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.

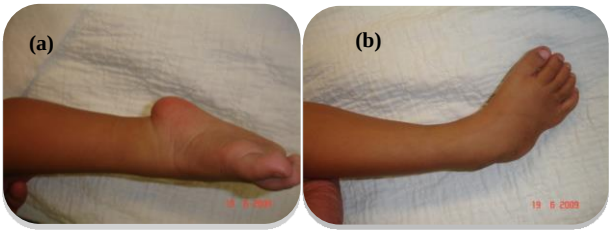

Figure 1: Example of clubfoot – the feet are (a) twisted and (b) inward

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,