THE ASSESSMENT OF THE CLUBFOOT CHILDREN'S ORTHOTIC NEED FOR THE DEVELOPMENT OF THE FOOT ABDUCTION ORTHOSIS (FAO) PROTOTYPE DESIGN

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Abstract - Foot abduction is an imminent component of treatment within the Ponseti method. It is a treatment procedure where the clubfoot patient adheres to the post-corrective bracing protocol to prevent relapse of the deformity that has turned the foot downward and elevated inwards. In order to encourage the patients' compliance to the foot abduction orthosis (FAO), various designs have been introduced in the market in the hope of improving the rate of compliance. The purpose of this paper is to elucidate the assessment of the clubfoot patients' FAO need at the orthopaedic clinic of Hospital Universiti Sains Malaysia in Kelantan, Malaysia. The assessment aims to understand the clubfoot patients' lower limb movements, in order to generate ideas for the prototype design development to improve the FAO design based on the existing product in the market. The FAO that was referred for further design improvements are the Denis Browne splint and the Markel shoes. In addition, a total of 10 clubfoot patients' parents were interviewed to obtain user experience data. This study suggests the need to eliminate the foot plates and the bulky protruding shoe and brace locks that are heavy due to the material use. Consequently, a conceptual design of the FAO was successfully developed as a proposal for potential future development of the working prototype to optimise the patients' dynamic movement.

Keywords - Clubfoot,Conceptual design, FAO design, Prototype development.

I. INTRODUCTION

Clubfoot, also known as Congenital TalipesEquino Varus (CTEV) is a congenital deformity of the foot among children. It is a condition where the deformity has turned the foot downward and elevated inwards. Initial treatment for this deformity incorporating the Ponseti method; a non-operative with serial manipulation and casting. This is the standard treatment for the correction of clubfoot deformity[1]. The method as [2]underlines in the book titled Clubfoot: Ponseti Management; a standard treatment throughout the world. The technique involves foot manipulation through a series of foot casting and foot bracing (see Fig.1, Fig.2). The objective of foot bracing in Ponseti protocol is to maintain the earlier manipulated foot for a certain period in abduction and dorsiflexion to prevent relapse. The brace is a metal bar, attached to straight-last open-toe shoes and referred as a foot abduction orthosis (FAO) in the medical field. During the intensive phase, the orthosis needs to be worn 23 hours a day for 4 months. It will be followed by the maintenance phase which is the wearing of the FAO at night time until the child is around 4 years old. To keep bracing the foot in the orthosis is extremely important in order to prevent relapse of the clubfoot. Newly developed brace designs have been introduced and this aims to improve the rate of compliance with post-corrective bracing [3]. Brace designs such as the Mitchell-Ponseti splint, the Dobbs dynamic splint, Steenbeek splint, and Denis Browne splint are the standard FAO products available in the market. However, as emphasised by [4] these newly designed braces are expensive and economically unpurchaseable to low-income population. The purpose of the current design research is to improve the design of the FAO by studying the clubfoot patients' lower limb movements and the physiologic connection to the technical design features of the Denis Browne splint and Markel shoes. On contrary, this study is not denigrating the two established FAO products, rather it proposes the potential of further design expansion, departing from the product that manifest well-built FAO design foundation. The study took place at the orthopaedic clinic of Hospital Universiti Sains Malaysia, in Kelantan, Malaysia.

Fig. 1:Serial Clubfoot casting.
Source:http://www.delhifootankleclinic.com

FIG. 2:CLUBFOOT BRACING USING THE FOOT ABDUCTED ORTHOSIS (FAO).
Source: http://www.nhs.uk

II. LITERATURE REVIEW

Clinicians are continually seeking for the ideal option on the management of clubfoot especially among infants involving the physiotherapy management and care [5]. In conjunction with this significance, the contribution of design in the development of medical devices is seen immanent for the past decades. According to [6] by highlighting [7] medical device design analysis in Medical Device Development: The Challenge for Ergonomics; in order to improve medical product design relating to patient safety and comfort, the input concerning current user needs is pivotal. The analysis further elucidated that the scintillating of good design context in improved patient safety has steered the studies and development of medical devices [7, 8, 9, 10, 11]. Following this, is the improvement of medical product design based on the original Ponseti brace design into Dobbs articulated brace which provides the foot to move while maintaining the required rotation of the foot. [12] propagated in 'Improved Bracing Compliance in Children with Clubfeet Using a Dynamic Orthosis', that new dynamic FAO designs resulted in improved compliance compared to the conventional straight abduction brace. The result of this clinical research shows that 81% of the clubfoot children were compliant with the dynamic abduction brace. In contrast, only 47% were compliant with the traditional foot bracing. Furthermore, the design of the dynamic FAO was developed in response to parents' criticism and frustrations with the standard brace. It is consequently becoming an alternative medical device to the static FAO.

In relevance to the technical perspectives, [13] in 'The Influence of the Brace Type on the Success Rate of the Ponseti Treatment Protocol for idiopathic Clubfoot' however, conclude as highlighted by [14] in their assessment and discussion on the factors predicting brace noncompliance among the clubfoot patients, that the straight abduction brace natheless remains ubiquitously significant as the new ones do not provide better compliance results. One example of the static FAO designs with a 'pinch' of design reverberation is the Mitchell-Ponseti brace design that consists of shoes made of very soft leather and a plastic sole that is moulded to the shape of the child's foot. The Steenbeek brace alternatively, was designed to be inexpensive with standard FAO procedure and easily made for the use in developing nations with the focus on the African region. [15] explicate in the published Journal of the American Academy of Orthopaedic Surgeons that the main factor contributed to the relapse of deformity is the noncompliance with the post-corrective bracing protocol. [16] added a statistic of 76% relapse rate of clubfoot patients whose families were unable to use the FAO as prescribed, compared to 16% of feet in patients whose families adhered to the treatment protocol. The rationale of this noncompliance issue is due to the expensive cost of the FAO that is prohibitive for many patients especially in the developing countries [17]. In addition, the shoes on the orthosis will need to be changed periodically to a bigger size as the child grows since the use of the orthosis is recommended until the age of 4 years. This may also be costly to some of the parents. Another related research that tackles the same issue in the discussion is [3] 'A New Dynamic Foot Abduction Orthosis For Clubfoot Treatment' that has manifested current FAO offered in the market to be expensive and economically unobtainable to low-income populations.

III. RESEARCH MODEL

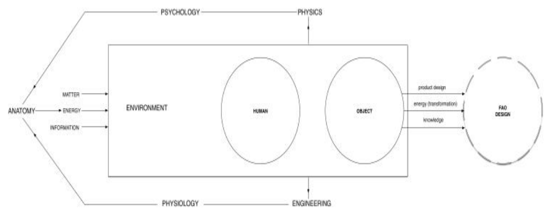

Fig. 3: The Ergosystem Research Model

The research model was based on the ergonomics ergosystem framework. The framework is a design model formulated to manoeuvre a designer's design thinking from the early stage of empathetically experiencing the case being studied, brainstorming and coming up with the solution for the user's need (based on the insights from the empathy stage), conceptualising, to the modelling and periodically testing the prototype design. Philosophically, the system is accelerated by five sets of ergonomics science elements namely Physics, Psychology, Anatomy, Physiology and Engineering, that enumerate one another to the surrounding boundary. According to [18], the foundation of the system incorporates the synchronisation of the 'people' and 'object' in an environment. To understand that connexion, one must understand the condition or situation (matter) of the user operating the product (object) in a particular environment or space. The condition or situation will illuminate the information regarding the user's reflection to the physics of the object being used or the environment being experienced, and how it affects the user's psychology. Furthermore, the articulation of the anatomy aspects and physiological needs will spur the energy and steer the design information to be further engineered. In relation to this research, the system is adopted and adapted in appropriation to the clubfoot patients' lower limb movements assessment with aims to develop the FAO prototype design. The synchronisation of the five elements is applied to illuminate the system's animation in the embodiment of the clubfoot patients' bodily movements and, subsequently steering design thinking activity strenuously towards the better understanding of the end user's need.

A. Method

The assessment via observational study was carried out at the Hospital Universiti Sains Malaysia, in Kelantan Malaysia for three months.
The assessment was divided into two sections; (1) the FAO design assessment and (2) the descriptive Event Sampling [18, 19]. It required the observation of the postural behaviour of 10 clubfoot patients who had been treated regularly at the hospital's orthopaedic clinic, with the focus on the lower limb dynamics. Majority of the patients use the Dennis Browne Splint (DBS) and the Markel shoes which their parents rented from the hospital's limited subsidiary unit.

In addition, the parents were asked to fill in a questionnaire on the extent of their compliance with the wearing instructions, the level of satisfaction with the FAO they were using at that time and if they would recommend it to others, and finally the recommendation for design improvement. With the amalgamation of the ergonomics contexts, the method framework divides the assessment procedures and illustrates the strategy in accomplishing this research objective. Figure 3 demonstrates the design assessment and postural behaviour assessment framework and Figure 4 illustrates the post-design assessment framework.

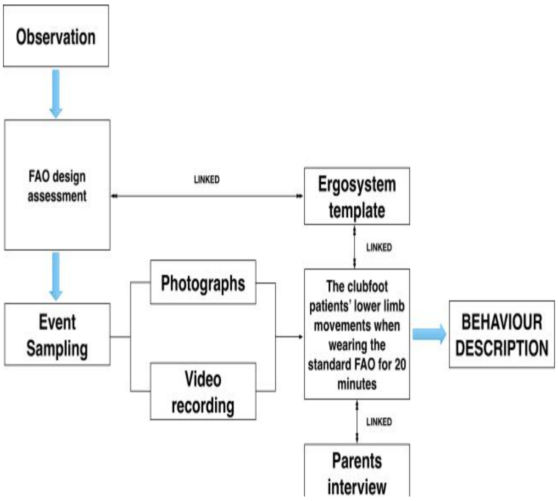

Fig. 4: The FAO design and postural behaviour assessment framework

B. Ethic Clearance

Verbally informed consent explaining the purpose and method of the study was undertaken to ensure the patient's parents of its confidentiality.

IV. DATA ANALYSIS

FAO Design Assessment and Event Sampling

All 10 clubfoot patients among children below 1 year old demonstrated identical abducted foot kicking (Figure 5 and Figure 6) and hip stretch (Figure 7) pattern to relieve waist tightness and pain. Below is the excerpt of the FAO design assessment data and clubfoot patients' postural behaviour data analysis.

Fig. 5: Analysis 1

During clinical assessment, all clubfoot patients were lying back agitatedly, crying and continuously kicking due to the foot abduction discomfort. As a solution, the patient(s) were then put to sleep on stomach. Sleeping on stomach restrains good lower limb dynamics. In addition, the knee was locked in that sleeping position (see red circle) that physiologically contributed to muscle stress. The design of the FAO that was heavy, stiff and bulky did not permit the patient's dynamic movements and therefore created discomfort.

Fig. 6: Analysis 2

The FAO foot abduction limited the children's lower limb movement and caused agitation. The legs as sampled in the red circle, could only be flexed and stretched. In addition, the children were struggling with the body movements due to the FAO design that was bulky and heavy. Moreover, when the children kicked, the protruding screws embedded underneath the shoe's outer-sole would easily injure anyone within the hand's reach.

Fig. 7: Analysis 3

The heavy FAO forced the children to pull up legs to adjust the body to the side. Such frequent postural reaction caused discomfort to the waist.

V. DISCUSSION

The results of this assessment have shown that there are rooms for improvement in relation to the FAO design feature. Although according to [4], the adherence and compliance with the bracing protocol is not influenced by the type and design of the FAO, this is contrary to our study that focuses on the connection between design, ergonomics significance with the end user needs. The application of the ergonomics ergosystems as a design model is immanent to signify the importance of design and its application for the user adherence and the compliance with the bracing protocol. In accordance with this significance, studies by [3] and [12] and several other studies have also established that the higher compliance rate and better results of treatment did improve when the new FAO was used as opposed to what the traditional FAO was used. However, all the new FAO design are much more expensive [15]. For instance, the Dobbs approximately costs at 950 Malaysian Ringgit (MYR) and Mitchell is costing around 1060 MYR.

In the present study, the majority of the clubfoot patients were using the hospital subsidiary traditional DBS (1000 MYR) and Markel shoes (600 MYR), and some even had to purchase the Ponseti bar (380 MYR) because of the limited FAO supply at the hospital. Essentially, the cost of purchasing the FAO is usually costly in the first year during this foot maintenance phase, as at least two pairs of shoes are needed due to the fast foot growth during infancy. Majority of parents being interviewed in the clinic agreed that the FAO was costly and expensive. In addition, majority of the parents belonged to the middle class M40 (average household income below 6275 MYR) and the bottom B40 (average household income below 3000 MYR) groups, thus economically the FAO is unobtainable to these low-income groups.
The design assessment data demonstrates possible design improvements that could benefit the patients from low-income group families and subsequently increase the adherence and compliance rate with the bracing protocol. Ergonomic considerations in the assessment of the clubfoot patients' lower limbs and body dynamics patterns are fundamental towards the development of the FAO design.
The clubfoot patients' wearing of the FAO is susceptible to waist tightness and pain. Therefore, they feel restless due to the heavy load of the FAO's foot plates and the bulky protruding shoe and brace locks.
In relation to this current research objective, design recommendations were made to manoeuvre the new FAO design process further:

Table 1. Design recommendation based on the FAO design assessment and Event Sampling

Existing Orthosis	Design recommendation
Outer-sole with embedded screw thread, foot plates, bolts and nuts	Flat surface
Bracing bar length and width	Rescale the length and width but adhere to the standard patients' shoulder distance between the inside heels of the shoes
Closed front upper sole design	Open front upper sole design with back heel hole/opening to check foot position

Potential design recommendation: To eliminate the foot plates and the bulky protruding shoe and brace locks that are hard and heavy. This subsequently will include the introduction of new material that is much lighter but with high density. This will be the proposal for the construction of the future FAO designs. Furthermore, we have also suggested that attractive cartoon images to be printed on the upper sole design in order to subdue the feeling of reluctance among the clubfoot patient's parents who may thing that the FAO serve as an orthotic for the disabled.
Throughout the assessment and interview sessions with the clubfoot patients' parents, we also educated parents about the proper way of handling the FAO. We realised that however appealing, simplistic and mechanically easy the new FAO design would be, the synchronisation of a strong family-treatment team participation in the attempt to fully correct the foot is crucial for the adherence to the brace protocol and subsequently decreasing of the noncompliance rate.

Fig. 8: The conceptual design of the FAO developed by this researcher's design team

CONCLUSION

With the initial design research data, it shows that the orchestration of the ergonomics ergosystem is essential in assessing the clubfoot patients' orthotic needs. The user experience assessment signifies the fundamental of design to spur the adherence and compliance with the bracing protocol, based on the patient's body dynamics reaction to the technical feature of the current FAO design. The conceptual design of the FAO has the potential to further develop into tangible products. This can be realised through the application of the elements recommended in the design recommendations. It is hoped with this development, the end product would benefit the clubfoot patients treated at the Hospital Universiti Sains Malaysia. Besides that, with the proposed design and material, the low-income group would be able to afford it. Finally, this could also help to increase the FAO compliance.

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