

ORIGINAL ABSTRACT

ORTHOSIS FOR SIMULTANEOUS THREE-DIMENSIONAL CORRECTION OF CLUB FOOT

The present subject matter relates an orthosis for correcting at least one foot in clubfoot characterized with the treatment of the foot independent from the other foot. The orthosis according to the present subject matter includes a holding element for holding a portion of a leg of a patient, and a base element for receiving and holding the foot. The base element is pivotally connected to the holding element by a torque adjusting mechanism. The torque adjusting mechanism is further provided with metered tuning to achieve a desired torque along the three axes of movements of the foot. These three axes in accordance with the foot movements include extension-flexion, inversion-eversion and adduction-abduction. Their respective movements are governed by respective knobs provided with the torque adjusting mechanism.

REFER FIG. 3

We Claim:

1. An orthosis **100** for correcting at least one foot in clubfoot independently, the orthosis **100** comprises:
 - a holding element **102** for holding a portion of a leg of a patient;
 - a base element **106** for receiving and holding the foot, the base element **106** being pivotally connected to the holding element **102** by a torque adjusting mechanism **108**;
 - the torque adjusting mechanism **108** being tuned to achieve a metered desired torque along the three axes of movements of the foot.
2. The orthosis **100** as claimed in claim 1 comprises a height adjusting element **104** for adjusting the height of the holding element **102**.
3. The orthosis **100** as claimed in claim 1 wherein the three axes of movements of the foot are along the three dimensions namely extension-flexion **X-X'**, inversion-eversion **Y-Y'** and adduction-abduction **Z-Z'**.
4. The orthosis **100** as claimed in claim 1 wherein the torque adjusting mechanism **108** comprises a plurality of knobs for metered tuning of the holding element **102** and the base element **106** along the desired axis.
5. The orthosis **100** as claimed in claim 1 wherein the magnitude of the torque adjusted by the torque adjusting mechanism **108** is measured by strain gauges.
6. The orthosis **100** as claimed in claim 1 wherein the torque adjusting mechanism **108** comprises a first knob **110** to adjust the extension and flexion **X-X'** of the feet of the patient.
7. The orthosis **100** as claimed in claim 1 wherein the torque adjusting mechanism **108** comprises a second knob **112** to adjust the inversion and eversion **Y-Y'** of the foot of the patient.
8. The orthosis **100** as claimed in claim 1 wherein the torque adjusting mechanism **108** comprises a third knob **114** to adjust the adduction and abduction **Z-Z'** of the foot of the patient.
9. The orthosis **100** as claimed in claim 1 wherein the orthosis **100** is lockable in three dimensions at any degree of rotation.

10. The orthosis 100 as claimed in claim 1 is made of plastics, leather, silicone rubber, cotton, wood and aluminum.

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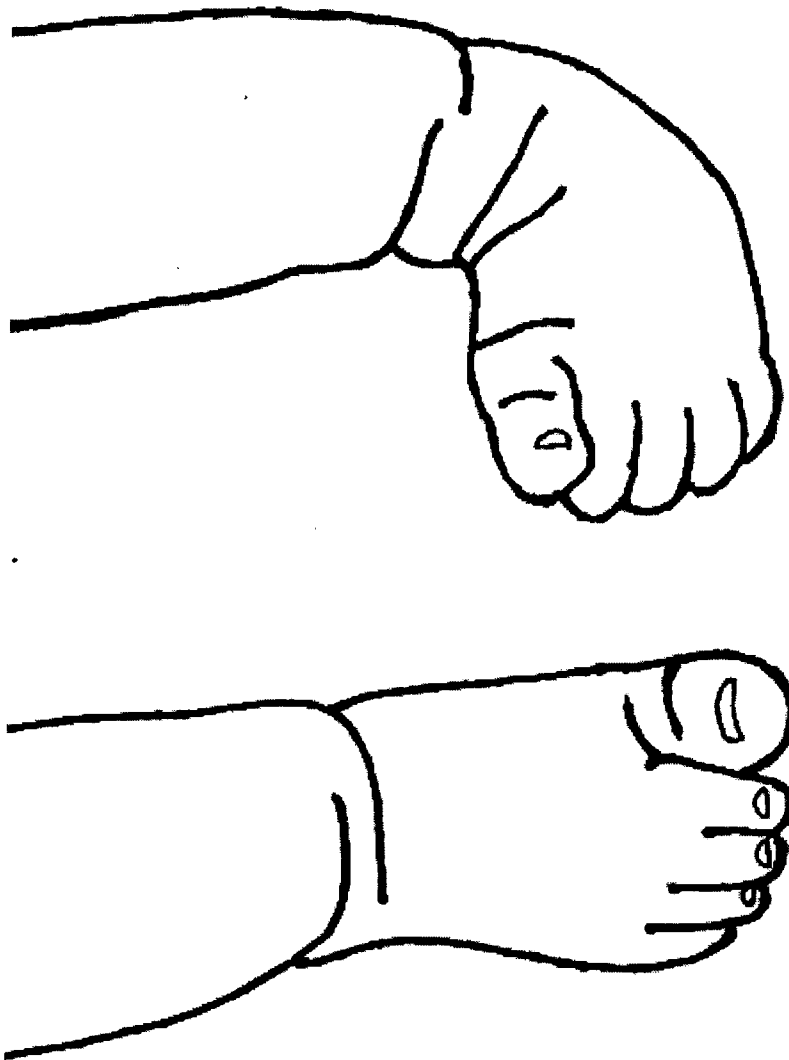


FIG. 1

Shanker

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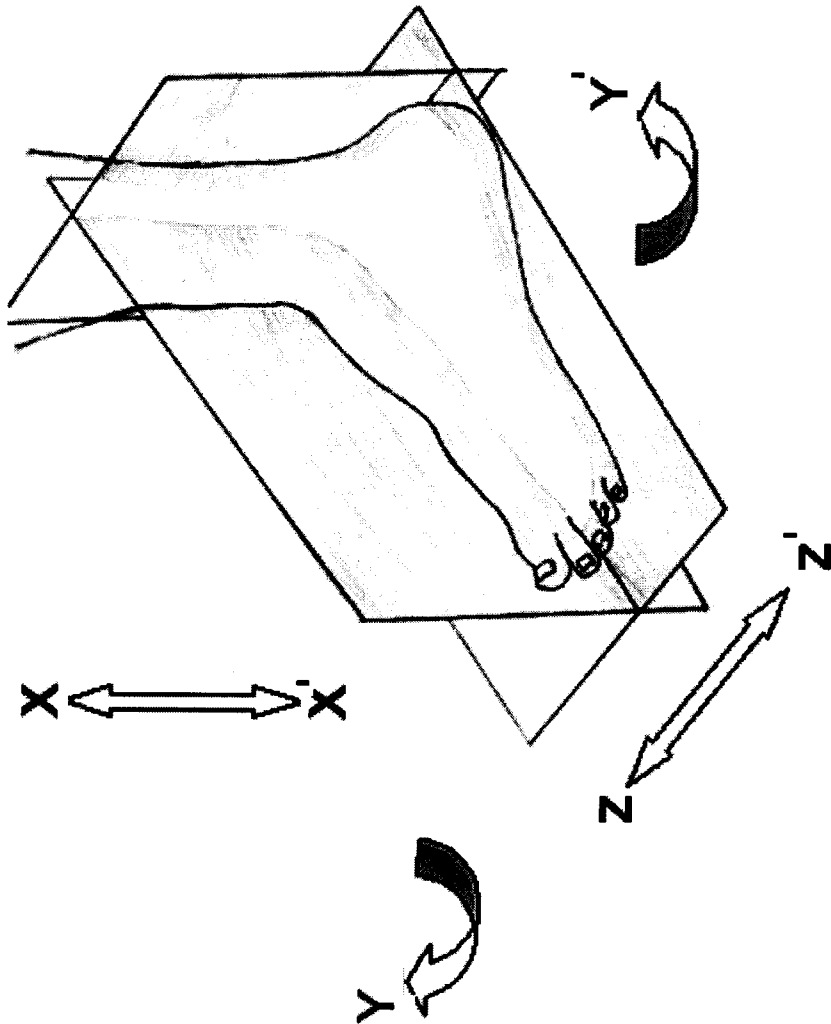


FIG.2

Shanker

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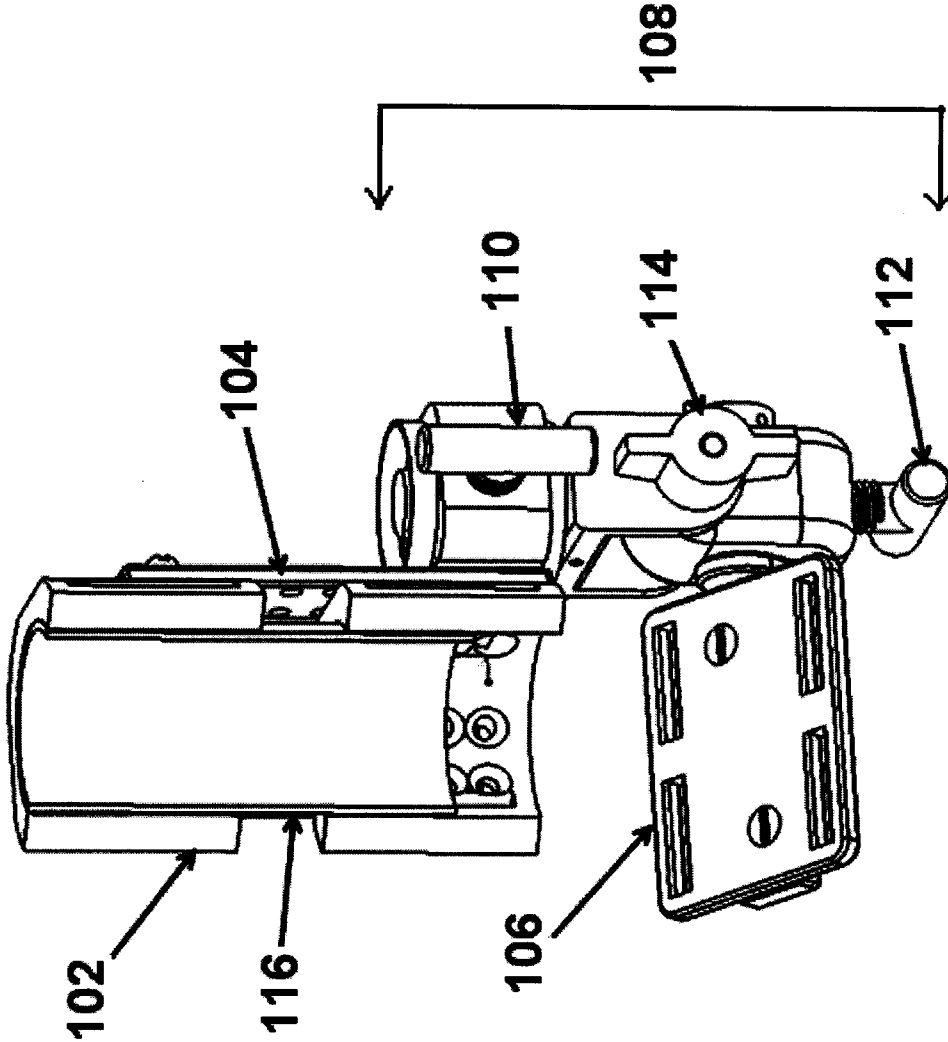


FIG.3

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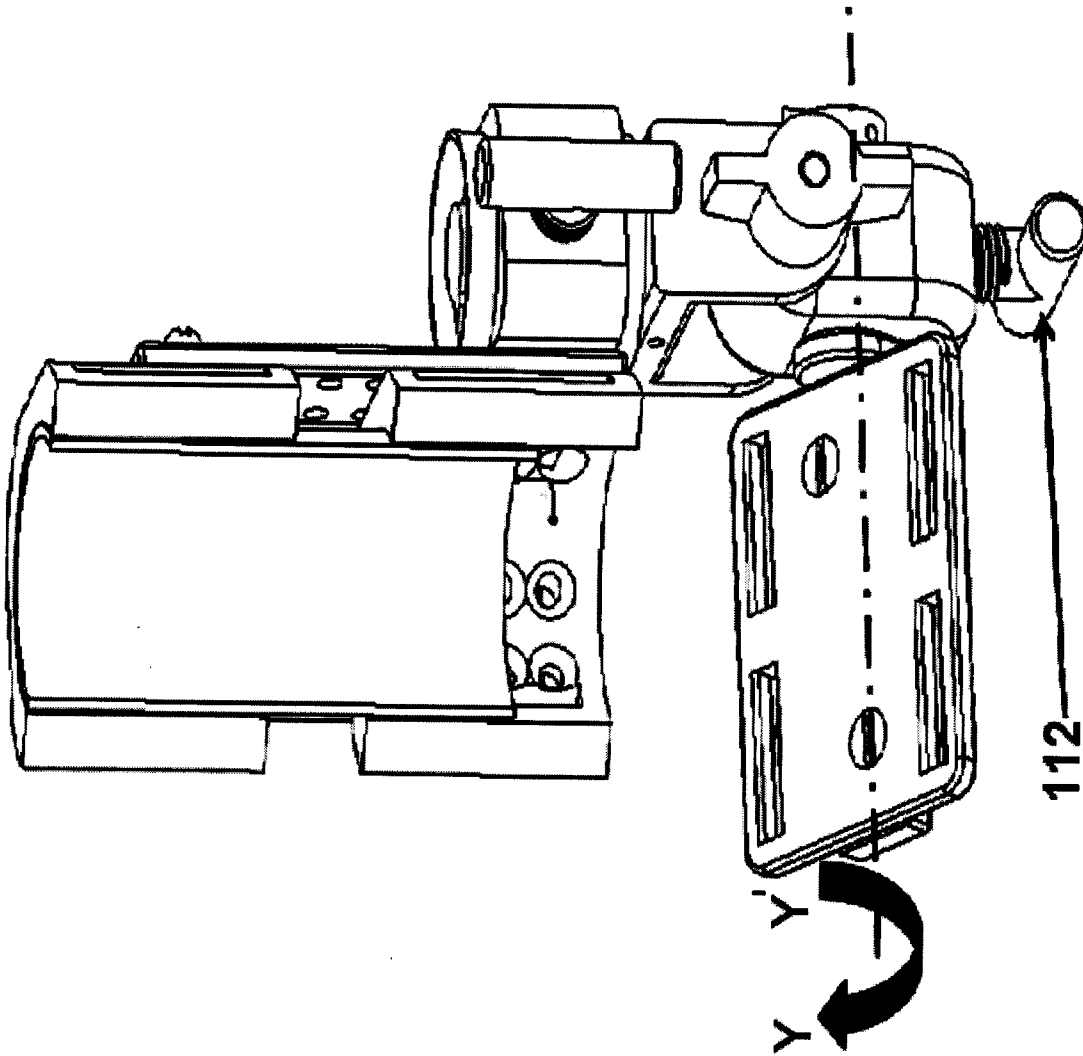


FIG.4

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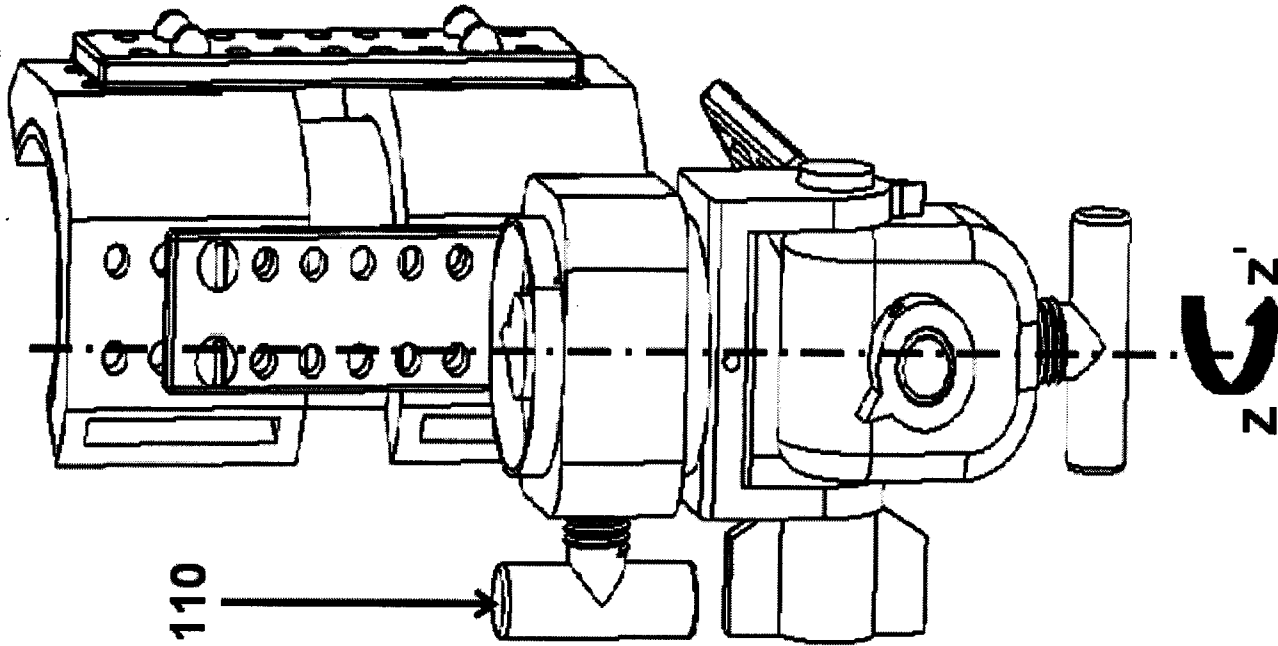


FIG.5

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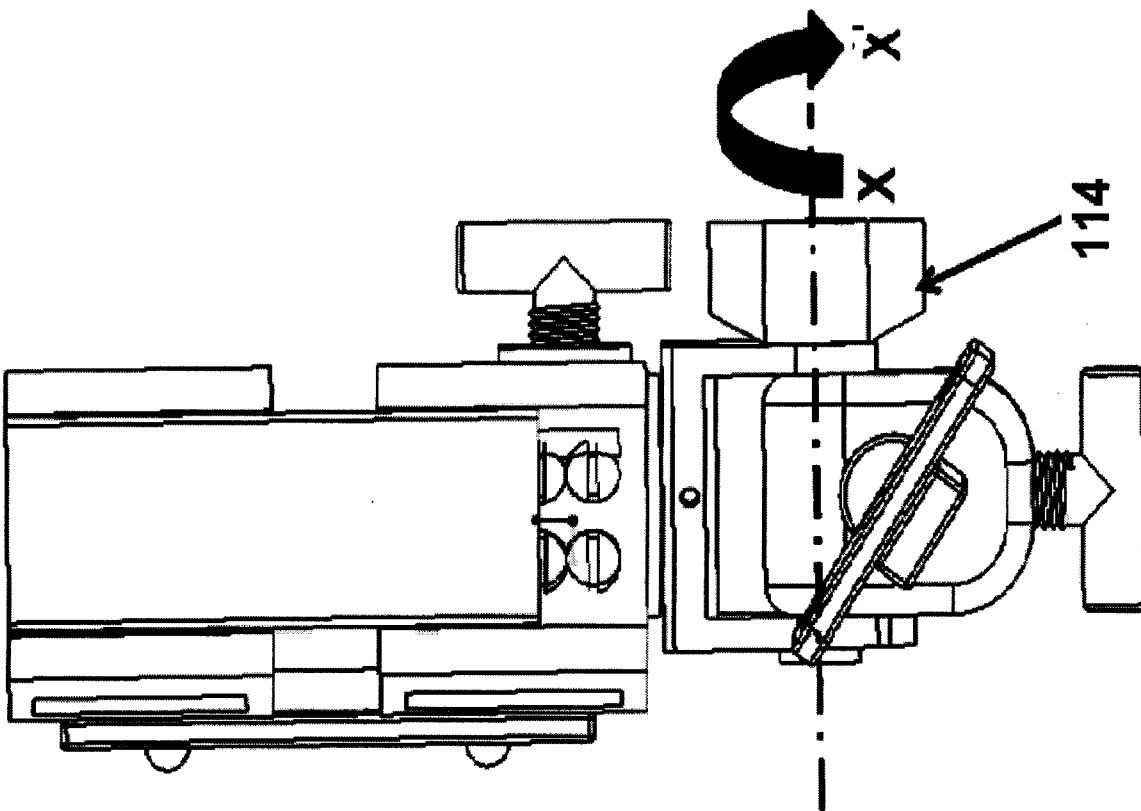


FIG.6

Shanker

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FIELD OF INVENTION

The present invention relates to an orthosis and, more particularly, to a customizable orthosis furnished with three dimensional movement of each foot independently.

BACKGROUND OF THE INVENTION

Generally, an orthosis is an orthopedic device that is typically applied to the limb or body to provide support, protection, pain reduction or replacement of lost function for a patient suffering from clubfoot. As shown in **FIG. 1**, Clubfoot is one of the most common problems in pediatric orthopedics that is characterized by a complex three-dimensional deformity of the foot. The clubfoot causes one or both feet twisted inward. Clubfoot affects all the joints, tendons and ligaments in the foot and is often technically referred to as 'Congenital Talipes Equino Varus (CTEV). In this regard, a lot of orthosis are available in the markets depending on the ages, diagnosis and the physical needs of the individual. A few of them are being discussed below also:

- By serial casting and manipulation skills: *Kite's technique, Ponseti's technique and French technique*

During Kite's method, the manipulation of the clubfoot is started soon after the birth of a child. Operationally, the forefoot is grasped and distracted while the other hand holds the heel. The navicular is pushed laterally while simultaneously applying counter pressure over the calcaneocuboid joint. This results in the eversion of the heels as the foot is abducted. The eversion is followed by the application of slipper cast extended below the knee of the patients wherein the foot is everted with gentle external rotation. The foot is subsequently pushed into dorsiflexion to correct the equines once the adductus and varus are corrected. The casts which are used in the method are changed every week. Once the feet are completely corrected, they are placed in a Denis Browne Bar.

Ponseti's method of treating clubfoot involves gradual correction of the clubfoot deformity through weekly casting for approximately five to seven weeks. The last plaster

is worn three weeks followed by the wearing of boots on a bar known as the Foot Abduction Orthosis (FAO), for two years to maintain the corrected position. FAO need to be worn by the baby for 23 out of 24 hours for three months. Thereafter they are worn for two years at night and nap times only. Thus, we can conclude that Ponseti's technique of treating clubfoot with serial casting is better than Kite's technique, but Ponseti's technique do not always give consistent success rate. Further, the prolonged uses of casts result in skin dehydration, ulcers, blood circulation problems, and the like. Additionally, relapses may appear in the maintenance phase of treatment during Ponseti's method,, which may subsequently lead to surgery in some cases also. Hence the treatment becomes more complex and lengthy.

French technique was introduced in France in the 1970s by Masse and Bensahel. It involved daily manipulation of the child's clubfoot by the physical therapist for atleast 30 minutes. This was followed by stimulation of the muscles to maintain the reduction achieved by the passive manipulation. The stimulation of the muscles is subsequently applied with adhesive strapping. The daily treatment continues for approximately two months and then reduced to three sessions per week for an additional six months. Strapping is continued until the patient becomes ambulatory (able to walk). After achieving ambulation, a night time splint is introduced and used for an additional two to three years. Hence, French technique leads to daily hospital visits and is very costly in long run too.

- Treatment with frames: *Ilizarov technique and Taylor spatial frame*

Ilizarov technique is less invasive and allows simultaneous correction of all components of the deformity without resection of the bone or shortening of the foot. Soft tissue viability and function can be accessed directly and the rate of correction can be adjusted accordingly. During, Ilizarov technique, the adaptability of fine wire frames allow for gradual correction of each component of a deformity, either simultaneously or sequentially.

The Taylor Spatial Frame is the more recent developments made in designing a multi plane external fixator. This device allows gradual deformity correction using a system of 6 articulated struts, tibial rings, a foot-plate, half-pins, and wires. However, both these techniques have so many complications such as, pin site infection, epiphysiolysis, flexion deformities of the toes, joint subluxation, bone cysts, and the like. Also, these techniques are unfortunately not preferred for infants.

- Operative techniques

Various surgical methods have been developed for treating clubfoot, yet there is no single procedure that gives a long lasting correction. Actually, the optimal age for treating clubfoot with surgery has been controversial. Turco recommends the surgery at around one year of age while Osterman and Marikanto recommend surgery at the earlier age of three to six months to utilize the remodeling potential of the foot. However, Danglemajor advises deferring surgery until one year of age, because surgery done earlier has a failure rate to 65%. Also the average number of operation per foot was 2.9 to achieve a full correction at skeletal maturity with earlier surgery. In addition to finding a higher incidence of failure, Turco reported the disadvantages of early surgery, as it is difficult to identify the anatomical structures and to handle the small cartilaginous bones when operating a small foot.

- By using orthosis

The correction of the clubfoot by using the orthosis is the most desired one as it overcomes all the disadvantages discussed in the above mentioned methods. It is because, orthosis demands neither serial casting nor surgery. Many orthosis have been designed and patented for correcting the deformity of clubfoot. However, all these orthosis have been designed by joining both feet of the baby patient. As both feet of the baby are tied to each other, the baby is unable to crawl freely which leads to uncomfortably for the baby patient. Additionally, both the feet of the baby remains tied upto atleast three years or till the full correction of the deformity is not achieved.

Besselink et al [“Clubfoot splint” with reference number PCT/NL2008/050730] have designed a splint for connecting a clubfoot for treating the foot of the patient, in particular for a baby patient. The splint, which is applied to the lower zone of the other leg of the patient, includes a shoe fitting around the foot; an element which can be coupled to the lower zone of the other leg; and a connecting rod which is present between the shoe and the element. The connecting rod is connected to the shoe and the element via two respective pivot means. These pivot means are designed with three rotation degrees of freedom. In particular, the degree of freedom of rotation around the central axis of the connecting rod defines a rotation angle range of at least 30° whereas each of the two other degrees of freedom of rotation define a rotation angle range of at least 135°.

Harald et al [“Orthosis for treatment of clubfoot” with reference number PCT/EP2007/002855] have designed an orthosis for treatment of clubfoot which has fastening means (24, 27, 28) for fastening a patient's feet, and a connection structure (1) that connects the fastening means and keeps them in defined positions relative to one another, and is at least partially elastic.

Further, Washington University et al [“Orthotic clubfoot device” with reference number US 7569023] came up with an orthosis wherein the patient's feet are maintained at a desired angle while allowing the patient to move in an otherwise normal manner and preventing blister formation. This orthosis generally comprises an orthotic splint assembly, two ankle foot orthosis and two custom molded inserts secured to the ankle foot orthosis. However, the available orthosis design are not user friendly and do not provide simultaneous three dimensional correction to club foot also. Additionally, the work done so far in designing of orthosis is by tying the feet of the baby by a bar. This results restricted movements of the baby patients. In other words, since both feet of the baby are tied to each other, the baby is unable to crawl freely and independently. Furthermore, the feet of the baby remained tied atleast upto three years or till the full correction of the deformity is not achieved. This creates a very uncomfortable situation for the baby patients.

Thus, there is a need for an orthosis which can overcome the above mentioned drawbacks.

OBJECTIVES OF THE INVENTION

In light of the foregoing, the following are the specific objectives of the proposed subject matter:

The principal objective of the invention is to design and develop a new orthosis for correcting at least one clubfoot independently.

Another objective of the invention is to design an orthosis which includes a holding element for holding a portion of a leg of a patient, and a base element for receiving and holding a clubfoot.

Yet another objective of the invention is to design an orthosis in which the base element is pivotally connected to the holding element by a torque adjusting mechanism.

Yet another objective of the invention is to design an orthosis wherein the torque adjusting mechanism being tuned to achieve a desired metered torque along the three axes of movements in the clubfoot.

Yet another objective of the invention is to design an orthosis using plastics, leather, silicone rubber, cotton, wood and aluminum.

Yet another objective of the invention is to design an orthosis in which torque applied along the three axes of movements in the clubfoot are measured by applying strain gauges on silicon rubber clubfoot model.

Yet another objective of the invention is to provide the orthosis with height adjusting element for adjusting the height of the holding element.

Yet another objective of the invention is to measure the torque of three axes of movements of the clubfoot along the three dimensions namely extension-flexion, inversion-eversion and adduction-abduction.

Yet another objective of the invention is to provide the torque adjusting mechanism with plurality of knobs for metered tuning of the holding element and the base element along the desired axis.

Yet another objective of the invention is to provide a first knob for adjusting the extension and flexion of the feet of the patient.

Yet another objective of the invention is to provide a second knob for adjusting the inversion and eversion of the foot of the patient.

Yet another objective of the invention is to provide a third knob for adjusting the adduction and abduction of the foot of the patient.

Yet another objective of the invention is to design the orthosis as lockable in three dimensions at any degree of rotation.

Yet another objective of the invention is to design the orthosis as easily attachable to the leg of the patient.

Yet another objective of the invention is to provide a cheaper, easily operable and efficient orthosis.

BRIEF DESCRIPTION OF DRAWINGS

FIG.1 shows the shape of clubfoot in comparison to normal foot in accordance with the general art of the present matter subject matter.

FIG.2 shows the foot joint motion in three planes namely adduction-abduction, inversion-eversion and extension-flexion in accordance with the present subject matter.

FIG.3 shows the perspective view of an orthosis in accordance with the present subject matter.

FIG.4 illustrates the controlling mechanism of inversion and eversion in the orthosis in accordance with the present subject matter.

FIG.5 illustrates the controlling mechanism of adduction and abduction in the orthosis in accordance with the present subject matter.

FIG.6 illustrates the controlling mechanism of extension and flexion in the orthosis in accordance with the present subject matter.

DETAILED DESCRIPTION

The embodiments of the present subject matter are described in detail with reference to the accompanying drawings. However, the present subject matter is not limited to these embodiments which are only provided to explain more clearly the present subject matter to the ordinarily skilled in the art of the present disclosure. In the accompanying drawings, like reference numerals are used to indicate like components.

The subject matter described herein is directed to a customizable orthosis which provides support, protection, pain reduction or replacement of lost function for a patient suffering from clubfoot. The clubfoot, as shown in **FIG. 1**, is the most common serious congenital deformities of the musculoskeletal systems in new born babies, with a frequency of 1 to 6 per 1000 of the world's population. The clubfoot is characterized with a typical appearance of pointing downwards and twisted inwards. Since the condition starts in the first trimester of pregnancy, the deformity is quite established at birth, and is often very rigid. The cause of the deformity is unknown. Irrespective of its causes, during development, the posterior and medial tendons and ligaments (in the back and inside) of the foot fail to keep pace with the development of the rest of the foot. As a result, these tendons and ligaments tether the posterior and medial parts of the foot down, causing the foot to point downwards and twist inwards. The bones of the feet,

therefore, are held in an abnormal position. Over time, if uncorrected, the bones will become misshapen.

In a preferred embodiment of the present subject matter, **FIG. 3** shows the orthosis **100** which can be implemented on a single feet without tying the foot together. The orthosis **100** includes a holding element **102** to hold the leg of a patient, mainly a baby patient. The holding element **102** is designed to receive the calf region of the leg of the patient. The holding element **102** is structured with non-resilient material provided with a front opening adapted to facilitate the receipt of the calf of the patient. The holding element **102** is also equipped with a height adjusting element **104** which advantageously adjusts the height of the holding element **102**. The base of the foot is acknowledged on a base element **106** designed to receive and hold the base of the foot of the patient. The base element **106** is pivotally connected to the holding element **102** by a torque adjusting mechanism **108** in an embodiment of the present subject matter. The torque adjusting mechanism **108**, as shown in **FIG. 3** is tuned to achieve a desired metered torque along the three axes of movements of the foot.

In a preferred embodiment of the present subject matter, the torque adjusting mechanism **108** creates the desired amount of torque in any of the three axes of the movement of the foot. The generation of independent torque along each respective axis facilitates a three dimensional movement of the foot. The three dimensions involved in the movement of the foot include extension-flexion **X-X'**, inversion-eversion **Y-Y'** and adduction-abduction **Z-Z'**, as is being described later with reference to **FIG. 2**. In a different embodiment of the present subject matter, the torque adjusting mechanism **108** in the orthosis **100** is provided with plurality of knobs designed for metered tuning of each axis. In particular, the knobs include a first knob **110** for adjusting adduction and abduction **X-X'**, a second knob **112** for adjusting inversion and eversion **Y-Y'**, and a third knob **114** for adjusting extension and flexion **Z-Z'**.

In another embodiment of the present subject matter, the orthosis **100** further includes a controlling mechanism to control the three movements of the foot. **FIG. 4** shows the control of inversion and eversion **Y-Y'**, in an embodiment of the present subject matter. Similarly, **FIG. 5** and **FIG. 6** show the control of movements in adduction-abduction **Z-Z'** and extension-flexion

X-X' respectively. In an embodiment of the present subject matter, the control of these axes is governed by various knobs which when tightened (or loosened as required) adjust the necessary movements along each of the axis at suitable degree of freedom. The control mechanism is as simple as it can be operated by the parents of the patients also.

In an embodiment of the present subject matter, the magnitude of various torques generated is measured by a strain gauge (**not shown**). Operationally, a test set up is developed with a clubfoot prototype model to experimentally establish forces and torque required to correct the deformity of clubfoot. During that set up, the magnitude of forces and torque required in three movements i.e. extension-flexion **X-X'**, inversion-eversion **Y-Y'** and adduction-abduction **Z-Z'** is measured by the strain gauges for different degrees of deformities.

The orthosis **100** according to the proposed subject matter is made of plastics, leather, silicone rubber, cotton, wood and aluminum, in an embodiment of the present subject matter. The silicon rubber is especially characterized with high flexibility and softness which substantially matches with those of babies. Thus, the presence of silicon rubber as inner material **116** of the orthosis **100** increases the safety of the babies' leg within the proposed orthosis **100**.

The orthosis **100** according to the present subject matter advantageously facilitates the application of the orthosis **100** on each foot independently which gives freedom from tying the feet together. Thus, the baby patients are able to walk and crawl freely now. Additionally, the orthosis **100** according to the present subject matter ensures the correction of deformity of the foot in three dimensions simultaneously. Further, the orthosis **100** is easily attachable and lockable to the leg of the patient also. Moreover, the orthosis **100** is easily adjustable by the parents with minimum requirement of visits to the hospitals. Hence, the proposed orthosis **100** reduces the overall cost of treatment of clubfoot too.

Although the subject matter has been described with reference to specific embodiments, this description is not meant to be construed in a limiting sense. Various modifications of the disclosed embodiments, as well as alternate embodiments of the subject matter, will become apparent to persons skilled in the art upon reference to the description of the subject matter. It is

therefore contemplated that such modifications can be made without departing from the spirit or scope of the present subject matter as defined.