Design And Development Of Ankle Foot Orthosis Using Additive Manufacturing Technique

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Abstract— *The main intention of manufacturing technology in medical field rely on providing ease to the patient by improving exactness truncating the time consumption and reducing the monetary encumbrance on the patient. The goal is to provide assistance to the patients suffering from foot deformity such as talipes equines and talipes calcaneus. This can be performed by fabricating customized orthosis for a subject affected with above mentioned foot deformity through fused deposition modeling in additive manufacturing (AM) technology with Acronitrile Butadiene Stryene (ABS) plastic as base material. It is performed in order to improve the patient's stability and thereby correcting the gait pattern in a comfortable manner. A pilot study has been performed regarding the foot deformities and their treatments, involving both surgical and non surgical methods. The pinnacle of this study leads to improve the customized ankle foot modeling by providing relieve to the patient suffering from the above foot deformities when compared with the traditional ponseti method. It overcomes the difficulties faced by the patient during the ponseti method of non-surgical treatment.*

Keywords—Ankle Foot Orthosis, Talipes Equinus, Talipes Calcaneus, Additive Manufacturing.

1. INTRODUCTION

The 3D printing has been developing the medical industry in several ways. In healthcare it makes possible for the development of new surgical cutting, drill guides, prosthetics, bones, organs and blood vessels. The customized products with tough geometry can be developed using Additive Manufacturing (AM) technology. It involves variety of products and huge applications to create a three dimensional products. In AM parts fabricated through layer by layer material addition process based on Computer Aided Design (CAD) model. The wide applications of AM involves the mechanical, aerospace, automobile, electronics, garments, healthcare and biomedical engineering [1]. The customized products (such as orthosis and prosthesis) are produced precisely through AM technology [2]. This paper focuses on the area of congenital or acquired deformity and development of the supportive complex product using AM technique.

The abnormal growth in the body shape with respect to genetic and hormone disorder leading to structural changes which can be either congenital or acquired [3],[4].

The foot deformity contains both surgical and non surgical method of treatments.

2. FOOT DEFORMITIES

There are various classes of foot deformities; out of many deformities some of the deformity which is treated using a common design is taken into account.

2.1 TALIPES EQUINUS

The talipes equinus is a type of deformity which comes under clubfoot deformities. It is due to the contraction of achilles tendon or calf muscle. The patient with this deformity faces the difficulty in maintaining the normal gait pattern.

Fig 1 Resembles the planar flexed [5]

It may be occurred in congenital or acquired . Physical examination by evaluating the ankles range while at flexion and relaxation state of knee and X-rays are used for diagnosis. Due to planar flexion of foot, patients may suffer from severe knee, hip and back pain. The radiographic images of planar flexed foot are shown in the figure1.

2.2 *TREATMENTS FOR TALIPES EQUINUS*

The surgical treatment involves tendo-achilles lengthening procedures during the Achilles is repaired. The surgical options are formal "Z" lengthening, percutaneus tenotomy or gastronomies aponeurosis lengthening [6]. The nonsurgical treatments for talipes equinus involve exercises which help in stretching of calf muscles or by wearing orthotics. A conservative treatment includes night splint, heel lifts, arch supports and physical therapy.

2.3 *TALIPES CALCANEUS*

The talipes calcaneus deformity is due to the weakness or absence of calf muscle that results in vertical orientation of calcaneus axis like dorsiflexion of foot.

Fig 2 Dorsiflexed foot [5]

This type of deformity is mostly occurred in congenital. In this deformity the foot which shows up the increased ankles of tendon towards the shin.The people with this deformity suffers to maintain their gait in abnormal surfaces further, this imbalance creates high pressure over the sole, thus results pain in lower body, hip and back. The complete study on patient with this deformity is performed using X-rays. The radiographic image of dorsiflexed foot is shown in figure 2.

2.4 *TREATMETS FOR TALIPES CALACANEUS*

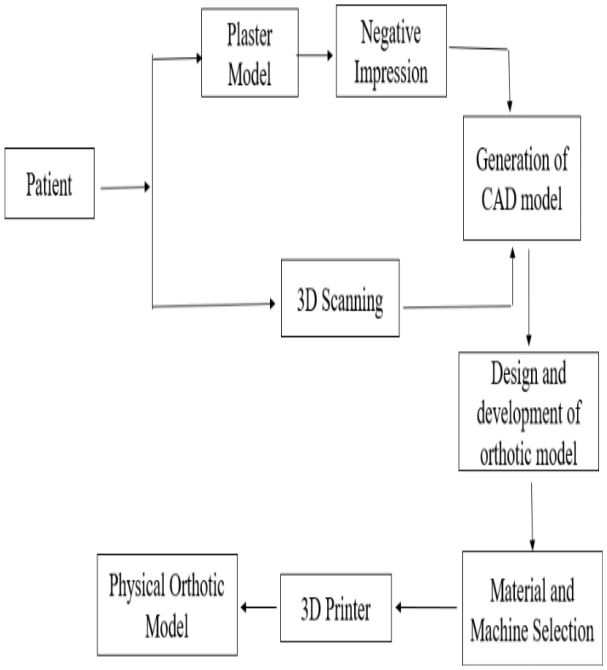
The surgical treatment is performed to flatten the arch. It involves calcaneus heel bone osteotomy-procedure performed using screws and saw, tendon transfers-moving tendon muscles bony surgery-fusion in joints [7]. The non surgical method involves fitting of a removable splint and the patient is asked to mobilize with non weight, partial weight bearings which is assessed by physiotherapist [8].

3.TRADITIONAL AND ADDITIVE MANUFACTURING ANKLE FOOT ORTHOSIS

The non surgical and traditional methods to cure these deformities involve casting procedure, taping, soft bandages, and stretching, splinting methods [9]. The treatment of clubfoot deformity was initially carried out using wrench apparatus [10]. "Gastrosoleal Stretching" is an important high success rate of treatment was stated by Hill [11].

Ponseti method of treatments involves mainly two phases corrective stage and maintenance stage. In corrective stage the serial plaster cast is manipulated and applied whereas in maintenance phase it is utilized for Ankle Foot Orthosis (AFO) braces was suggested by Agarwal and Suresh [12]. The difficulty in this treatment is cast slipping and swelling of forefoot [13]. The therapeutic shoes, foot orthosis and AFO influence the tactile and proprioceptive mechanisms results in sense of position and reduce risk of falling of deformed patients [14].

The most of the foot deformities overcoming braces are designed to offload high pressure areas, minimize shear forces, cushion site of tenderness, provide foot control and support. Further, types of braces in accordance with deformity types it includes arizona brace, planar fascia night splint and Molded Ankle Foot Orthosis (MAFO) [15]. 3D printed AFO is used to replicate traditional AFO and develop novel designs by increasing stiffness and reducing weights of patients [16]. An attempt to provide an alternative solution to the talipes equinus and talipes calcaneus foot deformity is made through AM technology. Focus



of this work is to develop a versatile device that provides greater corroboration and reducing the patient discomfort due to deformity. This method of production overcomes the difficulties faced by the traditional method of treatment. Figure3 illustrates the process flow of 3D printed AFO fabrication.

Fig 3 Process flow of 3D printed AFO

4.METHOD

The customized insole made of AM should show more evenly distributed pressure over entire deformed foot. The AM insoles are too rigid as these custom insoles show less discomfort, less dorsiflexion and overall better fit with reduced risk of injury [17]. Fused Deposition Modeling (FDM) is the most utilized prototyping in AM technology. It helps in fabricating with various thermoplastic materials like ABS-M30, Poly Carbonates (PC), Poly Phenyl Sulphone (PPSF), and ULTEM 90. FDM printed insole product is developed based on the design performed, such product is embedded in a shoe which performs as brace to overcome the talipes equinus and calcaneus deformity. E.Sun reported that polyjet for AM of shoe insole decreases heel and foot pressure [18]. The FDM printing is based on 3D model is rapidly used prototyping technology [19]. FDM is most commonly used on developing the versatile AFO device.

4.1 *MEASUREMENT OF DEFORMED FOOT*

The patient with the equines deformed foot is taken into account. The cross sectional and dimensional measurements of the traces are noted manually using vernier caliper. The impression of the foot measured is shown in figure 4.

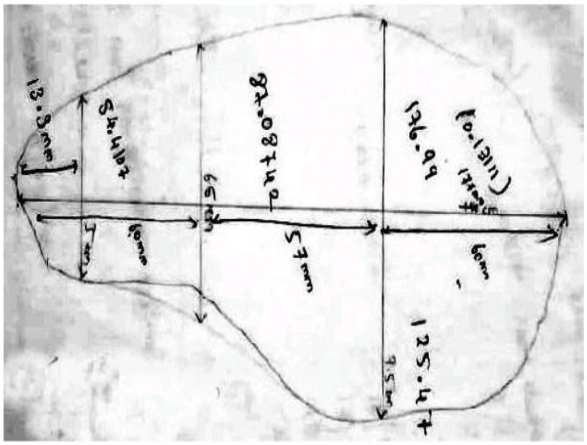


Fig 4 Measurement of deformed foot

Measurements:

Foot length	: 176.99mm
Foot width	: 95.00mm
Foot width (instep)	: 65.00mm
Heel length	: 60.00mm
Heel width	: 54.00mm

4.2 DESIGN *OF CUSTOMISED ORTHOSIS*

Initially, a 3D scanner kinect X-BOX 360 is used to scan the molded foot. It consists of a prime motion sensor embodied in a game controller for scanning, then with the help of software SCANET the cloud points are created and the unwanted geometrical portions are removed.

Due to involuntary patient response to scan their foot, a talipes equines patient's mold is taken under examination. Patient's talipes equines mold and scanning setup is shown in figure 5 and figure 6 respectively.

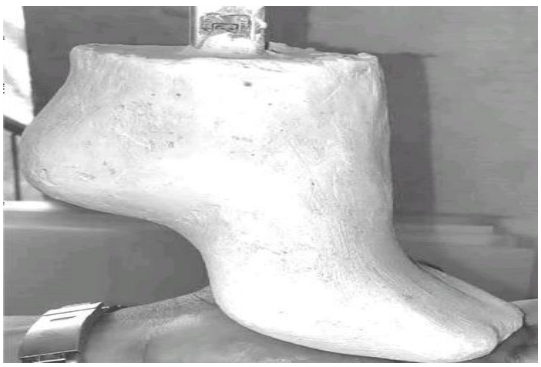


Fig 5 Talipes equinus mold

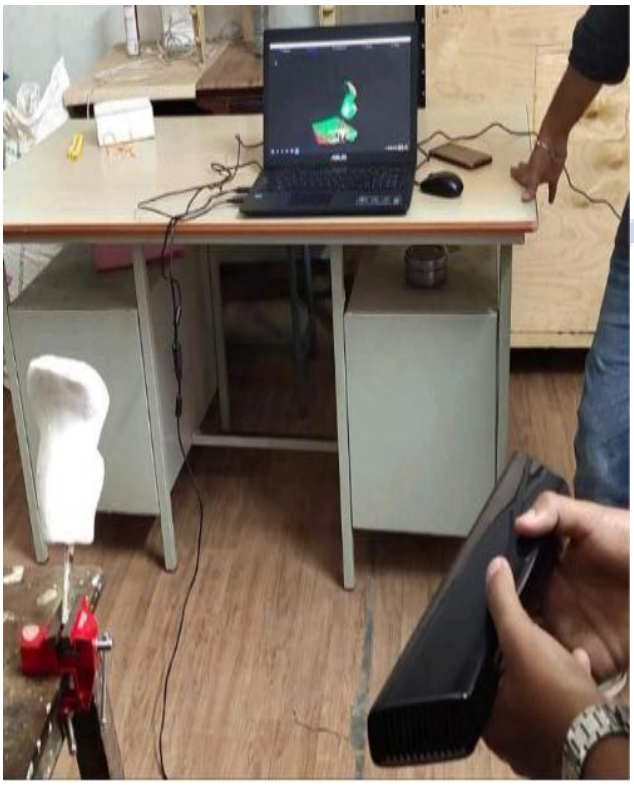


Fig 6 scanning the mold using x-Box 360

In figure7, the total foot model measurement using the 3D model is examined for the purpose of designing the insole .

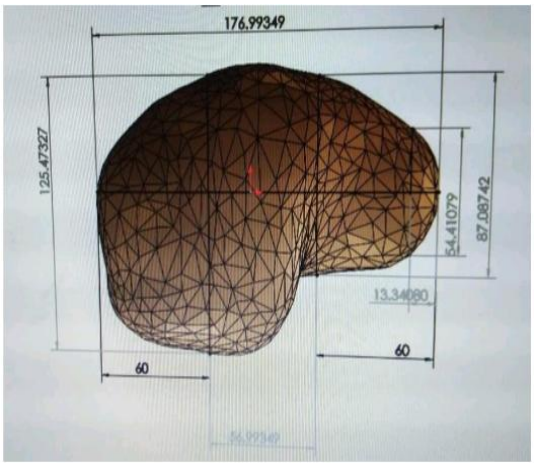


Fig 7 Measurement using CAD.

With negative impression of the scanned patient's foot a model is performed using the SolidWorks software. Further, with the help of the model a design procedure is carried out so as it to satisfy all the geometric and functional mechanisms and thereby providing ease to the patients comfort. The design of insole is made in CAD with respect to the negative impression of the foot in order to corroborate by distributing the pressure from the high pressure area to all regions of the foot equally.

4.3 *WORKING OF CUSTOMIZED ORTHOSIS*

The printed insole material is capable of providing comfort to the patient over the negative impression areas and thereby helps as an assistive tool in bringing back the normal gait pattern. It should weigh less and reducing the damage regarding the patients comfort [20]. Customized 3D printed insoles reduced the load of the metatarsals and distribute it to the mid foot area [21]. Using FDM with ABS plastic as raw material the insole is printed with respect to AM technology. The printed insole is then embedded in a shoe so that to produce a brace assisting the equines patient. The brace produced will combat the patient to overcome the deformity against the abnormal surfaces and acts as aid in bringing back the normal gait pattern. The CAD designed product of orthosis is converted to .stl format of the AM machine language for printing and it is carried out in print FDM machine. The mesh points used in the proper designing of the patient insole is shown in figure 8.

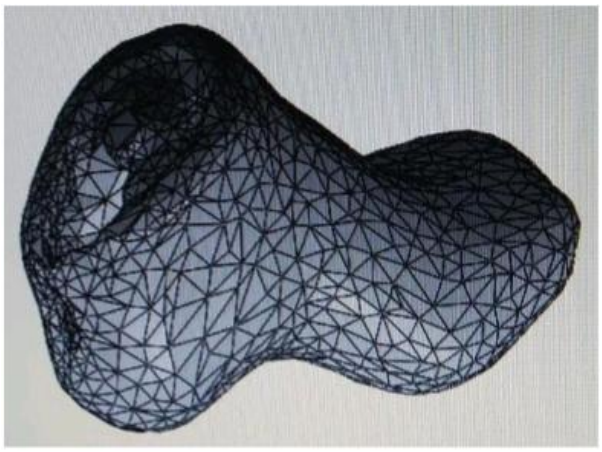


Fig 8 Mesh Points considered for design

4.4 *MATERIALS FOR CUSTOMISED ORTHOSIS*

The material selection serves as a major tool for manufacturing the customized orthosis product. The material used for 3D printing should be light weight, affordable cost and best in function. The ABS is a thermoplastic polymer. When the ABS of different layer of thickness is tested it shows the satisfaction towards intended properties of material [22]. It is found that the maximum strength of 3Dprinted ABS was approximately 92% of accepted [23]. Selected FDM machine has a layer thickness of 0.254mm and build volume of 8x6x6 inches. The properties of ABS plastic are shown below in figure 9.

Properties	Standard (ASTM)	Value
Ultimate Tensile Strength, MPa	D-638	33
Tensile Elongation at Break, %	D-638	6
Tensile Modulus of Elasticity, MPa	D-638	2200
Flexural Strength, MPa	D-790	53
Flexural Modulus, MPa	D-790	2100
Impact Strength (Notched Izod, Method A, 23°C), J/m	D-256	106
Heat Deflection (HDT) @ 66 psi, °C	D-648	96
Hardness (Rockwell)	D-785	109.5
Yield Strength		8,790 – 10,600 psi (60 – 73.1 Mpa)

Fig 9 Properties of ABS [24]

5.RESULTS AND FUTURE TRENDS

The printed insole is embedded in a shoe so that, it acts as a brace and it fulfills the sides of negative impression (blank areas) indeed it provides a cushion support over the areas of the foot and thereby it distributes the pressure all over the areas of the foot providing relief to the patient. It overcomes the time consumption required to design a brace through traditional ponseti method. The customized orthosis for the patient suffering from the state of talipesequinus will get a relief from their pains; this same technique is applied for the person with talipes calcaneus with similar foot measurements, in case of talipes calcaneus the support provided will be inverted towards the upright position of the foot [25]. The patient suffering from the talipes calcaneus deformity is a contradictory with the patient suffering from the talipesequinus; so the there is an idea to implement the same technique in an opposite manner to resolve the both deformities with the patient of similar foot size. In future ,the versatile devices play a major role in resolving foot deformity it will be based on the air based braces and emporium gel based braces as till now they are used for treating the injury in our reputation it can be designed to combat foot deformities.

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