# Design of Mechanical Bracing Device for Clubfoot Treatment

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***Abstract*—Clubfoot is one of the complex three-dimensional deformities of the foot. In Malaysia, clubfoot remains a significant problem and yields an unpredictable outcome due to the late presentation for treatment and ignorance of parents. Invasive and non-invasive treatment is applied for clubfoot. However, relapse can occur after the treatment, and the patient needs to use a bracing device for post-treatment maintenance. In this paper, the design of a new mechanical bracing device for clubfoot treatment is presented. Engineering design approach was applied to the device development. Problem identification and customer requirement, conceptual design, preliminary design, detail design and final design were conducted before the fabrication process. The device consists of adjustable foot width, dorsiflexion, shoe, a horizontal plate, foot pad and foot height. The prototype was fabricated, and SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis was conducted for evaluation purpose. The device consists of multi-adjustable joint that can be considered as a new concept for the bracing device.**

***Index Terms*—Bracing Device; Clubfoot; Foot Deformity; Non-Invasive.**

## I. INTRODUCTION

Congenital talipesequinovarus (CTEV), commonly known as clubfoot (as shown in Figure 1) is one of the most common deformities involving the musculoskeletal system of lower limb [1]. The congenital deformity has four main components which are cavus, adductus, varus and equinus (CAVE) [2]. The term "talipesequinovarus" is derived from the Latin words - Talus (ankle) and Pes (foot); Equines ('horse like' - the heel in plantar flexion) and Varus (inverted and adducted). According to [3], "despite common occurrence, CTEV is still a subject of controversy. It possesses a significant problem with unpredictable outcomes especially when the presentation for treatment is late". CTEV has an estimated birth prevalence of 1 per 1,000 live births with approximately 50% is bilateral [4]. Clubfoot is difficult to be corrected as it involved a musculoskeletal system that consists of malalignment of the bones and joints of the ankle and foot [5].

Some researchers had done a study on 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 [6]. Clubfoot could not be corrected spontaneously without proper treatment [7]. Clubfoot treatment can be divided into the invasive and non-invasive medical approach. The invasive approach is concerned with a typical foot surgery to correct the pathology of the foot which involve percutaneous tenotomy, posterior release, medical release, sub tarsal release and complete tendon transfer [8]. The non-invasive approach does not require surgery and widely preferred by patients.

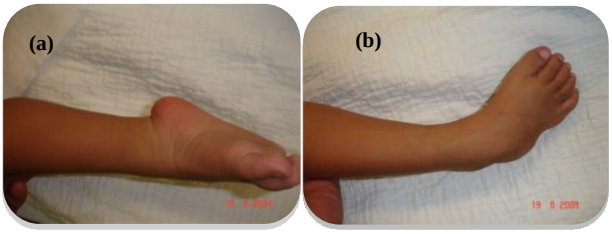


Figure 1: Example of clubfoot – the feet are (a) twisted and (b) inward

Ponseti is the well-known methods for the non-invasive approach. The method only requires a series of plaster casting and manipulation following brace management [9] to avoid relapse. Most of the time relapse deformity is difficult to be recognised at the early stage. The parents are only able to aware through child's walking posture [10]. Therefore, the maintenance treatment by wearing a brace is needed to avoid relapse after a certain period of initial treatment [11]. Brace wearing is one of the most important factors for the long-term success of the treatment [12].

Orthotics is an external device which using application of biomechanical forces to maintain the desired structures of the foot to control the deformity of musculoskeletal system [13]. The brace structure was designed based on the patients' foot size [14]. There are three different categories of brace design available including Ankle Foot Orthosis (AFO), Wheaton Brace and Foot Abduction Brace (FAB) [11]. To design an ergonomic bracing product, the protocol should be based on patient age, relapse rate associated with age and bracing hours [11]. The researchers had underlined that the new type of brace should able to avoid any effect on the foot growth and problems such as blistering, sleeping and dislodgement of the foot from the brace wearing [12].

The purpose of this research is to analyse the clubfoot treatment and develop a new bracing device to support the treatment. This paper will discuss the development process of the device based on mechanical design approach.

## II. METHODOLOGY

In this research, mechanical design process as proposed by [15] was applied as the research methodology. There are five stages involved in the mechanical design process including problem identification and customer requirement,

conceptual, preliminary, detail and final design. After the final design had been documented, in-house fabrication and SWOT (strengths, weaknesses, opportunities and threats) analysis were conducted to evaluate the new bracing device. In this section, each stage of the mechanical design process will be discussed.

### A. Problem Identification and Customer Requirement

The objective of the first stage was to identify the problem and requirement of the mechanical bracing device for clubfoot treatment. The process starts with analysing the literature review including the advantages and disadvantages of the existing device. From there, interview questions were developed, and interview sessions with orthopaedics were conducted to understand the requirement of the mechanical bracing device further. The interviews with orthopaedics were recorded, analysed and divided into small attribute including objective, function, constraint and mean. The information was converted into a list of table form and objective tree to show the relationship of the requirements for a new mechanical bracing device.

At the same time, sample foot measurement was also conducted during the first stage to obtain an example of foot size for the brace. The measurement only focuses on the foot size and not on the functionality of the brace. Three years old female infant was selected as a sample. The foot size was taken on both legs of infant including the height and width of the leg from knee to heel in the frontal plane, the length of leg and foot from knee to heel in the sagittal plane and the area of bottom foot first toe to heel in the horizontal plane. As shown in Figure 2, the infant's leg was placed on the white drawing paper, and the boundary of the leg was taken using Vanier Caliper and ruler. The data was recorded for the design purpose.

Figure 2: The foot sample measurement

### B. Conceptual Design

Conceptual design is part of the design process that plays a role to identify essential problem through abstraction and by establishing the function structure and working principle [16]. The objective of the conceptual design stage is to translate the customer requirement into engineering specification [17]. An analytical on the importance of the characteristics and function of the new brace was carried out after both data collection, and interview section was completed. House of Quality (HOQ) and Morphological chart method [17] was applied to the conceptual design.

HOQ is also known as Quality Function Deployment (QFD). HOQ is an analytical tool that uses to introduce the requirement of quality at the beginning of the design cycle. HOQ is also using to remind the designer of quality consideration throughout the design life cycle [18]. HOQ was widely applied in various research areas especially the product development [19].

The morphological chart is defined as a table that consists of several sub-functions that decomposed from the design problems. Each of the sub-functions possesses potential solution fragments and options. In this research, HOQ and the Morphological chart were used to analyse the functions of the new device, to generate design alternatives and to choose appropriate design concept from the available options.

### C. Preliminary Design

In the preliminary design stage, the engineering specification in conceptual design was converted into engineering drawing. Sketches, freehand drawing and computer design models are an example of the method available [17]. In this research, sketches method was applied to draw the new bracing device. Sketching is an important element in design because it allows the designer to explode and conveys the abstract ideas immediately. Orthographic, axonometric, oblique and perspective sketches are the example which designers routinely applied to convey the design ideas [17].

At the end of this stage, different sketches were developed based on the input from conceptual design. The weighted rating evaluation method was used to evaluate the sketches based on the criteria satisfaction. The rating will ensure that the selected sketch is reflected on the design objective stated in the conceptual design stage.

### D. Detail Design

In detail design stage, the design was become more detail and clearer in term of structure, dimension and function or working principle. The main task of the detail design is to transform the rough design from sketch drawing into smooth and accurate engineering drawing that can be used for fabrication purpose. Besides, detail design stage also involves refining, optimising and specify the design. There are three types of drawing used in this study including layout, detail and assembly drawing.

Layout drawing only involves the scale of the drawing and is changeable when the design process evolves. The detail drawing shows the tolerances of the drawing with details on the materials used for fabrication. The detail drawing also uses existing drawing standard and changing on the drawing is limited. Lastly, the exploded view of the product was shown in an assembly drawing. From the drawing, some components used can be identified using the bill of materials. The drawing with detail design is drawn using computer-aided design (CAD) software.

### E. Final Design

Final design stage shows the new mechanical bracing device for this research. Most of the work only involves documentation before the fabrication is conducted. All kind of fabrication specification is listed, including materials used, physical dimension, unusual assembly, external marking and so on. There is also some refinement needed with additional searching on the material and market survey

## III. Results and Discussion

This section discusses the results from the mechanical design process applied for this research. The focus of

discussion is on the objective tree, HOQ, final design and device evaluation.

### *A. Objective Tree*

The objective tree was developed based on the list of the attribute that obtained from the interviews feedback with the orthopaedics. The objective tree shows the overall relationship and interconnection of each component. As shown in Figure 3, the new brace design should maintain the foot correction, user-friendly and safe to use as the objectives. The constraint on the new brace design is to come up with the lightweight and low-cost device.

To maintain the foot correction, the new device should withstand the posture of medial and prevent relapse. The relapsed prevention can be achieved by applying the adjustable bar, rotation of the foot, internal of foot and dorsiflexion of the foot to support the foot. The constraint in foot maintenance is the skin irritation problem.

To achieve the user-friendly objective, the new device should be able to attach with the external shoe, and the children can walk after wearing it. The main constraint is to have a device that can be used by different foot size. For the safety use objective, the constraint is to avoid heat radiation when using the brace since the patient need to use the brace around 23 hours per day for few years.

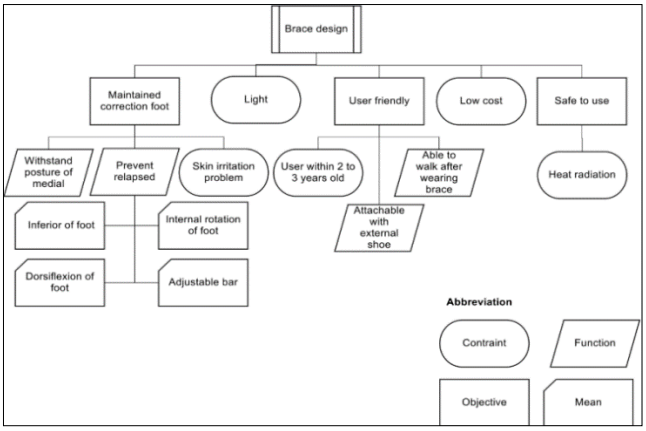


Figure 3: The objective tree

### *B. House of Quality (HOQ)*

The HOQ as shown in Figure 4 was applied during the conceptual design stage. The structure shows several important items to be considered such as customer need, engineering characteristic, customer satisfaction and the specific target value. The customer need consist of applications for different size of the foot, portable brace, fixed the foot, low cost, safety to use to the infant, user-friendly, good appearance, avoid skin irritation, able to attach with external shoe and adjustable length bar. The customer need was given the importance weightage based on the information from literature survey and discussion with orthopaedics.

There are eight engineering characteristics considered for the HOQ including rotation of sagittal and horizontal plane, the weight of the boot, length, rotation and weight of the bar, number of sharp and number of operation. Each engineering characteristics were listed with the specific indicator. At the same time, there are four different braces that available in the market selected as the reference including Steenbeek, Mitchell, Dennis Brown and Markell [20]. The available marketed products were rated based on the specific target value. For instance, the weight of the boot was targeted to be less than 1kg so that it is easier for the patient to use and move around with the device.

The objective of using HOQ method is to view the overall relationship between the items. For example, the roof of the structure shows whether the engineering characteristic is having a relationship between other items. For instance, the length of bar tends to increase the weight of bar when the bar has a longer dimension. On the other hands, the application of HOQ has also involved the performance comparison between current products by rating the performance based on customer needs as well as the engineering characteristics. The rating was based on the specific target value provided. The analysis was able to find out the weakness of each product. The challenge of this project is to come up with the low-cost product since three of the selected products were rated with low rating due to the higher cost as shown in the HOQ.

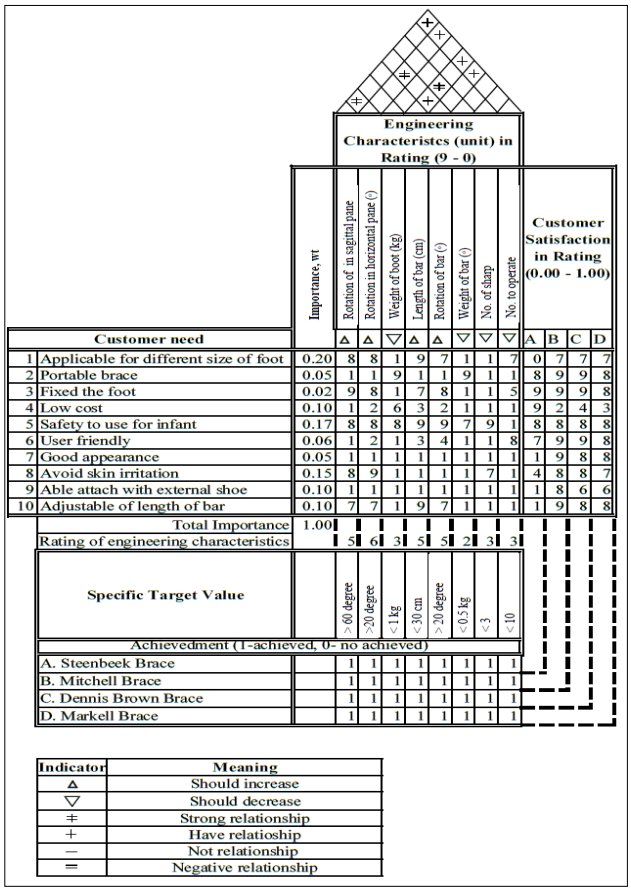


Figure 4: The house of quality (HOQ)

### *C. Final Design*

The final design of the new bracing device is shown in Figure 5. The main part of the device consists of adjustable foot width, dorsiflexion, shoe, a horizontal plate, foot height and foot pad. The end user can adjust the length of the device at the adjustable foot width area. The size of the adjustable foot width is measured from the width of the children's shoulder that is in between 25 to 40cm.

At the same time, adjustable dorsiflexion and the horizontal plate are used to adjust the degree of rotation of the foot. The dorsiflexion area is designed for the rotation between 0 to 15 degrees while the horizontal plate is designed for the rotation between 30 to 60 degrees. The foot will be tightened using adjustable shoe at the foot pad area. Lastly, the foot height can be adjusted based on the walking/movement stability.

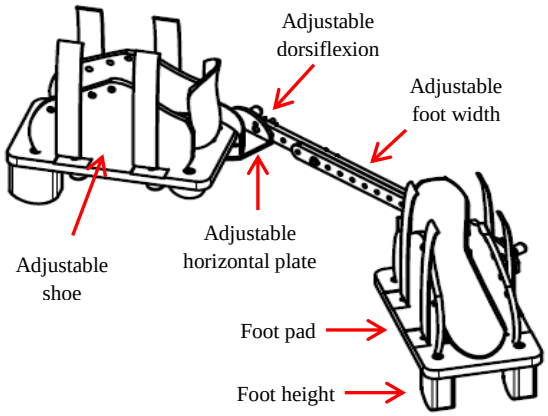


Figure 5: The final design

### D. The Fabricated Prototype Evaluation

The prototype of the new mechanical bracing device for clubfoot treatment is shown in Figure 6. The prototype is mainly constructed from mild steel (adjustable foot width area), aluminium (adjustable dorsiflexion and horizontal plate area), leather with cushion (shoe area) and wood (foot pad area). Based on cost analysis conducted, the device will cost around RM85 (around USD20) for one set.


Figure 6: The fabricated prototype with adjustable features

The SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis was conducted through discussion with orthopaedics to evaluate the design as shown in Table 1. The strength of the prototype is on the sole, adjustable component that able to fit children with age in between 2 to 3 years old. Besides, the device consists of the multi-adjustable joint in term of dorsiflexion, external rotation and brace bar with an acceptable price. The weakness of the prototype is on the difficulty to wear it compared to the available marketed product. Besides, the material selection needs to be improved to reduce the weight. At the same time, more input is needed from the stakeholders such as parent and patient before the design process is conducted.

The opportunity of the prototype is that the multi-adjustable joint for clubfoot maintenance device is considered as a new concept. Therefore, there is a potential for the prototype to advertise in the market. Lastly, the threat for the prototype is that the reliability and durability of the device are considered low. This is due to the non-human testing conducted for the prototype.

Table 1
The SWOT analysis

| Item | Analysis |
|---|---|
| Strength | • Adjustable sole component that able to fit children age between 2-3 years old<br>• Consist of multi-adjustable joints |
| Weakness | • Difficult to wear<br>• Considered heavyweight |
| Opportunity | • Considered as a new concept<br>• Potential for new market |
| Threat | • Considered low reliability and durability |

## IV. Conclusion

This paper discussed the design of a mechanical bracing device for clubfoot treatment. The usage of the device is important as post-treatment maintenance after gone through a Ponseti method in non-invasive medical approach. The end user or patient is needed to use the device about 23 hours per day for a few years. Therefore, there is a need to design a low cost, lightweight and durable device. The development was conducted based on the mechanical design process. A different method was applied to support the design process to achieve the research objective. In-house fabrication was conducted based on the detail design, and final prototype of the device was developed. SWOT analysis for the prototype was conducted through the discussion with orthopaedic. Some advantages can be found on the new device, and at the same time, some improvement needs to be conducted. Lastly, human testing can be considered to be implemented after the product is approved by the medical committee.

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