3DIMENSIONAL MODELING OF AN ANKLE FOOT ORTHOSIS FOR CLUBFOOT DEFORMITY

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This article is available online at www.ssjournals.com

ABSTRACT

Clubfoot deformity is a congenital deformity which is also called as congenital talipes equino varus (CTEV). This foot deformity is well established from birth. The causes for this deformity are numerous, but the major cause happens to be abnormal intra-uterine fetal positing. The clinical presentation is a child walking on the lateral border of the foot. The foot appears to be club shaped. This primary skeletal deformity in turn leads to muscular deformities like, tightening of the muscles that are constitute the medial border of the foot. Treatment is initiated from birth; severe bone and muscular deformity require surgical correction. But non surgical management is the most preferred way of treatment. Serial casting and braces are the management in practice. But these methods tend to be very uncomfortable; in turn the child gets irritated.

Ankle foot orthosis have been used to treat a variety of foot deformity, but its application in clubfoot is yet to be understood. This study concentrates on designing an ankle foot orthosis as an alternate option for the treatment of clubfoot. The orthosis is virtually modeled, instead of the traditional fabricating procedure. This study concludes by showing that virtual modeling can be a better advancement in the field of orthosis designing.

KEY WORDS: Congenital talipes equinovarus, Ankle foot Orthosis, Point cloud data, Voxels, Rapid prototype

INTRODUCTION

Clubfoot is a historical challenging foot deformity in babies and is normally observed from their birth (Congenital foot abnormality).Under this deformity the foot turns in and point down causing the subject to walk on the outside edges of the foot[1].

A **clubfoot**, or congenital talipes equinovarus (CTEV), is a congenital deformity involving one foot or both. The affected foot appears rotated internally at the ankle. TEV is classified into 2 groups: Postural TEV or Structural TEV. Without treatment, persons afflicted often appear to walk on their ankles, or on the sides of their feet. It is a common birth defect, occurring in about one in every 1,000 live births. Approximately 50% of cases of clubfoot are bilateral. This occurs in males more often than in females by a ratio of 2:1.The deformities affecting joints of the foot occur at three joints of the foot to varying degrees[2]. They are

- inversion at subtalar joint

- Adduction at talonavicular joint and
- Equinus at ankle joint.

The cause of clubfoot is not well understood. While it can be associated with other congenital malformations (such as spina bifida and arthrogryposis), it may also occur independently. The cause of clubfoot is not due something the mother did during pregnancy[2].

When a child is born with clubfoot, the tendons on the inside and the back of the foot are too short. The foot is pulled such that the toes point down and in, and it is held in this position by the shortened tendons.

Biomechanics of clubfoot deformity

The clubfoot is associated with poor bone alignment, the navicular, cuboid and calcaneus bone segments are medially displaced and found to be in inversion (turned around their axis) in relation to talus. The finding of the clubfoot study shows that the main anomaly resides in the medial and plantar flexion of the neck and head of the talus. It is also stated that the anomalies of the muscles, tendons and ligaments of the foot and leg were secondary to the skeletal deformity.

The following are the characteristics of clubfoot (ponseti, 1996)

- The foot has a kidney-shaped appearance with a high arc (cavus) at the midfoot, indicated by a transverse crease across the sole of the foot. The forefoot is turned towards other foot, known as adduction of forefoot.
- The heel is drawn up, because of tightened Achilles tendons, making it impossible to place the foot flat on the floor.
- The toes are pointed down, known as equines of forefoot.
- The bottom of the foot (heel) is twisted in, towards other foot, known as varus of heel.
- The foot and leg may be smaller in comparison to a comparatively normal child's foot and leg.
- The foot will lack motion and be noticeably stiff.
- The calf muscle may also be smaller

In all clubfoot, the talus is in severe flexion[3], its body is small and altered in shape, as compared to normal talus. The calcaneus is adducted and inverted underneath the talus and most of its anterior tuberosity is under head of the talus and not lateral to it, as in normal feet. Its body is consistently in severe flexion and slightly medially bowed. The cuboid is medially displaced and inverted in front of the calcaneus. The navicular is uniformly flattened or laterally wedge shaped and severely displaced medially and inverted. The cuneiform and metatarsals are very abnormal and its anterior joint is very narrow or absent, whereas the middle joints are varied in size[4]. The fibers in the muscles of the clubfoot are smaller in size and the muscles triceps surae, tibialise posterior, flexor digitorum longus (FDL), and flexor hallucis longus (FHL) are found to be in contracted position. In the ankle, the tendons of the tibialise anterior, extensor digitorum longus,and extensor hallucis longus are severely displaced medially while the tibialise posterior tendon is large and further enlarged down to its insertion. The medial talocalcaneal ligament is markedly thickened while the anterior part of the deltoid ligament and plantar calcaneonavicular ligament are short and thick in all clubfoot. The posterior tibiotalar, fibulotalar and the fibulocalcaneal ligaments are also thick and short and often matted together with abundant fibrous tissue.

The inversion and adduction of calcaneus is accounted and this heel varus along with adduction and inversion of navicular and cuboid are responsible for clubfoot supination. The forefoot skeletal components are adducted in front of the medially displaced navicular and cuboid while the cavus is resulted because of more flexion of first metatarsal than the lateral metatarsals.

Figures 1.1 and 1.2 represent the top view of normal and clubfoot's skeleton while in this figure *A* represent the talocalcaneal angle and *B* represent talonavicular angle in top view of foot skeleton. The normal range of the talocalcaneal angle (*A*) in top view is about 20–40 degrees, while it is abnormal if $A < 20$ degrees. Similarly the normal range of this in lateral view is about 25–50 degrees while it is abnormal if $A < 25$ degrees[5,6,1].

Non surgical management of clubfoot deformity

Nonsurgical management include serial manipulation and casting, taping, physical therapy and splinting, and continuous passive motion with a machine. The initial treatment of clubfoot, regardless of severity, is nonsurgical. Manipulation and casting using the Ponseti method is the technique used most frequently in the United States. The majority of clubfeet can be corrected in infancy in about six to eight weeks with the proper gentle manipulations and plaster casts. The technique requires training, experience, and practice. Fewer than 5 percent of infants born with clubfeet may have very severe deformities that are unyielding to stretching. These infants will require surgical correction.

Treatment should be initiated immediately upon diagnosis, preferably within the first week of life. Treatment for the newborn with clubfoot is by manipulation to correct the condition and then casting to maintain the correction. Casting begun at a later age may be more difficult due to the worsening ligamentous contracture and joint deformity. Long-leg plaster casts are used to maintain the corrections obtained through manipulations. Casts are changed at weekly intervals, and most deformities are corrected in two months to three months. Before applying the last plaster cast, which is to be worn for three weeks, the Achilles tendon is often cut in an office procedure to complete the correction of the foot. By the time the cast is removed the tendon has regenerated to a proper length. After the last cast is removed, the foot should appear overcorrected. The Ponseti method of casting and manipulation is the commonest management. This method was pioneered by Dr. Ignacio Ponseti in 1940s and is successful in most of the cases. The Ponseti method, if correctly done, is successful in >95% of cases in correcting clubfeet using non- or minimal-surgical techniques. Typical clubfoot cases usually require 5 casts over 4 weeks. Atypical clubfeet and complex clubfeet may require a larger number of casts. Approximately 80% of infants require an Achilles tenotomy (microscopic incision in the tendon requiring only local anesthetic and no stitches) performed in a clinic toward the end of the serial casting.

After correction has been achieved, maintenance of correction may require the full-time (23 hours per day) use of a splint—also known as a foot abduction brace (FAB)—on both feet, regardless whether the TEV is on one side or both, for several weeks after treatment. Part-time use of a brace (generally at night, usually 12 hours per day) is frequently prescribed for up to 4 years. Without the parents' participation, the clubfoot will almost certainly recur, because the muscles around the foot can pull it back into the abnormal position. Approximately 20% of infants successfully treated with the Ponseti casting method may require a surgical tendon transfer after two years of age. While this requires a general anesthetic, it is a relatively minor surgery that corrects a persistent muscle imbalance while avoiding disturbance to the joints of the foot.

Despite successful initial treatment, clubfeet have a natural tendency to recur. Bracing is necessary for several years to prevent relapses. There are several different braces that are commonly prescribed. All braces consist of a bar (the length of which is the distance between the child's shoulders) with either shoes, sandals, or custom-made orthosis attached at the ends of the bar in about 70 degrees of external rotation. The bar can be either solid (both legs move together) or dynamic (each leg can move independently). The brace is worn 23 hours a day for three months and then at nighttime for three to four years. The brace consists of a bar (the length of which is the distance between the child's shoulders) with high top open-toed shoes attached at the ends of the bar in about 70 degrees of external rotation.

Ankle foot orthosis for clubfoot deformity

Orthotic devices are intended to support the ankle to correct deformities, and to prevent further occurrences. A key goal of orthotic treatment is to assist the patient in achieving normal gait patterns. Different orthosis are used to enhance the ankle-foot position and mobility[5].

Ankle-foot orthosis (AFOs) are orthosis or braces, usually plastic, encompassing the ankle joint and all or part of the foot. AFOs are externally applied, and are intended to control position and motion of the ankle, compensate for weakness, or correct deformities. They control the ankle directly, and can be designed to control the knee joint indirectly as well. With careful impression techniques and model modification methods, a custom ankle-foot orthosis (AFO) may be fabricated to meet the requirements of a physician prescribing noninvasive treatment for postsurgical clubfoot care. The impression is obtained with maximum achievable correction and modified using three-point pressure systems that overcorrect the clubfoot deformity. This AFO is effective in protecting the surgical corrections from undue stresses early on as well as helping to prevent postoperative recurrence of the deformity. The postoperative time in a cast also may be shortened if proper orthotic treatment is achieved. Some advantages of a shorter cast period include convenience for patient and family and less risk of skin breakdown[2]. An ankle-foot orthosis (AFO) is fabricated during the final two weeks of casting and is fit and delivered when the final holding cast is removed. It is worn for 12 out of 24 hours for three to six months with convenience to the family dictating which hours of the day or night it is worn. If correction of adduction and supination proceeds rapidly, but the heel remains high and a midfoot breach occurs, a complete posterior release may be indicated. If more than one element of deformity persists after three months of casting, more comprehensive surgery is performed. Postoperative casting continues for at least two months after surgery, followed by application of an AFO. Postoperatively the foot is placed in a "0" splint, in which it is held in the corrected position with the knee, flexed to 90 degrees. Plaster bandage, is wrapped around the foot and continued up the medial and lateral sides of the leg and over the knee. At one week, the splint is removed, the wound is inspected, dressings are applied and a definitive full leg cast is applied. If complete correction is not obtained at this time, serial casting may be indicated. Postoperative casting continues for two months, and an impression for an AFO is obtained at fly weeks. The AFO is fit and delivered at the time of removal of the final cast Again, if medial spin persists, a Denis Browne splint may be used in conjunction with the AFO[4].

NEED FOR THE STUDY

Clubfoot deformity is a pediatric condition, and the traditional management of this condition is manipulation, serial casting, bracing and surgical management. Non surgical management like serial casting and bracing are found to be uncomfortable. The child tends to get irritated with a permanent cast and a movement restricting braces, an orthosis which is easy to don and doff, and comfortable to wear for a prolonged period of time is always a welcome. Apart from the regular management like splinting and braces, ankle foot orthosis for the correction of Clubfoot deformity is an option. This study is designing an AFO for the correction of clubfoot deformity. Traditional methods like negative casting and positive castings are the options in the fabrication of an AFO. This study explores virtual modeling of ankle foot orthosis. Computer aided designing and drafting (CADD) has been vastly used to design machineries in the industry, this designing tool can be used to design biomedical tools like an orthosis. The advantages of using CAD to design an orthosis will be dealt in this study.

AIM AND OBJECTIVE

To design a virtual model of an ankle foot orthosis for clubfoot deformity

- To make rapid prototype of a solid surface model of the abnormal ankle foot complex
- To demonstrate volume and surface rendering for a 2 dimensional CT image of the abnormal foot
- Fabricating an ankle foot orthosis for clubfoot deformity
- Measure the amount of pressure passing through the various components of the orthosis.

MATERIALS AND METHODOLOGY

CT scan of the abnormal foot (clubfoot deformity) are taken, the 2D CT slices are converted into a 3D image. Volume and surface is rendered for the 3D image. Point cloud data is generated for the surface rendered image. The point cloud data (PCD) is taken as the input parameter for the computer aided designing (CAD). From the point cloud data a rapid prototype (RPT) of the surface model is generated, the surface model is then converted to a solid model[3].

CT scan is the preferred tool because of the following reasons

- High precision when compared to the other methods
- Minute details are enhanced and highlighted
- Cost effective and easy availability

128 slices CT of the abnormal foot was taken with the subject in supine lying, the foot and the ankle joint in the biomechanical neutral alignment. The 2D CT images in the **dicom** format were taken as the input for the surface and volume rendering. The 2dimensional images are stacked into a 3dimensional image. Stacking is the process by which all the 2 dimensional slices are arranged in a 3D format. A 3D volume image includes a stack of 2D images. A 3D volume image can be stored in a single image file or multiple files where each file contains one image slice or plane[5].

Surface rendering

Surface rendering creates polygon-based 3D surface models from defined object boundaries. Surface rendering displays the surface model and allows changing the color and transparency properties of the rendered objects. 3D volume and surface area can be accurately calculated from these surface models[5,7,8].

"Simple surface rendering" command creates a simple 3D surface rendering using the boundary data generated from a 3D image. The algorithm used for the simple surface rendering is vector-based and is normally faster than other algorithms. 3D surface models generated by the 3D Rendering/Surface Rendering/Simple Surface command will have much less surface triangles and be more suitable for rapid prototyping and other applications that require a more simplified surface.Fig 2.

Volume rendering

Volume rendering creates a 3D display using both the 3D image and the boundaries. Voxels are ray-traced to show the image in a 3D space. Volume rendering supports several rendering modes, including transparency, where voxels are treated as transparent, direct object, where only surface voxels are displayed, and maximum density, where only the brightest voxel is displayed along each ray. Because volume rendering creates each view by ray-tracing the entire volume. For 3D volume rendering, the data can be saved to a XYZ file, where each voxel location is recorded as a point[5,7,8].

Point cloud data

The point cloud data of the surface and the volume rendered image are extracted. Meshes are generated. A rapid prototype of the surface model is created from which a solid model is generated. From the point cloud data, a RPT model is generated[5,7,8].

Orthosis modeling

The 3D surface rendered model of the foot is the base material based on which the ankle foot orthosis is generated. This ankle foot orthosis is designed in a CADD designing tool "**Pro E**".

An orthosis is modeled for the outer surface model of the deformed foot. The surface model of the orthosis is then converted into solid model. The rapid prototype of the orthosis is generated[9].

The solid model of this surface model is then generated by offsetting surface model to 5.0mm in outward direction giving a thickness of 5.0mm.This thickness is enough to sustain loads during corrective procedure. The RPT model of the foot and the orthosis are generated[10].

Mc kay strapping method is used to correct the deformity

- The velcro strip-1 is responsible for fixing the clubfoot's shank in AFO and it restricts the rotation of tibia of clubfoot in medial direction.
- The velcro strip-2 restricts the medial rotation of the calcaneous of clubfoot.
- The velcro strip-3 restricts the cavus of the medial border of clubfoot due to the forces at the base of the first metatarsal and at the base of the fifth metatarsal.

RESULT AND DISCUSSION

This research demonstrated the development of a customized, user-friendly dynamic AFO having provision of providing anatomic motion for correction of along a waited historical clubfoot deformity in new born babies. Since this AFO is specifically designed for tender age babies having clubfoot deformity and are not in the stage of walking and mostly lying on bed and the geometry of clubfoot is differ than the geometry of normal foot. The AFO after prototyping if fix on the clubfoot then due to its dynamic characteristic it bring the deform geometry of foot to normal foot geometry due to soft tissue behaviors at tender age level. The deform geometry slowly become normal foot's geometry with in an expected duration of 3 months and the overall ideas is to bring the deform geometry of clubfoot to normal foot's shape by the time baby starts taking steps and come in walking under aging growth. Once he/she starts walking with perfect gait, then there is no need of AFO and the clubfoot is corrected if walking gait is found satisfactory. In feature this model would be prototyped and plan to wear on the live clubfoot of baby patient by fixing through Velrco strips. The patient response will be used to improve the further design of this AFO. Clubfoot is a common pediatric orthopedic deformity. Despite the popularity of Ponseti's method and night splints such as the Denis–Browne method, there is still an 11–47% rate of deformity relapse reported in the literature. The technique to make traditional orthotics is dependent on a nonweight-bearing casting or foot imprint. These splints outdate clinical treatment trends and only apply to patients who are of nonwalking age. This study shows that a new procedure utilizing computer aided design. This new procedure allows the custom orthotic to be designed and analyzed within a day. The new orthotic design is composed of soft foam interior layers and a polymer supportive exterior layer. It is proved that rapid prototyping can be generated within a day.

CONCLUSION

The presented works evolve a novel 3D virtual model of ankle foot orthosis for non-surgical correction of light nature challenging clubfoot deformity in very young babies. The methodology is discussed and implemented for development of medical device for abnormal foot of babies. The works influence the medical community and related patient by providing a computer-aided tool in the form of 3D virtual modeling of AFO.

The presented study advances the correction of clubfoot deformity in young babies.

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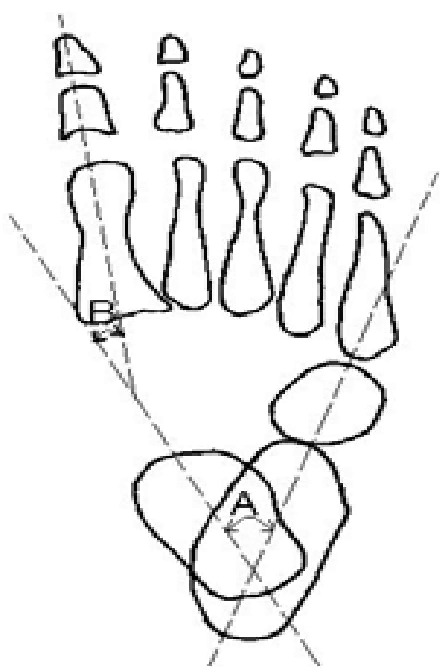

FIG. 1.1- TOP VIEW OF NORMAL FOOT

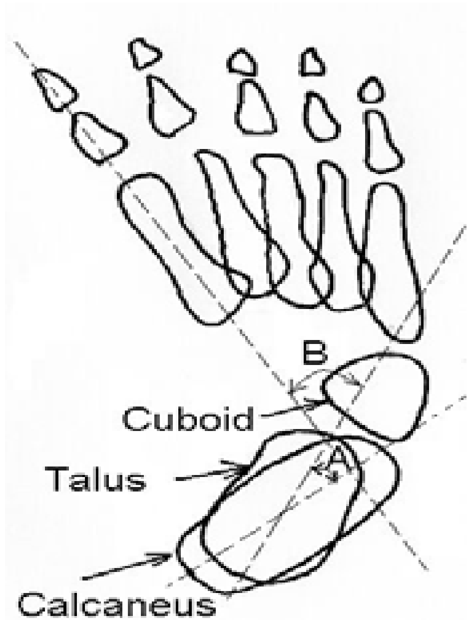

FIG. 1.2- TOP VIEW OF THE CLUBFOOT

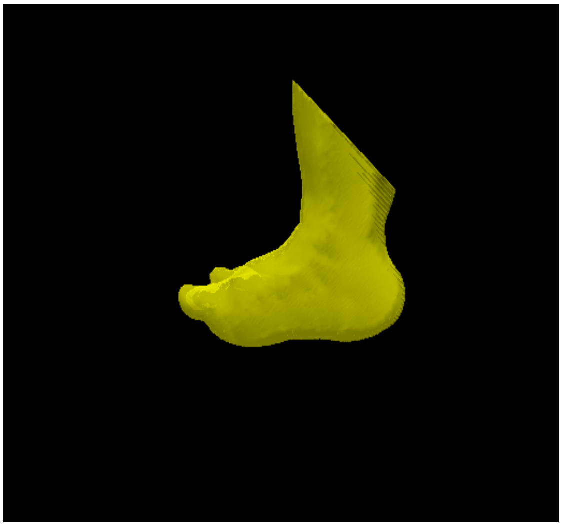

FIG 2.- Surface Model

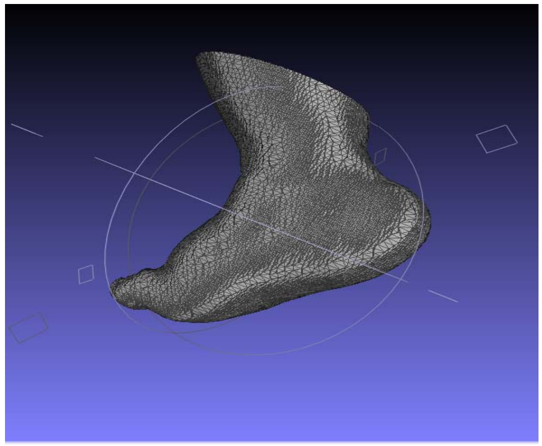

FIG 3.- Point Cloud Data

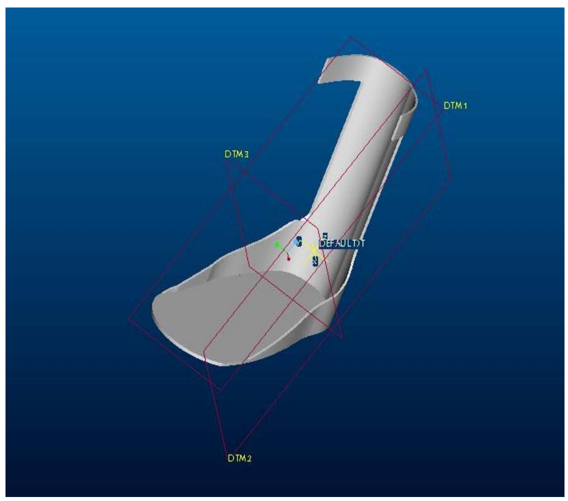

FIG 4.- Modeling in pro e

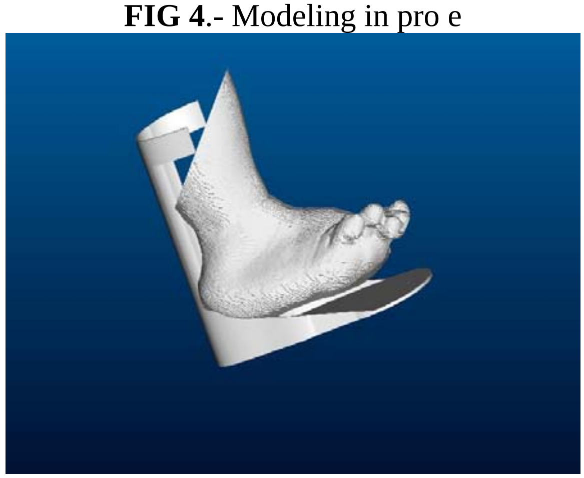

FIG 5.-Accurate fitting of the foot and Orthosis