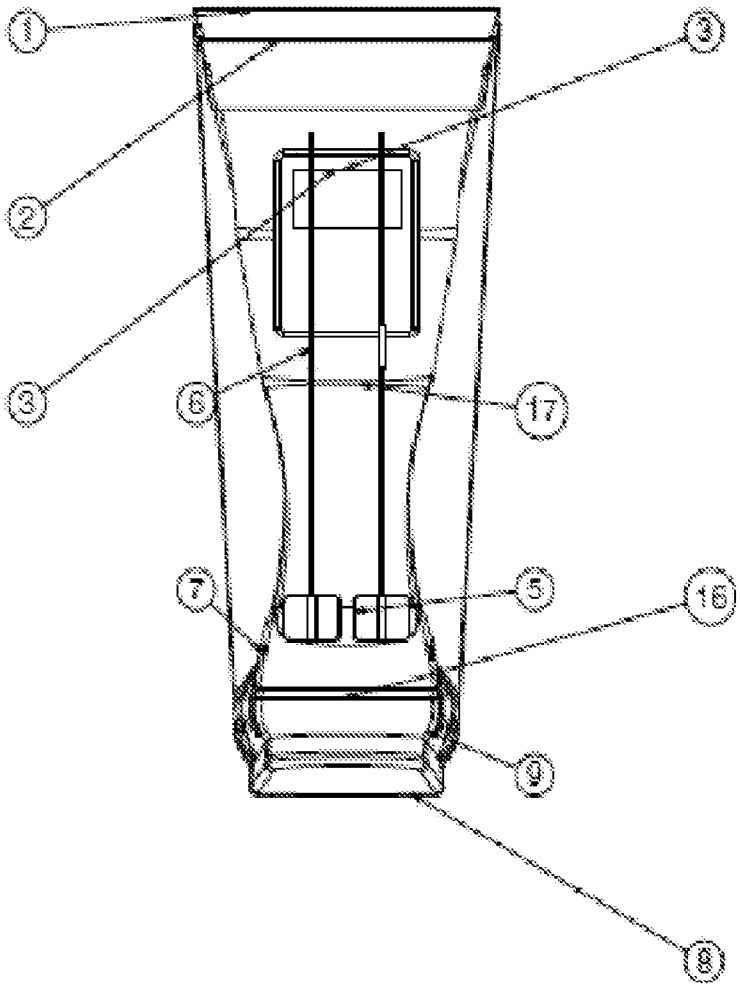


Figure 1d

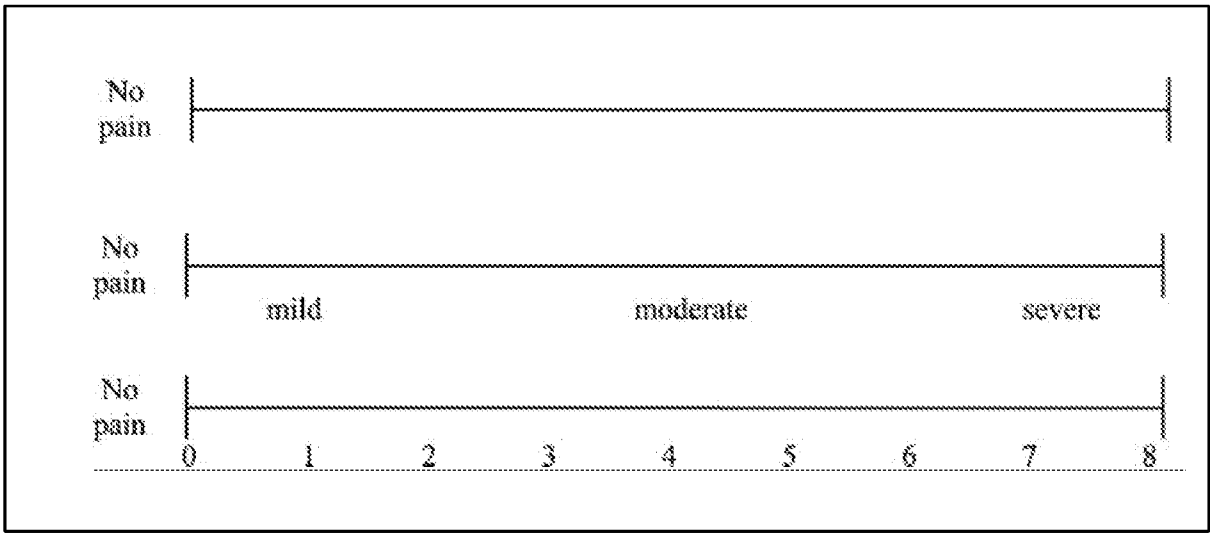


Figure 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2019/050425

A. CLASSIFICATION OF SUBJECT MATTER
A61F5/01 Version=2019.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Databases: Total Patent One, IPO Internal Database
Keywords:orthotic,functional electrical stimulation,adhesive electrode

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP0302148A1(UNIV STRATHCLYDE[GB])08 February 1989(08-02-1989) Abstract, Paragraphs[0034],Figures 1,2	1-6
Y	AU2015236546 (A1)(BIONESS INC[US])21 July 2016(21-07-2016) Abstract,Paragraphs[1043]-[1047]	1-6
Y	US2017266443 (A1)(EMKINETICS INC[US])21 September 2017 (21-09-2017) Abstract,Paragraphs[0183],[0194],[0318-0319],Figures 25-28	1-6
Y	US2017157396 (A1)(UNIV FLORIDA[US])08 June 2017 (08-06-2017) Paragraphs [0054],[0055],Figure 3,4	1-6

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/	Authorized officer
Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Devendra Kumar Deshmukh Telephone No. +91-1125300200

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2019/050425

Citation	Pub.Date	Family	Pub.Date
EP 0302148 A1	08-02-1989	GB 2186191 A	12-08-1987
		US 5121747 A	16-06-1992
AU 2015236546 A1	21-07-2016	US 2015265834 A1	24-09-2015
		EP 3122419 A1	01-02-2017
US 2017266443 A1	21-09-2017	AU 2007303223 A1	10-04-2008
		EP 2456512 A1	30-05-2012
US 2017157396 A1	08-06-2017	EP 3151914 A2	12-04-2017
		WO 2015199956 A2	30-12-2015

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Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

(54) **Title:** AN ORTHOTIC DEVICE FOR SUPPORTING A SHOULDER JOINT OF A USER

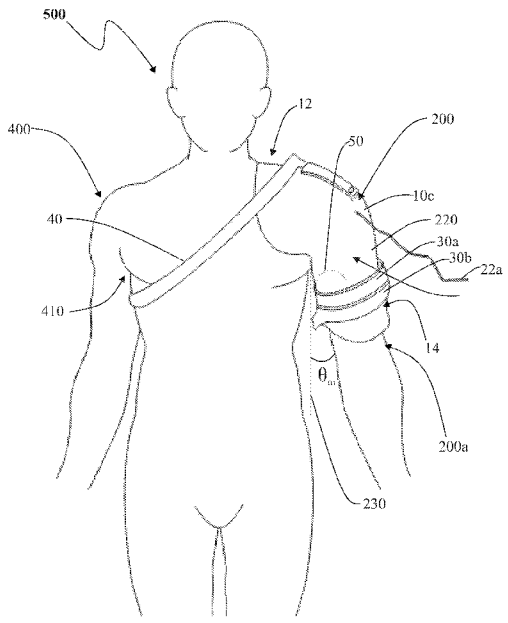

Figure 6

(57) **Abstract:** The present invention provides an orthotic device 100 for supporting a first shoulder joint 200 of a user 500. The orthotic device 100 includes a rigid support 10, at least one pair of electrodes 30a & 30b, at least one first strap 30 and the at least one-second strap 40. The rigid support 10 is having an outer surface 10a and an inner surface 10b and is resting against the first shoulder joint 200.The at least one first strap 30 is arranged on the rigid support 10 to wrap around an upper arm 220 of the first shoulder joint 200 for securing the orthotic device 100 on the first shoulder joint 200 of the user 500. The at least one-second strap 40 is extending from the rigid support 10 and adapted to wrap around an armpit 410 of a second shoulder joint 400 for efficiently treating a subluxation condition.

WO 2020/229885 A1

[Continued on next page]

Published:

— *with international search report (Art. 21(3))*

— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

"An Orthotic Device for Supporting a Shoulder Joint of a User."

Field of the Invention

[0001] The present invention relates to an orthotic device. More specifically, the present invention relates to an orthotic device for supporting a shoulder joint of a user. The orthotic device can be an orthosis.

Background of the Invention

[0002] Generally, orthosis is used to support body parts of patients under the circumstances such as injuries, dislocations, subluxation and the like. The orthosis is general term used for any orthotic device. These orthosis are also used to treat shoulder joint misalignments caused due to strokes (paralysis), shoulder subluxation and the like. A stroke is an acute onset of neurological dysfunction caused due to the abnormality in a cerebral blood circulation with resultant sign and symptom that correspond to the involvement of focal areas of the brain. It can give the symptoms like paralysis (hemiplegia) or weakness (hemiparesis). Shoulder subluxation is a common problem in the stroke. The subluxation causes shoulder pain and hinders activity.

[0003] Figures 1a & 1b illustrates schematic views of a shoulder joint 200 anatomy of a human (user) 500in a normal condition and a shoulder

subluxation condition respectively. A shoulder joint 200 is a ball and socket type of synovial joint with 3 degrees of freedom. It is the most mobile joint of the human body..

[0004] A normal stirring action of the force couple of supraspinatus and posterior fibers of the deltoid is affected due to a flaccid stage of the muscles. So, while abduction and flexion movement due to gravitational pull to the head of the humerus subluxates caudally. Presently, Orthotic devices (shoulder orthosis) are used to support the shoulder joint 200 to decrease the glenohumeral subluxation.

[0005] Further, when a patient (user) 500 suffering from the Shoulder subluxation condition is wearing the existing orthosis at the shoulder joint 200, an upper arm 220 of the patient can be moved away from a torso 240 up to a maximum of 30 degrees from a vertical reference 230. Whenever the patient moves the upper arm 220 away from the torso 240 (In medical terms, this movement is called an “abduction movement”) there will be a set of forces acting on the shoulder joint 200 and the upper arm 220. Angle of abduction movement can be referred as a movement angle θ_m. These set of forces are caused due to movements along a direction 250 away from the torso 240. These forces cause an enormous amount of pain to the patient even when the patient is wearing the orthosis. Furthermore, these movements also effect the subluxation condition of

the patient 500, thereby reduces efficiency of the orthosis in treating the subluxation condition.

[0006] Presently existing orthosis or any such devices are not effective in reducing effects caused due to forces developed during movements of an arm 200a of the user 500 (abduction movement) and also in efficiently treating the subluxation condition during abduction movements.

[0007] Further, the existing orthosis are costly, therefore not affordable.

[0008] Therefore, there is a need for an orthotic device (orthosis), which overcomes few or more problems of the prior art.

Objects of the Invention

[0009] An object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user.

[0010] Another object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which nullifies forces caused on the user due to movements of an arm of the user while wearing the orthotic device.

[0011] Still another object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which is simple in construction.

[0012] Further an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which is easy to use.

[0013] Further an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user, which is economical in construction.

[0014] Furthermore, an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user for reducing the pain of the user caused due to movements of an arm of the user while wearing the orthotic device.

[0015] Also, an object of the present invention is to provide an orthotic device for supporting a shoulder joint of a user for treating the subluxation condition of the patients effectively even if any movements of an arm(hand) of a user is occurred while wearing the orthotic device.

Summary of the invention

[0016] According to the present invention there is provided with an orthotic device for supporting a first shoulder joint of a user. The first shoulder can be a right shoulder joint of the user and a second shoulder joint is a left shoulder joint of the user and vice-versa. The orthotic device may include a rigid support, at least one pair of electrodes, at least one first strap and at least one-second strap. The rigid support is having an outer surface and an inner surface. The rigid support is resting against the first shoulder.

[0017] In a preferred embodiment, the rigid support is configured according to a shape of a shoulder the user and the rigid support is arranged on the first shoulder joint of the user with a surface contact of the inner surface of the orthotic device with the skin of the user. The rigid support includes a cushioning layer arranged on the inner surface of the rigid surface for providing the comfort of the user while wearing the orthotic device.

[0018] The at least one pair of electrodes arranged on the inner surface of the rigid support for pain relief modality. The at least one pair of electrodes are connected to a power source and a control unit for supplying and controlling current flow thereto. The at least one first strap is wrapped around an upper arm of the first shoulder for securing the orthotic device on the first

shoulder of the user. The at least one first strap is arranged with a pad. The pad is configured to provide support and pressure to the upper arm when the at least one first strap is wrapped around the upper arm of the user.

[0019] The at least one-second strap is extending from the rigid support and adapted to wrap around an armpit of the second shoulder joint. The at least one-second strap is extending from the outer surface of the rigid support. In an embodiment, the at least one-second strap is extending from the outer surface of the rigid support. More specifically, the at least one-second strap is extending from a corner of a shoulder profile of the rigid support. The at least one-second strap distributes the force exerted on the first shoulder and the upper arm along the second strap towards the armpit of the second shoulder joint thereby nullifying the forces occurred during movements of a first arm (hand) of the user. Also, the at least one-second strap enables the orthosis to treat the subluxation condition of the user efficiently even if the user moves his/her arm while wearing the orthosis.

Brief Description of the Drawings

[0020] The advantages and features of the present invention will be understood better with reference to the following detailed description of some embodiments of the impact energy absorber and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which;

[0021] Figure 1a shows a schematic view of a shoulder joint of a human with a normal condition;

[0022] Figure 1b shows a schematic view of a shoulder joint of a human with a shoulder subluxation condition;

[0023] Figures 2 shows an isometric view of an orthotic device for supporting a first shoulder joint of a user in accordance with the present invention;

[0024] Figure 3 shows a front view of a preferred embodiment of an orthotic device for supporting a first shoulder joint of a user in accordance with the present invention;

[0025] Figure 4 shows a side view of figure 3;

[0026] Figure 5 shows a top view of figure 3; and

[0027] Figure 6 shows a schematic view of a user (patient) wearing the orthosis shown in figure 3.

Detailed Description of the Invention

[0028] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising, "having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items, or meant to be limited to only the listed item or items.

[0029] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0030] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0031] Referring to figures 2, 3 4, and 6, various c views of an orthotic device 100 for supporting a first shoulder joint 200 (figure 1a & 1b) of a user 500 in accordance with the present invention are illustrated. The user 500 here refers to a patient suffering from a shoulder subluxation condition or similar health alignments and aided with the orthosis 100 for treating the same. For the

purpose of explanation, the first shoulder joint 200 is a left shoulder joint of the user 500 and a second shoulder joint 400 is a right shoulder joint of the user 500. Alternatively, the first shoulder joint 200 can be a right shoulder joint of the user 500 and the second shoulder joint 400 is a left shoulder joint of the user 500, which is obvious to a person skilled in the art. The orthotic device 100 is an orthosis.

[0032] The orthotic device 100 includes a rigid support 10, at least one pair of electrodes 20a & 20b, at least one first strap 30 and at least one-second strap 40. The rigid support 10 includes a shoulder section 12 and an arm section 14. More specifically, the shoulder section 12 covers a shoulder section of the user 500 and the arm section 14 covers an upper arm 220 section of the user 500. The rigid support 10 is having an outer surface 10a and an inner surface 10b. The rigid support 10 is resting against the first shoulder joint 200.

[0033] In a preferred embodiment, the rigid support 10 is configured according to a shape of a shoulder of the user 500. The rigid support is arranged on the first shoulder joint 200 of the user 500 with a surface contact of the inner surface 10b of the orthotic device 100 with the skin of the user 500. The rigid support 10 includes a cushioning layer 16 arranged on the inner surface 10b of the rigid support for providing comfort to the user while wearing the orthotic device 100. The cushioning layer 16 can be made from materials, such as medicinal

rubber or ethaflex and the like. The rigid support 10 is made from materials, such as polypropylene and the like.

[0034] The at least one pair of electrodes 20a and 20b are arranged on the inner surface 10b of the rigid support 10 for pain relief modality. The pair of electrodes 20a & 20b are connected to a power source (not show) and a control unit (not show) for supplying and controlling current flow thereto. The power source can be an external power source or at least a battery. In the present embodiment, the orthotic device 100 includes two pairs of electrodes 20a, 20b & 24a, 24b. The pair of electrodes 20a & 20bis connected to the power source and the control unit through wires 22a & 22b. The wires 22a & 22b passes through openings (not shown) configured in the rigid support 10. It may be obvious to a person skilled in the art to configure the openings for passing the wires 22a & 22b therethrough and connecting the wires 22a & 22b to the pair of electrodes 20a & 20b; and arranging the pair of electrodes 20a & 20b on the inner surface 10b. Amount of current needs to be passed to the pair of electrodes 20a and 20b for pain relief modality is according to a specific medical condition. This amount of current passed according to the specific medical condition is known to a person ordinarily skilled in the art. The person ordinarily skilled in the art can be a physiotherapist or an electrotherapist.

[0035] Further, the at least one first strap 30 is arranged on the rigid support 10 to wrap around an upper arm 220 of the first shoulder joint 200 for securing the orthotic device 100 on the first shoulder joint 200 of the user.

[0036] In the present embodiment, the orthotic device 100 includes two first straps 30a & 30b. The first straps 30a and 30b are having a securing arrangements, such as a snap lock, hook and loop arrangement or any such obvious securing engagements which are capable to secure the orthotic device 100 on the upper arm 220 of the user 500. The first straps 30a and 30b are having a pad 50. The pad 50 is arranged with the first straps 30a and 30b. The pad 50 is configured to provide support and pressure to the upper arm 220 when the first straps 30a and 30b are wrapped around the upper arm 220 of the user 500. More specifically, the pad 50 is arranged in a such a way that, when the first straps 30a & 30b are wrapped around the upper arm 220, an interior surface of the pad 50 is in contact with the skin of the upper arm 220 as shown in figure 6. In an alternative embodiment (refer figure 2), the orthotic device 100 can be configured without the pad 50.

[0037] Referring again to figure 6, a schematic view of a user 500 wearing the orthotic device 100 is shown. The at least one-second strap 40 is extending from the rigid support 10 and adapted to wrap around an armpit 410 of the second shoulder joint 400. In the present, the orthotic device 100 includes a second strap 40. . In an embodiment, the second strap 40 is extending from the

outer surface 10a of the rigid support 10. More specifically, the one-second strap 40 is extending from a corner 10c of a shoulder profile of the rigid support 10. The corner here refers to a geometric area where the shoulder section 12 and the hand section 14 of the rigid support 10 meets. In the present embodiment, the second strap 40 is pinned at the shoulder section 12 of the rigid support 10 as shown in figure 5. The at least one-second strap 40 includes securing arrangements such as a hook and loop arrangements, =for securing the -second strap 40 around a torso 240 of the user 500 at the armpit 410 of the second shoulder joint 400.

[0038] Further, when the strap 40 at a wrapped position, does not allow the user 500 to move his/ her arm 220 beyond 30 degrees (a movement angle $\theta_{m)}$ from a vertical reference 230. This restriction of movement helps in retaining a correcting position of the rigid support 10 on the first shoulder joint 200. Hence, the orthotic device 100 corrects an affected shoulder efficiently. Hence, the second strap 40 also enables the orthotic device 100 in treating a subluxation condition of the user 500 efficiently even if the user 500 moves his/her arm 220 while wearing the orthosis 100.

[0039] When the orthosis 100 is worn by the user 500 around the first shoulder joint 200, by securing the first strap 30a around the upper arm 220 and securing the second strap 40 around the torso 240 around the armpit 410 of

the second shoulder joint 400, the orthotic device 100 applies pressure on the first shoulder joint 200 according to a 3 point pressure system principle. In medical industry, this 3 point pressure system is known as a Jordon's principle. In the 3 point pressure system, the applied force and two counteracting forces are in the opposite direction to each other. Further, supplying therapeutic current through the pair of electrodes 20a & 20b results in pain relief of the user 500. This supplying therapeutic current is generally known as TENS (transcutaneous electrical nerve stimulation). More specifically, this TENS gives pain relief to the user in the shoulder subluxation condition. Therefore, the orthotic device 100 is beneficial in reducing the shoulder subluxation condition along with the pain relief effect.

[0040] Furthermore, when the user 500is wearing the orthotic device 100, if the user moves the arm 250 away from the torso 240, the second strap 40 distributes the force exerted on a first shoulder 202 and the upper arm 220 of the user 500 along the second strap 40 towards the armpit 410 of the second shoulder joint 400, thereby nullifying the forces occurred during movements of an arm 200a (first arm) of the user 500. When the forces occurred during movements of a first arm 200a of the user 500 are nullified, the resultant forces acting on the user 500 will be equal to zero. Therefore, the forces caused due to movement of the first arm 200a of the user 500 do not result in causing pain to the user 500 or any such discomforts.

[0041] Therefore, the present invention has the advantage of providing the orthotic device 100 for supporting the shoulder joint (200 or 400) of a user 500. The orthotic device 100 nullifies forces caused on the user due to movements of an arm 200a of the user 500. The orthotic device 100 is simple in construction. The orthotic device 100 is easy in use. The orthotic device 100 is economical in construction and operations. The orthotic device 100 reduces the pain of the user 500 caused due to movements of an arm of the user 500 while wearing the orthotic device 100. The orthotic device 100 efficiently treats the subluxation condition of the patients even if any movements of an arm 200a of a user 500 is occurred while wearing the orthotic device 100.

[0042] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the present invention and its practical application, and to there by enable others skilled in the art to best utilise the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omissions and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such omissions and substitutions are intended to cover the

application or implementation without departing from the scope of the claims of the present invention.

We Claim:

1. An orthotic device 100 for supporting a first shoulder joint 200 of a user, wherein the orthotic device 100 comprising:

a rigid support 10 having an outer surface 10a and an inner surface 10b, the rigid support 10 is resting against the first shoulder joint 200;

at least one pair of electrodes 20a & 20b arranged on the inner surface 10b of the rigid support 10 for pain relief modality;

at least one first strap 30 arranged on the rigid support 10, the at least one first strap 30a is wrapped around an upper arm 220 of the first shoulder joint 200 for securing the orthotic device 100 on the first shoulder joint 200 of the user; and

at least one-second strap 40 extending from the rigid support 10 and adapted to wrap around an armpit 410 of a second shoulder joint 400; wherein the at least one second strap 40 distributes the force exerted on the first shoulder joint 200 and the upper arm 220 along the second strap 40 towards the armpit 410 of the second shoulder 400 joint thereby nullifying the forces occurred during movements of the first arm 200a of the user and also efficiently treating a subluxation condition of the user even if the user moves his/her arm 220 while wearing the orthosis 100.

2. The orthotic device 100 as claimed in claim 1, wherein the first shoulder joint 200 can be a left shoulder joint of the user and the second shoulder joint 400 is a right shoulder joint of the user and vice-versa.

3. The orthotic device 100 as claimed in claim 1, wherein the rigid support 10 is configured according to a shape of a shoulder of the user and the rigid support 10 is arranged on the first shoulder joint 200 of the user with a surface contact of the inner surface 10b of the orthotic device 100 with the skin of the user.

4. The orthotic device 100 as claimed in claim 1, wherein the rigid support 10 includes a cushioning layer 16 arranged on the inner surface 10b of the rigid support 10 for providing comfort of the user while wearing the orthotic device 100.

5. The orthotic device 100 as claimed in claim 1, wherein the at least one pair of electrodes 20a & 20b are connected to a power source and a control unit for supplying and controlling current flow thereto.

6. The orthotic device 100 as claimed in claim 1, wherein the at least one first strap 30 is arranged with a pad 50, the pad 50 is configured to provide support and pressure to the upper arm 220 when the at least one first strap 30a is wrapped around the upper arm 220 of the user.

7. The orthotic device 100 as claimed in claim 1, wherein the at least one-second strap 40 is extending from the outer surface 10a of the rigid support 10.

8. The orthotic device 100 as claimed in claims 1 and 7, wherein the at least one-second strap 40 is extending from a corner 10c of a shoulder profile of the rigid support 10.

5

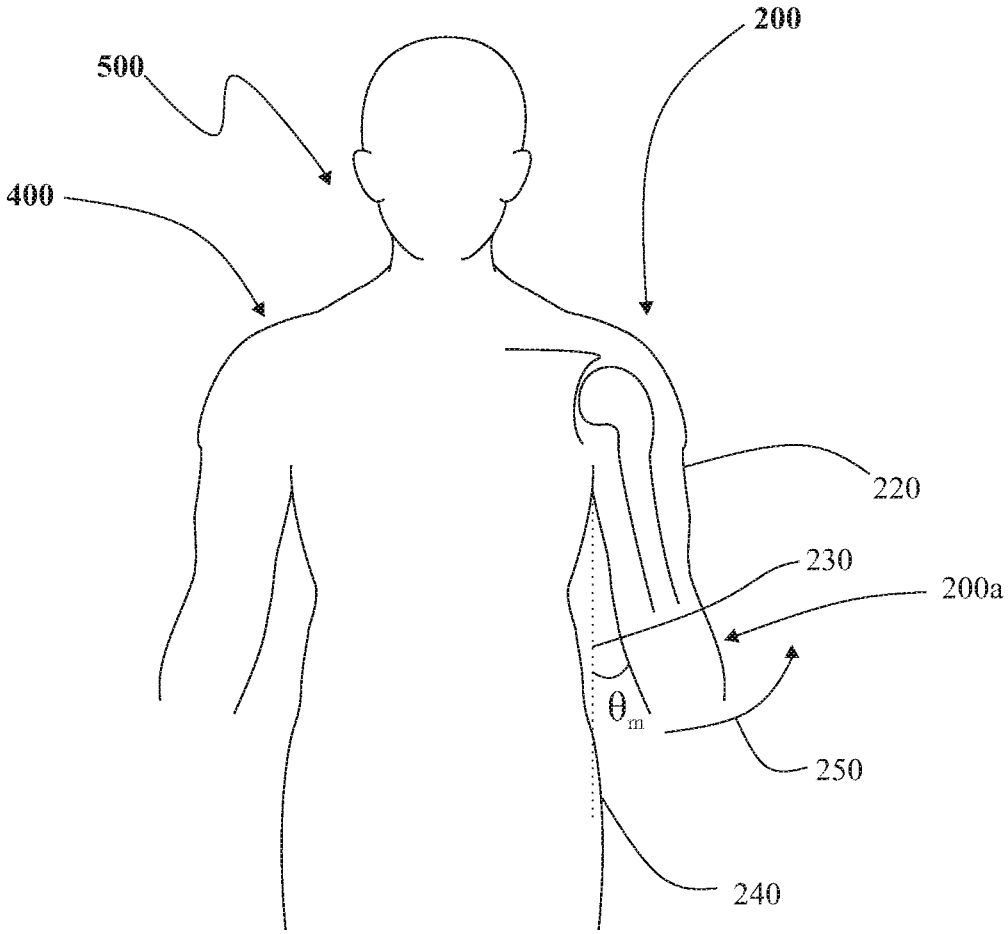

Figure 1a

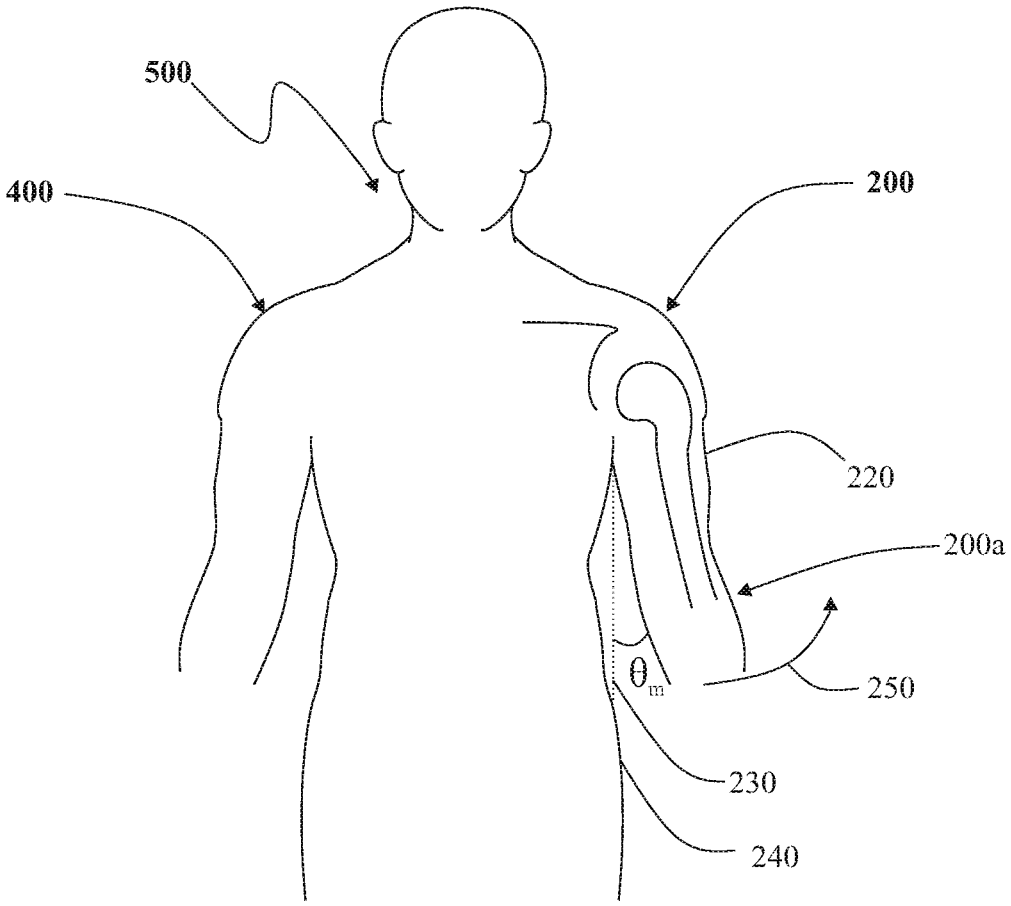

Figure 1b

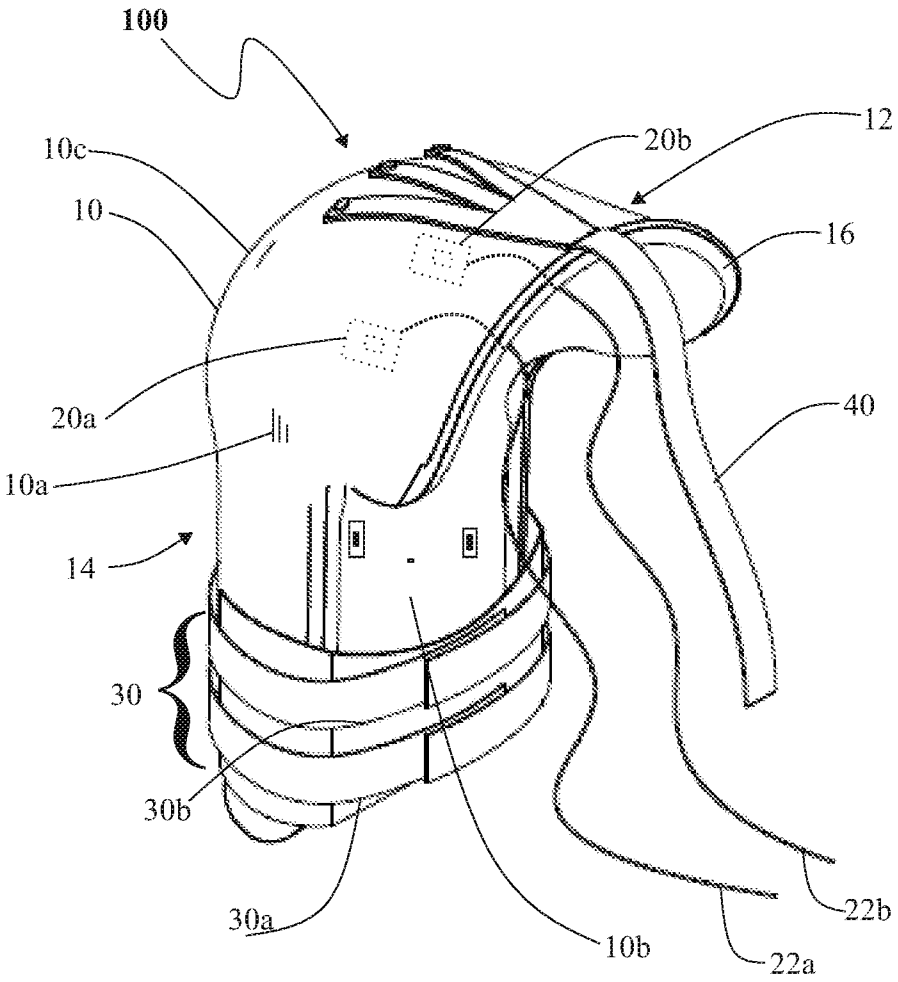

Figure 2

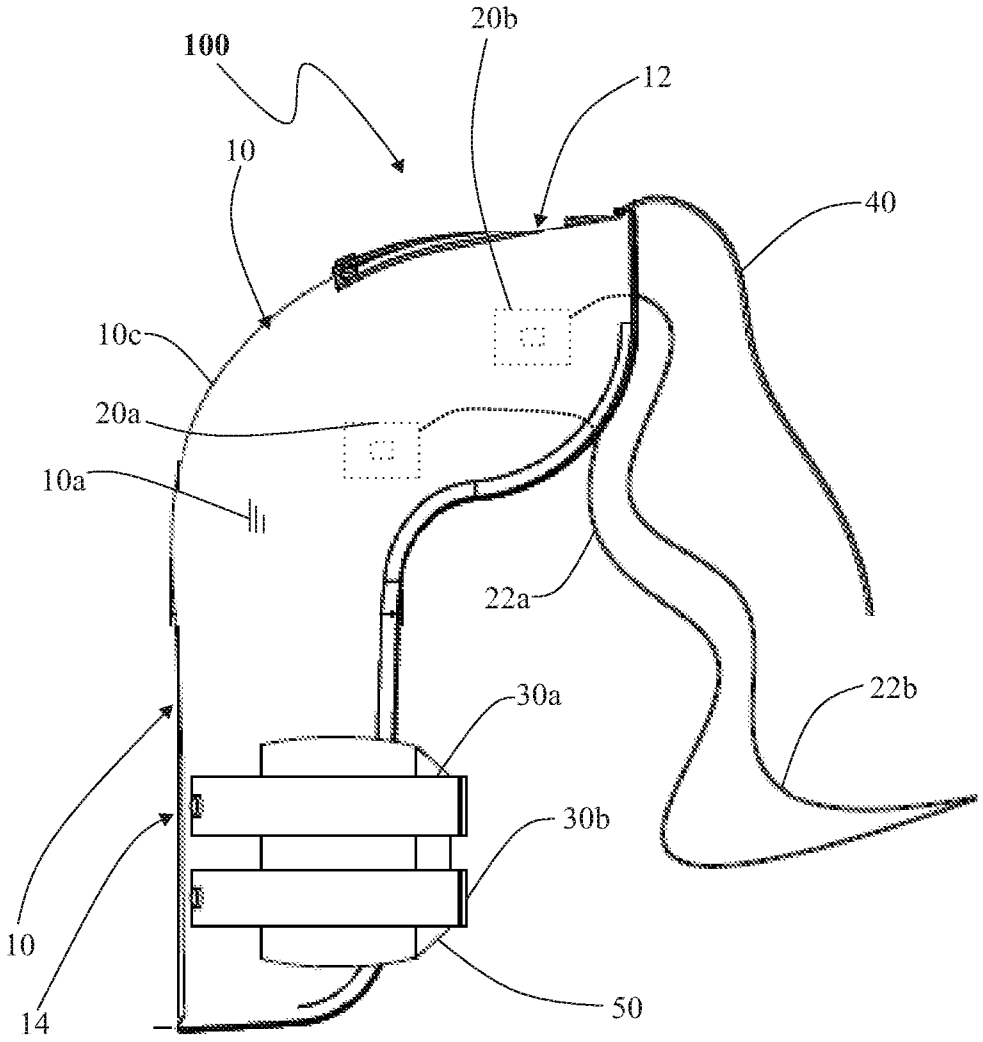

Figure 3

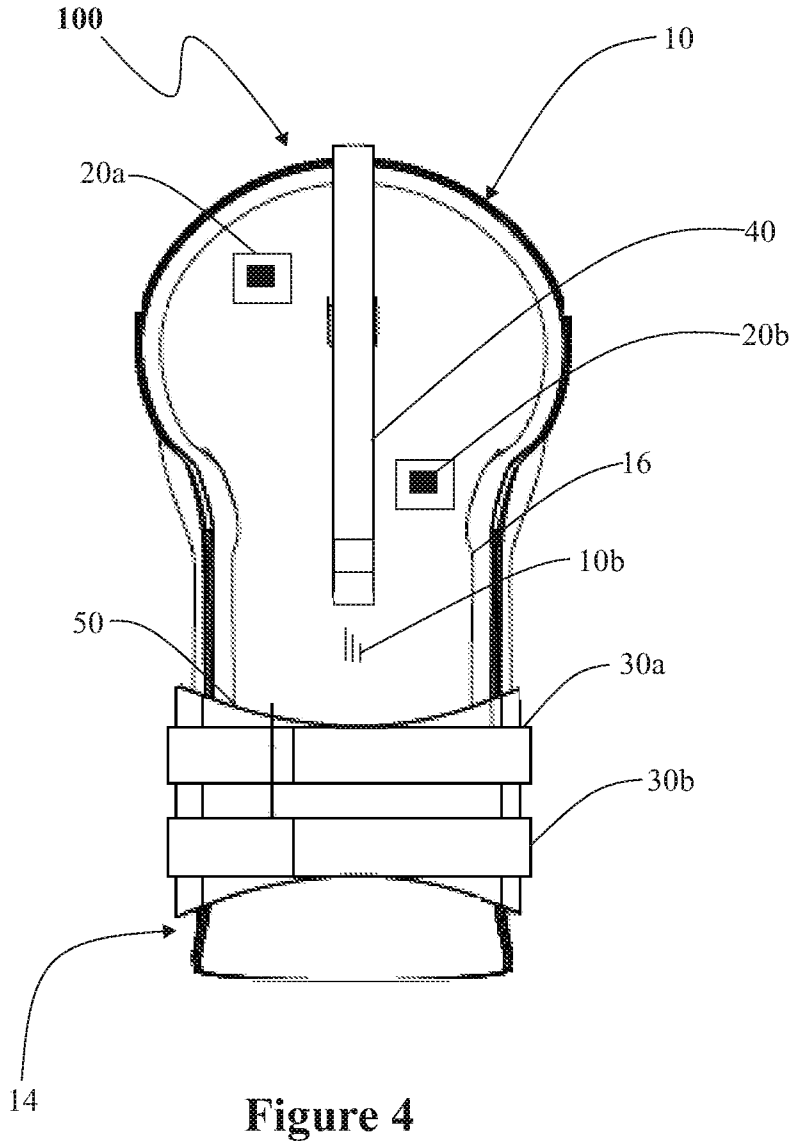

Figure 4

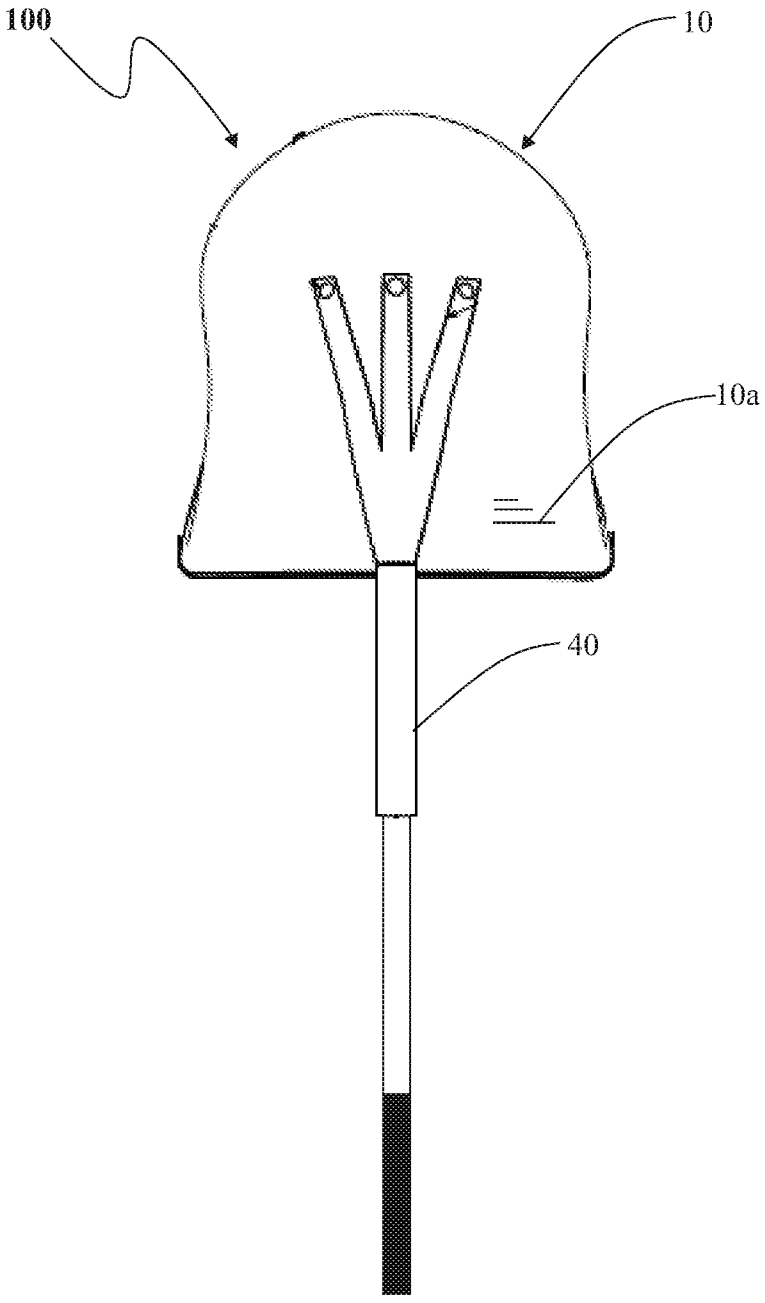

Figure 5

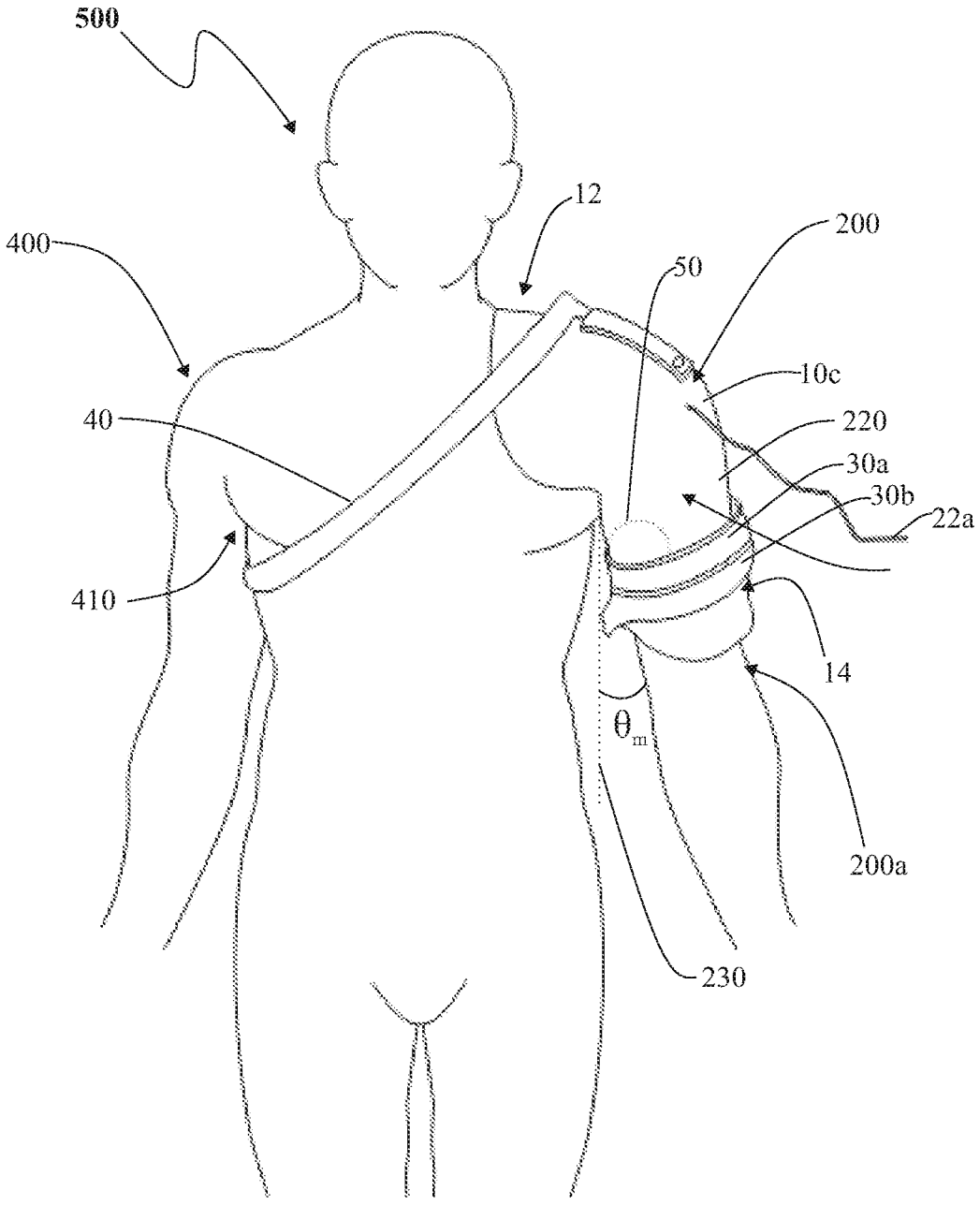

Figure 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2019/054653

A. CLASSIFICATION OF SUBJECT MATTER
A61F5/00 Version=2019.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Database: TotalPatent One, IPO Internal Database
Keywords: Shoulder, orthosis, brace, electric stimulation

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013072018 A1 (Andersson, ULF et. al.) 23-05-2013 (23 May 2013) claim 1, figures 1, 3 and related paragraphs	1-8
Y	FR 3036951 A1 (IMPLANTS SERVICE ORTHOPEDIE - ISO) 09-12-2016 (09 Dec 2016) figures 1, 2 and related paragraphs	1-8
Y	US 20130158456 A1 (VISION QUEST INDUSTRIES INCORPORATED DBA VQ ORTHOCARE) 20-06-2013 (20 Jun 2013) claims 1, 2, 5, paragraphs 57, 66-67	1-8

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03-10-2019	03-10-2019
Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Authorized officer Shivam Verma Telephone No. +91-1125300200

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2019/054653

Citation	Pub.Date	Family	Pub.Date
WO 2013072018 A1	23-05-2013	WO 2013072018 A8	01-08-2013
		DE 102011119397 A1	23-05-2013
		EP 2779964 A1	24-09-2014
		EP 2779964 B1	03-02-2016
US 20130158456 A1	20-06-2013	US 9198792 B2	01-12-2015
		CN 102438697 A	02-05-2012
		CN 102438697 B	29-07-2015
		KR 20120028928 A	23-03-2012
		WO 2010135288 A1	25-11-2010
		JP 2012527314 A	08-11-2012
		JP 6034186 B2	30-11-2016
		EP 2432549 A1	28-03-2012
		EP 2432549 A4	27-08-2014
		SG 175962 A1	29-12-2011
		CA 2762674 A1	25-11-2010
		AU 2010249782 A1	15-12-2011
		US 20100082079 A1	01-04-2010
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WO 2020/245640 A1

(54) Title: A DEVICE FOR MEASURING TENSION IN A WIRE OF AN ORTHODONTIC BRACES

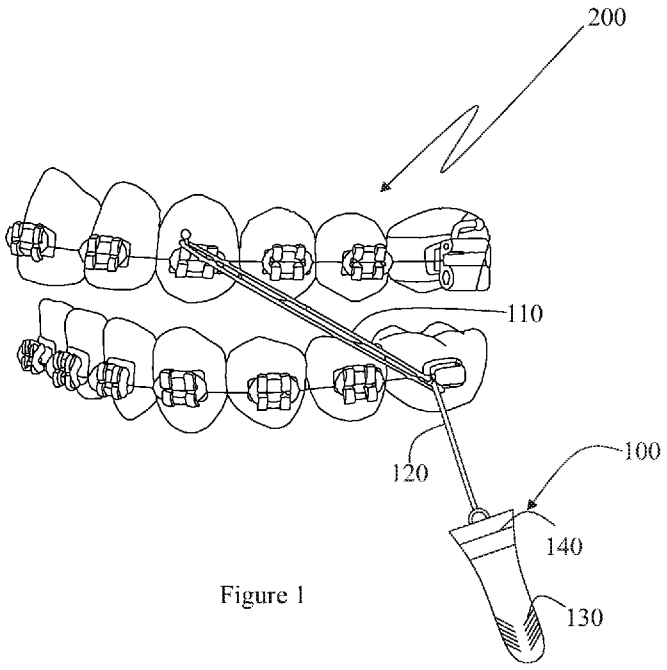

Figure 1

(57) Abstract: Title: A device for measuring tension in a wire of an orthodontic brace. The present invention is to provide a device 100 for measuring tension in a wire 110 of an orthodontic brace 200. The wire 110 is having a closed circumference and capable of being wind in a winding position around brackets 210 of two teeth. The device 100 includes an anchoring member 120, a holding portion 130 and a display 140. The anchoring member 120 is having a first end 120a attachable with the wire 110 in the winding position and a second end 120b attachable with the holding portion 130 of the device 100. The device 100 upon pulling the wire 110 by anchoring the anchoring member 120 along with its length, measures the tension exerted by the wire 110 on the teeth and displays the measured data on the display 140 of the device 100.

[Continued on next page]

SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

"A Device for Measuring Tension in a Wire of an Orthodontic Braces"

Field of the Invention

[0001] The present invention relates to a medical diagnostic instrument. More particularly, the present invention relates to a device for measuring tension in a wire of an orthodontic braces for effective tooth movement

Background of the Invention

[0002] Orthodontics in dentistry is associated with improvement of the general appearance of a patient's teeth and deals with the diagnosis, prevention and correction of misaligned or mal-positioned teeth and jaws. Orthodontics braces are the device which is used for correction of misaligned or mal-positioned teeth and jaws. Orthodontics braces are provided with wires and brackets. The brackets are fixed with each of the teeth and wires are winded around the teeth and are fixed with the brackets. The medical practitioner (orthodontist) adjusts the required tension on the wires depending on the complexity of misaligned teeth. Further, periodic adjustment of the wires is required for the proper alignment of the misaligned or mal-positioned teeth and jaws. The wires may be replaced with a rubber band or rubber chain or any other elastic material.

[0003] If the tension required on the wire arranged between the mal-aligned teeth is known to the practitioner at each stage of the treatment, the alignment period and the diagnosis term can be substantially reduced. Improper adjustment of the wire in varied tension may unnecessarily extend the term of diagnosis and thereby delaying the alignment period. Wires or elastic materials are available with predefined tension which can be applied across the brackets. However, these wires cannot be customised according to the need of the patient.

[0004] Hence there is a requirement of a dental device which can measure the tension of the wire / elastic wound around a bracket of two teeth in an orthodontic brace treatment which may overcome few or all drawbacks of the existing dental devices.

Objects of the Invention

[0005] An object of the present invention is to provide a device for measuring tension in a wire configured around a bracket of two teeth in an orthodontic brace treatment.

[0006] Another object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which substantially shortens the time duration of treatment.

[0007] Yet another object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which provides accurate and precise historical data of the wire tension allowing the medical practitioner to ease the examination procedure.

[0008] One more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which reduces the alignment period of the treatment.

[0009] Further object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which has a lesser complexity in operation.

[0010] One more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which can measure extra oral force accurately and precisely so that we can modify growing facial structures.

[0011] Still one more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, which measures and records force or tension in the wire simultaneously which helps in further research and studies.

[0012] Further one more object of the present invention is to provide a device for measuring tension in a wire of an orthodontic brace, in which the recorded force can be used for monitoring patient in future appointment and medico-legal purposes .

Summary of the invention

[0013] According to the present invention, a device used for an orthodontic (brace) treatment is provided. The device is specifically for measuring tension in a wire of an orthodontic braces. In the orthodontic braces treatment, wires, elastic members or the like are used to adjust the tension between the teeth. In the orthodontic braces, brackets are attached with each tooth, and the wires are configured around the brackets of two teeth. The wire is having a closed circumference and is capable of being wind in a winding position around the brackets of two teeth. The wires can be attached with the adjacent brackets. The wires are tightened according to the required tension. Once the tension is set across the brackets, the device can be used to verify the tension across the wire.

[0014] The device is a force measuring instrument having an anchoring member, a holding portion and a display. The anchoring member is adapted to attach with the wire. Specifically, a first end of the anchoring member which is the distal end of the device is attachable with the wire in the winding position. A second end of the anchoring member is attached to the holding portion

of the device. In an embodiment, the anchoring member can be detachable from the holding portion and can be replaced with anchoring members of different length and sizes. Upon pulling the device after anchoring the anchoring member with the wire along the length of the anchoring member and away from the wire facilitates the device to measure the tension across the wire. The device measures the tension across the wire and displays the measured data on the display attached therewith.

Brief Description of the Drawings

[0015] The advantages and features of the present invention will be understood better with reference to the following detailed description and claims taken in conjunction with the accompanying drawings, wherein like elements are identified with like symbols, and in which:

[0016] Figure 1 illustrates a device for measuring tension in a wire of an orthodontic brace in accordance with the present invention; and

[0017] Figure 2 illustrates a schematic view of the device in accordance with the present invention.

Detailed Description of the Invention

[0018] An embodiment of this invention, illustrating its features, will now be described in detail. The words "comprising, "having, "containing," and "including," and other forms thereof, are intended to be equivalent in meaning and be open ended in that an item or items following any one of these words is not meant to be an exhaustive listing of such item or items, or meant to be limited to only the listed item or items.

[0019] The terms “first,” “second,” and the like, herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “an” and “a” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item.

[0020] The disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms.

[0021] Referring to figures 1 and 2, a device 100 used for an orthodontic brace treatment in accordance with the present invention is illustrated. The device 100 is specifically for measuring tension in a wire 110 of an orthodontic brace 200. In the orthodontic brace treatment, wires, elastic members or the like are used to adjust the tension between the teeth. If the tension is adjusted between the teeth according to the need, the teeth are likely to be aligned in a proper orientation which may help the patient an easy recovery.

[0022] In the orthodontic braces 200, brackets 210 are attached with each tooth, and the wires 110 are configured around the brackets 210 of two teeth. The wire 110 is having a closed circumference and are capable of being wind in a winding position (as shown in figure 1) around the brackets 210 of two teeth. The wire 110 can be attached with the adjacent brackets 210. The wire 110 can be replaced with elastic members such as rubber bands, and the like. The wires 110 are tightened according to the required tension. Once the tension is set across the brackets 210, the device 100 can be used to verify the tension across the wire 110.

[0023] Referring to figure 2, the device 100 is a force measuring instrument having an anchoring member 120, a holding portion 130 and a display 140. The anchoring member 120 is adapted to attach with the wire 110. The anchoring member 120 is an elongated member having a hookable portion configured on a first end 120a of the anchoring member 120 for anchoring the device 100 with the wire 110. Specifically, the first end 120a of the anchoring member 120 which is the distal end of the device 100 is attachable with the wire 110 in the winding position. The tension across the wires 110 are at the maximum in the winding position.

[0024] A second end 120b of the anchoring member 120 is attached to the holding portion 130 of the device 100. In the present embodiment, the anchoring member 120 is fixed with the holding portion 130 of the device 100.

In an embodiment, the second end 120b of the anchoring member 120 is connected pivotally and detachably with the holding portion 130 to provide enough degree of freedom for the anchoring member 120. The anchoring member may be detachable from the holding portion 130 and can be replaced with anchoring members 120 of different length and sizes. The holding portion 130 is for holding and providing sufficient gripping to the device 100.

[0025] Upon pulling the device 100 after anchoring the anchoring member 120 with the wire 110 along the length of the anchoring member 120 and away from the wire 110 facilitates the device 100 to measure the tension across the wire 110. Specifically, the device 100 measures the tension across the wire 110 and displays the measured data on the display 140 attached therewith. The display 140 can be either analogue or digital. The holding portion 130 and the display 140 are integral to the device 100.

[0026] Therefore the present invention has an advantage of providing a device 100 for measuring tension in a wire 110 configured around a bracket 210 of two teeth in an orthodontic brace treatment. The device 100 substantially shortens the time duration of treatment. It also provides accurate and precise historical data of the wire 110 tension allowing the medical practitioner to ease the examination procedure. Further, the device 100 reduces the alignment period of the treatment. Also, the device 100 has a lesser complexity in operation.

[0027] The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the present invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The embodiments were chosen and described in order to best explain the principles of the present invention and its practical application, and to thereby enable others skilled in the art to best utilise the present invention and various embodiments with various modifications as are suited to the particular use contemplated. It is understood that various omissions and substitutions of equivalents are contemplated as circumstances may suggest or render expedient, but such omissions and substitutions are intended to cover the application or implementation without departing from the scope of the claims of the present invention.

We Claim:

1. A device 100 for measuring tension in a wire 110 of an orthodontic brace 200, the wire 110 is having a closed circumference and capable of being winded around brackets 210 of two teeth, the device 100 comprising:

an anchoring member 120 having a first end 120a attachable with the wire 110 in a winding position and a second end 120b attachable with a holding portion 130 of the device 100, the holding portion 130 is for holding and gripping the device 100; and

a display 140

wherein the device 100 upon pulling the wire 110 by anchoring the anchoring member 120, measures the tension exerted by the wire 110 between the teeth and displays the measured data on the display 140.

2. The device 100 as claimed in claim 1 wherein the anchoring member 120 and the display 140 are integral to the device 100.

3. The device 100 as claimed in claim 1 wherein the anchoring member 120 is an elongated member having a hookable portion configured on the first end 120a for anchoring the device 100 with the wire 110.

4. The device 100 as claimed in claim 1, wherein the second end 120b of the anchoring member 120 is connected pivotally and detachably with the holding portion 130 to provide enough degree of freedom for the anchoring member 120.

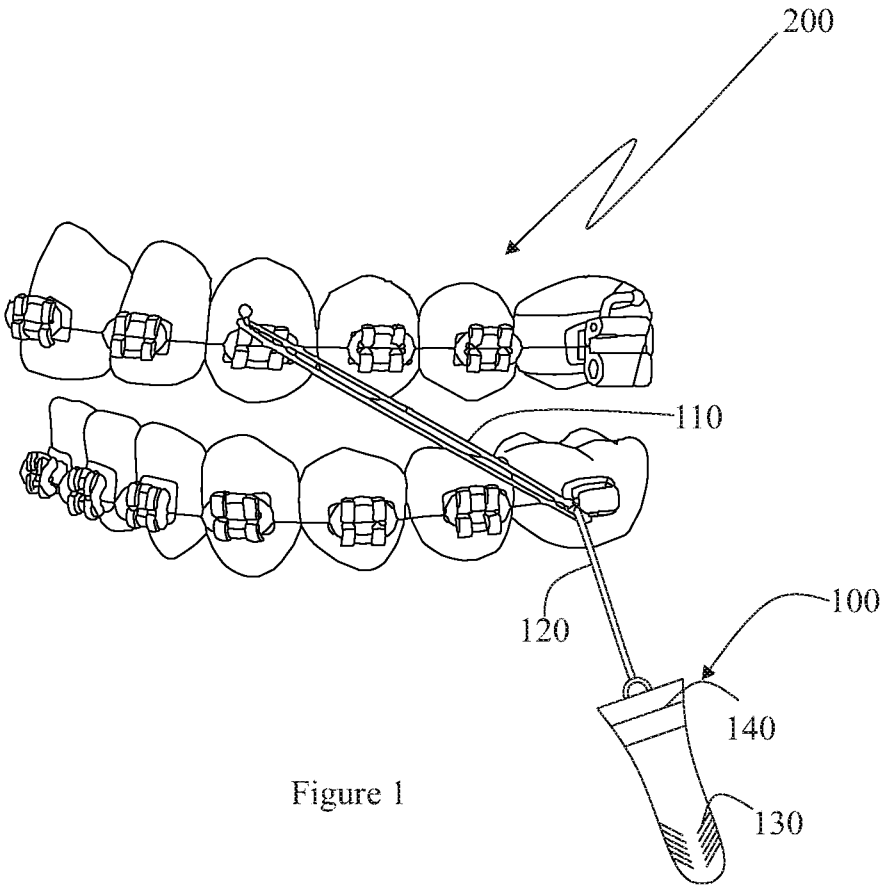

Figure 1

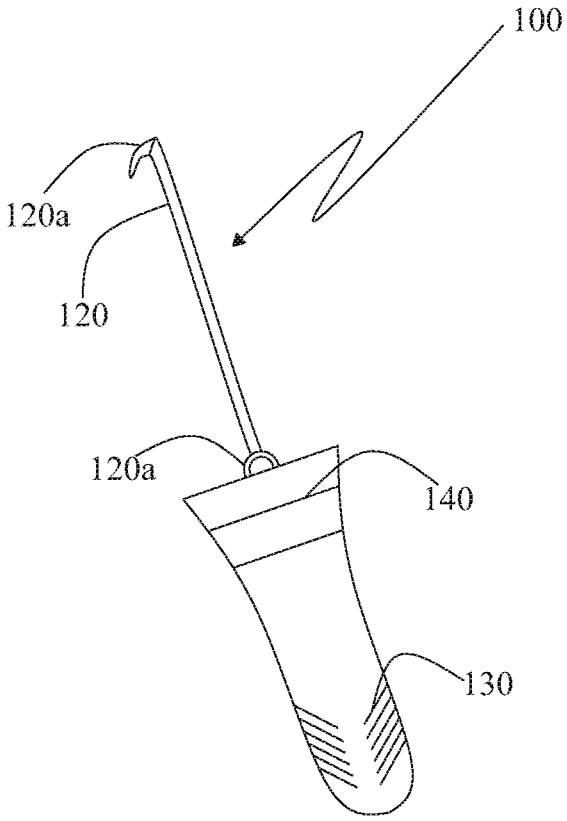

Figure 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2019/055210

A. CLASSIFICATION OF SUBJECT MATTER
A61C7/14 Version=2019.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

TotalPatent One, IPO Internal Database
Keywords: Orthodontic brace, wire, display, tension

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20130280671 A1 (BIOLUX RES LTD (US)) 24 October 2013 (24.10.2013) Abstract, Description	1-4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27-09-2019	27-09-2019
Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Authorized officer Pritish Ranjan Pal Telephone No. +91-1125300200

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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(54) Title: A LIP POSTURE CORRECTOR

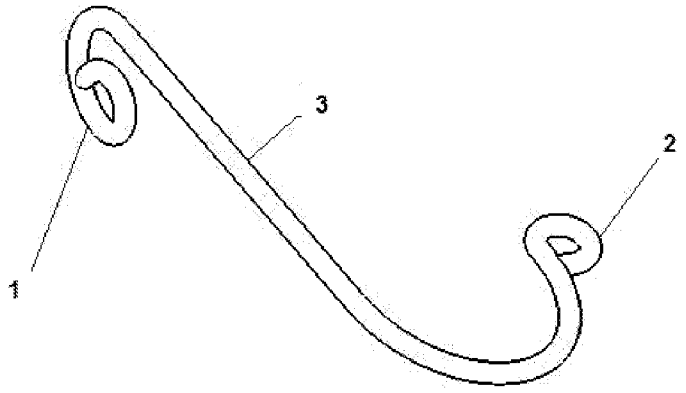

Figure 1

(57) **Abstract:** Disclosed is a lip posture corrector consist of an intra-oral component (1); an ear support component (2); a connector (3) being positioned between the intraoral component (1) and ear support component (2); wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2; wherein the sodium acrylate and acrylamide is 10:90 by weight.

WO 2020/255151 A1

FIELD OF THE INVENTION

The present invention relates to a medical device. More particularly, the present invention relates to a device (could be medically said as a “corrector”) which can improve the lip posture of a patient suffering from facial paralysis.

BACKGROUND OF THE INVENTION

Facial paralysis is a debilitating condition that is often associated with dramatic functional, psychological, and cosmetic sequel. Varied functional deficits pose significant physiologic challenges. The inability to express oneself with spontaneous facial expression or intelligible speech can have extraordinary psychological ramifications, and facial asymmetry can scar a patient’s self-image, rendering him or her less secure in everyday interactions with the world.

Manifestations of facial nerve paralysis are the facial laxity, asymmetric smile, lower lip asymmetry at rest, droopy oral commissure (from the weakened major and minor zygomatic muscles), inspiratory nasal collapse, oral incompetence (difficulty with mastication and speech), lower-eyelidectropion or laxity, lagophthalmos, a sense of disfigurement etc. Therefore, the goals of reconstruction of the paralyzed face may be the facial symmetry at rest, oral competence and eye closure; & voluntary facial movements with spontaneous facial expression

The surgical team has an armamentarium of surgical strategies for facial reanimation. These procedures are categorized as either dynamic or static.

Dynamic procedures aim to reanimate the face by local muscle transfer or by nerve grafting and free muscle transfer; they should be considered in every patient with facial nerve paralysis. But they may not be suitable for a patient who is debilitated or terminally ill (Why). Surgical correction, though, can be done, but it has its own limitations like prolonged treatment time, effects and consequences of surgery itself,

patients existing physical and mental condition to withstand surgery and bear its effects.

Static techniques are employed to suspend the soft tissue structures of the face, but they do not provide facial reanimation. There are often adjunctive maneuvers performed in conjunction with dynamic techniques to enhance facial symmetry.

However, static procedures may also be performed alone for patients who are not candidates for dynamic reanimation procedures (because of physical debilitation, advanced age, increased time delay from injury to repair, or poor health) but who would still benefit from the restoration of facial symmetry.

A literature reveals [Cerio DR. Static reconstruction for facial nerve paralysis. Downloaded from https://emedicine.medscape.com/article/1289348-print] that at times (e.g., in elderly patients), dynamic facial reanimation is not possible or indicated, and static reconstruction is performed. The goals of static suspension procedures are to protect the cornea by restoring eyelid competence, to enhance mastication and speech production through commissure elevation, and to achieve cosmetic improvement by restoring facial symmetry at rest. Not every patient is a suitable candidate for a dynamic procedure for facial reanimation. Patients who are severely debilitated or elderly may not be able to endure the lengthy operations required by dynamic reconstructions, nor can they wait for the delayed results generated by dynamic modalities (which sometimes take as long as 2-3 years to develop), given that their life expectancies are limited by advanced age or terminal illness. For these patients, static suspension of the lower face with autologous or alloplastic materials can provide symmetry at rest and may improve oral incompetence and nasal collapse. These improvements in function enhance quality of life despite life expectancy.

This literature also addresses that the static techniques generally are unsatisfactory as a single modality for rehabilitation of the paralyzed lower face and thus should not be used as a primary modality of reconstruction. Static procedures are most appropriate for debilitated patients who are unable or unwilling to endure the extensive operations of dynamic reanimation or those who are not expected to have a life expectancy beyond the nerve and muscle recovery period following dynamic strategies. They can also enhance dynamic reanimation by augmenting facial symmetry.

A static surgical approach suggested by Rana et al., [Rana H., Shaikh MF., Shah A., Dodia H. Static suspension technique wih fascia lata for facial reanimation in facial palsy. IOSR-JDMS:16(4);90-96] in which it was found that the static facial suspensions are an effective method of correcting facial nerve deficits in cases where nerve repair is not planned or possible.

Another literature [Iseli TA., Harris G., Dean NR., Iseli CE., Rosenthal EL. Outcomes of static and dynamic facial nerve repair in head and neck cancer. Laryngoscope 120:478-483] reveals that although elderly patients with parotid malignancy have traditionally been considered poor candidates for nerve grafting, still it was found that nerve grafting is the good method of facial nerve reconstruction.

As all the aforesaid approaches are surgical, these approaches may not be suitable for the patients who cannot be subjected for surgery due to significant health high risk issues and who have lower lip deficit causing drooping of lip and drooling of saliva, effacement /obliteration of nasolabial fold on the affected side [Affected side means the side which has been affected by paralysis due to inappropriate nerve conduction resulting in loss of muscle function. Due to this, drooping of lip and its consequences as stated above occurs].

Currently, the existing device takes the support from teeth (in persons with teeth present i.e. dentulous) or they are attached to complete dentures (in persons without any teeth i.e. edentulous). These devices are more of support to cheek than lips. Hence they are termed as cheek bumpers or cheek plumbers. They actually have no effect on correction of lip posture. Their function is to correct cheek position and is more of an aesthetic/cosmetic appliance rather than a functional appliance. When these appliances take support from teeth (in dentulous condition), they make the patients very uncomfortable and when these are component of complete denture, (in edentulous condition) these device make complete denture very heavy and reduce the ease of their use.

Currently, various synthetic polymers are used intra-orally. One of the polymers is PMMA i.e. polymethylmethacrylate acrylic resin *[(Bhola et al., Biocompatible Denture Polymers – A Review, Trends Biomater. Artif. Organs, Vol 23(3), pp 129-136 (2010)]* which may be good in view of tensile strength but leaching of MMA resulting stomatitis is reported over this literature. Further PMMA is carciogenic over Bhola et al. Therefore, it is a need of hour to provide a solution such that PMMA can be used intra-orally safely.

Regarding drug treatment, the facial paralysis or idiopathic Bell's palsy are normally treated with oral glucocorticoids such as Deltasone (prednisone) within three days of symptom onset. Individuals with severe cases often receive the combination of Deltasone (prednisone) and Valtrex (valacyclovir). Botox (botulinum toxin) injections can be beneficial for patients who do not completely recover. However, these drugs are known with the side effects.

Prior art:

JP3129305 discloses lip dysplasia correction tool in which the tool is capable of preventing a lip perfection by improving the function of the oral cavity and correcting the dentition by normalizing the posture of the tongue and the posture of the jaw.

JP'305' is applicable for correcting tongue and jaw not lip. Also, it requires the teeth support.

US9936792 discloses a facial lift device to be placed behind the lips and above the gums disposed alongside the buccal and facial surface of a living human maxilla or a human mandible no further than the most posterior tooth of one side to the most posterior tooth of the opposite side of said maxilla or mandible. The facial device embodies an outward lifting force when placed within the human mouth under the lips and alongside the anterior vestibule centered on the frenulum, such that when said facial lift device is forced behind the maxilla or mandible lips, the facial lift will forcibly lift out the dermal layer reducing and removing lower facial wrinkles within the perioral region. US'792' does not suggest the improvement of lip posture. Again it needs the teeth support.

Therefore, there is a need of hour is to provide a non-surgical approach (also could medically be said as an "external device or a lip posture corrector") that could improve/correct the lip posture of a patient suffering from facial paralysis or of those who cannot be subjected for the surgery. There is a further need to provide a solution for correcting lip posture without drugs.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a device or a corrector that could improve the lip posture of a patient who is suffering from facial paralysis.

It is another objective of the invention is to provide a lip posture corrector for those who cannot be subjected for the surgery for instance surgical sling procedure.

It is yet another objective of the invention is to provide a device for improving the lip posture without teeth support.

It is yet another objective of the invention is to provide a lip posture corrector using a novel polymeric combination.

It is yet another objective of the invention is to provide a lip posture corrector without any toxic effect on human body.

It is yet another objective of the invention is to provide a device which can be used to improve the lip posture of the patients who have undergo MRI or CT scan.

It is another objective of the invention is to provide a lip posture corrector which itself is capable of correcting the lip posture in other words, no oral or other dose is simultaneously required in order to correct the lip posture.

It is further objective of the invention is to provide a lip posture corrector which is cost effective, easy to use and having minimum discomfort.

SUMMARY OF THE INVENTION

Accordingly there is provided a lip posture corrector consists of:

an intra-oral component (1);

an ear support component (2);

a connector (3) being positioned between the intraoral component (1) and ear support component (2);

wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2;

wherein the sodium acrylate and acrylamide is 10:90 by weight.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with componenticular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates the lip posture corrector in accordance with the present invention;

Figure 2 is the image (front view) of a patient suffering from facial palsy and drooping of the affected side of the lip in accordance with present invention;

Figure 3 is the image (side view) of a patient suffering from facial palsy and drooping of the affected side of the lip in accordance with present invention;

Figure 4 is the image (front view) of a patient illustrating the clinical application of the device in accordance with the present invention;

Figure 5 is the image (side view) of a patient illustrating the clinical application of the device in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

The phrase “device”, “static suspension device”, “lip posture corrector” herein is the same and could be used interchangeably.

The phrase “static suspension” herein refers to equilibrium or balancing of the lip posture.

The present invention provides a static suspension device for improving a lip posture of a patient suffering from facial paralysis.

As shown in Figure 1, the device of the present invention consists of three components:

an intra-oral component (1)

an ear support component (2)

a connector (3) between the intraoral component (1) and ear support component (2)

In preferred embodiment of the invention, the shape of the intra-oral component and ear support component is the circular or the like.

In preferred embodiment of the invention, the diameter of the intra-oral component is 18-22mm, while the diameter of the ear support component is 41-49mm. In preferred embodiment, the length of the connector is 90-130mm.

The whole device according to the present invention is made up of a polymeric blend which should be met with the following properties i) sufficient strength such that the device would not be deformed during the use; ii) should not exhibit the toxic effect to the user; iii) should be light weight such that the user would not feel the discomfort. In preferred embodiment, the polymeric blend is a combination of polymethylmethacrylate acrylic resin (PMMA) and copolymer of sodium acrylate: acrylamide 10:90 (PAA 1115). Both the polymers are well known in pharmaceutical/medical field for various applications including thickening agent, viscosity enhancer, sustained release polymer. Use of PMMA in denture application is also known *[(Bhola et al., Biocompatible Denture Polymers – A Review, Trends Biomater. Artif. Organs, Vol 23(3), pp 129-136 (2010)].* Bhola et al., addresses PMMA as a good polymer as the strength is concerned, but it leaches the free-radicals (MMA and formaldehyde) which causes stomatitis and this prior art also addresses the MMA/PMMA as carciogenic.

The present inventor surprisingly found that a weight ratio of PMMA and PAA 1115 1:2 provides the desired effect i.e. lip-lifting without the toxic effect of PMMA to the user.

In present invention, the method for preparing the device is known flasking procedure, except the polymer ratio.

As the device of the present invention is made up without metal, it can be used in MRI, CT scan and other detection parameter.

The present invention is now illustrated with non-limiting examples:

Example 1:

PAA 1115 (sodium acrylate: acrylamide 10:90) was purchased from Suyog Chemical, Nagpur, Maharashtra, India and PMMA was procured from SMCO International, Mumbai India.

The working of the device to establish the advantageous effect of the present invention is demonstrated in Figure 2 and 5. The studies were performed at **Krishna Institute of Medical Sciences and Krishna Hospital, Karad** and 10 elder patients suffering from drooping of lip (facial paralysis) and not be subjected to the surgery were chosen from each group as follows:

Group 1: The static suspension device using PMMA and PAA 1115 1:1; &

Group 2: The static suspension device using PMMA and PAA 1115 1:2

Both front (Figure 2 & 4) and side view (Figure 3 & 5) of the patient (Patient 5, Age 68) was taken before and after using the device. The patients (Group 1 & 2) were worn (Figure 4 & 5) the device in which the Intra-oral component (1) was retained through the buccal mucosa and another component (2) was retained through the ear support in a manner like a spectacle (Through connector 3). The patients were given the prescribed oral doses as required for other purposes for instance the patient who was suffering from diabetes and facial paralysis, the prescribed dose of metformin HCl was given but no oral/parenteral dose of the glucocorticoid (as referred in the background) was given to him/her.

The improvement (100%) was evaluated by correcting the lip posture to its original position of above patients and there was symmetry of the lip bilaterally (both left side and right side of the face). For example, if the lip had dropped to 1cm below its

normal level (here normal level means position of the lip on the other unaffected side), and if the device brings the lip position back to its normal position by lifting it to 1cm.

Table 1

Group 1 (The static suspension device using PMMA and PAA 1115 1:1)	Lip drooping/Lip lifting		Side effects
	Lip drooping	Lip lifting	
Patient 1 (Age 60)	0.8cm	0.8cm	Stomatitis
Patient 2 (Age 62)	0.5cm	0.5cm	Stomatitis
Patient 3 (Age 64)	0.9cm	0.7cm	Stomatitis
Patient 4 (Age 66)	0.8cm	0.6cm	Stomatitis
Patient 5 (Age 68)	1.0cm	1.0cm	Stomatitis and allergic reaction
Patient 6 (Age 70)	0.8cm	0.7cm	Stomatitis
Patient 7 (Age 72)	0.8cm	0.7cm	Stomatitis
Patient 8 (Age 74)	0.8cm	0.6cm	Stomatitis
Patient 9 (Age 76)	0.8cm	0.5cm	Stomatitis
Patient 10 (Age 80)	0.9cm	0.9cm	Stomatitis, allergic reaction

Wherein the patient was worn the device up to 6 months from the date of first using the device.

Table 2

Group 2 (The static suspension device using PMMA and PAA 1115 1:2)	Lip drooping/Lip lifting		Side effects
	Lip drooping	Lip lifting	
Patient 1 (Age 60)	0.8cm	0.8cm	No sign of stomatitis and allergic reaction
Patient 2 (Age 62)	0.5cm	0.5cm	
Patient 3 (Age 64)	0.9cm	0.9cm	
Patient 4 (Age 66)	0.8cm	0.7cm	
Patient 5 (Age 68)	1.0cm	1.0cm	
Patient 6 (Age 70)	0.8cm	0.8cm	
Patient 7 (Age 72)	0.8cm	0.8cm	
Patient 8 (Age 74)	0.8cm	0.8cm	
Patient 9 (Age 76)	0.8cm	0.8cm	
Patient 10 (Age 80)	0.9cm	0.9cm	

Wherein the patient was worn the device up to 6 months from the date of first using the device.

Figure 4 & 5 shows the clinical improvement of the lip posture.

The present inventors found that the static suspension device using PMMA and PAA 1115 1:2 shows the desired effects i.e. 100% lip-lifting effect without toxicity (Patient 5, Table 2). Further, the present inventors found that the static suspension

device itself is a sufficient in order to correct the lip posture i.e. without glucocorticoid.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the componenticular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

CLAIMS:

1. A lip posture corrector consists of:

   an intra-oral component (1);

   an ear support component (2);

   a connector (3) being positioned between the intraoral component (1) and ear support component (2);

   wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2;

   wherein the sodium acrylate and acrylamide is 10:90 by weight.

2. The lip posture corrector as claimed in claim 1, wherein the shape of the intra-oral component is circular or the like.

3. The lip posture corrector as claimed in claim 1, wherein the shape of the ear support component is circular or the like.

4. The lip posture corrector as claimed in claim 1, wherein the length of the connector is 90-130mm.

5. The lip posture corrector as claimed in claim 1, wherein the diameter of the intra-oral component is 18-22mm.

6. The lip posture corrector as claimed in claim 1, wherein the diameter of the ear support component is 41-49mm.

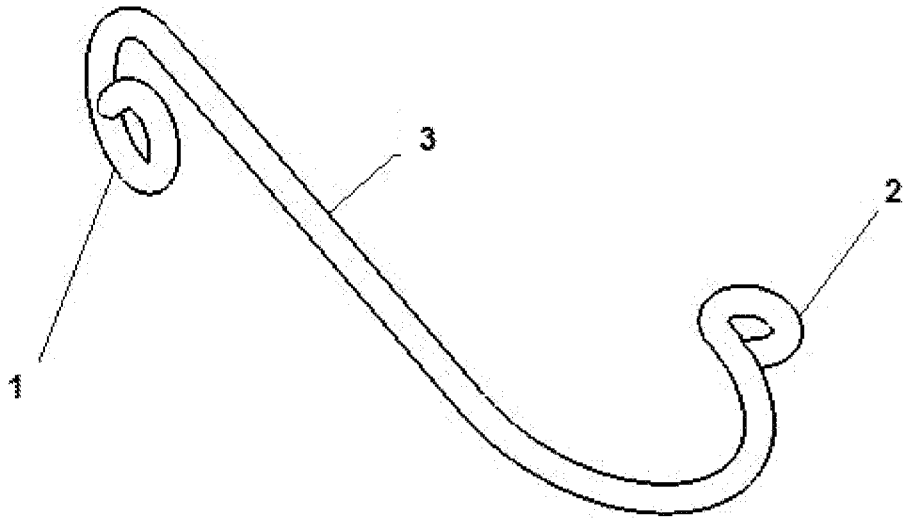

Figure 1

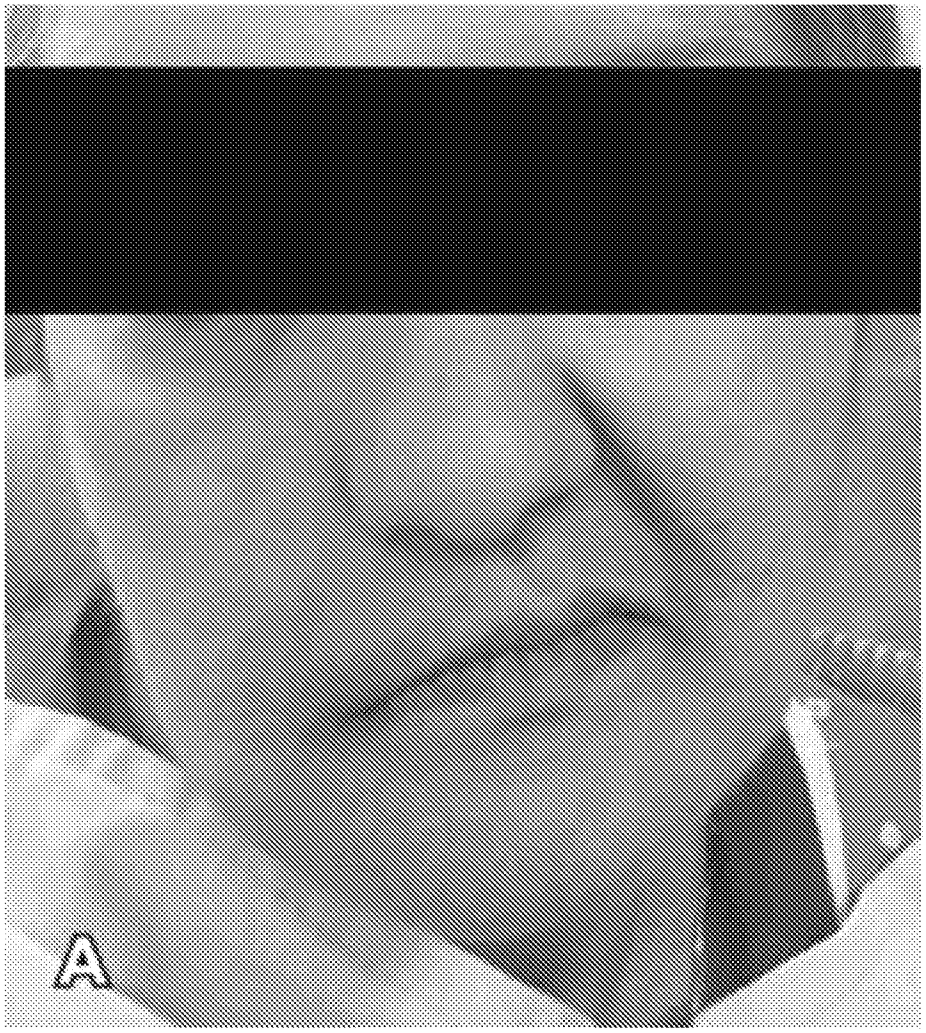

Figure 2

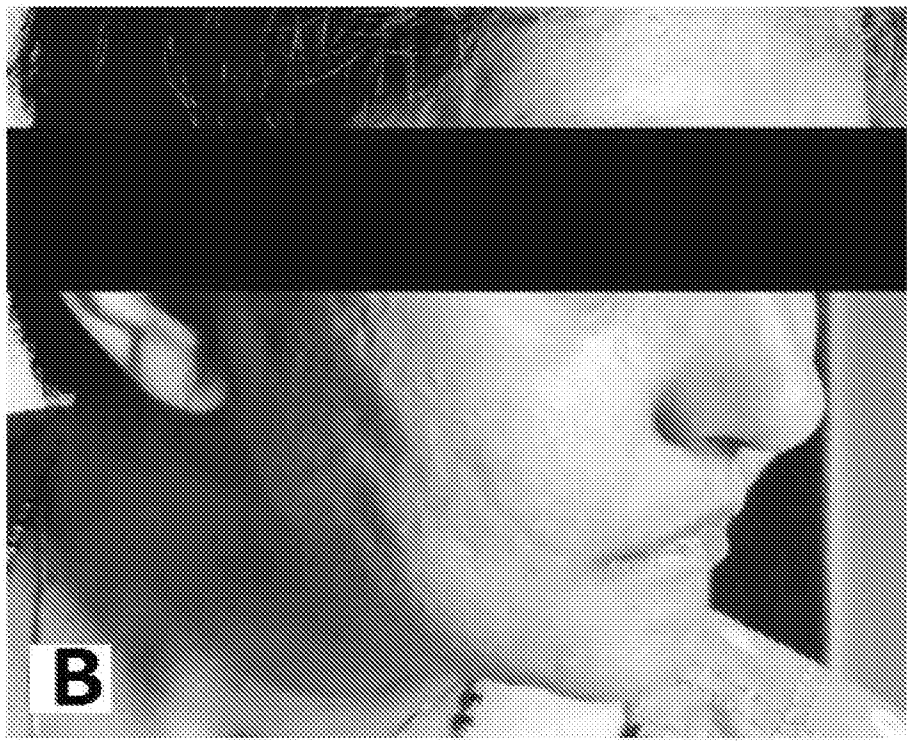

Figure 3

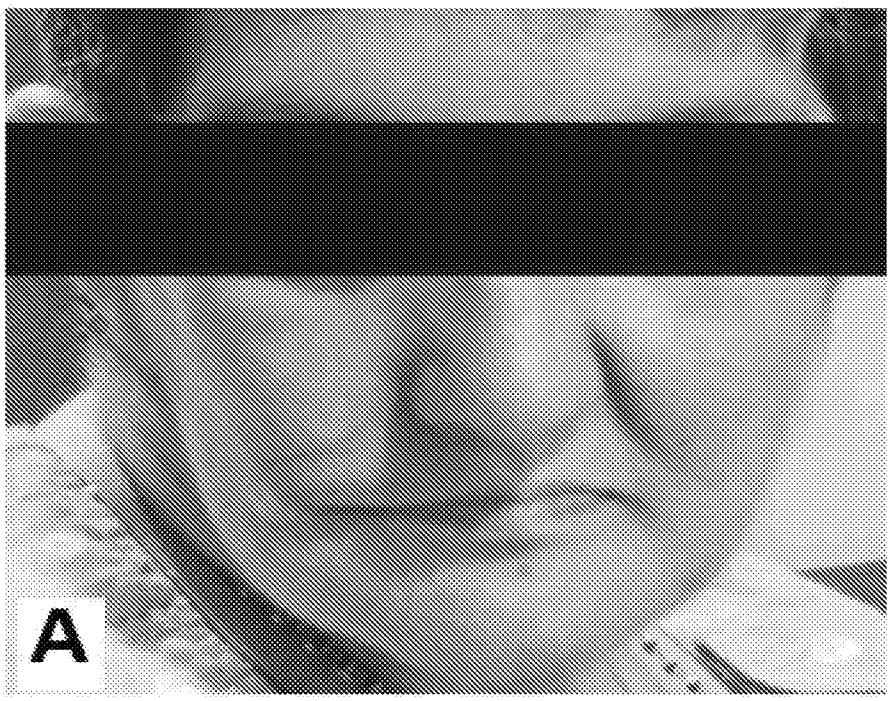

Figure 4

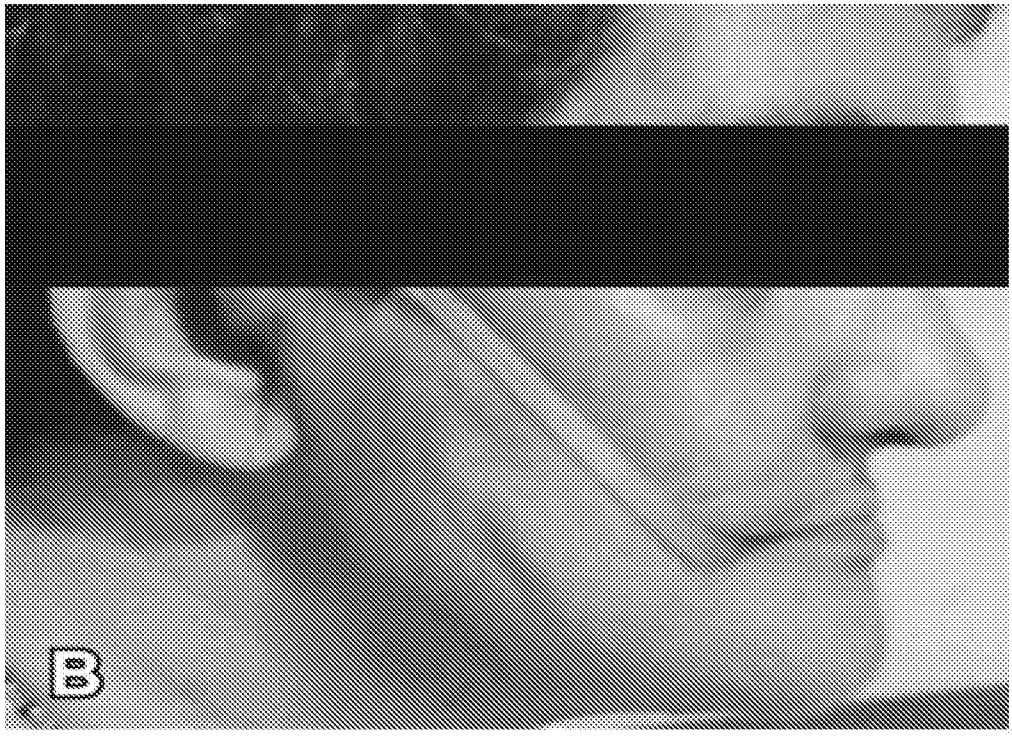

Figure 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2019/050596

A. CLASSIFICATION OF SUBJECT MATTER
A61C7/00,A63B23/03 Version=2019.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A63B; A61C;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DATABASES: TotalPatent One, IPO Internal Database
KEYWORDS: intra-oral component; ear support component;

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KR100932956B1 (BAIK, OK SEON), 22 December 2009 (22-12-2009). whole document	1-6
A	KR100817325B1 (KOREA MEDICAL SCIENCE INSTITUTE), 27 March 2008 (27-03-2008). whole document	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17-09-2019	17-09-2019
Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Authorized officer Pradeep Dhakad Telephone No. +91-1125300200