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Alternative Approach for Treatment of Clubfoot Deformity

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Abstract: This work is to identify the method for treating deformities by the application of additive manufacturing methods to healthcare products. Medical researchers are seeking innovative manufacturing methods to produce health care products alike; artificial limbs, prosthetic, orthotics, implants, surgical-planning models of internal body structures faster and more accurately. In this paper, types of deformities are discussed and was identified that congenital talipes equinovarus (clubfoot) deformity is a complex 3Dimensional foot deformity which has to be corrected using non-surgical treatment which is ponseti method (serial casting procedure). It was identified that for correcting clubfoot deformity using ponseti methods results in few drawbacks alike recurrence of foot, pressure on skin due to cast, itching, cast loosening, frequent follow by the patients and parents, decreased mobility due to weight of the cast and it takes long duration to correct the deformity. The above mentioned limitations / drawbacks were studied by developing a questionnaire based on the knowledge of deformity and were surveyed amongst the orthopaedic surgeons and paediatric doctors. From the drawbacks identified from the data collections an alternative approach is found to be a necessity to correct the deformity. This paper highlights a suitable method for correcting clubfoot deformity by incorporating additive manufacturing technology.

Key words: Additive manufacturing · Congenital talipes equino varus · Ponseti

INTRODUCTION

Additive manufacturing (AM) formally called as Rapid prototyping (RP) refers to the fabrication of parts layer by layer [1]. It is a technique for direct conversion of three dimensional CAD data into a physical prototype [2]. AM technology has the ability to build products with geometrical complexity and material complexity which could not be produced by subtractive manufacturing processes [3]. AM allows for automatic construction of physical models and has been used to significantly reduce the time for the product development cycle and to improve the final quality of the designed product.

Additive manufacturing technology has contributed almost all engineering areas that include mechanical, materials, industrial, aerospace, healthcare and biomedical engineering [4]. Healthcare plays a vital role as well as growing population increases the potentiality for customized products. [5], stated that physical models of anatomical structures can be fabricated directly by RP technology, which can also be useful for preoperative planning, design and manufacturing of implants and surgical aid tools. [6], addressed with the development of RP/RM technology there are potential requirements for manufacturing of health care products alike; artificial limbs, prosthetic, orthosis, implants, surgical-planning models of internal body structures faster and more accurately. [7], designed a customized foot orthosis for clubfoot deformity and found out to have significant reduction in the pressure at heel region and at lateral foot. [8], pointed out that congenital talipes equinovarus (CTEV or Clubfoot) is a complex deformity that is difficult to correct and one of the most common congenital deformities. The ratio of male to female is 3:1 and 40% of cases are bilateral.

Clubfoot is a complex 3 Dimensional foot deformity which is a common congenital deformity, involving correction of the foot with surgical and non-surgical treatments. [9], emphasized for correcting clubfoot deformity involves surgical and non-surgical techniques. According to [10], the non-surgical treatment involves, French method, Ponseti method that are related to manipulation of the foot serial casting procedure and bracing of the foot. They also pointed out about the drawbacks of these non-surgical treatments namely the pronation or eversion of the foot, long plasters,

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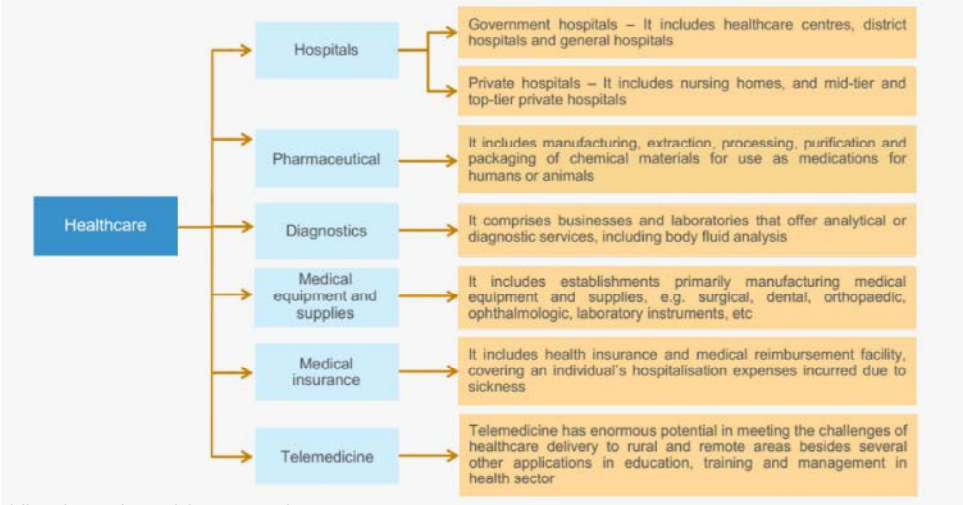


Fig. 1: Classification of Health care Industry
Source: Hospital Market-India by Research on India, TechSci Research (2015).

cast pressure, infection, bracing complications [11]. In order to overcome the above difficulty, this paper is dealt with identifying an alternative method for the treatment of Clubfoot deformity by applying AM technology.

Literature Review: Specified that additive manufacturing provides a wide range of application from building test prototypes with material properties close to those of particular parts to be fabricated to models. Nearly 41% of all RP models are being used for fit and function applications, adding together the "fit/assembly" and "functional models" segments. About 27% use RP as visual aids for engineering, toolmaking. More than 23% of RP models are being used as patterns for prototype tooling and metal casting, as well as for tooling inserts [12].

Health care plays a vital role in the growing population, increase in the population, increases the potential of customized products. AM technology is emerging as a cost effective, efficient and customised manufacturing option for the medical devices industry This technology promises to deliver on various counts such as personalization according to patients or users, flexibility in design and manufacturing, decreased material wastage, elimination of specialized tooling and low lifecycle costs [13]. The health care industries (Figure 1) are divided into five sectors such as hospitals, pharmaceuticals, medical equipment's, diagnostic and medical insurance. Here in this paper we are considering only the medical equipment's and the scope of this paper is limited to manufacturing method of medical equipment's and instruments.

AM processes is a dominant mode of production for medical devices that are used inside the body, such as implants, transplants and prostheses, for their ability to replicate organic shapes and enclosed volumes that are difficult to fabricate. The following section deals with the literature related to RP which involves in the area of foot related deformities. Orthopaedic problems in children are common, whether it can be congenital, developmental or acquired, including those of infectious, neuromuscular, nutritional, neoplastic and psychogenic origin [14].

Congenital Malformations: Congenital defects or malformation or deformity is that affects a body part or physiologic function and is present at birth. It is caused by the abnormal ontogenetic development of the fetus. According to [15], congenital malformation is affected by genetic, environmental or both factors. A significant proportion of congenital malformations likely to have an important genetic component and malformations with an increased recurrent risk, such as cleft lip and palate, anencephaly, spina bifida, certain congenital heart diseases, pyloric stenosis, hypospadias, inguinal hernia, talipes equinovarus and congenital dislocation of the hip, fit in the category both of multifactorial disease and polygenic inherited disease [16]. They can be classified to three degrees like; first degree, second degree and third degree. In the first degree the deformity is mild which can be corrected using passive stretching techniques. The second degree deformity is the shortening in the soft tissue, prevents full passive correction of the deformity whereas the third degree of deformity are rigid and cannot be corrected by passive techniques [17].

Further, the cause of congenital malformations can be divided into three categories as unknown, genetic and environmental [18]. According to [19], congenital defects are classified as Malformations, Deformations, Disruptions and Dysplasia, where deformations affects the muscular skeletal system, altering the alignment, distorting position of some structures which can be reversed with the help of orthopedic maneuvers. Congenital deformity occurs right from the birth and it requires medical attention for correction of the deformity which was found out that the correction technique for the deformities are surgical and non-surgical methods. According to [20], talipes equinovarus is one of the more common congenital abnormalities affecting the lower limb which can be challenging to correct the foot using surgical corrections. Ponseti method of clubfoot management requires a period of bracing in order to maintain correction. [21], indicated that cause for this deformity happens to be abnormal intra-uterine fetal position and as a result the foot appears to be club shaped and fabricated an Ankle Foot Orthosis (AFO) which was used during the final two weeks of the casting processes and AFO was fitted when final cast is removed. They modelled the AFO using 3D virtual modelling technique with CAD and Point cloud data's.

[22], compared AFO with foot abduction orthoses and identified that after correcting the foot by ponseti method it was found that recurrences is less when using foot abduction orthoses. [23], developed brace designs which were claimed to be more comfortable, easier to use and prevents dislodgement of the foot from the brace, making them more efficient and improve patient compliance. [24], studied about the various types of brace available and pointed out that there are some biomechanical effects on soft tissues also in terms of functionality of the braces.

[25], pointed out that clubfoot is a complex congenital deformity that includes components of equinus, varus, adductus and medial rotation of the foot to be corrected. They indicated that the classification is based on Etilogic and Dimeglio. Figure 2 gives Dimeglio classification which describes clubfoot and is classified based on stiffness and range of motion in equinus, adduction, varus and medial rotations.

[26], detailed that clubfoot deformity is the common deformity of lower deformity which requires treatment for correcting the foot it involves manipulation and serial casting of the foot. [27], developed an ankle foot orthosis for clubfoot deformities taking the point cloud data of the foot and developed a model. The orthotic devices are intended to support the ankle and to prevent a further occurrence which enhances the ankle-foot position and mobility. [28], fabricated a silicone rubber made clubfoot and studied the mechanical properties for Young's modulus and Poisson's ratio and found out that the silicone rubber of different hardness for soft tissues can be used. It was found that most work done in clubfoot is related to the fabrication of orthotic devices for the correction of clubfoot. Also the non-surgical treatment of clubfoot needs serious improvement as it causes discomfort to the children a lot. As a result it requires a manufacturing method for replacing casting procedure. The following section deals with classification of deformity and its types and current treatment procedures.

Deformity: Congenital deformity occurs right from the birth and it requires medical attention for correction of deformity which was found out that the correction technique for the deformities are surgical and non-surgical methods. Considering only the non-surgical treatment, the deformities Congenital Talipes Equinovarus (CTEV) deformities is considered. The non-surgical treatment for clubfoot deformity used are correcting the foot using ponsetti method by manipulating the foot by serial casting procedure and attaching to external fitting like braces. [29], identified that the braces will be more effective for reducing or preventing the foot from returning back to original position. [30], through their

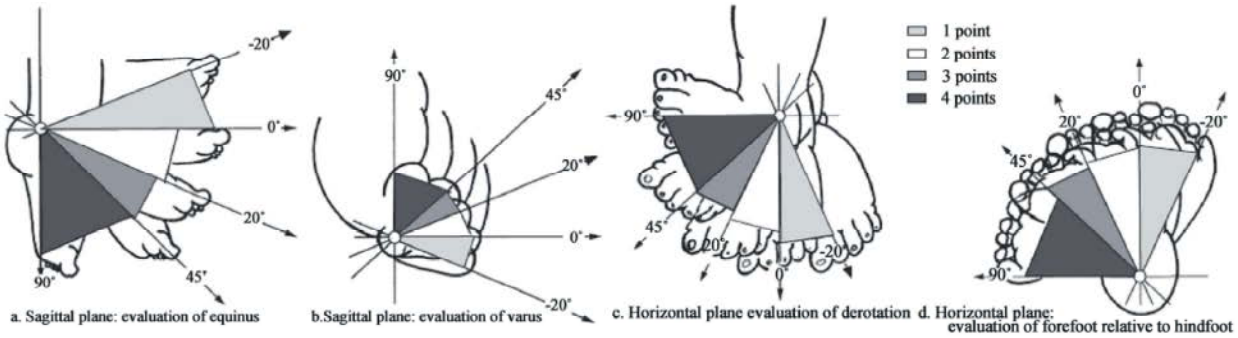


Fig. 2: Classification of clubfoot based on Dimeglio

work detailed, clubfoot is a congenital deformity involving one foot or both. It is a complex 3-Dimensional musculoskeletal abnormality where the affected foot appears to have been rotated internally at the ankle. According to [31], foot seems to be rotated along coronal, sagittal and transverse plane and the foot is turned in these terms (adduction-abduction, inversion – eversion, extension – flexion). The ankle can be twisted at a sharp angle making the foot resemble a gold club. The severity of club foot can range from mild to severe with half of affected babies having both feet affected and is a relatively common birth defect occurring about one in every 1000 live births [32].

Club Foot Treatment: The non surgical treatment for club foot involves french function and ponseti method. French function method or physiotherapy method (Figure 3) consists of gentle manipulation, stretching, taping and splinting to maintain the correction of the foot. A splint is then used untill the child is two or three years old to prevent relapse. This treatment aims to obtain full correction of the foot in five months [33]. [34] indicated that the disadvantage of this method is that it requires enormous time from the parents as the children has to undergo daily formal physical therapy for a period of 2 months.

Another treatment for clubfoot is the Ponseti method (Figure 4), [35] pointed out that a gentle sequential manipulation of the foot is performed to achieve a plantigrade, functional foot. Included in the method is the use of a foot abduction brace to prevent relapses as well as strategies to treat relapses which occur based on age of the child. The stages of clubfoot ponseti treatment are shown in (Figure 4).

[36], indicated that four order of the deformity are cavus, adductus, varus and equinus these should be treated where the process is repeated weekly for six weeks until the foot can be abducted from underneath the talus allowing the foot to be safely dorsiflexed without crushing the talus. Clubfoot affects three bones namely calcaneus, talus and navicular. The corrective process utilizing the Ponseti technique can be divided into two phases: The treatment phase, during which time the deformity is corrected and the maintenance phase, during which time a brace is utilized to prevent recurrence. Treatment phase indicates that aligning the fore-foot with mid-foot and hind-foot by rotating along three planes (coronal, sagittal and transverse plane) every week aligning the foot along adduction, abduction, inversion, eversion, extension and flexion.

Fig. 3: French function treatment

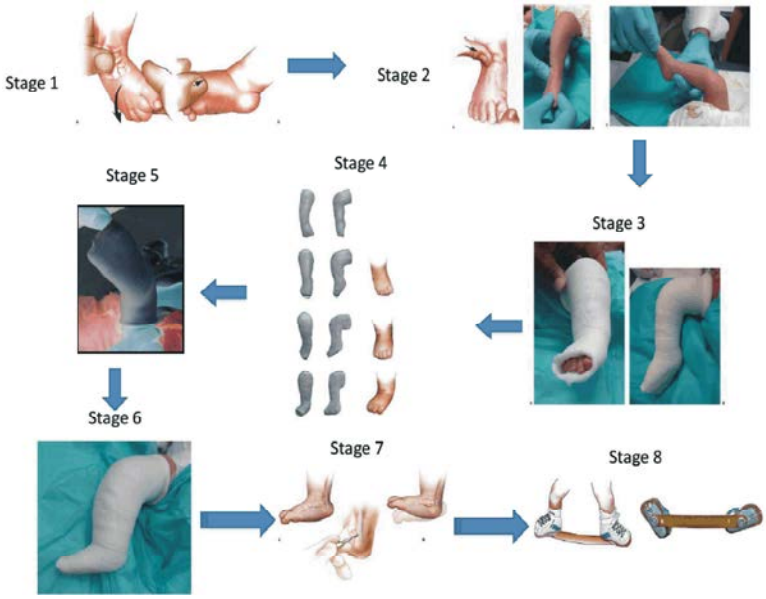


Fig. 4: Ponseti treatment

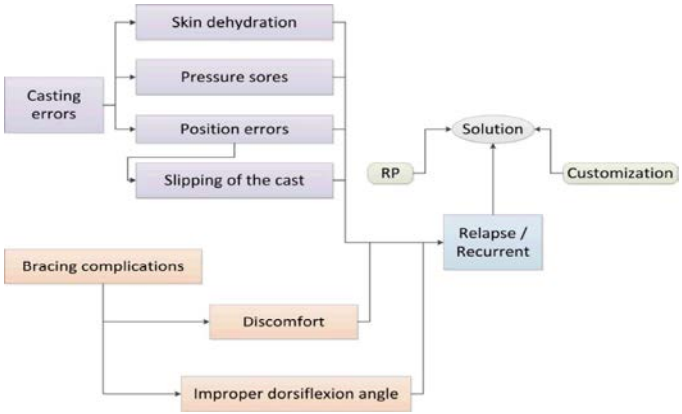


Fig. 5: Difficulties faces by casting method.

[37] summarized that for correcting the cavus deformity is by supinating the forefoot with direct pressure under the first metatarsal which can be done with a single cast. Before the final cast correction of residual deformity is done by small surgical release (tenotomy) of the tendon, allowing the ankle to be positioned at right angle with the leg. [38] and [39] stated that the final long leg cast is applied after the tenotomy and the foot is positioned in 70°of abduction and only 10° - 15° of dorsiflexion and the cast is to be retained for three weeks before removing. Upon removal of the final cast, maintenance phase starts by wearing a brace / orthosis with shoe attachment is mounted on a bar to maintain the foot in its corrected position. The difficulties found during this method are casting errors and bracing complications and due to this the foot gets to original position, described in figure 5. The casting problems includes like skin dehydration, pressure sores, slipping of cast and bracing difficulties are discomfort and not corrected angle of dorsiflexion [40].

Figure 5, consolidates issues related to casting and bracing compliances which leads to the relapse of the corrected clubfoot, thereby a solution is required to overcome the above difficulties. A customized orthosis can be provided by incorporating AM technology to overcome the difficulties and correct the foot.

Methodology: In order to develop customized orthotics, it is required to identify the methods of treating deformities. These are identified by developing questionnaires based on the percentage level of deformities, method of treatment, severity of the deformity, difficulties encountered while treatment, comfortness of usage of any external brace fittings. These questions were framed depending on the level of knowledge on deformities, their types and their treatment methods. These questions were targeted basically by orthopedic surgeons and paediatric doctors from coimbatore region for a sample size of 66 numbers. The questionaire was personally communicated with the orthopedic and paediatric surgeons and surveyed.

Data Collection and Analysis: From the questionnaire collected, it has been identified that more percentage of deformities are found in congenital rather than acquired deformities and among the congenital deformites identified were Talipes Equinovarus (Clubfoot), Metatarsalgia, Pescavus, Pesplanus and Calcaneovalgus and under acquired deformity identified are Hammer toe, Mallet toe, Claw toe and Hallux valgus. It's identified that Talipes Equinovarus (Clubfoot) is the most commonly affected deformity under congentital deformity and Hallux valgus under acquired deformity. Both these deformities requires non surgical treatment to be the most efffective way of treating.

The sample size of 66 respondents are grouped according to the years and nature of work in the field of orthopedics as Orthopaedic / Paediatric surgeons. Table 1 details the survey questions collected from the orthopedic and paediatric surgeons depending on their years of experiences and it gives the percentage of deformities that affects the childrens. From the data collected it is been identified that congenital deformity is the most commonly affected with clubfoot deformity acquired by many and it is treated by non surgical ponseti method. Chart 2 infers that Ponseti method (Serial casting or plastering technique) as the most suitable non surgical treatment of clubfoot and can be done at the very earliest stages of a child. The treatment of clubfoot below one year of age is identified as the best suitable age group for childrens affected from clubfoot as it is easy to correct the deformity when the bones are in their supple stage.

Table 1: Average Percentage of deformities – Congenital and Acquired

Years of Experience	Average % of Congenital	Average % of Acquired	Average % of Clubfoot deformity
2	81	19	82
5	79	21	79
10	83	17	81

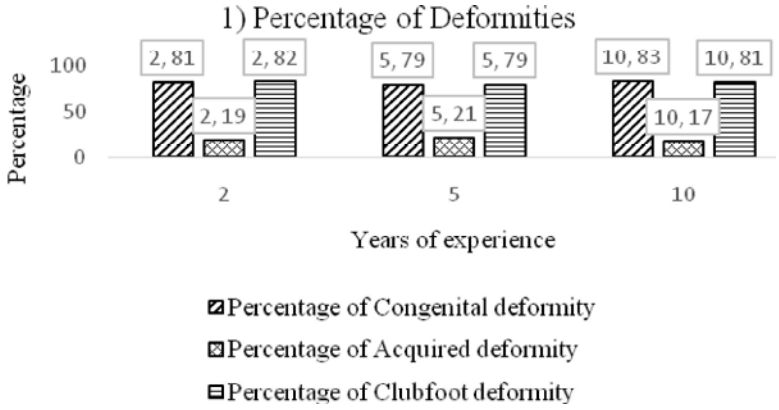
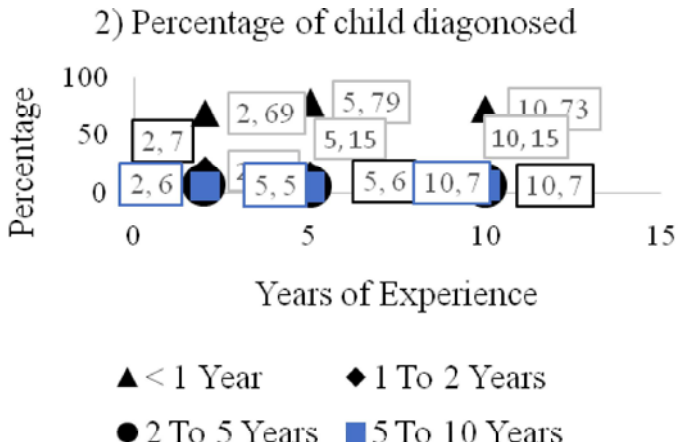


Chart 1: Average Percentage of deformities – Congenital and Acquired

Chart (1) describes the average percentage level of deformity from sample size of 66 numbers. All these samples were gathered from the male population, with maximum being 10 years of experience as Orthopaedic / Paediatric surgeons. From the observations, it has been identified as on an average congenital deformity were around 81%, acquired deformity around 19% and Clubfoot deformity as 82% for 2 years of experience. Similarly for 5 and 10 years of experience it was identified as (79%, 21%, 79%) & (83%, 17%, 81%).

Table 2 & Chart 2: Treatment for clubfoot deformity and percentage of age group classifications.

Orthopedician/Paediatrician Years of Experience	Average children's diagnosed (less than 1 year)	Average children's diagnosed (1 - 2 year)	Average children's diagnosed (2 - 5 year)	Average children's diagnosed (5 - 10 year)
0 - 2	69	19	7	6
2 - 5	79	15	6	5
5 - 10	73	15	7	7



From chart (2) summarizes the average percentage level of children's treated under the age groups of (less than 1 year), (1 – 2 year), (2 – 5 year) & (5 – 10 year). The age groups were grouped based on the orthopedicians / paediaticians years of experienciences for the treatment of clubfoot defomity. From the observations maximum percentage contributes to children's diagonosed at the age group of (less than 1 year) and least percentage for age group of (5 – 10) years.

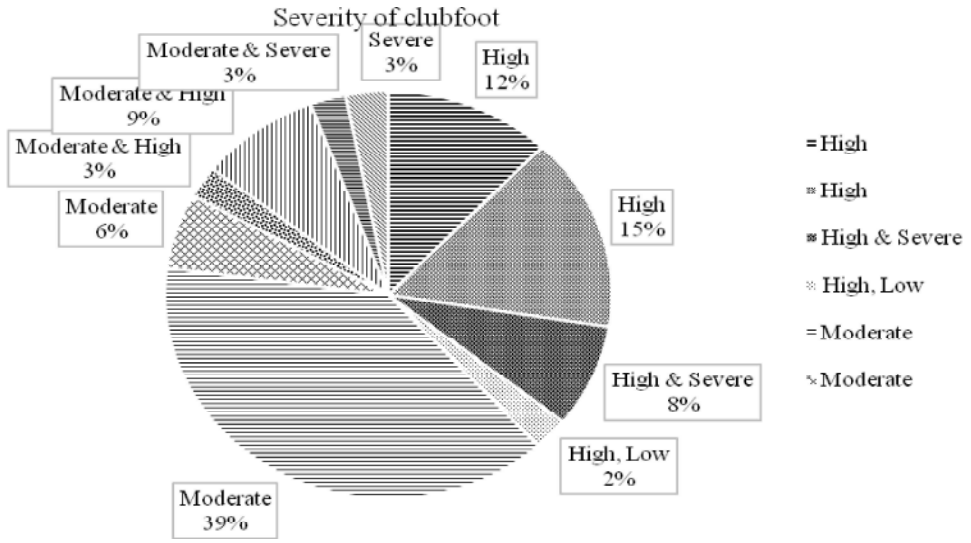


Chart 3: Severity of clubfoot and feet mostly affected.

Table 4: Difficulties faced while treating clubfoot

	Difficulties faced the physicians	Bracing complications
Comfortable	Inability to apply POP under anaesthesia	Decreased mobility and weight.
	Pressure on skin by casts or braces. Recurrent deformities	Compliance of parents and Occasional usage
	Cast loosening, Recurrence of the deformity	Improper fitting and not regular usage
	Arthogryposis	Poor patients compliance, Occasional usage
	Long duration of treatment, recurrence, follow up, skin ulceration	Frequent change of brace, difficulty in maintenance
	Time constraints for surgeons, compliance, follow up by patients,	Frequent change, non-availability of customized shoe based on
	skin ulceration,	the degree of foot, regular usage.
	Recurrence.	Occasional usage
	Pressure sores, loosening.	Improper fitting and not regular usage
	Itching, Time constraints for surgeons.	Occasional usage of brace
	Long duration of treatment.	Improper fittings
	Irregular follow up, Time constraints for surgeons.	Frequent change
	Cast loosening, Recurrence of the deformity	Decreased mobility
	Pressure sores, follow up compliance	Decreased mobility
	Time constraint, follow up by the patient.	Decreased mobility
	Recurrence.	Decreased mobility
	Recurrence of the deformity, Itching	Frequent change of brace, difficulty in maintenance
	Cast loosening, pressure sores.	Occasional usage of brace
	Frequent follow up.	Decreased mobility
	Cast loosening, Recurrence of the deformity	Need to improve the comfort level of the braces
	Prolonged treatment, frequent follow up.	Need to change brace
	Pressure on skin by casts, Cast loosening, maintenance is cumbersome.	Non-availability of customized shoe based on the degree of foot
	Frequent follow up	Comfort needed and poor fitting
	Long duration of treatment, recurrence.	Improper fitting and not regular usage
	Frequent follow up requirement	Decreased mobility and difficult to maintain
	Pressure on skin by casts.	Comfort needed and poor fitting
Uncomfortable	Compliance of patient towards plaster. Frequent follow up requirement	Need to improve the comfort level of the braces
	Cast loosening, Recurrence of the deformity	Poor fittings and Occasional usage
	Patient's compliance and irregular follow up, time constraints for surgeons.	Frequent change of size and fittings, regular usage.
	Recurrence of the deformity, Cast loosening,	Poor fittings and Occasional usage
	Recurrence of the deformity, Itching	Poor fittings and Occasional usage
	Recurrence of the deformity, Itching	Need to improve the comfort level of the braces
	Recurrence of the deformity, Itching	Need to improve the comfort level of the braces
	Recurrence of the deformity, Itching	Need to improve the comfort level of the braces
	Recurrence of the deformity, Itching	Occasional usage due to weight of the braces
	Recurrent deformity, weight	Occasional usage due to weight of the braces
	Pressure sores	Occasional usage due to weight of the braces
	Patient's compliance.	Difficult to wear due to weight
	Skin ulceration.	Occasional usage of brace

Table 4: Continued

	Difficulties faced the physicians	Bracing complications
Uncomfortable	Frequent follow up requirement	Frequent changes needed
	Recurrence of the deformity, Itching.	Non-availability of customized shoe based on the degree of foot
	Recurrence of the deformity, Itching.	Frequent change of brace, difficulty in maintenance
	Cast loosening, Recurrence of the deformity	Reduction of residual deformity
	Patient compliance towards casts.	Compliance of parents towards braces
	Recurrence, long follow up.	Comfort needed and poor fitting
	Irregular follow up.	Difficulty in maintenance
	Time constraints.	Frequent change
	Cast loosening, Recurrence of the deformity	Occasional usage due to weight of the braces
	Itching, cast weight	Not frequent usage
	Long duration of treatment.	Comfort needed and poor fitting
	Recurrent deformity.	Frequent change of brace,
	Cast loosening, time constraint.	Occasional usage due to weight of the braces
	Weight of the cast	Frequent change of brace, difficulty in maintenance
	Long duration of treatment, recurrence.	Difficulty in maintenance
	Itching, cast weight, pressure on skin.	Need to change brace
	Long duration of treatment.	Difficult to wear due to weight
	Recurrence.	Occasional usage due to weight of the braces
	Cast loosening, time constraint.	Need to change brace
Comfortable + Any other alternate methods needed	Cast loosening, Itching, Pressure sores	Occasional usage due to weight of the braces
	Pressure on skin by casts, Cast loosening, maintenance is cumbersome	Reduction of residual deformity
	Skin ulceration, maintenance is difficult	Occasional usage due to weight of the braces
	Pressure on skin by casts, Cast loosening, maintenance is cumbersome.	Comfort needed and poor fitting
	Pressure on skin by casts, Cast loosening, maintenance is cumbersome.	Decreased mobility and difficult to maintain
	Skin ulceration, parents compliance towards casts	Comfort needed and poor fitting

Chart 3 summarizes the severity level of clubfoot, the deformity is based on the complexity of the foot rotated and it is classified based on the Dimeglio classifications as moderate, high and severe. Most of the clubfoot deformity affects both the foot (Bilateral) and commonly treated with Ponseti. 39% of the population analysed was found be moderate while 3% had the deformity to a severe state.

Table 4, indentifies and summarizes the data collection about the possible difficulties while correcting clubfoot deformity using Ponseti method (serial casting and plastering technique). Commonly faced difficulties are a) recurrance of the foot back to original position by not using braces properly, b) pressure sore and itching problems regarding casting, c) cast gets loosened, d) decreased mobility due to the weight of the casting, e) poor fitting of the brace, f) parents find very difficulty towards casting / platering techniques.

Chart 1 and Chart 2 summarizes that most commonly affected deformities are congenital and clubfoot deformity, treatment of clubfoot and possible age group to be treated. Chart 3 gives the outline about the severity of clubfoot and commonly is the bilateral clubfoot. Table 4 states the difficulties faced while treating with Ponseti method which is widely accepted treatment for treating clubfoot deformity, but it may lead to the recurrence of the foot. Uncomfortability for the childrens as it results in the decreased mobility due to weight, causes pressure sores and itching sensations. From the table (data source) it could be seen that though Ponseti method is the widely accepted method, it provides discomfort both to the childrens and to that of parents. Thereby, considering the difficulties and drawbacks from the ponseti, an alternative approach can be provided for treating clubfoot by involving additive manufacturing technology.

CONCLUSION

The deformities related to foot were studied and found that the literature study revealed about congenital talipes equino varus (Clubfoot) deformity. The non-surgical treatment of clubfoot was identified as ponsetti method and the relapsing of the foot occurs when treated by serial casting method and not using braces properly, as a result the foot returns back to original condition. In order to avoid relapse of the foot back to original position, a customized orthosis solution are to be provided. In this paper, the need for a new method for correcting clubfoot by non-surgical method is highlighted. This is by replacing the conventional casting method by applying additive manufacturing technologies.

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Data collection on foot deformities

Name:
Specialization:
Gender: Male ☐ Female ☐

Years of experience as paediatric surgeon: Below 2 years ☐ 2 - 5 years ☐ 5 - 10 years ☐ Above 10 years ☐

1. Number or % of children diagnosed for deformity in leg
   a. Congenital Deformities ☐ b. Acquired Deformities ☐

2.If Congenital represent in percentage
   Talipes Equinovarus (Clubfoot) ☐ Metatarsalgia ☐ Pescavus ☐ Pesplanus ☐ Calcaneovalgus ☐

3. If Acquired represent in percentage

Hammer toe ☐ Mallet toe ☐ Claw toe ☐ Hallux valgus ☐

4. No of children's diagnosed in the age group of less than 10 Years (Numbers)

	Total	Percentage
a.Less than 1 year	_____	_____
b.1 – 2 Years	_____	_____
c.2 – 5 Years	_____	_____
d.5 – 10 Years	_____	_____

5.Common methods of Treatment of Congenital deformities (Please tick)

Surgical ☐ Non-Surgical ☐

6.What is common method for treating Congenital talipes Equinovarus (Clubfoot)

_____

7. Percentage of treatment of Non-surgical treatment for clubfoot

French function ☐ Ponseti method☐

8.Severity of clubfoot deformity:

Low ☐ Moderate ☐ High ☐ Severe ☐ Very Severe ☐

9. Feet most commonly affected:

Unilateral ☐ Bilateral ☐ Both ☐

10.Degrees of rotation of foot:

Unilateral ☐ Bilateral ☐

Degrees Dorsiflexion: ____ Degrees Dorsiflexion: ____

Degrees Abduction: ____ Degrees Abduction: ____

11.Experience of clubfoot treatment by the patient:

☐ Comfortable ☐ Uncomfortable ☐ Any other alternate methods needed.

12.What are the possible difficulties faced for treating non-surgical treatment of clubfoot

_____

_____

13.Among the External fittings which are more commonly used (Please tick and specify comfort levels):

		Low	Medium	High
a.AFO	☐	☐	☐	☐
b.FAB	☐	☐	☐	☐
c.Wheaton Brace	☐	☐	☐	☐

14.What are the possible difficulties faced while fitting the above identified external fittings

_____

_____

15.Frequency of usage of Braces.

☐ Regular ☐ Occasional ☐ Not frequent ☐ Others_____