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CLUBFOOT KICKBAR: DEVELOPMENT OF AN IMPROVED BRACE FOR USE FOLLOWING CORRECTION OF CLUBFOOT

Spencer Kuhl[1]
Protostudios
Iowa City, Iowa

Thomas M Cook[2]
Clubfoot Solutions
Coralville, Iowa

Jose Morcuende
University of Iowa
Hospitals and Clinics
Iowa City, Iowa

Nicole Grosland
University of Iowa
College of Engineering
Iowa City, Iowa

ABSTRACT

The critical final phase of treatment for congenital talipes equinovarus, commonly referred to as clubfoot, using the Ponseti Method requires parents to use a brace in order to maintain the correct foot posture for 12-14 hours each night until four years of age. Parents have been vocal about a desire to allow their children some mobility while maintaining correct alignment for the treatment of this deformity. To that end, the University of Iowa's medical device prototyping facility Protostudios utilizes 3D CAD design, rapid prototyping principles and state of the art 3D printers to quickly iterate upon the concept of a reciprocating brace that allows for the prescribed posture of abduction and dorsiflexion in a corrected clubfoot while allowing more mobility and higher degrees of comfort for the child. Each iteration of the design was tested for fitment with the commercially available shoe and platform system developed for the Ponseti Method of Clubfoot correction. Special attention was paid to the attachment and removal process of the brace to ensure that parents of children with the deformity would have no problem employing the brace for the prescribed frequency and duration while preventing the children from removing or destroying the brace or being pinched by its reciprocating action.

Keywords: clubfoot, Ponseti Method, medical device prototype, 3D printing

1. INTRODUCTION

The most common musculoskeletal deformity among newborn babies around the world is a condition commonly referred to as clubfoot. The medical term for this condition is congenital talipes equinovarus, meaning the foot is abnormally turned downward and inward. The resulting posture resembles a club, hence the English name for this deformity. Although the cause of clubfoot remains a mystery to modern medical science, it is not related to positioning of the fetus in the womb or to any behavior of the mother during pregnancy. Clubfoot is not an embryonic malformation but a condition in which a normally developing foot turns into a clubfoot during the second trimester of pregnancy. It can often be detected by ultrasound examination after the 16th week of gestation.

Approximately 200,000 babies are born with this condition every year, one every three minutes or about one in every 750 live births. Fifty percent of babies have this condition in only one foot; the other 50% have it in both. Clubfoot is twice as common in males as in females. The deformity occurs in every country around the world and shows only small variation in its incidence among different ethnic groups. There are also no economic or cultural causal factors when it comes to clubfoot.

If left untreated, clubfoot persists as a rigid, unsightly deformity and is one of the most common causes of physical disability. Children with clubfoot often go on to a life of poverty and isolation. As is the case with most disabilities, females are especially disadvantaged by clubfoot since they are less likely to obtain an education and more likely to suffer abuse. In some cultures, children with birth deformities are abandoned or given up for adoption. Clubfoot is one of the most prevalent deformities among orphans worldwide. In other cultures, there are reports of very few individuals with clubfoot because children born with this deformity are said to "die in childbirth" in disproportionately high numbers.

With the advent of modern surgery in the 20th century, treatment for clubfoot, at least in high-income countries, consisted of a surgeon cutting and lengthening tendons and ligaments and realigning the bones of the foot and ankle. Unfortunately, surgery is not a satisfactory solution for clubfoot deformity. Children who undergo surgery as infants will undergo an average of 2.3 additional surgeries as they grow into adolescence and

[1] Contact co-author: spencer-kuhl@uiowa.edu
[2] Contact co-author: thomas-cook@uiowa.edu

adulthood and their quality of life will be seriously limited. It is not uncommon for some patients to eventually request an amputation because of painful, rigid, and weak feet as adults.

The Ponseti Method is now considered the "gold standard" for treating clubfoot deformity worldwide. It consists of a series of gentle manipulations to stretch the shortened tissues and to gradually realign the bones of the foot, followed by precisely applied plaster casts to hold the new position. Casts are removed weekly and the manipulations and stretching are repeated and another cast is applied, each holding the foot in a progressively better position. After a series of 4-6 casts, over 4-6 weeks, the deformed foot takes on a normal appearance and function. The results of numerous scientific studies have shown that the Ponseti method is 95% (or more) effective when administered by a properly trained healthcare provider. There is overwhelming evidence that this low-cost, low-risk, low-tech method is far superior to surgery and leads to a normal, active, productive life. In addition, the Ponseti method can be used successfully to correct clubfoot deformity everywhere in the world, since it requires minimal resources and relies primarily on the skill of the treating healthcare professional and the cooperation of the child's parents or caregivers.

The critical final phase of the treatment process is for the child to sleep in a foot abduction brace until age four to maintain the correction and to prevent the return of the deformity. A typical clubfoot brace consists of specialized shoes attached to a connecting bar to maintain the feet at abducted and dorsiflexed angles. The brace is worn for 23 hours a day for a period of a few months and then worn while the patient naps and at night for a period of up to age four.

Most traditional braces have utilized a single rigid bar to connect the patient's shoes together to prevent motion or rotation of the feet relative to each other (Figure 1). Understandably, this restriction of motion can lead to the patient not tolerating the brace for as long as prescribed and eventually contributing to a return of the deformity. There is a need for a more comfortable and more tolerable product for maintaining the proper positioning of the feet while also allowing greater freedom of movement for the child. The reciprocating connecting bar assembly, referred as the Kick-Bar (patent pending), meets this need.

This device incorporates a parallelogram configuration into the connecting bar to allow the patient to move his/her feet in an up-and-down (kicking) motion while maintaining the prescribed posture of 60-70 degrees of abduction and 15-20 degrees of dorsiflexion in a corrected clubfoot. The allowed reciprocal kicking motion is designed to promote greater comfort when wearing the brace and lead to higher compliance with the bracing protocol. In addition, this bar configuration may allow a patient to stretch important anatomical structures in their affected legs. The ability to kick and crawl also aids in a patient's physical and social development.

Figure 1. The Iowa Brace. A commercially available Ponseti Method brace and shoe apparatus to correct the clubfoot deformity utilizing a single rigid bar. (clubfootsolutions.org)

2. MATERIALS AND METHODS

2.1 Design and 3D Printing Process

The design, rapid prototyping process, 3D printing, and fitment testing were conducted at the University of Iowa's medical device prototyping hub, Protostudios (MERGE suite 9, 136 S. Dubuque Street, Iowa City, IA 52240) Each iteration of the reciprocating bar design was developed in Autodesk's cloud-based CAD platform software, Fusion 360 (San Rafael, 94903 California, U.S) Each prototyped version of the reciprocating bar maintained specific design principals that would lend themselves to eventual industrial scale production utilizing injection molding. Initial design files were exported to an STL (Standard Tessellation Language) file format and imported into the 3D printer slicing and project management software GrabCAD (Stratasys, Eden Prairie, Minnesota, United States). Prototypes were printed on a Stratasys J750 polyjet 3D printer (Stratasys, Eden Prairie, Minnesota, United States) using a mixture of 85% digital-ABS material and 15% VeroBlack material at the high-quality settings of 14 microns layer height (0.00055 in.). This combination was intended to achieve a balance of strength and flexibility. Subsequent versions of the design were exported to STL format and imported into the 3D printer slicing and project management software Eiger (Markforged, Watertown, MA 02472) and printed on a Markforged Mark II 3D printer utilizing ONYX FDM (Fused Deposition Modeling) filament (Nylon 6 with chopped carbon fiber) and strategically placed continuous carbon fiber filament embed within the FDM matrix to stiffen and strengthen the parts. The ONYX material was printed at a 37% infill density utilizing a triangular infill pattern which maximizes strength while reducing weight and material (Figure 2). Four roof layers and four floor layers were combined with two wall layers encapsulating the infill and continuous carbon fiber filament. The layer height utilized in this device was 125 microns (0.005 inches).

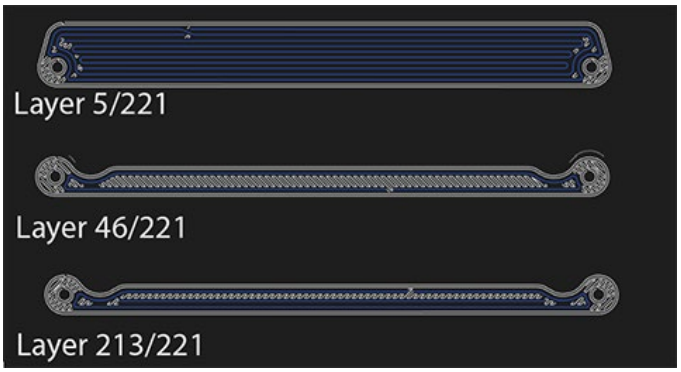

Figure 2. Internal software X-Ray view through Eiger illustrating the build process of the cross bar component to the design. Blue lines indicate a continuous carbon fiber filament deposition, and white lines indicate the pattern of deposition of the ONYX filament.

2.2 Fitment and Usage Testing

Prior to testing on patients, the Protostudios team focused on three central usage scenarios: child safety while the device is in motion; ease of parental application and removal; and difficulty or prohibition of child removal of the device. Due to the reciprocating motion of the Kick-Bar's design, there exists a potential for the patient to injure him or herself by placing fingers between the two reciprocating cross bars. To avoid this, a small guard was employed to cover the negative space between the bars (Figure 3). In addition, all edges were filleted by a radius of 0.025 in.

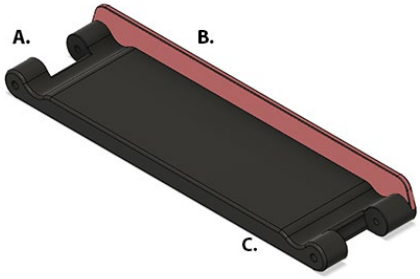

Figure 3. Isometric view of one of the Kick-Bar cross bars (A.) Highlighted in pink, the small protective guard (B.) and the 0.025 inch radius fillet (C).

The parameters of the snap arm(s) (Figure 4) that connects the reciprocating mechanism to the patient's correctional shoe were optimized for ease of insertion and removal by parents, for the difficulty in removal by children, and for overall strength of connection to the shoe.

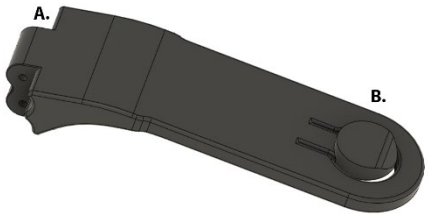

Figure 4. Isometric view of the snap arm component (A.) and the locating button (B.)

The dimensions of the locating button's live hinge, the height of the button, and the angle and length of the button's leading edge were subject to several itterations over the course of several weeks.

2.3 Pre-clinical testing

The solid bar of Iowa braces being used by four children who had had their clubfoot deformity corrected using the Ponseti method were replaced with the prototype of the reciprocating Kick-Bar as a preliminary evaluation of the device (Figure 5). All four patients in the pre-clinical evaluation were under the age of two years. Their initial response to use of the Kick-Bar was observed and subjectively evaluated by each child's parents and by the clinical staff. In addition, pictures and video tapes were made of the session and used to measure the child's movements in the brace.

Figure 5. Isometric view of the prototype Kick-Bar.

This testing was undertaken after the University of Iowa Institutional Review Board (IRB) had determined that "the project does not meet the regulatory definition of human subjects research and does not require review by the IRB, because this is a clinical care activity."

3. RESULTS AND DISCUSSION

The basic configuration of the device appears to accomplish its intended purpose. The parallelogram configuration only allows relative motion between the shoe attachment pieces in the XY (vertical) plane. As a patient bends a knee(s) to raise or lower one foot relative to the other, the shoe attachment plate pivots about the four hinge(s) and maintains the desired correctional orientation of both feet.

The initial response to the reciprocating bar was judged to be positive, both by all four sets of parents and by the supervising healthcare personnel. The two children who were not yet of walking age soon began to reciprocally "kick" their feet while lying of their back. The two older children were also immediately active. One child slid off the examining couch and began to walk using a waddling motion allowed by the device. The pictures and videos (Figure 6) confirmed that the desired correctional angles were maintained in all four patients as they undertook kicking and various other movements while using the Kick-Bar.

Figure 6. A patient wearing the Kick-Bar highlighting the high degree of movement and the desired correctional angle required.

Because the connecting bar apparatus consists of two identical crossbars and two identical shoe attachment pieces, the use of pairs of identical components minimizes the number of unique parts needed in the device's manufacture. The use of two crossbars increases the strength of the brace compared to single bar designs. This simple design results in low manufacturing costs and does not require careful adjustment by a trained medical professional, whose services may be costly or difficult to obtain, especially in low-and middle income countries.

4. CONCLUSION

It is our hope that this improvement on an existing successful medical device will have far reaching benefits for both the parents and children that are affected by the most common musculoskeletal deformity among newborn babies. A rigorous clinical trial is being planned to confirm the results of the limited pre-clinical testing.

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