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Development of Adjustable Foot Corrective Device for Clubfoot Treatment

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ABSTRACT

Congenital talipes equinovarus (CTEV) or clubfoot is a complex deformity of the foot that is characterised by four main deformities; forefoot cavus and adductus, hindfoot varus and ankle equinus. Currently, the Ponseti method is the most general and recognized treatment with a high success rate of over 90%. The treatment involves gentle manipulation and serial casting. However, the casting method could create complications for the patients such as soft-tissue damage and inconvenience in following the treatment schedule especially for those living far away from hospital. The aim of this research is to develop an adjustable corrective device for clubfoot treatment based on the techniques in the Ponseti method and at the same time attempt to eliminate the side-effects. The prototype consists of six adjustable movements from six different mechanisms to correct the four deformities. The prototype was developed using 3D printing method and the main material used is polylactic acid (PLA), rubber, aluminium and cotton fabric with sponge. The total weight of the prototype is around 300 g.

Keywords: 3D printing, clubfoot, CTEV, design and fabrication, Ponseti method

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INTRODUCTION

Congenital talipes equinovarus (CTEV), commonly known as clubfoot, is one of the most common deformities involving the musculoskeletal system of the lower limb (Zeno & Sorin, 2014). It is estimated that one or two in a thousand of newborns are affected with this deformity (Bass, 2011). The congenital deformity has four main components which are cavus, adductus, varus and equinus (CAVE) (Gray et al., 2014). Ultrasound screening is normally used in diagnosing the condition of the deformity at birth or prenatally (Novak, 2013). Some research has been done to study the etiologic of clubfoot such as genetic effects, environmental conditions, abnormal muscle insertion and vascular abnormalities. However, the cause of the deformity is still controversial (Hallaj-moghaddam et al., 2015). Clubfoot cannot be corrected spontaneously without treatment (Novak, 2013). The treatment of clubfoot can be separated into operative and conservative treatments (Maranho & Volpon, 2011). Among the treatments available, Ponseti management has been most widely accepted with a high success rate of over 90% for initial correction and low relapse rates of 10% to 30% (Bhaskar & Patni, 2013).

Ponseti Method

The Ponseti treatment consists of a series of gentle manipulations of the foot followed by above-knee casting using plaster of Paris (POP) (Maranho & Volpon, 2011) as shown in Figure 1. After the treatment phase, the patients are required to wear the bracing and orthosis full-time for ten weeks to maintain the corrected result (Docker et al., 2007). Adherence to the foot adduction orthosis (FAO) is important to prevent clubfoot relapse (Bhaskar & Patni, 2013).

Figure 1. Ponseti casting method

Hui et al. (2014) indicated that the use of POP could cause injury to the skin of the foot and create difficulty in removing the cast for the next correction. Accidents might occur when sawing the cast for removal purpose. Besides, the exothermic reaction that occurs when curing might also lead to injury to the skin. Skin infection would affect the treatment as it would be unsuitable for the child to continue the casting method. This problem could be solved by changing the cast material for example to semi-rigid fibre-glass which is lighter, durable, has a fast curing time, has a low risk of thermal burn and is ease to remove. The research found that the alternative casting materials give the same results in terms of the number of casts required for successful clubfoot treatment.

Another study by Baindurashvili et al. (2012) showed that improper casting techniques and definitive pressure during the casting could cause soft tissue lesions in the children. Ponseti management usually takes more than five treatment sessions and the treatment is performed weekly. Commitment is needed in complying with the follow-up schedule. This could burden many parents associated with distance and transportation as well as in time management. Parents also worry when seeing their child receiving the manipulation and casting.

The objective of this research is to develop a new approach to eliminate the problem related to the Ponseti casting method. In this paper, the design and development of an adjustable foot corrective device is presented. The device consists of six movements that replicate the Ponseti serial manipulation sequences. The new approach is aimed at creating safe, sustainable and economical solutions for clubfoot treatment.

MATERIALS AND METHODS

Problem Identification and Data Collection

This study started with identifying the process related to the Ponseti method. As shown in Table 1, the Ponseti corrective technique should follow the sequences of cavus, adductus, varus and equinos (CAVE). Each correction technique consists of different types of foot manipulation with different week involved. In general, the foot manipulation has different degrees of rotation that need to be focused for the new approach. Besides that, sample of children foot size was measured. In this study, one child with the age of two years with normal leg and foot was selected as a sample. Table 2 shows the detail measurements conducted. The measurements are used later in the design process.

Table 1
Ponseti corrective technique

Correction	Descriptions	Week Involved
Step 1: Cavus correction	• Forefoot is supinated in relation to the hindfoot • First metatarsal is elevated	1 – 2 weeks
Step 2: Adductus and Varus correction	• The head of talus is pressed as the fulcrum of rotation • The foot is in slight supinated condition and in equinus • The forefoot is adducted up to 70 degrees without pronation	3 – 4 weeks
Step 3: Equinos correction	• The sole of the foot is being exerted pressure entirely and stretched gradually • A percutaneous tenotomy is performed	3 weeks

Table 2
Foot measurements

Part	Value (mm)
1. Foot sole length	115
2. Forefoot width	58
3. Hindfoot width	38
4. Foot height	60
5. Calf diameter	33.4
6. Thigh diameter	82
7. Leg length	150
8. Knee to thigh length	60

Design Process

After the process of gathering all the related information about this project, the design of the Ponseti orthosis was conducted. The orthosis was designed by using CAD software. Design is an innovative and highly iterative process. When designing, words and pictures with written and oral forms are needed to assist the designers in explaining the designs to people of many disciplines (Budynas & Nisbett, 2015). The design process can be divided into several phases, namely conceptual design, embodiment design and followed by detail design (Dieter & Schmidt, 2013). The design process is shown in Figure 2.

The first phase in engineering design is the conceptual design. This phase consists of four steps which are defining the problem, gather information, concept generation and evaluation of concepts. Problem identification and information collection has already been described. After a concept was generated, a few basic ideas for designs were sketched by hand as shown in Figure 3. Sketching is an important element in design because it allows the designer to explore and convey abstract ideas to others quickly. A number of designs with different degrees of freedom (DOF), shape, mechanism of hinge or joint and appearance were generated during the stage of conceptual design. Orthographic, axonometric, oblique and perspective sketches were the example which designers routinely use to convey design ideas.

The second phase in engineering design is the embodiment design which consists of product architecture, configuration design, and parametric design. After the conceptual design, one of the designs was chosen and configurations were made. Arrangement of physical elements such as hinge and foot braces was decided. Preliminary selection of materials and manufacturing processes were made during this step.

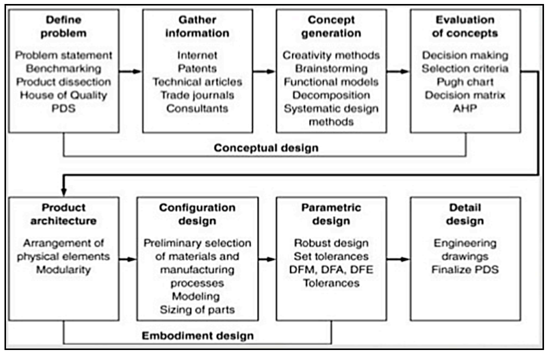


Figure 2. Engineering design process (Dieter &Schmidt, 2013)

In this phase, the design became more detailed and clearer in terms of structure, dimensions and tolerances. The drawings with specific dimensions were accomplished by using Computer-aided Design (CAD) software. The design of the prototype was drawn in 3D so that each view from different angle of the design can be shown clearly and in detail. Besides, the number of parts used in the design could be identified clearly from the drawing. In addition, CAD software features simulation functions that can be used for further presentation of the design.

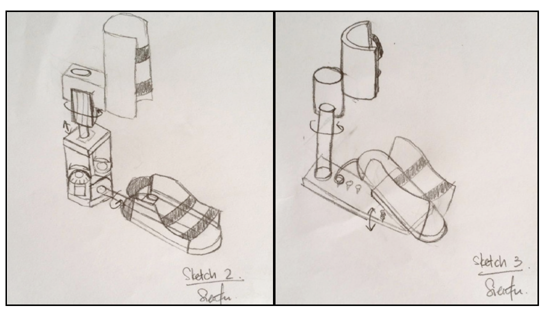


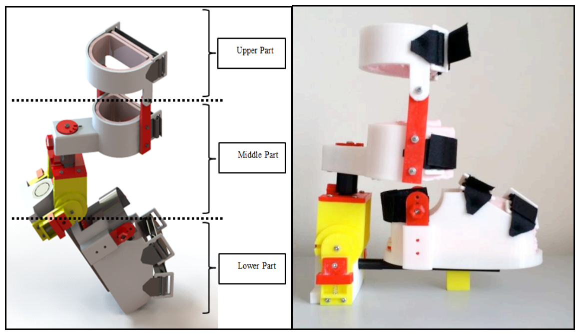
Figure 3. Example of ideas generation using sketching technique

Prototype Fabrication

After the design was finalized, a prototype was fabricated using a 3D printer. The prototype used polylactic acid (PLA) and rubber filament as the 3D printing material. The prototype also made of aluminium, and cotton fabric with sponge for the selected parts. The idea is to have light, non-corrosive and good surface finished materials.

RESULTS AND DISCUSSION

The final design and fabricated prototype of the adjustable foot corrective device is shown in Figure 4. The device can be divided into three areas which are the upper, middle and lower part. The upper part of the design is used to tighten up the thigh, providing more support to the leg when the foot is corrected. The upper part functions as the above knee casting that is used in the Ponseti method. The middle part of the device constitutes the main working mechanism. The adductus, varus, and equinus corrections are performed in the middle part of the device. Lastly, the lower part consists of the shoes to cover and exert forces on the foot. Cavus correction is performed at the lower part.



(a) (b)

Figure 4. (a) The final design; and (b) the fabricated prototype

In general, the prototype consists of six mechanisms to replicate the Ponseti method movement as shown in Figure 5. The first mechanism is made up of a screw and nut with a connector between the thigh and shank brace. The second mechanism is focusing on the adductus correction. The mechanism consists of a bearing and shaft that can be adjusted and locked based on the desired measurement. The mechanism enables the foot to be adducted by up to 70 degrees similar to the requirement in the Ponseti method. The third mechanism focuses on the equinus correction. The mechanism consists of an extendable shaft that is locked by a screw. The extendable shaft is required to prevent the foot brace from colliding with the shank brace.

The fourth mechanism focuses on the varus correction. The working mechanism is similar to the adductus correction feature. A bearing is pressed fitted into the shaft and a lock which is taper drilled at one end is added to the mechanism to prevent the shaft from rotating after correction is performed. Similar to the shaft in the adductus corrector, the shaft in this feature also has a decagonal shape. This is to ensure that the angles of correction between adductus and varus correction are the same as both corrections are performed at the same time.

The fifth mechanism is developed for equinos correction. The mechanism consists of several holes that represent different angles of 90, 60, 30, 0 and -20 degrees that are needed for equinos correction. The correction is maintained by a lock which is made up of a knob, screw and spring. The screw will prevent the rotation when it is fitted to the 'holes' of the adjustor. The suspension of the spring will ensure this feature is always locked. When equinus correction is to be made, the spring will be pushed down to unlock the system. The sixth mechanism is for cavus correction. A plate with the size of the foot is put inside the shoes. The plate has three segments which represent the forefoot, middle foot and hindfoot. These three segments are connected by masking tape. The forefoot plate is designed with the first metatarsal is extruded. It functions to elevate the first metatarsal of the foot during the cavus correction. The forefoot is supinated by using the wedge with several angles, which are 5, 10 and 15 degrees. This feature should be custom made based on the foot size of the patient. Based on the cost analysis conducted, the total cost for the prototype is around RM400. The total weight of the prototype is around 300 g.

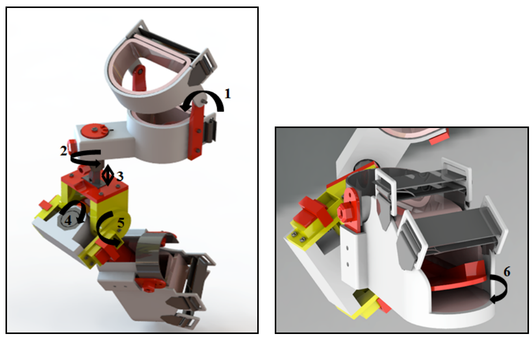


Figure 5. Six movement mechanism of the prototype

CONCLUSION

This paper discussed the design and fabrication of an adjustable foot corrective device for clubfoot treatment. The prototype consists of six adjustable mechanisms that replicate the movement during clubfoot treatment using the Ponseti method. Each mechanism consists of a unique movement and is expected to reduce problems related to the Ponseti method. The prototype was developed using 3D printing and the main material used is PLA, rubber, aluminium and cotton fabric with sponge. The treatment using the prototype is considered cheaper compared to the existing method. However, further investigation needs to be conducted since the device has not been tested with real patients.

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