DESIGN AND DEVELOPMENT OF A SOFT PEDIATRIC SUPPORT GARMENT FOR ANKLE-FOOT ORTHOSES WEARERS

by

Danielle A Civil

A thesis submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for Master of Science in Fashion and Apparel Studies

Spring 2019

DESIGN AND DEVELOPMENT OF A SOFT PEDIATRIC SUPPORT

GARMENT FOR ANKLE-FOOT ORTHOSES WEARERS

by

Danielle A Civil

Approved: ____
Michele Lobo, PT, Ph.D.
Professor in charge of thesis on behalf of the Advisory Committee

Approved: ____
Huantian Cao, Ph.D.
Interim Chair of the Department of Fashion and Apparel Studies

Approved: ____
John Pelesko, Ph.D.
Interim Dean of the College of Arts and Sciences

Approved: ____
Douglas J. Doren, Ph.D.
Interim Vice Provost for Graduate and Professional Education

ACKNOWLEDGMENTS

Throughout the course of this research and my master's program, I have received an incredible amount of support, guidance, and assistance. I would first like to thank my advisor Dr. Michele Lobo whose guidance and expertise was incredibly invaluable. I am extremely appreciative of her support and encouragement throughout this process and so inspired by her passion and drive to help children. I'd also like to thank the rest of my committee, Dr. Huantian Cao and Dr. Karin Grävare Silbernagel, for their expertise and feedback that made my research stronger.

Thank you so much to the Move To Learn lab team who has offered an incredible amount of support to me during the span of this research. Specifically, thank you to Andrea Cunha for your helpful contributions to the functional testing and data analysis; her expertise, hard work, and kindness was invaluable throughout the duration of this research. I'd also like to thank Joey Lanzona for his coding assistance.

I was so lucky to work with three incredible families and children that inspired me each time I had the chance to visit them. The kindness and positivity that each participant and their families offered motivated this research, and without them, none of this could have been accomplished.

Lastly, I'd like to thank my family and friends who offered so much love and support throughout the course of this research. Thank you for keeping me sane and motivated.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Children who utilize ankle-foot orthoses (AFOs) benefit from the support they provide to help stabilize the position and control the motion of the ankle and foot, assist weakness, or correct deformities (AliMed, 2014). Although they are a useful support wearable, a high percentage of non-use is reported for individuals with AFOs; this is due to a variety of reasons, including the design, functionality, comfort, and lack of ability to wear one's preferred shoes in combination with AFOs. This research aimed to develop a soft ankle support garment through user-centered research as an alternative to an AFO for the purpose of dressing up or participating in activities, like dance or formal events, which would be difficult while wearing a hard, bulky AFO. The first phase of this study involved performing a content analysis on perceptions of AFO use from published research, online forums, and interviews with our participants to identify frequently mentioned aspects of satisfaction and dissatisfaction. We then designed and tested prototypes, with 3 participants, to address commonly mentioned aspects of dissatisfaction with existing AFOs. Data derived from interviews, iterative prototyping with participants, usability testing, and functional testing to compare our designs with traditional AFOs. By utilizing various testing metrics, we were able to validate that a soft ankle support garment would be a beneficial and desirable alternative for children who wear AFOs that would allow users flexibility in their footwear options. Based on this research, we outline the importance of user-centered design, a desire for a soft alternative to AFOs, and how brace design affects one's desires to express themselves through footwear.

Chapter 1

INTRODUCTION

Fifteen to twenty million children have chronic conditions in the United States, and of that number, approximately 5-10% have physical impairments that decrease their ability to play and participate in typical childhood activities (Klingbeil, Whitaker, & Dunn, 2000). Children who utilize ankle-foot orthoses (AFOs) benefit substantially from the support they provide to help stabilize the position and control the motion of the ankle and foot, assist weakness, or correct deformities (AliMed, 2014). Typical AFOs are made from relatively thick plastic, which aims to hold the ankle and foot in ideal alignment, as the rigid nature of the material provides support while restricting movement (Lusardi, 2013). Although they are a useful support wearable, a high percentage of non-use is reported for individuals with AFOs; this is due to a variety of reasons, including the design, functionality, comfort, and lack of ability to wear one's preferred shoes in combination with AFOs (Holtkamp et al., 2015). Children who wear AFOs struggle with the additional challenge of fitting in with their peers regarding how they dress and what activities they participate in, such as dance class and organized sports. This research aimed to develop a soft ankle support garment through user-centered research as an alternative to an AFO for the purpose of dressing up or participating in activities, like dance, which would be difficult while wearing a hard, bulky AFO. The prototype's aim is not to replace AFOs but act as an substitute between wearing nothing and wearing an AFO. The population that we are aiming to serve is children with mild-moderate ankle impairments who wear AFOs on a daily basis but would like a supportive alternative to the rigidity of a traditional brace on occasion.

Chapter 2

REVIEW OF LITERATURE AND BACKGROUND

2.1 The Foot and Ankle

Understanding the anatomical and mechanical structure of the foot and ankle is essential to design a device created to support this part of the body. The foot and ankle is a complex system of ridged segments, bones, that are hinged at joints and linked by a multitude of muscles and ligaments (Morris, 2007a). Feet act as a stable weight-bearing base to absorb shock and to propel the body (Quinn, 2019).

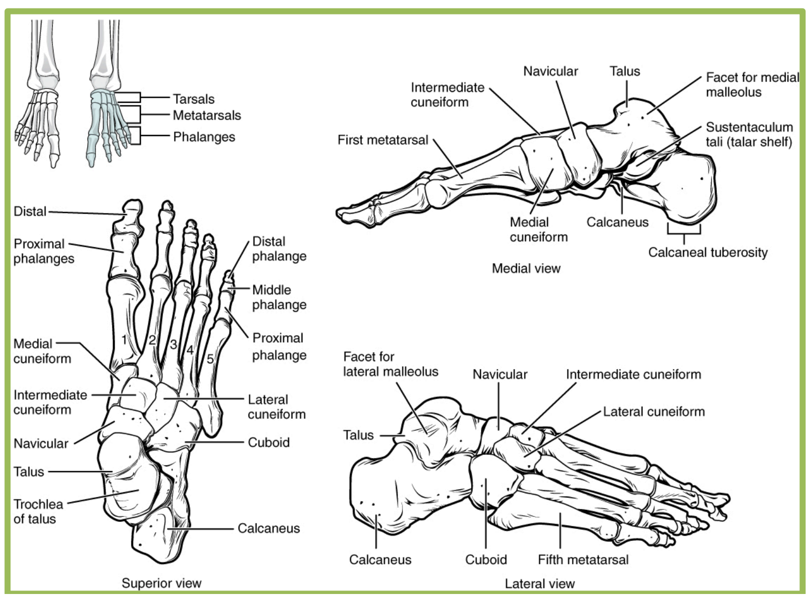
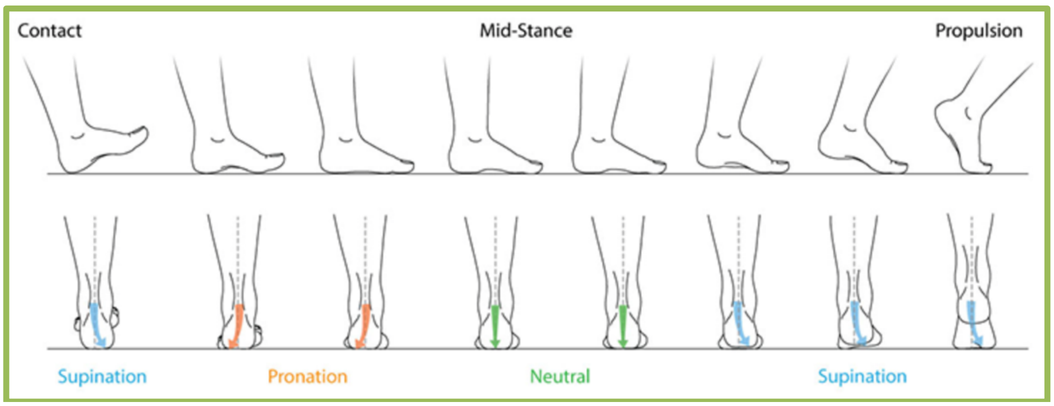


Figure 1: Diagram of Foot Anatomy (Betts et al., 2017)

When a person runs, walks, or jumps, a significant amount of force is applied to each foot, up to 2.5 times a person's body weight. The bones, joints, ligaments, tendons, and muscles of the foot and ankle absorb that force (Betts et al., 2017). Strong ligaments on either side of the foot and ankle support the ankle; tendons translate forces from muscles to allow for movement of the foot, including dorsiflexion and plantar flexion. Additionally, these ligaments provide stability against unwanted side to side and twisting motions that could lead to injury (e.g., resisting excessive inversion or eversion of the heel of the foot) (Betts et al., 2017).

Dorsiflexion of the foot occurs when the ankle joint moves the top of the foot toward the front of the leg; plantar flexion does the reverse, pointing the foot down (Betts et al., 2017). Normal range of motion for dorsiflexion and plantar flexion are respectively 0-20 degrees and 0-50 degrees (Moroz, 2017). Foot inversion occurs when the foot moves inward toward the midline of the body, while eversion occurs when the bottom of the foot moves away from the midline of the body; both are important to stabilize the foot while walking on uneven surfaces or playing sports such as basketball or soccer (Betts et al., 2017). Normal range of motion for inversion being 0-30 degrees and for eversion would be 0-25 degrees (Moroz, 2017).

Foot and ankle alignment affect the rest of the body's alignment; thus, an individual needs a stable base for support. Body alignment is affected by the angles at joints connecting body segments. External forces (gravitational, environmental or orthotic) or internal forces (muscular, ligaments, or inertial) can alter these angles (Morris, 2007a). The ideal foot and ankle alignment has been proposed to be a vertical hindfoot, level forefoot, and 3-4 degrees of dorsiflexion; an AFO device's purpose is to keep the foot at this position (DAFO, n.d.-a). See Figure 2 for a visual diagram of ideal foot movement throughout the gait cycle; the center image of a neutral foot is what orthoses are often aiming to achieve (DAFO, n.d.-b). Orthoses help to accomplish this ideal alignment by combining three sources of force manipulation; ground reaction force, forces generated in the body, and interaction with the environment (Morris, 2007a).



(DAFO, n.d.-b)

Figure 2: Diagram of Ideal Foot Position and Movement During Gait

2.2 Orthoses

According to the International Standards Organization, orthoses are externally applied medical devices that are used to modify the structural and functional characteristics of both the neuromuscular and skeletal systems; they aim to achieve this by applying an external force to the body (Morris, 2007b). An alternative definition is that they are external devices that assist, allow, or resist motion of specified body parts for therapeutic purposes (Redford, 2000). Orthotics are designed to affect body functions, structures, and activity, such as improving gait, preventing deformities, and overcoming activity limitations to provide a fuller involvement in life activities (Lusardi, 2013; Morris, 2007b). Orthoses offer many benefits, but noncompliance is evident across multiple research studies (Swinnen & Kerckhofs, 2015).

Pediatric orthotics are simple in mechanics but enable kids to sit, stand, and walk, which allows for fuller participation in activities of daily life. The goal of orthotic intervention is not only solving biomechanical problems but improving a child's wellbeing (Morris, 2007b). Pediatric bracing is unique due to children's dynamic state of growth, which requires frequent modification of braces or frequent fabrication of new braces when a child outgrows the brace, or it is no longer positioning the foot correctly (Eckles, 2017; Klingbeil et al., 2000). Despite the challenges related to creating orthoses for children, pediatric orthotics allow children to have higher functional independence to play, learn, and grow (Klingbeil et al., 2000).

2.2.1 Ankle Foot Orthotics (AFOs)

Ankle-foot-orthotics (AFOs) are support devices that stabilize the ankle and its motion, support the lower extremities for individuals with weakness and help to correct deformities (AliMed, 2014; Chang & Cardenas, 2000); They also absorb forces and help to generate power. AFOs are the most widely used orthoses (Chang & Cardenas, 2000) and account for 26% of all orthotics used in the US (AliMed, 2014). They assist weak limbs and help to bring the legs and feet into safe, functional positions (AliMed, 2014). Additionally, AFOs provide mobility support while standing, transferring, or walking (Chang & Cardenas, 2000). The devices are typically designed as ridged L-shaped frames that go around the wearer's foot in a variety of heights and forms, but many begin just below the knee and continue until the metatarsal head of the foot. AFOs are made from a variety of materials, including heat-moldable plastics, metal, leather, and carbon composite (Morris, 2007c). Most children who wear AFOs wear custom braces, but off the shelf varieties are also available (Agrawal, 2013).

2.2.1.1 Types of AFOs

2.2.1.1.1 Solid (Rigid AFOs)

Solid or rigid AFOs are the most commonly used AFO (AliMed, 2014). Solid AFOs have a hard plastic shell applied to the posterior calf, ankle, and foot with strapping to secure the heel inside the orthosis; thus the foot and ankle are solidly braced (Agrawal, 2013; Morris, 2007c). They work to stabilize the ankle in a specified level of dorsiflexion (Morris, 2007c) and accommodate a variety of needs; from providing mild to maximum support for the user. Traditional plastic AFO's can be molded to create a custom fit for each patient (AliMed, 2014).

Figure 3: Pediatric Solid AFO (Surestep, n.d.-a)

2.2.1.1.2 Hinged AFOs

Hinged AFOs are designed to control the amount of either plantar or dorsiflexion by creating a hinge at the ankle, with optional limitations in either direction to manage possible movement (Morris, 2007c). Hinges in AFOs can reduce the energy cost of walking, improve stride length, cadence, muscle tone, and walking speed compared to walking barefoot (Lusardi, 2013). Clinicians create these braces by physically placing a hinge between the foot and ankle portion of the orthosis, or a clinician can trim material away at the ankle to make the AFO more flexible (Morris, 2007c). There are many different types of hinges with a variety of resistances and functions that can be selected for specific end goals in mind. Hinged AFOs can improve functional activities such as rising from the floor, maneuvering stairs, and walking up or down inclines (Lusardi, 2013).

Figure 4: Hinged AFO (Surestep, n.d.-b)

2.2.2 Orthotic Materials

Orthotics can be created from a variety of materials, including plastic, foam, metal, leather, and fabric (See Table 1). Plastics, specifically polypropylene (Eddison, Mulholland, & Chockalingam, 2017), are the most commonly used material for AFOs and other orthotics, due to their high strength, lightweight properties, and adjustability. Fabrics are frequently used for covers or fasteners (Morris, 2007d; Park et al., 2014). Material selection and characteristics have a significant effect on the orthotics usefulness, but there is very little published research that elaborates on the materials or design of AFOs (Eddison et al., 2017). New materials that are being tested include 3D printed braces that utilize additive manufacturing; this method can print braces in detailed and precise ways with a variety of materials that have a superior fit and can be very lightweight (Mavroidis et al., 2011; Schrank & Stanhope, 2011; Telfer et al., 2012). A stiff and strong material (like plastic or metal) is often used for external stability of a brace if the support device needs to conform closer to the body a more flexible material is chosen (Kogler, 2013).

Table 1: Materials Commonly Used for Fabricating Orthoses

Plastics	**Foams and rubber**	**Metals**	**Leather**	**Fabrics**
-Sheets come in a variety of thicknesses, colors, and patterns(Morris, 2007d). -High strength and lightweight(Chang & Cardenas, 2000). -Used in AFOs and most orthotics(Morris, 2007d).	-Open cell foam compresses easily (Morris, 2007d). -Closed cell more resilient (Morris, 2007d). -Variety of densities (Morris, 2007d).	- Heavy, but greater strength and stiffness over plastic (Morris, 2007d). -Used in KAFOs (Morris, 2007d).	-Variety of properties (Morris, 2007d). -Used as liners (Morris, 2007d).	-Used as covers (Morris, 2007d). -Velcro as a fastener (Morris, 2007d). - There is an interest in using Lyrca and other fabrics to make orthoses (Morris, 2007d).

-Most common (Chang & Cardenas, 2000)				

2.3 User Satisfaction with AFOs

Holtkamp et al. (2015) surveyed a population of 211 people with a mean age of 48.8 (SD = 25.0) found that 1 out of every 15 prescribed AFOs was not used correctly and 25% of users are dissatisfied their devices. Swinnen and Kerckhofs (2015) completed a systematic review of the compliance of patient's orthotic devices and shoes and found that patient compliance was only about 20%; this review included studies assessing a variety of orthotics, but several evaluated AFOs. The highest groups of people to report dissatisfaction included females, people living alone, and those under 18 years of age (Holtkamp, Wouters, van Hoof, van Zaalen, & Verkerk, 2015). Common complaints included device dimensions, comfort, weight, safety, design, and effectiveness. Dissatisfaction in AFO use comes from numerous factors; the most significant influences are that the design neglects the specific needs of the end user, comfort, and the aesthetic design of the device (Holtkamp et al., 2015; Swinnen & Kerckhofs, 2015). Users dissatisfaction in the aesthetics of the orthotics included that the devices are unattractive, cosmetically unacceptable, and it inhibits shoe selection. (Bapat & Sujatha, 2017; Holtkamp et al., 2015; O'Reilly, Hunt, Thomas, Harris, & Burns, 2009; Swinnen et al., 2018; Swinnen & Kerckhofs, 2015; Van Der Wilk, Hijmans, Postema, & Verkerke, 2018). User satisfaction and acceptance determine compliance of using assistive devices; thus, points of dissatisfaction should be considered in orthotic design (Swinnen et al., 2018).

2.4 Measuring AFO Effectiveness

Methods to measure AFO effectiveness primarily rely on data such as stride length, step length, walking velocity, and cadence. Stride length being the distance one foot travels in a gait cycle, walking velocity is the time it takes to walk a meter, and cadence is the frequency of steps taking during gait often as steps per minute. Step length is the distance between each foot during a stride. Other methods of assessment include foot pressure, range of motion, muscle control and strength, and joint alignment and integrity (Morris, Gryfakis, El-Shammaa, & Dias, 2007). Gait analysis is a preferred method of measuring the usefulness of AFOs since walking is a crucial lower extremity functional activity. The gait cycle utilizes dynamic interactions involving the hip, knee, foot, and ankle to advance the body and the muscles used to control joints (Chang & Cardenas, 2000).

Gait analysis is used to assess walking ability and balance by analyzing a patient's gait cycle. A gait cycle is the initial foot contact with the ground through the next contact on the same side or one stride. Parameters examined during gait analysis include stride length, step length, walking velocity, and cadence. Testing begins with the individual standing in a normal upright position. The individual will then walk a defined distance and then turn back. The examiner will observe the placement of the feet and body movements. Gait analysis can involve a few different varieties of walking, including walking on toes or heels to further assess balance (Betts et al., 2017). Through gait analysis, AFOs has been shown to improve children's stride length and gait speed as compared to barefoot (Lintanf et al., 2018).

There are three general methods of gait analysis, the first being observational; this is when the clinicians observe gait by watching the individual. The reliability of this method depends on the expertise of the clinician. Video gait analysis can be a more beneficial way of measuring gait cycles because one can re-watch the video, slow it down, and compare an individual's video side by side with and without an orthosis on. 3D gait analysis is a more in-depth method of gait analysis utilizing 3D motion capture technology with the individual wearing reflective markers (Morris et al., 2007). 3D gait analysis has been used in multiple research studies to get an in-depth picture of how orthotics affect the body and its movement (Eriksson, Bartonek, Ponten, & Gutierrez-Farewik, 2015; Manousaki, Czuba, Hagglund, Mattsson, & Andriesse, 2016; Zifchock & Davis, 2008)

Functional based assessment is essential to understand a user's baseline levels of ability as well as determine goals for intervention (Mohamed, Craig, Worden, & Ayyappa, 2013). Other indicators of efficacy in an orthotic are identifying if the user can don/doff the device and if they can transition from sitting to standing with their device (Lusardi, 2013). Assessing range of motion, muscle control and strength, balance, and joint alignment and integrity are essential before prescribing an orthotic device, but these types of functional tests can be repeated during or after treatment to look for changes (Morris et al., 2007).

2.4.1 How to Assess Patient Satisfaction with Orthotic Devices

To accurately gauge non-adherence of orthotic devices, it is crucial to be able to assess the user's satisfaction with AFO braces. Questionnaires are most commonly used to understand patient preference, and they should evaluate both function and perceptions of the assistive device. Specific items can include questions related to influence on activity, pain, time used, comfort in wearing, the simplicity of use, and cosmetic appearance (Bettoni et al., 2016). Two common questionnaires used to evaluate patient satisfaction with assistive devices are the Quebec User Evaluation of

Satisfaction with Assistive Technology 2.0 (QUEST 2.0) – Table 2 and Orthotics and Prosthetic Users' Survey (CSD-OPUS) – Table 3, both questionnaires are generic and intended for use by all assistive technology or orthotics/prosthetic users respectively (Bettoni et al., 2016).

Table 2: Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST 2.0)

1	2	3	4	5
not satisfied at all	not very satisfied	more or less satisfied	quite satisfied	very satisfied

ASSISTIVE DEVICE ***How satisfied are you with…***					
1. the **dimensions** (size, height, length, width) of your assistive device? *Comments:*	1	2	3	4	5
2. the **weight** of your assistive device? *Comments:*	1	2	3	4	5
3. the **ease in adjusting** (fixing, fastening) the parts of your assistive device? *Comments:*	1	2	3	4	5
4. how **safe and secure** your assistive device is? *Comments:*	1	2	3	4	5
5. the **durability** (endurance, resistance to wear) of your assistive device? *Comments:*	1	2	3	4	5
6. how **easy** it is to use your assistive device? *Comments:*	1	2	3	4	5
7. how **comfortable** your assistive device is? *Comments:*	1	2	3	4	5
8. how **effective** your assistive device is (the degree to which your device meets your needs)? *Comments:*	1	2	3	4	5

Table 3: Orthotics and Prosthetic Users' Survey (CSD-OPUS).

	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**	**Not Applicable**
1. My skin is free of abrasions and irritation	☐	☐	☐	☐	☐
2. My device is comfortable throughout the day	☐	☐	☐	☐	☐
3. My device looks good	☐	☐	☐	☐	☐
4. My device is pain free to wear	☐	☐	☐	☐	☐
5. My device is durable	☐	☐	☐	☐	☐
6. My device fits well	☐	☐	☐	☐	☐
7. It is easy to put on my device	☐	☐	☐	☐	☐
8. The weight of my device is manageable	☐	☐	☐	☐	☐

2.5 Commercially Available Ankle Support Devices

Ankle support devices are available in many stores, including drug stores, grocery stores, and sporting goods stores for people who temporarily injure themselves, whether from sports or other forms of muscle strain and need support. These devices have design features, functional characteristics, and fabrications that work to support the ankle in a variety of ways. We evaluated popular types of braces to identify trends within non-medical brace design, see Appendix A.1 for a summary of our findings. Many braces are fabricated with seamless compression knit fabric and have some form of adjustability either with straps or supportive lace-up mechanisms. Figure 8, 6, or X strapping formations were repeatedly utilized, these configurations are inspired by athletic taping. Additional supports were added to braces in the form of lateral stays or gel inserts within the fabric; gel was also used inside the brace to help keep the brace in position.

(Shock Doctor, n.d.)

Figure 5: Ultra Knit Ankle Brace w/ Figure 6 Strap & Stays

2.6 Design Theory

2.6.1 Medical Design

The typical orthotic design and development process begins with a referral then cycles through measurements, manufacturing, fitting, delivery, acceptance, and then follow-ups as necessary to fine tune the device (Morris et al., 2007; Redford, 2000; Swinnen et al., 2017). It is crucial that the child and family accept the orthosis; one method of attempting to increase acceptance is allowing children to select from various colors and patterns for the materials (Morris et al., 2007). Orthotics primarily are designed for function, but many patients have cosmetic concerns; it is essential to ensure balance between the user's opinions with the functional needs, so the functional effects are not sacrificed to satisfy aesthetic concerns. Client preference is one of the most critical aspects of orthotic design (Chang & Cardenas, 2000); thus should not be overlooked in the creation process (Lusardi, 2013). Acceptance of the device is vital for the device to produce the desired effects, users have to understand the purpose of the intervention, find it useful in meeting their needs, and the device has to avoid disrupting their lifestyle (Lusardi, 2013; Redford, 2000). Improving the design of AFOs through a user-centered approach can meet the needs of the patient as well as improve acceptance (Van Der Wilk et al., 2018).

2.6.1.1 Design Characteristics of an Ideal Orthotic Device

AFO designs should protect the foot, ankle, and skin as well as support proper foot alignment and allow for correct gait mechanics. Lusardi (2013) and Redford (2000) have outlined baseline design and development considerations for creating ideal orthotic devices. We modified and combined both to create a design characteristic model for developing ideal orthotic devices. There are five constructs to the model, including function, comfort, cosmetics, fabrication, and cost.

Design Characteristics of an Ideal Orthotic Device		
	Function	Meets mobilty needs and goals Optimize stabilty Minimize abnormal alignment Safe
	Comfort	Can be worn for long period of time Easy to don/doff Lightweight Does not cause skin discomfort
	Cosmetics	Design allows for users clothing to fit in with peers
	Fabrication	Made in the shortest amount of time Minimally complex design Adjustable Respond to growth and body changes Durable
	Cost	Minimal cost to make Minimal cost to maintain

Figure 6: Design Characteristics of an Ideal Orthotic Device

2.6.2 Apparel Design Process

The apparel design process cycles through three phases, including problem identification, creative exploration, and implementation. The problem identification stage is when the problem is defined, and research is then completed to understand existing solutions, requirements, and standards. Creative exploration is when the designer ideates many different potential solutions, creates prototypes based on the most promising designs, and evaluates them through an iterative process. The final stage, implementation is when the designer will refine prototypes to produce a final design solution ready to be formally assessed (LaBat & Sokolowski, 1999).

2.6.2.1 Functional Design Theory

Recent research has utilized a model of user-centered medical device design that is a stark contrast to the typical medical model, this process incorporated interdisciplinary approaches, a user-centered focus, and addressed broad needs of users rather than function alone (Hall & Lobo, 2017; Lobo et al., 2016). User-centered design is a process of designing where the user is involved at every step of the development process from initial ideation to final testing. When implemented, it can lead to a design that matches a user's requirements and increases the items practical use (Ma, Wu, & Chang, 2007). User-centered design is necessary to design a medical device that patients want to wear rather than tolerate (Bapat & Sujatha, 2017).

Holtkamp et al. (2015) suggested an orthotics design system which involved the user at all steps through the design and evaluation process along with their therapist, physicians, prosthetists, and orthotists. Traditional medical device creation often involves engineers and clinicians isolated away from the needs of the user to create devices that can be costly and inaccessible. When the broad needs of users are met, a more desirable product has the potential to be designed and potentially have higher device acceptance and compliance (Hall & Lobo, 2017).

2.6.2.2 FEA Framework

The FEA model framework will be used to guide the design of this research, specifically the modified version by Hall and Lobo (2017). The FEA framework was developed by Lamb and Kallal (1992) to help design students and designers think critically about the needs of users from an apparel perspective. It emphasizes that designing clothing for people with disabilities should not be any different than creating for any other consumer. The framework proposed that apparel designers should address three overarching considerations functionality, expressiveness, and aesthetics. These three factors can be applied to any garment with an emphasis in whichever category(s) are most important to the intended end product. The framework has to revolve around the consumer's needs at all stages of the design process. It emphasizes that there should not be a distinction between functional and fashionable clothing; a design could be both without sacrificing the other (Lamb & Kallal, 1992b). Hall and Lobo (2017)'s updated model adds a fourth dimension to make sure functional designs are created to address the needs for accessibility in addition to functional needs, aesthetic requirements, and expressive desires (Hall & Lobo, 2017).

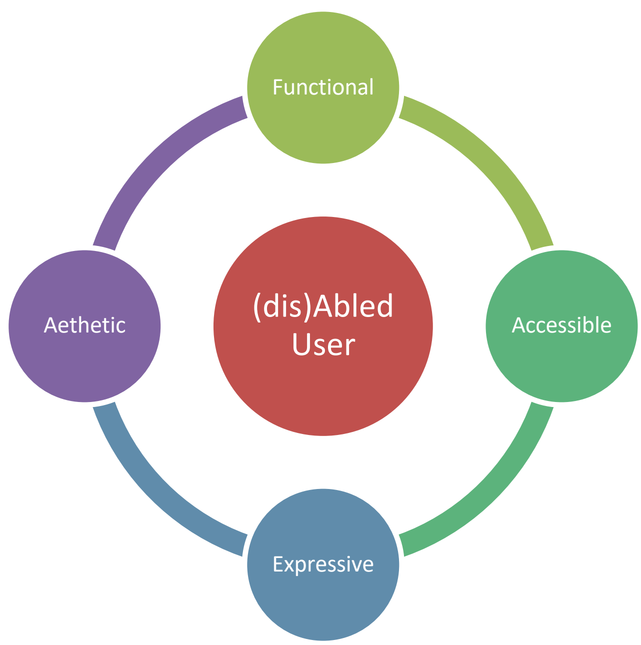


Figure 7: FEA 2.0 (Hall & Lobo, 2017)

Chapter 3

DESIGN AND DEVELOPMENT OF A PEDIATRIC SUPPORT GARMENT: RESEARCH OBJECTIVES AND JUSTIFICATION

AFO braces serve an essential purpose for many individuals, including children, because they help them to reach developmental milestones and participate more fully in life via playing and walking (Klingbeil et al., 2000). Braces also help children's feet and legs develop in an ideal manner (Morris, 2007b). As helpful as they are, users have reported a variety of complaints regarding AFOs some of which include the dislike of design, difficulty in wearing with shoes, decreased muscle development, and hindering participation in physical activities such as soccer. These inherent complaints with available AFO styles commonly lead to problems with adherence. The current medical device design process often leaves the consumer's wants and needs out of the final products; research studies have noted the need for user-centered and interdisciplinary research (De Ana, Umstead, Phillips, & Conner, 2013). When consumers are more directly involved in the development process, a device that maximizes compliance can be created. Lower limb orthotics, such as AFOs, are widely used but are a form of rehabilitation which has not benefitted from much research and innovation of design in recent years (Bapat & Sujatha, 2017).

Based on conversations with a pediatric physical therapist and our participants, many AFO wearers, especially children, will spend some time during the day without their brace on, whether that be to assist muscle development, for comfort purposes, they don't like wearing them, or other reasons. We set out to create an alternative option for kids who utilize AFOs to wear when it is not ideal for wearing an AFO, such as to a formal event, sports, or when having break time from the brace. The alternative we aimed to develop will offer support and stabilization in a soft fabric variety. This device would not be created to take the place of a hard-orthopedic brace, but to act as an alternative to the brace for short periods of use.

This research could give young children who wear braces on a day to day basis an option to more fully participate in a variety of events. If the initial research is promising, the design and development could be expanded on to create a device that could help older children as well as adults. A final goal of this phase of research is to develop a prototype that could be made accessible to users or their families by downloading a digital guide that will be published afterward.

Chapter 4

METHODS

4.1 Participants

For our research, we recruited 3 participants between the ages of 5 and 14 with mild to moderate ankle impairment, who utilize AFOs daily. The participants were given informed consent documentation and explained risks of participating in the research. Our research and procedures fall under Michele Lobo, PT, Ph.D.'s existing University of Delaware's IRB approved research, [704060-5] Clothing Design for Individuals with Adaptive Clothing Needs.

Participant 1 is a very active 4yo boy who wears a pair of hinged AFOs every day. His braces lock at 90 degrees preventing unwanted plantarflexion; dorsiflexion is uninhibited. Every other night he wears Abduction Dorsiflexion Mechanism (ADM) braces while sleeping. He loves sports, motorcycles, and being active. He can walk and run with and without braces, but without his braces, his ankles evert, and he tends to lock his knees. To build up his leg muscles, his parents allow for 1-2 hours every night out of braces; usually, he is barefoot during this time because socks are too slippery for the bare floors in his house. Barefoot can be tough on his feet because they sometimes crack from the abrasion of being in braces all day long. His parents struggled to find shoes for many years that fit his feet and braces; they have found a few adequate sneaker options, but the choices of shoes that will fit are still limited. Pants are also tricky to purchase; the family looks for wide leg styles. He participated in soccer this past season and was very successful according to his parents. He will sometimes get irritation from his braces, but usually, that is because they need adjusting.

Participant 2 is a 3yo girl who wears a pair of traditional AFOs every day. She also wears KAFO braces when she is walking and standing. Without her KAFO's, she is not independently mobile. She also wears hinged AFOs two hours a day to work on ideal foot alignment. She loves all things pink, purple, sparkly, and having to do with princesses or animals. She is enrolled in a dance class and loves it so far, although she is not able to wear tap shoes like other kids because of her AFO braces. Her braces can be awkward to put on correctly, which is a concern for her parents if her pre-school teachers have to take on/take off her braces. The braces "catch on everything," especially the Velcro straps, and rip her parents' clothes. Similarly, to participant 1, her family also has difficulty finding shoes that work with her braces. She wears a lot of leggings and dresses with tights, sometimes dresses and skirts can get stuck in her braces. The participant selected a pink pattern for her braces and her parents try to dress up her sneakers with bows to make them "cute." The bulky nature and uncomfortable material on the inside of the brace are not ideal. She is in braces for 23 hours a day, thus allowed 1 hour per day without them.

Participant 3 is a 13yo girl who wears a hybrid AFO with a dynamic posterior leaf spring AFO in combination with a supra malleolar orthosis (SMO) on her right foot. This combination allows for her to move her ankle and build muscle, which she was unable to do very well in her previous solid ankle AFO. Even with this new brace, she still noted that the braces are bulky and heavy. Like our other participants, she has had a hard time finding shoes to fit her orthosis; she has only found two shoes that will fit her braces in the three years she has had them. She has been able to utilize

Nordstrom's shoe policy which allows for customers to purchase shoes in two different sizes, even with that policy most women's shoes are too narrow; thus she has been purchasing men's shoes. Anytime she leaves the house she wears both parts of her orthotic, when she is at physical therapy, she will only wear her SMO to work her ankle more, and anytime she is at home, she always takes off her braces. Due to her medical condition, she has a limited sensation of temperature and pain in her legs, so she will sometime not realize that her brace is becoming uncomfortable. She can walk without her braces, but sometimes need to hold onto items, like railings, for support. While wearing her brace she finds that maneuvering stairs can be awkward, running to be hard, and she has been avoiding trying to learn how to ride a bike. Gym is part of her school curriculum, and she participates in gym class but with modifications to the side. She expressed an inner conflict about wanted to participate in group sports during gym class but being self-conscious about slowing her team down. She tries not to let her brace affect how she dresses and most often wears leggings or skinny jeans and utilizes all different sock types with her AFOs. While discussing what she would like from an alternative, she expressed an interest in a brace that was discrete in color, as her everyday brace is rainbow colored. She would be excited to have an alternative option for a casual outing like going to the beach or for a school formal, both being occasions that she would want to wear different shoes than her everyday sneakers which would be nearly impossible while wearing her AFOs.

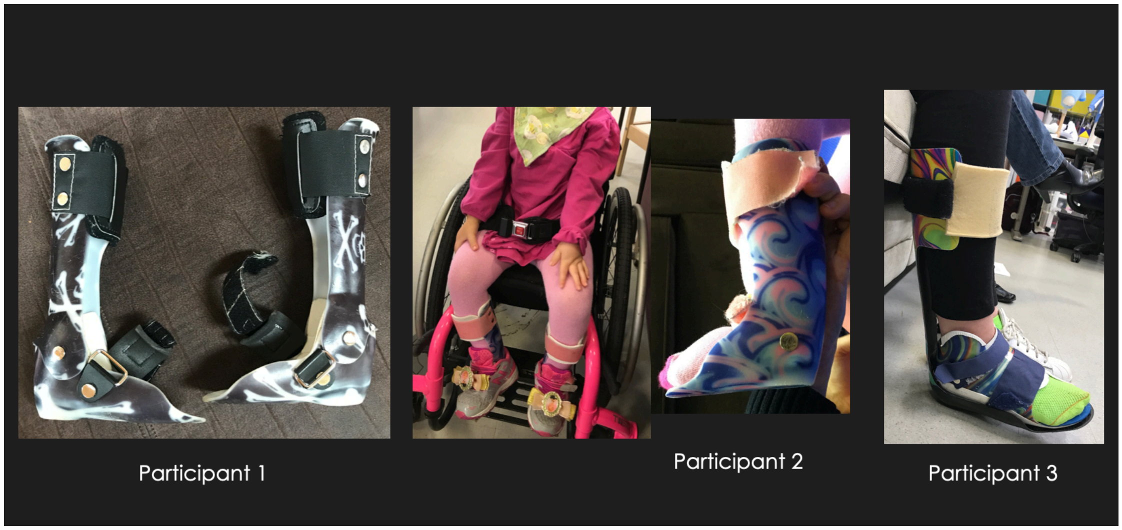


Figure 8: Participant's Daily AFOs

4.1.1 Participant Medical Conditions

Participants 1 and 2 were born with arthrogryposis multiplex congenita (arthrogryposis) and congenial talipus equinovarus (CTEV). Arthrogryposis is a condition that has a range of deformities associated with muscles and joints that affects 1 out of every 3,000/5,100 babies (Eriksson et al., 2015; Morris & Dias, 2007). Before birth, one or more of a child's joints will be fixed in position, which can lead to muscle atrophy (Genetic and Rare Diseases Information Center (GARD), 2015). Children born with arthrogryposis can have a range of conditions from severe to milder. A child's lower extremities are most often affected by the disorder (Eriksson et al., 2015; Eriksson, Villard, & Bartonek, 2014). Early treatment, including physical therapy, bracing, and exercise, is essential to increase the child's range of motion and surgery is often necessary (Eriksson et al., 2014; Genetic and Rare Diseases Information Center (GARD), 2015). Arthrogryposis is not a specific diagnosis but a classification of physical symptoms and is associated with many different conditions

(Genetic and Rare Diseases Information Center (GARD), 2015). AFOs are frequently prescribed medical devices for children with arthrogryposis because clubfoot is very common in children with this diagnosis (Eriksson et al., 2015; Morris & Dias, 2007).

CTEV or clubfoot is a condition that 1 out of every 1000 babies is born with (AAOS, 2014; Morris & Dias, 2007) and can be associated with other conditions, like arthrogryposis, 20% of the time (Desai, Oprescu, DiMeo, & Morcuende, 2010). Several classifications of clubfoot exist and vary in severity (Morris & Dias, 2007). A child with clubfoot will have a foot or feet turned inward; the bottom of their foot can face inward or even upward. Their tendons that connect the leg muscle to the foot bones are too short and tight in places, and this causes the foot to turn inward. Clubfoot does not hurt a child, but if it is not treated, children can experience permanent deformity and not be able to walk typically. Typical treatment involves stretching, casting, bracing, and sometimes Achilles tendon surgery (AAOS, 2014; Morris & Dias, 2007). After the child's foot has been corrected, they will often have to wear braces for the first 3-4 years of life to be sure issues do not reappear (AAOS, 2014). AFOs are typically the orthotic that children with clubfoot will wear, although there is limited research regarding clubfoot and bracing (Manousaki et al., 2016).

Participant 3 experienced a spinal cord stroke 2 years ago when she was 11 years old. A spinal cord stroke or infarction is caused by "thickening or closing of the major arteries to the spinal cord" (National Institute of Neurological Disorders and Stroke, 2019, para. 1). It is a rare medical condition for children to experience (Nance & Golomb, 2007) and can lead to weakness, paralysis, loss of deep tendon reflexes, loss of pain and temperature sensation, and more (National Institute of Neurological Disorders and Stroke, 2019). Treatment is dependent on symptoms, but typically, physical therapy and occupation therapy are necessary treatments for weakness and paralysis. Prognosis varies based on the level of damage to the spinal cord and how quickly treatment was administered as well as follow up with medical support and therapy (Nance & Golomb, 2007; National Institute of Neurological Disorders and Stroke, 2019).

4.2 Procedure

Once recruited in this study, participants had an initial meeting to discuss the challenges that their braces pose. This initial meeting was vital to identify what the participants' needs are and what the participant likes and dislikes regarding orthotics' function, appearance, ease of use, and comfort through recorded loosely structured interviews. The participants filled out a perception survey that combined questions from both QUEST 2.0 and CSD-OPUS. This meeting also provided an opportunity to take necessary body measurements. A participant's body function and structures were assessed to learn more about their range of motion (ROM), muscle tone, muscle strength, and function. The participants' fine motor skills were evaluated using clothing fastener samples.

After the initial meeting, the research team worked to create potential design solutions to meet the needs and desires of the participants. This first step in this involved a review of existing AFO solutions as well as a review of alternative solutions for providing ankle support (reported above in the background). Participants and their families were involved in the design process by providing feedback throughout the prototyping phase. To prepare for the second meeting, researchers combined the users' wants and needs with background research to develop a few prototypes. At the second meeting, the participants tried on the prototypes, provided feedback, and performed some functional tests to evaluate effectiveness. After evaluating the feedback from the second meeting, "final" prototypes were developed for testing, and any necessary adjustments related to fit, comfort, appearance, and function were made. The third meeting was when final prototype testing occurred to assess user satisfaction and functionality of the device. After the third session, the prototypes were left with the participants, so they would be able to wear them for more extended periods to further evaluate durability, effectiveness, and comfort.

4.3 Review of Users' Wants and Needs

To get a comprehensive picture of users' and their caregivers' thoughts, likes, dislikes, and other perceptions, we collected information from a variety of sources including published research, in-person interviews, and online forums.

We included a total of 9 published resources that were both scientific articles and books(Bapat & Sujatha, 2017; Desai et al., 2010; Holtkamp et al., 2015; Morris et al., 2007; O'Reilly et al., 2009; Swinnen et al., 2017, 2018; Swinnen & Kerckhofs, 2015; Van Der Wilk et al., 2018). Terms that were used to find these articles included combinations of these terms: perceptions of AFOs, ankle-foot orthotics, pediatric orthotics, pediatric ankle-foot orthotics. The sources used for this content analysis all reported perceptions of AFOs.

We included 17 online forums that varied in topic, but all discussed AFO use and perceptions of wear. Searches were completed on Google, and terms used included a combination of the following terms: pediatric AFOs, ankle-foot orthotics, AFOs, perception, pediatric, forum, kids. The top 3 pages of search results were included if, after an initial review, the forum discussed AFO perceptions. We only used publicly accessible forums, which were mainly posted in the mid-2000s to mid-2010s; many support groups have gained popularity within private groups on Facebook in the last five years.

The information from our in-person interviews came from transcribing our initial video interviews with our 3 participants.

We reviewed these sources to develop a comprehensive list of terms and perceptions related to AFO use organized by category. Two independent coders reviewed all sources and noted the frequency of each occurrence of each type of concern/comment. Inter-coder reliability was 93.78%.

4.4 Design and Prototyping

Prototype design was guided by the FEA framework (Lamb & Kallal, 1992b), specifically FEA2 (Hall & Lobo, 2017). The constructs of ideal orthotic device design (Table 6) were taken into consideration within the FEA framework to meet the needs related to orthotic design. Prototypes were developed based upon the below FEA model for each participant (Figure 9). The design goal was to create a device that is stable, but also flexible and less bulky so it can fit into a variety of shoes (Bapat & Sujatha, 2017; Van Der Wilk et al., 2018).

Figure 9: FEA 2.0 Model for our Research Goals

4.5 Prototype Testing

4.5.1 Functional Measures

Metrics were utilized to assess how successful the final prototypes were. Final prototype testing involved a repeated functional PT assessment to determine that the device did not restrict movement in an unwanted manner. To characterize their body function and structure, children were assessed once to estimate their range of motion

(ROM) and muscle strength per the International Classification of Functioning, Disability, and Health [ICF, (Rosenbaum & Stewart, 2004)]. We also assessed gross motor performance and functional mobility across 3 conditions: a) barefoot, b) prototype (while wearing our prototype), and c) AFO (while using an AFO).

To perform the clinical measurement of range of motion (ROM), a mechanical goniometer was used, and accepted values were considered as described by Reese and Bandy (2010). ROM is dependent on two components, joint ROM and muscle length. Joint ROM is the motion available at any single joint, and it is influenced by the bony structure, ligaments, and joint capsules. Muscle length refers to the ability of a muscle to be lengthened across the joint (Reese & Bandy, 2016). For this assessment, the lower limb's joint angles considered were: hip flexion, hip abduction, knee flexion, and ankle flexion.

Muscle strength was assessed with measurements performed manually according to the D&W Manual Muscle Testing (MMT) protocol (Avers, Brown, Hislop, & Daniels, 2018). This assessment is graded on a six-point scale, where 0 signifies no muscle contraction and 5 means the person actively moved through a full range of motion against high resistance. This measurement had been used in children with neuromuscular disease (Kaya, Alemdaroğlu, Yılmaz, Karaduman, & Topaloğlu, 2015), spina bifida (Tan, Thomas, & Johnston, 2017) and Duchenne muscular dystrophy (Bozgeyik, Alemdaroğlu, Bulut, Yılmaz, & Karaduman, 2017). For muscle strength, the movements tested were grouped and averaged by their corresponding movements: hip flexion, hip extension, hip abduction and hip adduction; knee flexion and knee extension; and ankle dorsiflexion and plantar flexion.

Gross Motor Function was assessed by the Gross Motor Function Measure (GMFM-88), which is an assessment tool designed and evaluated to measure the change in gross motor function over time or with intervention in children with cerebral palsy (D. J. Russell, Rosenbaum, Wright, & Avery, 2013). The GMFM-88 is the original 88-item measure, and it has also been validated for use with other populations, such as children with Down syndrome, osteogenesis imperfecta, or lymphoblastic leukemia (D. Russell et al., 1998). Test items are divided into 5 dimensions; A: lying and rolling, B: sitting; C: crawling and kneeling, D: standing, and E: walking, running, and jumping. This assessment is graded on a four-point scale for each item: 0 = does not initiate, 1 = initiates, 2 = partially completes, and 3 = completes (D. J. Russell et al., 2013). Scores for this assessment are shown as percentages that represent ratios of the child's score to the total possible score within each dimension [(Performed raw score/ Total raw score)*100] and across all dimensions [(%A+ %B + %C+ %D+ %E)/ 5]. GMFM-88 scores were calculated for each condition (barefoot, AFO, and prototype) for each child.

To characterize functional mobility, participants were asked to perform two tests: Time Up & Go test [TUG, (Podsiadlo & Richardson, 1991)] and 10-meter walk test [10MWT, (Wade, 1992)] in the three conditions (barefoot, prototype and AFO). Each condition was repeated 2-3 times. These tests are simple to administer, low cost, and user-friendly (Chrysagis, Skordilis, & Koutsouki, 2014). The TUG is a functional mobility test that measures, in seconds, the time required for an individual to stand up from a standard chair, walk 3m, turn around, walk back to the chair, and sit down again (Podsiadlo & Richardson, 1991). It has been widely used in clinical practice as an outcome measure to evaluate functional mobility, fall risk, and dynamic balance in elderly populations and adults with motor impairment (Bohannon, 2006). Because of its practicality, the TUG has begun to be used in children and adolescents, especially those with motor and/or balance impairments (Gan, Tung, Tang, & Wang, 2008; Katz-Leurer, Rotem, Lewitus, Keren, & Meyer, 2008; Williams, Carroll, Reddihough, Phillips, & Galea, 2005).

Participants were asked to stand up from a seat, walk, and touch the hand of the examiner, then come back to sit down in the three conditions (barefoot, prototype, and AFO). A seat without arms was selected from the child's environment. The seat height was chosen so the child's knee angle was 90° (± 10°) flexion with feet flat on the floor. The instructions were "to walk as fast as you can." The timer was started as the child left the seat, rather than on the instruction 'go,' and stopped when the child's bottom touched the seat, in order to measure movement time only. A stopwatch was used to measure the time in seconds.

The 10MWT is a functional test that measures gait speed. It has demonstrated high test-retest reliability (Wade, 1992) and high correlation with gross motor function showing it to be a valid functional assessment for children with CP (Chrysagis et al., 2014; Drouin, Malouin, Richards, & Marcoux, 1996; Yun, Kim, & Kim, 2016)

Participants were asked to walk on a mat with a grid without assistance 10 meters (32.8 feet), and a stopwatch measured the time for the intermediate 6 meters (19.7 feet). Timing started when the toes of the leading foot crossed the 2-meter mark and timing stopped when the toes of the leading foot crossed the 8-meter mark. Participants were asked to perform two trials, at their preferred walking speed (Self-Selected velocity) and fastest speed possible (Fast-Velocity) in the three conditions (barefoot, prototype, and AFO). Self-Selected velocity and Fast-Velocity were calculated by dividing 6 by seconds for each trial and reported as meters per seconds (m/s).

Cadence, step length, and stride length were estimated using the Kinovea® software. This free, open-source tool allows for the measurement of distance and time, tracking of joint position, and calculation of segment and joint angles from video recordings of movement in a natural setting (Baude, Hutin, & Gracies, 2015; Littrell, Chang, & Selgrade, 2018). The mat with the grid was used to calibrate the measures into the Kinovea® software. The grid mat was divided into 15 centimeter (cm) squares with 5 cm markers within each square.

Cadence was estimated as the number of steps per minute (rate at which a person walks) expressed in steps per minute; step length was measured as the distance between the point of heel contact of one foot and that of the other foot (in cm). Stride length was estimated as the distance between successive points of contact of the heel of the same foot (≅2 x step length, in cm).

Joint angles at the ankle were identified from the video frames while performing the 10MWT. One camera was positioned perpendicularly to the side of the participant to record movements in the sagittal plane. The camera remained stationary while the participant moved. The initial stance phase of gait was identified as the moment of heel strike to allow us to assess the amount of dorsiflexion movement. The joint angles were assessed from videos by one coder (a pediatric PT) using the Angles Video Goniometer© app (Angles© app). The Angles Video Goniometer© app (Angles© app) was developed to serve as an inexpensive and user-friendly goniometric tool to measure joint angles from a video of functional activity across a variety of environments (Cunha et al., 2019). The anatomical landmarks to estimate the ankle's angle in the sagittal plane were identified from the video and marked in the Angles© app. Landmarks were the lateral condyle of the tibia, the lateral malleolus, and the fifth metatarsal bone.

For all measures, descriptive analysis (Mean ± SD, percentage) was used to describe the participants' performance and to compare differences among the 3 conditions (barefoot, prototype, and AFO).

4.5.2 Perception of Device

A survey and questionnaire evaluated the perception of their AFO and our prototype. The survey included a combination of open-ended responses, Likert scale questions, and rank order questions. Perception of the soft AFO alternative was assessed via a questionnaire that was created by combining measures from QUEST 2.0 and CSD-OPUS. Each measure was evaluated on a 5-point Likert scale with 1 meaning not satisfied at all and 5 being very satisfied. This was used to help identify if and how the prototype offers support to the participants and their perception of the device's characteristics. Each participant filled out a perception questionnaire for their existing AFO and our prototype. For all measures, descriptive analysis (Mean and SD) was used to describe the participants' characteristics and differences among the 2 conditions (prototype and AFO).

4.5.3 Prototype Testing Metrics

Essential metrics for success were identified, and means of measuring each was laid out in a metrics chart. Table 4 outlines the parameters, what user need is addressed (according to the FEA model), our target outcome, and our assessment method. For measures that had repeated trials, such as weight and ankle angles, non-parametric statistical analysis was used to evaluate the significance of results.

Table 4: Prototype Testing Metrics

Metric	User Needs	Target Outcome	Assessment Method
Flexion ability	Functional	Prototype doesn't limit dorsiflexion, limits plantar flexion to 10-20 degrees	Functional assessment
Prototype doesn't limit other functions	Functional	No limitations any other functions according to the PT assessment	D&W MMT protocol and GMFM-88 PT assessments
Stride Length	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment
Step Length	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment
Gait Speed	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment
Cadence	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment
Weight of prototype	Functional	< AFO weight	Weight of prototype on balance
Adjustable fit	Functional	Able to adjust the prototype to fit the user	The user is able to adjust the prototype to fit.
Safety	Functional	Comply with childrenswear safety standards	Visual inspection of the final prototype and research on the safety of all materials.
Comfort	Functional	User able to wear the garment without expressing emotional signs of discomfort or showing physical signs of skin irritation	Emotional affect of the child was assessed throughout the testing based on facial expression and vocalizations. Skin irritation was assessed by visual inspection of the skin after a 1-hour period of wear.
Ease of donning/doffing	Functional	<5 minutes	The parent was timed donning and doffing the garment for the first time without any instruction.
Washable	Functional	Able to wash prototype	Wash the prototype either by hand or in a machine
Product Appeal	Aesthetic	User/family satisfaction with design; positive or neutral ratings for aesthetics	User rating of aesthetic appeal on a scale from 1 (low)–5 (high).
Sleekness	Aesthetic	Maximum protrusion of the components of the garment no more than 1 cm from the child's body	Identify the location with the highest level of component protrusion of the garment and measure the perpendicular distance to the child's body using a tape measure.
Quality construction	Aesthetic	Typical wear and care should cause no damage or distortion	Visual inspection of the garment after 1 hour of wear and after washing.

Social psychological comfort	Expressive	Matches users' needs for discretion or attention based on users' early input on design preferences	User-written feedback on perception survey.
Allow for a variety of footwear	Expressive	Users are able to wear shoes other than sneakers (i.e., dance shoes, soccer cleats)	Have users try on shoes with the prototype.
Cost	Accessibility	<$100.00 in material cost per until	Sum of final material cost
Availability	Accessibility	Solution that lends itself to the creation of an open-access DIY material list and fabrication guide	Compilation of a complete material list and step-by-step illustrated DIY fabrication manual.

Chapter 5

RESULTS

5.1 Summary of Users' Wants and Needs

See Table 6 for a summary of the medical concerns, functional concerns, general device problems, aesthetic concerns, psychological concerns, and suggestions for alternative solutions.

Table 5 has a summary of all coded perceptions from the sources reviewed, and Figure 10 shows the top 10 perceptions mentioned throughout the source material. The top perception mentioned is that finding shoes was difficult in reference to wearing AFOs (N = 18). The next most frequently mentioned opinion was that the AFOs were painful (N= 13), followed by an opinion that AFOs were cosmetically unacceptable or unattractive (N = 12) and that they were hot/need better moisture control (N = 12).

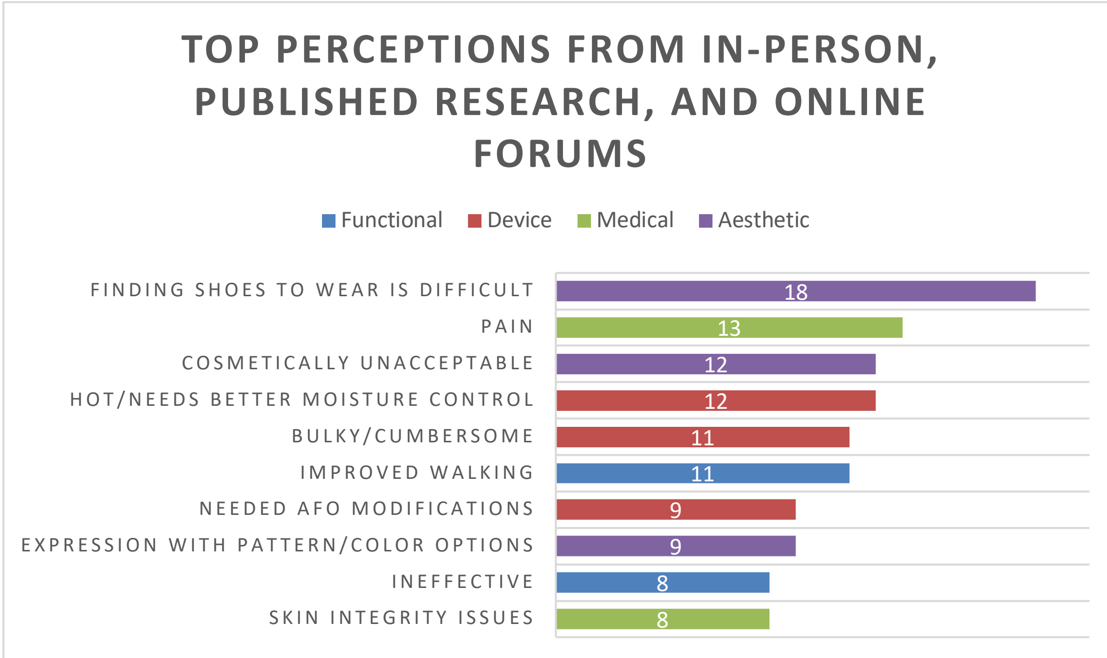


Figure 10: Top Perceptions from In-person, Published Research, and Online Forums

Medical concerns for patients who wore AFOs included irritation from AFO use, such as sores, redness, and pain from wear. Problems associated with the function of the device varied, but many people reported concerns with or believed that AFOs weakened calf muscle development, and users thought the braces hindered movement (Swinnen & Kerckhofs, 2015). Wanting the option to wear or not to wear AFOs for sports and special occasions was also discussed online (Wheely1996, 2016). Users noted the cumbersome nature of AFOs, such that they were heavy, did not fit well, damaged shoes and clothing, and adjustability was burdensome.

The published research found that most concerns were related to the device itself; such as the cumbersome nature, lack of adjustability, and being uncomfortable. On the contrary, forum posts related to the aesthetics of AFOs were most common when compared to other types of discussions. Overwhelmingly the public used online forums to discuss how wearing AFO made it extremely difficult to find shoes to wear, and how that limited the types of footwear they could use, thus limiting their personal expression (3pookies, 2006; Bunsmom, 2006; Dunooncampbell, 2010; GAMZu, 2011; Jbell2435, 2011; Jr0819, 2015; Noah, 2014; Suzannah, 2014; Swann, 2010; Whitehume, 2013). It was commonly reported that the design of AFOs was unacceptable and not aesthetically pleasing. Online forums were also a place where users could ask and give suggestions about alternatives to AFOs after discussing their dissatisfaction; some alternatives mentioned were various forms of taping such as Kinesio taping, off the shelf bracing, as well as boots and high-top sneakers to provide added support.

Table 5: Summary of User Perception Coding

Total	Perception	Category
18	Finding shoes to wear is difficult	Aesthetic
13	Pain	Medical
12	Hot/needs better moisture control	Device
12	Cosmetically unacceptable	Aesthetic
11	Bulky/cumbersome	Device
11	Improved walking	Functional
9	Needed AFO modifications	Device
9	Expression with pattern/color options	Aesthetic
8	Skin Integrity issues	Medical
8	Ineffective	Functional
8	Donning/doffing is hard	Device
8	Uncomfortable	Device
7	Hinder movement or negatively altered mobility	Functional
7	Muscles weakened	Medical
7	Damaged shoes/clothes	Device
7	Difficulty or not wanting to wear dresses, skirts, shorts	Aesthetic
6	Heavy	Device
6	Fit problems	Device
6	Helped wobbliness/balance	Functional
5	Want to wear something else besides an AFO different activities	Functional
5	Changes gait	Functional
4	Pressure sores	Medical
4	Changes in physiology	Medical
4	Durability	Device
4	Comfortable	Device
4	Not fitting in with peers because of orthotic	Psychological

4	Not interested in wearing	Psychological
3	Pinching or nipping	Medical
3	Fatigue from wearing	Medical
3	Driving a car is difficult	Functional
3	Keeps foot in right position	Functional
3	Expensive	Device
3	Rigid or not flexible materials	Device
3	Outgrow braces quickly/need new braces often	Device
3	Concern for safety	Device
3	Uses brace covers	Aesthetic
3	Parental concerns about development	Psychological
3	Blue rocker alternative	Alternative
3	Graphite model alternative	Alternative
3	Using stairs is difficult	Functional
3	Difficult to wear with pants	Aesthetic
3	High top sneakers used as an alternative	Alternative
2	Delivery and maintenance of orthotic is not ideal	Device
2	Brace has a lack of adjustability	Device
2	Not ready to accept	Psychological
2	Kinesio taping as an alternative	Alternative
2	Blisters	Medical
2	Use to avoid surgery	Functional
2	Slipping of the foot inside the brace	Device
2	Brace is slippery without shoes	Device
2	Dissatisfaction in lack of involvement in design process	Device
2	"Function over fashion"	Aesthetic
2	Lyrica splints as an alternative	Alternative
2	Figure 8/U strapping as an alternative	Alternative
2	Prefer Metal braces as an alternative to plastic AFOs	Alternative
2	Skate shoes as an alternative	Alternative
1	Bunions	Medical
1	Inflammation	Medical
1	Odor problems	Device
1	Sports bandages as an alternative	Alternative
1	SAFO as an alternative brace	Alternative
1	Noodle AFO as an alternative brace	Alternative
1	Chafing	Medical
1	Skin cracking	Medical
1	Difficult to use the bathroom	Device

Table 6: Summary of User Satisfaction from Online Forums, Published Research, and In-person Interviews

	Online	Published	In-Person
Medical	Pressure sores on top of feet (Adedo, 2013; Dreamwalkr949, 2012)	Chaffing (Bapat & Sujatha, 2017; Swinnen & Kerckhofs, 2015)	Feet will crack from wearing braces all day (Participant 1)
	Painful(Dreamwalkr949, 2012; Jr0819, 2015; SRS, 2014)	Pain (Bapat & Sujatha, 2017; Swinnen et al., 2018; Swinnen & Kerckhofs, 2015)	Skin can become irritated (Participant 1) (Participant 3)
	Pinching behind knees (Dreamwalkr949, 2012; JDWilson, 2010)	Pinching behind knees(O'Reilly et al., 2009)	

	Online	Published	In-Person
	Blisters (Dreamwalkr949, 2012; SRS, 2014)	AFO induced inflammation (Holtkamp et al., 2015)	
	Rubbing and red marks (Noah, 2014; SRS, 2014)	Rubbing (Morris et al., 2007; O'Reilly et al., 2009)	Rubbing if wears nighttime brace every night (Participant 1)
	Bunions (JDWilson, 2010)	Soreness (Morris et al., 2007)	
Function	Muscles weakened with AFO (Adedo, 2013; Jr0819, 2015; Noah, 2014)	Ineffective (Holtkamp et al., 2015; Swinnen et al., 2018)	Concerned about muscle weakness, goes without AFOs for 1-2 hours (Participant 1)
	Braces hinder movement (Adedo, 2013)	Failed to improve mobility (Swinnen & Kerckhofs, 2015)	Likes to walk without braces at night, gets tired of wearing braces all day (Participant 1) (Participant 3)
	Changes gait (Dunooncampbell, 2010)	Can manage without them (Swinnen & Kerckhofs, 2015)	Stairs are difficult (Participant 1) (Participant 3)
	Teenager wanting to stop wearing AFOS for "basketball training, games and other special occasions" (Wheely1996, 2016)	Difficult to Use (Holtkamp et al., 2015; O'Reilly et al., 2009; Swinnen et al., 2017, 2018)	Braces keep foot in right position (Participant 1) (Participant 2)
	AFO gives freedom to walk again (Whitehume, 2013)	Improved walking (Van Der Wilk et al., 2018)	Braces avoid surgeries (Participant 1)
	Helped wobbliness (BearHugz, 2008)	Driving a car is difficult (Van Der Wilk et al., 2018)	Muscle weakness with braces (Participant 3)
		Walking up and down stairs is difficult (Van Der Wilk et al., 2018)	Running is difficult (Participant 3)
		Weakened muscles with AFO use (Desai et al., 2010)	Modifications needed during gym (Participant 3)
Device	AFOs slipping up and down (Adedo, 2013)	Brace tends to slip down (Swinnen & Kerckhofs, 2015)	AFOs slippery without shoes (Participant 1)
	Costly (Dreamwalkr949, 2012)	Process of delivery and maintenance (Bapat & Sujatha, 2017; Holtkamp et al., 2015; Swinnen et al., 2017)	Treads on the bottom of nighttime AFOS help with traction (Participant 1)
	Heavy (Swann, 2010)	Too heavy (Holtkamp et al., 2015; Swinnen et al., 2018; Swinnen & Kerckhofs, 2015)	Heavy (Participant 1) (Participant 3)
	Rigid (Swann, 2010)	Materials (Holtkamp et al., 2015; Swinnen et al., 2018)	Velcro snags clothing (Participant 1) (Participant 2)
	Damages shoes (Swann, 2010; Whitehume, 2013)	Damages clothes (Holtkamp et al., 2015)	Child can take braces off, but not put them on (Participant 1)
	Not fitting correctly (JDWilson, 2010; Noah, 2014)	Poor fit (Holtkamp et al., 2015; Swinnen & Kerckhofs, 2015)	Multiple adjustment needed before the may fit properly/comfortable (Participant 1) (Participant 2)
	Kids outgrow them in 6-9 months (3pookies, 2006)	Adjustability (Holtkamp et al., 2015)	1-2 braces per year (Participant 1) (Participant 2)
	Bulky(Suzannah, 2014; Whitehume, 2013)	Cumbersome (Holtkamp et al., 2015; Swinnen et al., 2018; Swinnen & Kerckhofs, 2015)	Bulky (Participant 1) (Participant 2) (Participant 3)
	Uncomfortable, (SRS, 2014)	Uncomfortable (Holtkamp et al., 2015; Morris et al., 2007;	Uncomfortable if not fitting properly (Participant 1)

	Online	Published	In-Person
		Swinnen et al., 2017, 2018)	uncomfortable (Participant 3)
	Can make feet very hot (Jbell2435, 2011; Noah, 2014)	Device needs better moisture control (Bapat & Sujatha, 2017; Holtkamp et al., 2015)	Can make feet very hot during the summer (Participant 1)
		Lack of involvement in the design process (Holtkamp et al., 2015)	Odor (Participant 1)
		Durability (Holtkamp et al., 2015; Swinnen et al., 2017; Van Der Wilk et al., 2018)	Difficult to put on (Participant 2)
		Safety (Bapat & Sujatha, 2017; Holtkamp et al., 2015; Swinnen et al., 2018)	Material inside of brace is uncomfortable (Participant 2)
		Hot in the summer (O'Reilly et al., 2009)	Difficult to use the bathroom in braces (Participant 2)
			Braces should be flexible at the ankle (Participant 3)
			Difficult to adjust (Participant 3)
			Can't wash braces (Participant 2)
Aesthetic	Finding shoes to wear with AFOs is challenging (3pookies, 2006; Bunsmom, 2006; Dunooncampbell, 2010; GAMZu, 2011; Jbell2435, 2011; Jr0819, 2015; Noah, 2014; Suzannah, 2014; Swann, 2010; Whitehume, 2013)	Difficult for find shoes (Bapat & Sujatha, 2017; O'Reilly et al., 2009; Swinnen et al., 2018; Swinnen & Kerckhofs, 2015; Van Der Wilk et al., 2018)	Struggled finding shoes (Participant 2) (Participant 1) (Participant 3) Can't fit into soccer cleats (Participant 1) Can't wear dance shoes like other kids (Participant 2)
	Uses Lyrca Covers/lack of availability (Metronycguy, 2009)	Finish (Holtkamp et al., 2015)	Pants get damaged (Participant 1)
	Have to wear shoes that lace up or have a strap across (Dunooncampbell, 2010)	Design (Holtkamp et al., 2015)	Child picked out patter/color (Participant 1) (Participant 2) (Participant 3)
	"function over fashion" (Dunooncampbell, 2010; Whitehume, 2013)	Color Options (Holtkamp et al., 2015)	Socks damaged often (Participant 1) (Participant 2)
			Difficulty fitting into soccer shin guards (Participant 1)
	Ugly (Whitehume, 2013)	Cosmetically unacceptable (O'Reilly et al., 2009; Swinnen et al., 2017, 2018; Swinnen & Kerckhofs, 2015)	Would like something more fashionable/ less intimidating (Participant 2)
	Difficult to wear with fitted pants (Whitehume, 2013)		Finding pants that work with orthotics is difficult (Participant 1)
	Looks awful with a dress (Whitehume, 2013)		Skirts can get stuck (Participant 2)
	Won't wear with dress shoes (BearHugz, 2008; GAMZu, 2011; SRS, 2014)		Can't wear cute shoes (Participant 2) Wants to wear other shoes than her everyday (Participant 3)
			Not designed with users' needs in mind (Participant 3)

	Online	Published	In-Person
			Prefer a discrete brace for special occasions (Participant 3) Green for an expressive version (Participant 3)
Psychological		Not ready to accept them (Swinnen & Kerckhofs, 2015)	
		Parents worry their child won't fit in with peers(O'Reilly et al., 2009)	
		Not interested in wearing them (Swinnen & Kerckhofs, 2015)	
Alternatives	Kinesio Taping (Adedo, 2013; Marieangela, 2010; Mark5701, 2013)		Taping (Participant 1) (Participant 2)
	Coban wrap (Adedo, 2013)		Stretching (Participant 1) (Participant 2)
	SMOs (Adedo, 2013)		
	Theratogs (Adedo, 2013)		
	High top sneaker (Adedo, 2013)		
	Old Ski Boot (Mark5701, 2013)		
	Allard Blue Rocker (Dreamwalkr949, 2012)		
	SAFO (Silicone Ankle Foot Orthoses) (Swann, 2010)		
	Ankle brace (Metronycguy, 2009)		
	Arizona Brace (Dunooncampbell, 2010)		

5.2 Initial Patient Interviews

Participant preferences were identified by an assistive device questionnaire and a loosely structured interview format. Results of the questionnaire indicated that our participants and/or their families were most dissatisfied with the dimensions (size, height, length), weight, ease of adjusting, comfort, and ease of use (donning, doffing) of their AFOs. Other insights gained from our interview indicated that our participants struggled with the bulkiness of their braces compared to their size, especially for participants 1 and 2. Summer also proved to be a challenging time of year for them because of sweat from having to wear socks under their AFOs and their lack of breathability. Buying shoes to fit AFOs were again brought up as a significant challenge for their families, both shoes for everyday wear as well as special occasion shoes and activity-specific footwear such as tap shoes, formal shoes, and soccer cleats. The participants' parents reported that the AFOs damaged clothing of both the parent and the child, as well as socks frequently. All participants took advantage of the expressive options of the AFO design process; participant 1 selected a blue/black camo pattern, participant 2 picked a swirly pink/purple pattern, and participant 3 selected a rainbow pattern. Participants or their caregivers were asked to rank the importance of 5 aspects (function, appearance, ease of use, comfort, cost) related to their brace(s) with 1 being the most important, participants 1 and 2 rated that function was most important followed by comfort as second. Appearance and ease of use differed for each participant (appearance: P1 = 5, P3 = 3, ease of use: P1 = 3 P3 = 5) while both participants rated cost as 4. An overarching theme that came from these interviews was that AFOs are not designed with users' needs and wants in mind.

Figure 11: Initial Interview from Participants – Dissatisfaction with AFOs

5.3 Physical Therapy Characteristics

Two children with arthrogryposis [1 male (4 yo), 1 female (3yo) and one child post-stroke (1 female, 13 yo) were assessed using different tools by a pediatric physical therapist. Sample characteristics are presented in

Table 7 (starred values were considered as "limited/impaired"). In general, the three children showed limited ROM and muscle strength of the lower limbs, especially for the ankle joint.

Table 7: Participants' Characteristics of Body Function and Structure.

		Participant 1	**Participant 2**	**Participant 3**
		Body Function and Structures		
ROM	*Hip flexion*	90.0º/90.0 º	125.0º/125.0º	125.0º/125.0º
	Hip abduction	45.0º/45.0º	50.0º/50.0º	45.0º/45.0º
	Knee flexion	25.0º/45.0º *	110.0º/130.0º	140.0º/140.0º
	Ankle dorsiflexion	10.0º/5.0º *	5.0º/5.0º *	10.0º/15.0º *
MMT	*Hip flexion*	4.0/4.0	2.0/2.0*	5.0/5.0
	Hip extension	4.0/4.0	2.0/2.0*	5.0/5.0
	Hip abduction	3.0/3.0	2.0/2.0*	5.0/5.0
	Hip adduction	3.0/3.0	1.0/1.0*	5.0/5.0
	Knee flexion	0.0/0.0	1.0/1.0*	5.0/5.0
	Knee extension	1.0/1.0	1.0/1.0*	5.0/5.0
	Ankle dorsiflexion	1.0/1.0	0.0/0.0*	2.0/5.0*
	Ankle plantar flexion	2.0/2.0*	1.0/1.0*	5.0/5.0
Age		4 y	3 y	13 y
Gender		Male	Female	Female
Diagnosis		Arthrogryposis	Stroke	Arthrogryposis

ROM: range of motion assessment; MS: muscle strength assessment.
Values reported as right/left
* Values considered as "limitation/ impairment"

5.4 Design and Development of Prototypes

Initial designs were inspired by existing off the shelf braces, research about how AFOs work, and insight from our participants and review of users' needs and wants. Performance fabrics were sourced and evaluated by our team and participants. Original fabric ideas included power net, varieties of spacer fabric, various weights of neoprene, and four-way stretch medium weight and heavyweight Ponte de Roma. The initial design was inspired by a figure 8 wrapping sports tape technique (Figure 12) with additional design options that wrapped in different ways or laced up. Materials for stabilization were corset boning and feeler gauges. Once the boning and feeler gauges were cut, the edges were sharp; to make them safe for participants, the edges were dipped in Plasti Dip® (Plasti Dip Multi Purpose 11.5oz container) which coated them securely. Initial prototypes were evaluated by our participants and led to final iterations for each participant.

Figure 12: Figure 8 Wrapping Technique

The final designs were created from 5mm neoprene (Seattle Fabrics, part number: N5FT-BLACK), heavyweight 4-way stretch Ponte de Roma in various colors (Spandex World Inc., product ID: 14502), knit interfacing for fabric stability (Pellon® SK135 Sheer-Knit™), as well as corset boning (Bias Bespoke, 1/4" Wide Spiral Steel Corset Boning), and .02mm feeler gauges (TBI®, Brass Feeler Gage Strips, Item number: BF-2) were included for lateral support. We created two different base designs, one with an elastic figure 8 wrap functionality (elastic – Dritz®, 1.5 inch Soft Waistband Elastic, item number: 9577B) and another that laced up (laces – Derby Lace ®, Solid Black Waxed Roller Derby Skate Lace, SKU: DLW72-SOLID-BLACK). Both braces incorporated tunnels for corset wire and feeler gauges. The colors and design of the braces varied for each child. Participant 1's braces were lime green fabric with black elastic; participant 2's braces had bright pink fabric, pink elastic, and flower appliques; and participant 3's brace was made with black fabric and black elastic.

Participant 1 and 3 received both designs. Participant 2 received the wrap design only (photos are of the front and back of wrap prototype).

Figure 13: Prototype Designs

Figure 14: Lateral Stays Covered in PlastiDip

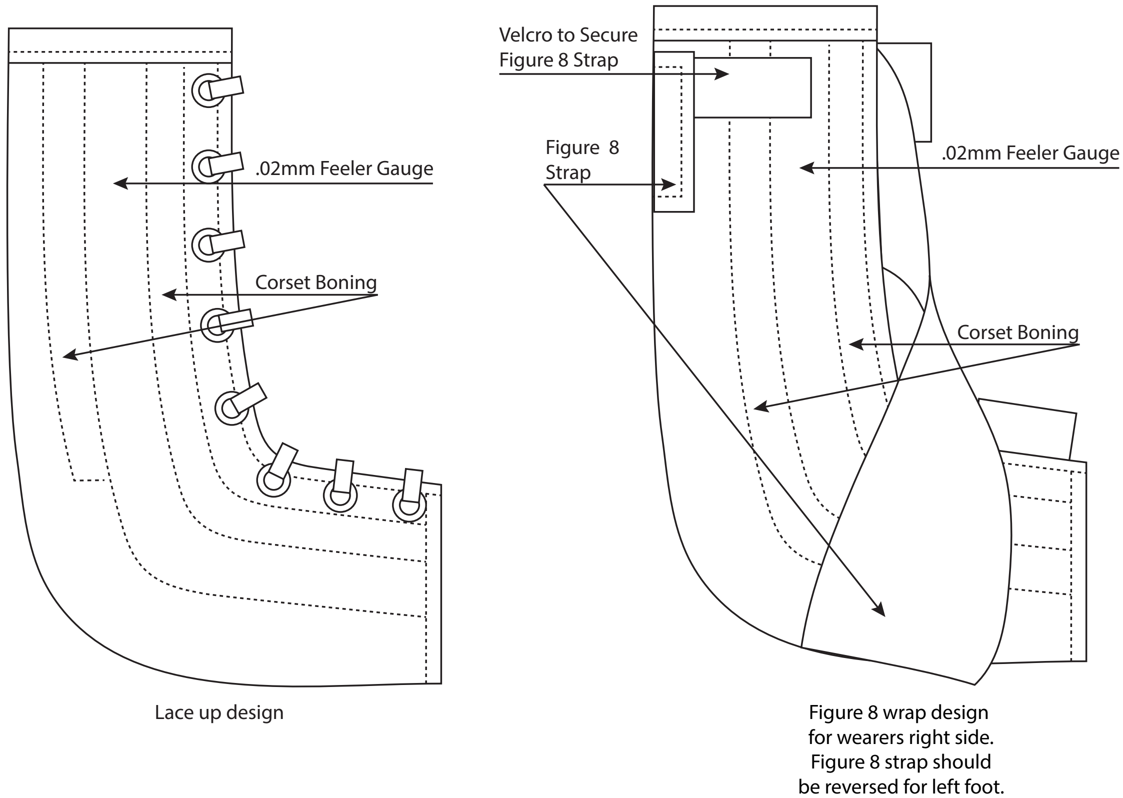


Figure 15: Technical Sketch of Prototypes

5.5 Prototype Testing

Final prototypes were tested in various ways with two of our participants (participants 1 and 3) to evaluate how well they addressed users' wants and needs, as well as functional requirements. Due to a geographic difference between the researchers and participant 2, we were unable to complete all aspects of prototype testing with her. Results derived from the perception questionnaires, functional assessment, and product testing/research are reported in the metric outcomes Table 11 below. Results reported are averages from both prototypes because they performed similarly.

5.5.1 Gross Motor Performance

Participant 2 had a lower score of gross motor performance compared to Participants 1 and 3. In relation to the differences among the three conditions, Participant 3 had better gross motor performance (D and E dimensions, and the total score) while wearing the prototype and AFO than without any support. Neither the AFO nor the soft support garment limited function.

Table 8: Gross Motor performance across the three conditions: barefoot, prototype and AFO (percentage).

Gross Motor Performance				
		Participant 1	*Participant 2*	*Participant 3*
GMFM-88	*A: Lying and Rolling*	100%	94.20%	100%
	B: Sitting	100%	81.7 %	100%
	C: Crawling and Kneeling	38.1%*	0%*	100%
	D: Standing	76.90%	0%*	92.30%
	E: Walking, Running, and Jumping	44.4%*	0%*	79.20%
	Total	71.88%	35.2%*	94.30%
GMFM-88 (AFO)	*A: Lying and Rolling*	100%	94.20%	100%
	B: Sitting	100%	81.7 %	100%
	C: Crawling and Kneeling	38.1%*	0%*	100%
	D: Standing	76.90%	2.6%*	94.80%
	E: Walking, Running, and Jumping	44.4%*	0%*	84.70%
	Total	71.88%	35.7%*	95.90%
GMFM-88 (Prototype)	*A: Lying and Rolling*	100%	94.20%	100%
	B: Sitting	100%	81.7 %	100%
	C: Crawling and Kneeling	38.1%*	0%*	100%
	D: Standing	76.90%	0%*	94.80%
	E: Walking, Running, and Jumping	44.4%*	0%*	83.30%
	Total	71.88%	35.2%*	95.60%

GMFM-88: Gross Motor Function Measure

* Values considered as “limitation/ impairment

5.5.2 Gait analysis

Functional mobility and gait results are presented in Table 9 and

Table 10. Across all of the gait tests, differences among conditions were either too small to be clinically meaningful or favored use of one of the support devices (AFO and/or support garment). Some differences may be large enough to note. For instance, Participant 1 had a higher self-selected velocity with the support garment but a lower selected fast velocity with the support garment and AFO relative to the barefoot condition. It is important to note, however, that the movement and weight-bearing patterns Participant 1 exhibited when moving quickly in the barefoot condition would be likely to lead to future secondary musculoskeletal impairments and pain; hence, the need for ankle support devices.

Although step and stride lengths were smaller for the support garment and AFO conditions, Participant 1 had a higher number of steps per minute while using his AFO and the support garment. There were no differences among conditions for cadence for Participant 3. It may be that more differences in function and gait were observed for Participant 1 compared to Participant 3 because Participant 1 has impairments bilaterally, while Participant 3 has one typically functioning side of her body. In terms of ROM at the ankle, condition (barefoot, AFO, prototype) was shown to affect the initial contact ankle angle significantly, $H(2)=11.146$, $p=.004$ (Figure 16) Pairwise comparisons with adjusted p-values showed that there were no significant differences between the initial contact angles for participants wearing their AFO and the prototype ($p=1.000$, $r=.253$) or between participants wearing the prototype and barefoot condition ($p=.053$, $r=.604$). There were significant differences in initial contact angle between the participants wearing their AFO and the barefoot condition ($p=.003$, $r=.831$). More dorsiflexion was observed at initial contact (heel strike) for the left foot for Participant 1 (but not for the right foot) and for the right foot for Participant 3 (N/A on the other, unaffected foot) with both the support garment and AFO. The support garment and AFO performed similarly. We are unsure why similar effects were not observed on the right side for Participant 1 with either the support garment or the AFO. However, these results suggest that both the support garment and AFO have the potential to provide stability for dorsiflexion during gait.

Table 9: Gait performance during three conditions: barefoot, prototype and AFO.

Functional Mobility			
		Participant 1	**Participant 3**
TUG (Barefoot)		8.5s	9s
TUG (AFO)		9.3s	8.9s
TUG (Prototype)		10.2s	9.3s
10MWT (barefoot)	*Average Self selected*	1.3 m/s	1.5m/s
	Average Fast-Velocity	2.5 m/s	2m/s
10MWT(AFO)	*Average Self selected*	1.5 m/s	1.4m/s
	Average Fast-Velocity	1.7 m/s	1.8m/s
10MWT (Prototype)	*Average Self selected*	1.7 m/s	1.5m/s
	Average Fast-Velocity	2 m/s	1.8m/s
Gait Parameters			
Cadence (barefoot)	*Steps/min*	67.5	66
Cadence (AFO)	*Steps/min*	95	67
Cadence (Prototype)	*Steps/min*	81	67
Step length (barefoot)		51.6 cm ± 1.6	65.6 cm ± 3.2
Step length (AFO)		46.9 cm ± 3.2	55.3 cm ± 3.1
Step length (Prototype)		47.8 cm ± 1.6	58.1 cm ± 5.6
Stride length (barefoot)		103.1 cm ± 3.2	131.2 cm ± 6.5
Stride length (AFO)		93.7 cm ± 6.5	110.6 cm ± 6.2
Stride length (Prototype)		95.6 cm ± 3.2	116.2 cm ±11.2

TUG: Time Up & Go test; 10MWT:10-meter walk test

Table 10: Flexion ability for the initial contact phase during three conditions: barefoot, prototype and AFO.

	Gait Phase	Flexion ability Side	Participant 1	Participant 3
Barefoot	Initial contact	Left	31.1º ± 1.8	NA
	Initial contact	Right	25.1º ± 3.9	28.8º ± 0.8
AFO	Initial contact	Left	6.9º ± 2.5	NA
	Initial contact	Right	9.78± 0.4	1.5º ± 5.9
Prototype	Initial contact	Left	9.6º ± 4.2	NA
	Initial contact	Right	13.9º± 5.2	4.6º± 2.7

Degrees of plantarflexion reported

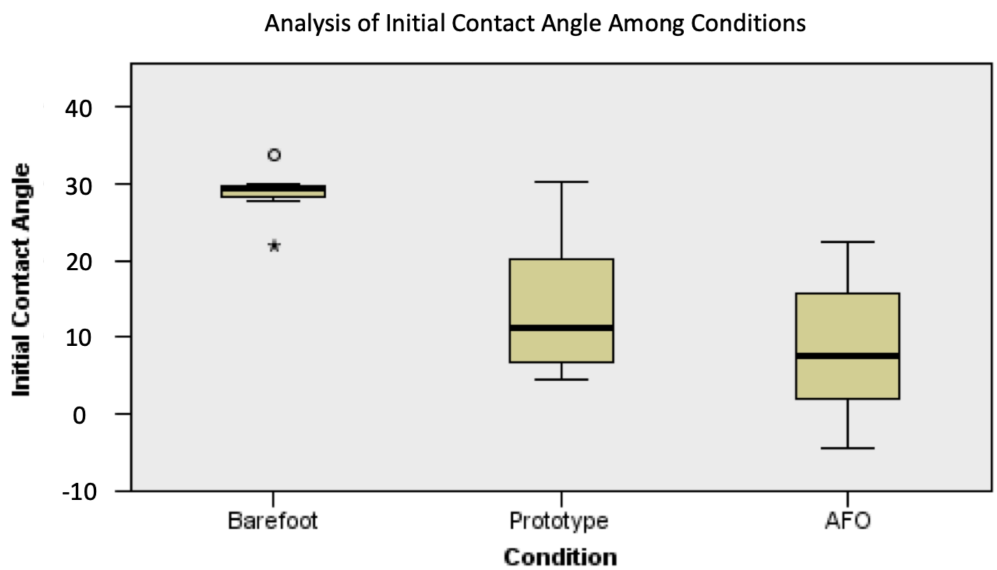


Figure 16: Initial Contact Angle Analysis

5.5.3 Metric Testing Outcomes

Details about product development were analyzed in addition to functional measures and are also reported in Table 11. The averaged prototype weight was less than half of the weight of the averaged weight of our participants AFOs; weight of the devices in grams was significantly different between conditions (AFO - prototype), $H(1)=4.048$, $p=.044$, $r=.601$ (Figure 17). The prototype was adjustable because of the stretch fabric and elastic strapping, whereas traditional AFOs have limited adjustability beyond adjustments made by an orthotist. The fabrics and notions used in the designs complied with safety standards, and all potentially sharp metal end pieces were coated with plastic to ensure safety. The materials used to make the prototypes were safe to be machine washed using the delicate cycle or hand washed (laces should be removed before washing) and air dried. Participants were asked to don/doff their existing AFO as well as the prototypes without instruction one time. Donning and doffing of our prototypes by the participant or their caregiver respectively took an average of 62.9 seconds (SD = 32.1) and 30.2 seconds (SD = 26.2) with the donning and doffing of the lace-up design taking more time than the wrap design. Donning and doffing of the participant's AFOs by the participant or their caregiver respectively took an average of 36.8 seconds (SD = 18) and 20.6 seconds (SD = 17.5). After visual inspection of the skin after use, there was minor redness from the laces or straps visible. Participants rated the comfort of the prototypes an average of 4.4 (SD = .89) for comfort out of a scale of 1-5, with 5 being the most comfortable and rated the comfort of their AFO as (M = 3.3, SD = .33).

Users rated of the aesthetic appeal of both the prototype and their existing AFOs, our prototype averaged 5 (SD = 0) out of a scale from 1-5, 5 being the most appealing, while they rated their AFOs 4.5 (SD = .5). During follow up visits, the prototypes showed little signs of wear; besides that, a few grommets came loose from the lace-up design for Participant 1. Based on written feedback, the participants and their caregivers did not think the support garment would significantly change the way that others treated them but may allow for more variety of footwear because shoes were much easier to put on with the support garments. This could allow users to potentially fit in better with their peers and in various activities.

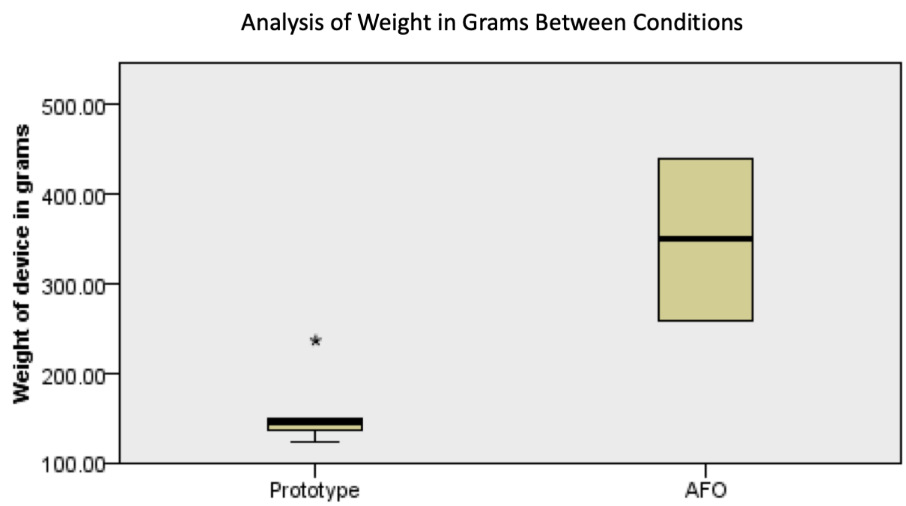


Figure 17: Weight of Device in Grams

Table 11: Prototype Testing Metrics Chart

Metric	User Needs	Target Outcome	Assessment Method	Outcome - Barefoot	Outcome - Our Prototype	Outcome - AFO
Flexion ability	Functional	Prototype doesn't limit dorsiflexion, limits plantar flexion to 10-20 degrees.	Functional assessment (dorsiflexion angle at initial stance) Reported side with greatest change for Participant 1; reported affected side for Participant 3	Participant 1 = 31.1º ± 1.8	Participant 1 = 9.6º ± 4.2	Participant 1 = 6.9º ± 2.5
				Participant 3 = 28.8º ± 0.8	Participant 3 = 4.6º ± 2.7	Participant 3 = 1.5º ± 5.9
Perception of Ankle Stability	Functional	User provided perception of ankle stability	Perception questionnaire and survey	N/A	Participants provided feedback of ankle stability. Average rating of effectiveness was 5 (SD = 0) out of a scale of 1 – 5, with 5 meaning very satisfied.	Participants provided feedback of ankle stability. Average rating of effectiveness was 4.7 (SD = .6) out of a scale of 1 – 5, with 5 meaning very satisfied.
Prototype doesn't limit other functions	Functional	No limitations any other functions according to the PT assessment	D&W MMT protocol and GMFM-88 PT assessments	Motor function for each participant:	Motor function for each participant:	Motor function for each participant:
				participant 1 = 71.88%	participant 1 = 71.88%	participant 1 = 71.88%
				participant 2 = 35.2%	participant 2 = 35.2%	participant 2 = 35.7%
				participant 3 = 94.3%	participant 3 = 95.6%	participant 3 = 95.9%
Stride Length	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment	participant 1 = 103.1 cm ± 3.2	participant 1 = 95.6 cm ± 3.2	participant 1 = 93.7 cm ± 6.5
				participant 3 = 131.2 cm ± 6.5	participant 3 = 116.2 cm ±11.2	participant 3 = 110.6 cm ± 6.2

Step Length	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment	participant 1 = 51.6 cm ± 1.6	participant 1 = 47.8 cm ± 1.6	participant 1 = 46.9 cm ± 3.2
				participant 3 = 65.6 cm ± 3.2	participant 3 = 58.1 cm ± 5.6	participant 3 = 55.3 cm ± 3.1
Gait Speed	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment	Participant 1 self-selected pace = 1.3 m/s	Participant 1 self-selected pace = 1.7 m/s	Participant 1 self-selected pace = 1.5 m/s
				Participant 1 fast-velocity = 2.5 m/s	Participant 1 fast-velocity = 2 m/s	Participant 1 fast-velocity = 1.7 m/s
				Participant 1 TUG: 8.5s	Participant 1 TUG: 10.2s	Participant 1 TUG: 9.3s
				Participant 3 self-selected pace = 1.5 m/s	Participant 3 self-selected pace = 1.5 m/s	Participant 3 self-selected pace = 1.4 m/s
				Participant 3 fast-velocity = 2 m/s	Participant 3 fast-velocity = 1.8 m/s	Participant 3 fast-velocity = 1.8 m/s
				Participant 3 TUG: 9s	Participant 3 TUG: 9.3s	Participant 3 TUG: 8.9s
Cadence	Functional	Barefoot<Our Prototype<AFO Brace	Gait Assessment	Participant 1: 67.5 steps/min	Participant 1: 81 steps/min	Participant 1: 95 steps/min
				Participant 3: 66 steps/min	Participant 3: 67 steps/min	Participant 3: 67 steps/min
Weight of prototype	Functional	< AFO weight	Weight of prototype on balance	N/A	The weight of our prototypes averaged 156.33 grams (SD=40.2 grams).	The weight of Participant AFO's averaged 348.5 grams (SD=127.99 grams).
Adjustable fit	Functional	Able to adjust the prototype to fit the user	The user is able to adjust the prototype to fit.	N/A	All prototypes were able to be easily adjusted with either elastic wraps or laces.	Small adjustments can be made by user via Velcro straps. Most adjustments need to be done by a trained technician.
Safety	Functional	Comply with childrenswear safety standards	Visual inspection of the final prototype and research on safety of all materials.	N/A	All metal pieces were coated for safety. Fabrics and notions comply with safety standards. The lace up prototype would not be suitable for children under 3 due to the usage of small metal grommets which may pose a choking hazard. (U.S. Consumer Product	Participants rated their existing AFOs a 5 for safety from a scale of 1-5, 5 being the safest.

					Safety Commission, 2015; Velazquez, 2016). Participants rated the prototypes a 5 (SD = 0) for safety from a scale of 1-5, 5 being the safest	
Comfort	Functional	User able to wear the garment without expressing emotional signs of discomfort or showing physical signs of skin irritation	Emotional affect of the child was assessed throughout the testing based on facial expression and vocalizations. Skin irritation was assessed by visual inspection of the skin after a 1-hour period of wear.	N/A	During initial testing users' feedback was that the prototypes were comfortable. After visual inspection minor redness from laces or straps was visible. Participants rated comfort an average of 4.4 (SD = .89) for comfort out of a scale of 1-5, with 5 being the most comfortable.	Participants rated comfort an average of 3.3 (SD = .33) for comfort out of a scale of 1-5, with 5 being the most comfortable.
Ease of donning/doffing	Functional	<2 minutes	The parent was timed donning and doffing the garment for the first time without any instruction.	N/A	Donning and doffing of our prototypes by the participant or their caregiver respectively took an average of 62.9 seconds (*SD* = 32.1) and 30.2 seconds (*SD* = 26.2). Donning and doffing of the lace up design (*M* = 135.1 seconds, *SD* = 31) took more time than the wrap design (*M* = 49.3 seconds, *SD* = 20.9).	Donning and doffing the participants AFOs by the participant or their caregiver respectively took an average of 36.8 seconds (SD = 18) and 20.6 seconds (SD = 17.5).
Washable	Functional	Able to wash prototype	Wash the prototype either by hand or in a machine	N/A	The materials used to make the prototypes are safe to be machine washed on the delicate cycle or hand washed (laces should be removed before	Unable to machine wash. To clean the user must wipe with rubbing alcohol and/or soap and water (SureStep, 2016).

					washing) and should be air dried.	
Product Appeal	Aesthetic	User/family satisfaction with design; positive or neutral ratings for aesthetics	User rating of aesthetic appeal on a scale from 1 (low)–5 (high).	N/A	Users rating of aesthetic appeal averaged 5 (SD = 0) out of a scale from 1-5, 5 being the most appealing	Users rating of aesthetic appeal averaged 4.5 (SD = .5) out of a scale from 1-5, 5 being the most appealing
Sleekness	Aesthetic	Maximum protrusion of the components of the garment no more than 1 cm from the child's body	Identify the location with the highest level of component protrusion of the garment and measure the perpendicular distance to the child's body using a tape measure.	N/A	The maximum protrusion of the garments averaged 7.7 mm (*SD* =. 36).	Brace thickness varies typically from 3mm to 9mm with other components protruding further (IRC Physical Rehabilitation Programme, 2010)
Quality construction	Aesthetic	Typical wear and care should cause no damage or distortion	Visual inspection of the garment after 1 hour of wear.	N/A	During follow up visits, the prototypes showed very little signs of damage from wear besides for a few grommets that were coming loose. Participates rated the prototypes durability as 5 (SD = 0) out of a scale from 1-5 with 5 being the most durable.	Participants rated their AFO brace durability as 4.7 (SD = .6) out of a scale from 1-5 with 5 being the most durable.
Social psychological comfort	Expressive	Matches users' needs for discretion or attention based on users' early input on design preferences	User-written feedback on perception survey.	N/A	Based on written feedback the participants and their caregivers they don't think it will significantly change the way that others treat them but may allow for more variety of footwear which would allow them to fit in better with their peers.	AFOs are bulky and can draw attention to the wearer. Design of the braces limit the varieties of shoes the user is able to wear.
Allow for a	Expressive	Users are able to	Have users try on	N/A	The prototype was much	Severely limits the type of

variety of footwear		wear shoes other than sneakers (i.e. dance shoes, soccer cleats)	shoes with the prototype.		easier for participants to fit into shoes compared to their traditional braces, thus allowing for more shoe options.	shoes the user can wear, as shoes need to be very wide and durable
Cost	Accessibility	<$100.00 in material cost per unit	Sum of final material cost	N/A	Average cost for one garment is $26.65.	Custom pediatric AFO braces cost approximately $1500
Availability	Accessibility	Solution that lends itself to the creation of an open-access DIY material list and fabrication guide	Compilation of a complete material list and step-by-step illustrated DIY fabrication manual.	N/A	A material and construction guide will be created and published online for custom creation by a seamstress or community member with moderate sewing experience.	AFOs have to custom made by a clinician.

5.5.4 Perception Assessment

Users rated the ease of both donning and doffing the prototypes as an average of 4.5 (SD = .71) on a scale of 1-5 with five being the easiest and they did not suggest any changes that would make it easier to take on/off. Participant 3 responded that "I think it's equally as easy to put on as a shoe, which isn't difficult!" Noticeable discomfort from participant 1 was described as some light red marks to the lacing in the front of the lace-up variety, and it was suggested to add a shoe tongue or pad under the laces potentially. Participant 3 reported no noticeable discomfort. Participants were asked if they had any suggestion for an improved appearance, and participant 1 responded by saying, "If they became a permanent thing in the future, possibly more color and patterns. Otherwise, we love them and the green [color]." When asked if the prototype met their expectations, both participants rated them as a 5 out of a 1 - 5 scaled with five meaning that it far exceeded their expectations. No suggestion was given when asked if any suggestions would make the prototypes meet your expectations and responses were as following "I think it's good (P3)" and "we love it (P1)". Participants 1 and 3 favored the lace-up design as compared to the wrap variety. During initial prototype testing, participant 2's caregiver preferred the wrap design as she thought it provided more support.

Additional measures, some of which are included in Table 11, were rated on a 5 point scale with 1 being not satisfied at all and 5 being very satisfied in the assistive device questionnaire included dimensions, weight, ease of adjusting, safe and secure, durability, ease of use, comfort, effectiveness, appearance, and fit – see Table 12 for results. In all categories, the prototypes were rated equal to or higher than the participants existing AFO brace.

Table 12: Perception of Assistive Device Questionnaire Results

	Dimension	Weight	Adjustability	Safety	Durable
Traditional brace average	3.2 (SD = 1)	4 (SD = 1)	2.3 (SD = .6)	5 (SD = 0)	4.7 (SD = .6)
Our prototype average	5 (SD = 0)	5 (SD = 0)	4.5 (SD = .7)	5 (SD = 0)	5 (SD = 0)

	Easy to Use	Comfort	Effective	Looks	Fit
Traditional brace average	3.2 (SD = 1)	3.3 (SD = .6)	4.7 (SD = .6)	4.5 (SD = .5)	4.2 (SD = .8)
Our prototype average	4.5 (SD = .7)	5 (SD = 0)	5 (SD = 0)	5 (SD = 0)	4.5 (SD = .7)

5.6 Follow Up Visit Wearing Times and Feedback Results

After the prototype testing visit, caregivers or users were asked to log the number of times and length of wear the child wore each of the prototypes. Results from Participant 1 and 3 are reported in Table 13.

Table 13: Average self-reported wearing frequency and duration throughout a 3-week testing period based on reports from the participant log.

Prototype		Participant 1	Participant 3
Lace Up	Frequency (count)	5	6
	Duration (average hours	.25 (*SD* = .15)	4 (*SD* = 0)

	per use)		
Wrap	Frequency (count)	7	2
	Duration (average hours per use)	.17 (*SD* = .05)	4 (*SD* = 0)

Participant 1 provided written feedback along with the wear log which included comments that after more extended periods of wear some of the corset wire starting to bother him due to its location under the foot and suggested adding additional padding in those areas. The family loved the appearance of them, and they reported that the prototypes exceeded expectations. The child wore them around the house as an alternative to his traditional AFO or being barefoot; and would wear them outside the house in the future if extra padding were added to the areas of discomfort.

Participant 3 also provided comments about the prototype after wearing them for longer durations of time. She did not report any noticeable discomfort after wearing them on her own. When asked how the brace makes her feel while wearing, she responded, “ I feel comfortable! It’s nice to not have a clunky AFO on 24/7” and reported that the prototype exceeded her expectations. She indicated that she wore the brace about 2-3 days a week, especially on the weekends. During weekends she wore them almost all day and on weekdays for about 2 hours at a time. Over the 3-week period, she wore the prototypes at home and to places she is familiar with, such as a restaurant and to an event at her local hospital. She indicated that she would not be as inclined to wear them if she was going to a location that she is unfamiliar with or where she would need to walk a lot because she is not as used to them. She also mentioned that she will be going to the 8th grade semi-formal soon and is planning on buying a new pair of shoes, to wear with our prototype, that will match her dress. Furthermore, she expressed excitement over the option to wear other shoes than the existing pair she has that fits her brace.

Chapter 6

DISCUSSION

The results of this study highlight the need for user-centered design in orthotic creation. AFOs are the most prescribed orthotic (Chang & Cardenas, 2000) and even though high levels of non-use had been reported (Holtkamp et al., 2015; Swinnen & Kerckhofs, 2015) design development and innovation is lacking. The findings in this study are unique because they evaluated opinions/wants/needs of users from many different sources to get a clear picture of what users identify as the aspects of AFOs that could use improvement, thus building upon research currently available (Bapat & Sujatha, 2017; Holtkamp et al., 2015; Swinnen et al., 2017, 2018; Van Der Wilk et al., 2018). Insight from that review led to the development and testing of an alternative bracing option that was designed to meet the broad needs of users and their caregivers. Results validated the functional, expressive, and aesthetic requirements of our soft alternative prototype.

We surveyed users' level of satisfaction through the content analysis of published research, participant interviews, and forums. Figure 10 illustrates what the most commonly reported perceptions of AFOs were, both negative and positive. Notably, the most frequently mentioned perception of AFOs was that when wearing them, it severely limited the shoe options for a user. The opinion that AFOs helped users walk was tied for the 5th most often mentioned point after comments related to pain, cosmetically unacceptability, hotness, and bulkiness. This ranking of perceptions relates to the design of a traditional AFO and how that design is associated with the

FEA2 design framework. An inability to wear a user's desired shoes relates to the expressive design requirements and it may limit activities that a user wants to participate in or produce feelings of not fitting in with peers because they cannot wear similar shoes as others. The primary aesthetic consideration missing is simply the fact that users do not like the way a brace looks from a design standpoint. Orthotics design does allow wearers to choose different colors and patterns for their braces, and it should be noted that all three of our participants took advantage of color and pattern options available to them. Additional functional requirements that were problematic for users were related to the comfort of the device, the heat, and bulkiness that is inherent with most AFOs. These results support and build on previous research into user dissatisfaction with orthotics and AFOs (Holtkamp et al., 2015; Swinnen & Kerckhofs, 2015).

Our prototypes were designed with a user-centered focus; thus, design goals were established to incorporate the top perceptions discovered in our review. This aspect of our research is valuable to the future of orthotic innovation and design so that product designers can incorporate users' wants and needs beyond the functional requirements. Two theories that guided the design were the FEA2 design framework and the five constructs of an ideal orthotic device (Figure 6) that we discovered in our research. The FEA2 model has four constructs that relate to function, expression, aesthetics, and accessibility (Hall & Lobo, 2017; Lamb & Kallal, 1992a). These design requirements directed the development of our prototype testing metrics chart.

AFOs serve an essential purpose. Thus, we needed to validate the functionality of our alternative support garment design. To do this, we analyzed users' activity, muscle strength, and various aspects of gait and functional testing. In general, similar results were found between the prototype and AFO conditions. After analyzing the data collected from functional testing, the prototype was shown to provide comparable stability and support for the ankle joint as compared to an AFO when performing activities in standing and during walking and it did not limit activity or participation. Additional function measures that we looked at included the weight of the prototype, adjustability, safety, comfort, ease of donning/doffing, and machine washability; all target metric outcomes were met. These design outcomes addressed 7 of the most commonly mention perceptions of AFOs, as reported in Figure 10.

The prototype that we developed met the expressive needs of our users by creating a solution that would allow for a variety of footwear options, thus they could wear different types of shoes such as formal shoes or dance shoes. When trying on the prototypes, all participants mentioned how much easier it was to get their feet into, and Participant 1's family noted that this could open up a lot of potential footwear options. Participant 3 was excited to be able to buy a new pair of shoes for a school semi-formal. As mentioned, the most common perception of AFOs is that they severely limit footwear options that can be worn with the devices; thus, the design we developed would address the most common complaint about having to wear AFOs.

Aesthetic considerations of our support garment revolved around consumer feedback, and we designed prototypes in colors and patterns that users desired. We also created the garments to be as sleek as possible. These design attributes addressed two of the common perceptions of AFOs, their unattractive nature and taking advantage of color/pattern options.

Accessibility is the additional construct that Hall and Lobo (2017) added to the original FEA model by Lamb and Kallal (1997). We worked to assure that the prototype was easy to use by making the device adjustable, easy to take on/off, affordable, and widely available. The device met our desired metric outcome of that it takes less than 2 minutes to put on, but it did still take longer to put on than their traditional AFOs, with the lace-up design taking the longest. This could be because the users or their families are accustomed to donning/doffing their everyday devices. Our prototype costs less than $30 to make one unit, but due to minimum purchasing quantities, it may cost more than that. Since a device similar to our prototypes is not commercially available and if more AFO users want them, the researchers may be unable to keep up with requests for garments; thus a material and construction guide is in the process of being created for publication online. It should be noted that the support garment is somewhat complicated to construct and would require someone with more advanced sewing skills.

Through this research, we were able to create a novel prototype that met the various needs of users. Both Participants 1 and 3 preferred the lace-up version over the wrap variety because it looked more like shoes. During our testing, additional comments included the excitement over the device we created because it met a need for children who did not want to be in braces all of the time. We also received feedback that this device would allow users to try to purchase other shoes that were outside of the scope of shoes that they would typically consider. After leaving the prototypes with Participant 1, his parents noted that he had some discomfort due to the location of the corset wire tunnels being slightly under his feet, so future design iterations for young children should move the location of those tunnels, so they do not sit under his feet. Participant 3 didn't report any discomfort and wore the prototypes about 2/3 days a week for a duration of 2 hours or longer.

This study was exploratory in nature to understand and design a solution for problems that AFO users' experience on a daily basis. The initial results and feedback were very promising, but some limitations may impact the results. First of which would be that we utilized a small participant group so we could more precisely understand their wants and needs as well as design custom braces for each child. A larger group of participants could lead to more generalizable results. Functional tests may be more accurate if future studies utilize 3D gait analysis and pressure sensors to get a better picture of how the AFO and prototypes affect the body. Time was also a limitation in the fact that the research had to be completed in 9 months for a master's thesis if this study took place over a more extended period the design could have gone through more iterations and follow-up.

Chapter 7

CONCLUSION

This study has allowed for a further understanding of the challenges and desires of children who wear AFOs and how those challenges relate to orthotic design. The goal was to develop an alternative solution to bulky AFOs when it may not be ideal for wearing them, such as a formal event or dance class. Our research contributed to the broader knowledge of published research about satisfaction with AFOs by analyzing sources from published articles and books, interviews with our participants, and online forums. We were able to identify the most commonly mentioned aspects of satisfaction and dissatisfaction about wearing AFOs. Published research that we reviewed suggested many different types of dissatisfaction but typically focused on the device functionality. Our analysis showed that users' most commonly mentioned point of dissatisfaction was that the device design did not allow them to wear shoes that they desired. This related to the design framework that we used to develop our prototype, the FEA2.0 Model because the design of typical orthotics is focused on functionality while the expressive, aesthetic, and accessibility requirements are seemingly a second thought. Existing AFOs do attempt to appease users' aesthetic desires by allowing for a variety of color and print options for the brace itself, but the design of the braces severely impacts users' expressive desires by not allowing them to wear shoes that they desire. This may affect how they fit in with others or if they can wear activity-specific footwear, such as dance shoes, sandals, and formal shoes.

Apparel and clothing are a form of self-expression that impacts how everyone goes about their day. Most people take advantage of the fact that they can wear a boot when it is cold, a sandal when it is warm, or dress up with dress shoes. The next phase of this research involved creating a prototype that would allow for child users to have a supportive option instead of wearing an AFO that would not as severely limit shoe options available to them. The prototype also aimed to solve some other frequently mentioned problems of AFOs including heaviness, unattractive design, tendency to be hot, and bulkiness. The design direction was user-focused and guided by the 5 constructs of an ideal orthotic device and the FEA2 design framework. The 5 constructs of an ideal orthotic device were developed by combining information from Lusardi (2013) and Redford (2000); these constructs could be a useful tool for future designers of orthotics.

The final support garment prototypes were mainly fabric based with tunnels incorporated for lateral stays and secured by a figure 8 wrapped elastic strap or laces. A soft support garment like the one we develop helped to address many of the common complaints about AFOs. AFOs are designed to serve a functional purpose, so testing the functional validity was very important to make sure that our device offered a level of support that was between that of a plastic AFO and being barefoot. Functional testing did show results that the prototypes provided support and functional assistance during the tasks administered. Results from our surveys and interviews with participants and their families validated the research by giving feedback that our prototypes are a beneficial alternative that does not already exist as an option, and should allow for users to wear a variety of styles of shoes.

It was evident in the research that our prototype is a product that other users or families may find useful, so to address the importance of accessibility, a construction guide will be created and made publicly available. This research is important because it describes a design process for orthotics that is centered around user needs and wants. The methods described can serve as a direction for future orthotic designs or any functional product design because if we can identify users' needs from multiple perspectives, including aesthetics, expressive desires, accessibility concerns, as well as meet functionality needs, that will result in better-designed products. Future research could explore more design iterations, expand the participant group size, conduct more in-depth functional testing, or create a product for older children and adults.

REFERENCES

3pookies. (2006). Does anyone's toddler wear orthotics? [Online Forum]. *Fertile Thoughts*. Retrieved from https://www.fertilethoughts.com/forums/general-parenting/475020-does-anyones-toddler-wear-orthotics.html

AAOS. (2014). Clubfoot. Retrieved October 23, 2018, from https://orthoinfo.aaos.org/en/diseases--conditions/clubfoot/

Active Ankle. (n.d.-a). AS1 PRO Brace. Retrieved December 20, 2018, from https://www.activeankle.com/active-ankle-as1-pro.html

Active Ankle. (n.d.-b). T2 Ankle Brace. Retrieved December 20, 2018, from https://www.activeankle.com/active-ankle-t2.html

Adedo. (2013). Alternative to AFOs. Is there an alternative to AFOs? [Online Forum]. *BabyCenter*. Retrieved from https://community.babycenter.com/post/a42384904/alternative_to_afos._is_there_an_alternative_to_afos

Agrawal, S. (2013). AFO Tips. Retrieved October 31, 2018, from http://complexchild.org/articles/2013-articles/november/afo-tips/

AliMed. (2014). AFOs or Ankle Foot Orthosis Article. Retrieved September 22, 2018, from https://www.alimed.com/afo-info-blog/

Avers, D., Brown, M., Hislop, H. J., & Daniels, L. (2018). *Daniels and Worthingham's Muscle Testing: Techniques of Manual Examination and Performance Testing*. Elsevier Health Sciences.

Bapat, G. M., & Sujatha, S. (2017). Identification and analysis of knee–ankle–foot orthosis design requirements based on a feedback survey of orthosis users in India. *Disability and Rehabilitation: Assistive Technology*, 1–9. https://doi.org/10.1080/17483107.2017.1416187

Baude, M., Hutin, E., & Gracies, J.-M. (2015). A bidimensional system of facial movement analysis conception and reliability in adults. *BioMed Research International*, *2015*.

BearHugz. (2008). Share Your Story [Online Forum]. *March of Dimes*. Retrieved from http://share.marchofdimes.org/forum/archives/f/archives/3378/afo-s-cerebral-palsy#.W-TosRNKi7o

Bettoni, E., Ferriero, G., Bakhsh, H., Bravini, E., Massazza, G., & Franchignoni, F. (2016). A systematic review of questionnaires to assess patient satisfaction with limb orthoses. *Prosthetics and Orthotics International*, *40*(2), 158–169. https://doi.org/10.1177/0309364614556836

Betts, J. G., Kruse, D. H., Young, K. A., Poe, B., DeSaix, P., Korol, O., … Womble, M. (2017). *Anatomy and physiology*. Houston, TX: OpenStax. Retrieved from https://openstax.org/details/books/anatomy-and-physiology

Bohannon, R. W. (2006). Reference values for the timed up and go test: a descriptive

meta-analysis. *Journal of Geriatric Physical Therapy*, *29*(2), 64–68.
Bozgeyik, S., Alemdaroğlu, İ., Bulut, N., Yılmaz, Ö., & Karaduman, A. (2017). Neck flexor muscle strength and its relation with functional performance in Duchenne muscular dystrophy. *European Journal of Paediatric Neurology*, *21*(3), 494–499.
Bunsmom. (2006). Shoes to wear with AFO's? [Online Forum]. *Mothering Forum*. Retrieved from https://www.mothering.com/forum/157-special-needs-parenting/584369-shoes-wear-afo-s.html
Chang, M. W., & Cardenas, D. D. (2000). Ankle-Foot Orthoses: Clinical Implications. *PHYSICAL MEDICINE AND REHABILITATION*, *14*, 435–454.
Chrysagis, N., Skordilis, E. K., & Koutsouki, D. (2014). Validity and clinical utility of functional assessments in children with cerebral palsy. *Archives of Physical Medicine and Rehabilitation*, *95*(2), 369–374.
Cunha, A. B., Babik, I., Harbourne, R., Cochran, N. ., Stankus, J., Szucs, K., & Lobo, M. A. (2019). Assessing the Validity and Reliability of a New Video Goniometer App for Measuring Joint Angles in Adults and Children. *Archives of Physical Medicine and Rehabilitation (In Review)*.
DAFO. (n.d.-a). The Cascade Dafo Institute. Retrieved October 2, 2018, from https://cascadedafo.com/course-information
DAFO. (n.d.-b). *The DAFO Guide*. Retrieved from https://daniz53y71u1s.cloudfront.net/documents/dafo_guide_web.pdf
De Ana, F. J., Umstead, K. A., Phillips, G. J., & Conner, C. P. (2013). Value driven innovation in medical device design: A process for balancing stakeholder voices. *Annals of Biomedical Engineering*, *41*(9), 1811–1821. https://doi.org/10.1007/s10439-013-0779-5
Desai, L., Oprescu, F., DiMeo, A., & Morcuende, J. A. (2010). Bracing in the treatment of children with clubfoot: past, present, and future. *The Iowa Orthopaedic Journal*, *30*, 15.
DICK'S Sporting Goods. (n.d.-a). Copper Fit Advanced Compression Ankle Sleeve. Retrieved December 20, 2018, from https://www.dickssportinggoods.com/p/copper-fit-advanced-compression-ankle-sleeve-17av5ucpprftdvncdspm/17av5ucpprftdvncdspm
DICK'S Sporting Goods. (n.d.-b). P-TEX Ankle Brace With Stabilizers. Retrieved December 20, 2018, from https://www.dickssportinggoods.com/p/p-tex-ankle-brace-with-stabilizers-17pteuptxnklbrcwsspm/17pteuptxnklbrcwsspm
DICK'S Sporting Goods. (n.d.-c). P-TEX Kinetic Lace up Ankle Brace. Retrieved December 20, 2018, from https://www.dickssportinggoods.com/p/p-tex-kinetic-lace-up-ankle-brace-16pteaptxfgr8nkllspm/16pteaptxfgr8nkllspm
DICK'S Sporting Goods. (n.d.-d). P-TEX PRO Knit Compression Ankle Sleeve. Retrieved December 20, 2018, from https://www.dickssportinggoods.com/p/p-tex-pro-knit-compression-ankle-sleeve-16pteuptxprkntcmpspm/16pteuptxprkntcmpspm
Dreamwalkr949. (2012). Working out in AFOs [Online Forum]. *Care Cure Community*. Retrieved from http://sci.rutgers.edu/forum/showthread.php?188772-Working-out-in-AFOs
Drouin, L. M., Malouin, F., Richards, C. L., & Marcoux, S. (1996). Correction

between the gross motor function measure scores and gait spatiotemporal measures in children with neurological impairments. *Developmental Medicine & Child Neurology*, *38*(11), 1007–1019.
Dunooncampbell. (2010). AFO questions [Online Forum]. *MS World*. Retrieved from https://www.msworld.org/forum/showthread.php?104916-AFO-questions
Eckles, R. (2017). Key Insights On Orthotics, AFOs And Casting For Kids. *Podiatry Today*, *30*(6). Retrieved from https://www.podiatrytoday.com/key-insights-orthotics-afos-and-casting-kids
Eddison, N., Mulholland, M., & Chockalingam, N. (2017). Do research papers provide enough information on design and material used in ankle foot orthoses for children with cerebral palsy? A systematic review. *JOURNAL OF CHILDRENS ORTHOPAEDICS*, *11*(4), 263–271. https://doi.org/10.1302/1863-2548.11.160256
Eriksson, M., Bartonek, A., Ponten, E., & Gutierrez-Farewik, E. M. (2015). Gait dynamics in the wide spectrum of children with arthrogryposis: a descriptive study. *BMC MUSCULOSKELETAL DISORDERS*, *16*. https://doi.org/10.1186/s12891-015-0834-5
Eriksson, M., Villard, L., & Bartonek, Å. (2014). Walking, orthoses and physical effort in a Swedish population with arthrogryposis. *Journal of Children's Orthopaedics*, *8*(4), 305–312. https://doi.org/10.1007/s11832-014-0597-9
GAMZu. (2011). Sandals/sneaker sandals to fit over orthotics? [Online Forum]. *Mothering Forum*. Retrieved from https://www.mothering.com/forum/157-special-needs-parenting/1303574-sandals-sneaker-sandals-fit-over-orthotics.html
Gan, S.-M., Tung, L.-C., Tang, Y.-H., & Wang, C.-H. (2008). Psychometric properties of functional balance assessment in children with cerebral palsy. *Neurorehabilitation and Neural Repair*, *22*(6), 745–753.
Genetic and Rare Diseases Information Center (GARD). (2015). Arthrogryposis multiplex congenita. Retrieved December 21, 2018, from https://rarediseases.info.nih.gov/diseases/777/arthrogryposis-multiplex-congenita
Hall, M. L., & Lobo, M. A. (2017). Design and development of the first exoskeletal garment to enhance arm mobility for children with movement impairments. *Assistive Technology*, *00*(00), 1–8. https://doi.org/10.1080/10400435.2017.1320690
Holtkamp, F., Wouters, E., van Hoof, J., van Zaalen, Y., & Verkerk, M. (2015). Use of and Satisfaction with Ankle Foot Orthoses. *Clinical Research on Foot & Ankle*, *03*(01). https://doi.org/10.4172/2329-910X.1000167
IRC Physical Rehabilitation Programme. (2010). *Manufacturing guidelines: Ankle-Foot Orthosis*. Retrieved from https://www.icrc.org/en/doc/assets/files/other/eng-afo-2010.pdf
Jbell2435. (2011). AFO Brace Liner?? [Online Forum]. *MS World*. Retrieved from https://www.msworld.org/forum/showthread.php?115843-AFO-Brace-Liner
JDWilson. (2010). AFO Braces Nipping [Online Forum]. *Scope*. Retrieved from https://community.scope.org.uk/discussion/16996/afo-braces-nipping
Jr0819. (2015). What is it like to wear afo braces [Online Forum]. *Scope*. Retrieved from https://community.scope.org.uk/discussion/28551/what-is-it-like-to-wear-

afo-braces
Katz-Leurer, M., Rotem, H., Lewitus, H., Keren, O., & Meyer, S. (2008). Functional balance tests for children with traumatic brain injury: within-session reliability. *Pediatric Physical Therapy*, *20*(3), 254–258.
Kaya, P., Alemdaroğlu, İ., Yılmaz, Ö., Karaduman, A., & Topaloğlu, H. (2015). Effect of muscle weakness distribution on balance in neuromuscular disease. *Pediatrics International*, *57*(1), 92–97.
Klingbeil, F. T., Whitaker, B., & Dunn, C. (2000). Principles and Clinical Practice of Lower Limb Orthotics in Children. *PHYSICAL MEDICINE AND REHABILITATION*, *14*(3), 515–532.
Kogler, G. F. (2013). Materials and Technology. In *Orthotics and Prosthetics in Rehabilitation* (pp. 143–160).
LaBat, K. L., & Sokolowski, S. L. (1999). A three-stage design process applied to an industry-university textile product design project. *Clothing and Textiles Research Journal*, *17*(1), 11–20. https://doi.org/10.1177/0887302X9901700102
Lamb, J. M., & Kallal, M. J. (1992a). A conceptual framework for apparel design. *Clothing and Textiles Research Journal*, *10*(2), 42–47.
Lamb, J. M., & Kallal, M. J. (1992b). A Conceptual Framework for Apparel Design. *Clothing and Textiles Research Journal*, *10*(2), 42–47. https://doi.org/10.1177/0887302X9201000207
Lintanf, M., Bourseul, J.-S., Houx, L., Lempereur, M., Brochard, S., & Pons, C. (2018). Effect of ankle-foot orthoses on gait, balance and gross motor function in children with cerebral palsy: a systematic review and meta-analysis. In *CLINICAL REHABILITATION* (Vol. 32, pp. 1175–1188). 1 OLIVERS YARD, 55 CITY ROAD, LONDON EC1Y 1SP, ENGLAND: SAGE PUBLICATIONS LTD. https://doi.org/10.1177/0269215518771824
Littrell, M. E., Chang, Y.-H., & Selgrade, B. P. (2018). Development and Assessment of a Low-Cost Clinical Gait Analysis System. *Journal of Applied Biomechanics*, *34*(6), 503–508.
Lobo, M. A., Koshy, J., Hall, M. L., Erol, O., Cao, H., Buckley, J. M., … Higginson, J. (2016). Playskin Lift: Development and Initial Testing of an Exoskeletal Garment to Assist Upper Extremity Mobility and Function. *Physical Therapy*, *96*(3), 390–399. https://doi.org/10.2522/ptj.20140540
Lusardi, M. (2013). Principles of Lower Extremity Orthoses. *Orthotics and Prosthetics in Rehabilitation*, 219–265.
Ma, M. Y., Wu, F. G., & Chang, R. H. (2007). A new design approach of user-centered design on a personal assistive bathing device for hemiplegia. *Disability and Rehabilitation*, *29*(14), 1077–1089. https://doi.org/10.1080/09638280600949712
Manousaki, E., Czuba, T., Hagglund, G., Mattsson, L., & Andriesse, H. (2016). Evaluation of gait, relapse and compliance in clubfoot treatment with custom-made orthoses. *GAIT & POSTURE*, *50*, 8–13. https://doi.org/10.1016/j.gaitpost.2016.08.005
Marieangela. (2010). 15 month old getting AFOs [Online Forums]. *Mothering Forums*. Retrieved from https://www.mothering.com/forum/157-special-needs-

parenting/1232989-15-month-old-getting-afos.html
Mark5701. (2013). AFO’s - cheap alternatives for the beach, water etc [Online Forum]. *Care Cure Community*. Retrieved from http://sci.rutgers.edu/forum/showthread.php?226417-AFO-s-cheap-alternatives-for-the-beach-water-etc
Mavroidis, C., Ranky, R. G., Sivak, M. L., Patritti, B. L., DiPisa, J., Caddle, A., … Bonato, P. (2011). Patient specific ankle-foot orthoses using rapid prototyping. *Journal of NeuroEngineering and Rehabilitation*, *8*(1). https://doi.org/10.1186/1743-0003-8-1
McDavidUSA. (n.d.). Ankle Brace w/Straps. Retrieved December 20, 2018, from https://www.mcdavidusa.com/the-195tm-ankle-brace-w-straps-195tm
Metronycguy. (2009). my afo / freaky leg cover [Online Forum]. *Care Cure Community*. Retrieved from http://sci.rutgers.edu/forum/showthread.php?120630-my-afo-freaky-leg-cover
Mohamed, O., Craig, D., Worden, H., & Ayyappa, E. (2013). Clinical Assessment of Gait. In *Orthotics and Prosthetics in Rehabilitation* (pp. 104–142). https://doi.org/10.1016/B978-1-4377-1936-9.00005-9
Moroz, A. (2017). Physical Therapy (PT) - Special Subjects. Retrieved January 9, 2019, from https://www.merckmanuals.com/professional/special-subjects/rehabilitation/physical-therapy-pt
Morris, C. (2007a). Biomechanical Principles. In C. Morris & L. S. Dias (Eds.), *Paediatric Orthotics* (1st ed., pp. 4–12). London, UK: Mac Keith Press.
Morris, C. (2007b). Introduction. In C. Morris & L. S. Dias (Eds.), *Paediatric Orthotics* (1st ed., pp. 1–3). London, UK: Mac Keith Press.
Morris, C. (2007c). Lower-Limb Orthoses. In C. Morris & L. S. Dias (Eds.), *Paediatric Orthotics* (1st ed., pp. 44–66). London, UK: Mac Keith Press.
Morris, C. (2007d). Materials, Components and Fabrication. In C. Morris & L. S. Dias (Eds.), *Paediatric Orthotics* (1st ed., pp. 28–33). London, UK: Mac Keith Press.
Morris, C., & Dias, L. S. (2007). Congenital Deformities. In C. Morris & L. S. Dias (Eds.), *Paediatric Orthotics* (1st ed., pp. 67–76). London, UK: Mac Keith Press.
Morris, C., Gryfakis, N., El-Shammaa, M., & Dias, L. S. (2007). Assessment. In C. Morris & L. S. Dias (Eds.), *Paediatric Orthotics* (1st ed., pp. 13–27). London, UK: Mac Keith Press.
Nance, J. R., & Golomb, M. R. (2007). Ischemic spinal cord infarction in children without vertebral fracture. *Pediatric Neurology*, *36*(4), 209–216. https://doi.org/10.1016/j.pediatrneurol.2007.01.006
National Institute of Neurological Disorders and Stroke. (2019). Spinal Cord Infarction Information Page. Retrieved May 8, 2019, from https://www.ninds.nih.gov/Disorders/All-Disorders/Spinal-Cord-Infarction-Information-Page
Noah. (2014). What its like to Wear AFO’s? Any tips or advice? [Online Forum]. *Scope*. Retrieved from https://community.scope.org.uk/discussion/25415/what-its-like-to-wear-afos-any-tips-or-advice
O’Reilly, T., Hunt, A., Thomas, B., Harris, L., & Burns, J. (2009). Effects of ankle-foot orthoses for children with hemiplegia on weight-bearing and functional

ability. *Pediatric Physical Therapy*, *21*(3), 225–234. https://doi.org/10.1097/PEP.0b013e3181b126fb

Park, Y.-L., Chen, B., Pérez-Arancibia, N. O., Young, D., Stirling, L., Wood, R. J., … Nagpal, R. (2014). Design and control of a bio-inspired soft wearable robotic device for ankle–foot rehabilitation. *Bioinspiration & Biomimetics*, *9*(1), 16007.

Podsiadlo, D., & Richardson, S. (1991). The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society*, *39*(2), 142–148.

Quinn, E. (2019). Foot Anatomy and Physiology. Retrieved January 8, 2019, from https://www.verywellhealth.com/foot-anatomy-and-physiology-3119204

Redford, J. B. (2000). Orthotics and orthotic devices: General Principles. *PHYSICAL MEDICINE AND REHABILITATION*, *14*(3), 381–394.

Reese, N. B., & Bandy, W. D. (2016). *Joint Range of Motion and Muscle Length Testing-E-Book*. Elsevier Health Sciences.

Rosenbaum, P., & Stewart, D. (2004). The World Health Organization International Classification of Functioning, Disability, and Health: a model to guide clinical thinking, practice and research in the field of cerebral palsy. In *Seminars in pediatric neurology* (Vol. 11, pp. 5–10). Elsevier.

Russell, D. J., Rosenbaum, P. L., Wright, M., & Avery, L. M. (2013). *Gross Motor Function Measure (GMFM-66 and GMFM-88). User's Manual.* (2nd Editio).

Russell, D., Palisano, R., Walter, S., Rosenbaum, P., Gemus, M., Gowland, C., … Lane, M. (1998). Evaluating motor function in children with Down syndrome: validity of the GMFM. *Developmental Medicine & Child Neurology*, *40*(10), 693–701.

Schrank, E. S., & Stanhope, S. J. (2011). Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework. *Journal of Rehabilitation Research & Development*, *48*(1), 31. https://doi.org/10.1682/JRRD.2009.12.0195

Shock Doctor. (n.d.-a). Compression Knit Ankle Sleeve. Retrieved December 20, 2018, from https://www.shockdoctor.com/compression-knit-ankle-sleeve

Shock Doctor. (n.d.-b). Compression Knit Ankle Sleeve with Gel Support. Retrieved December 20, 2018, from https://www.shockdoctor.com/compression-knit-ankle-sleeve-with-gel-support

Shock Doctor. (n.d.-c). Ultra Gel Lace Up Ankle Brace Support & Ankle Compression Wrap. Retrieved December 20, 2018, from https://www.shockdoctor.com/ultra-gel-lace-ankle-support

Shock Doctor. (n.d.-d). Ultra Knit Ankle Brace w/ Figure 6 Strap & Stays. Retrieved December 20, 2018, from https://www.shockdoctor.com/ultra-knit-ankle-brace-w-figure-6-strap-stays-2052

Shock Doctor. (n.d.-e). Ultra Wrap Lace Up Ankle Support with Compression. Retrieved December 20, 2018, from https://www.shockdoctor.com/ultra-wrap-lace-ankle-support

SRS. (2014). If you or your child wears custom foot orthotics... [Online Forum]. *The Well-Trained Mind*. Retrieved from https://forums.welltrainedmind.com/topic/521980-if-you-or-your-child-wears-

custom-foot-orthotics/
Surestep. (n.d.-a). advanced afo. Retrieved December 19, 2018, from http://surestep.net/products/advanced-afo/
Surestep. (n.d.-b). hinged afo. Retrieved December 19, 2018, from http://surestep.net/products/hinged-afo/
SureStep. (2016). Wear and Care. Retrieved May 10, 2019, from https://www.youtube.com/watch?v=VNkkZoqnyIw
Suzannah. (2014). AFOs [Online Forum]. *ALSForums*. Retrieved from http://www.alsforums.com/forum/general-discussion-about-pls/27560-afos.html
Swann, R. (2010). AFO Recommendations [Online Forum]. *Care Cure Community*. Retrieved from http://sci.rutgers.edu/forum/showthread.php?131071-AFO-Recommendations
Swinnen, E., & Kerckhofs, E. (2015). Compliance of patients wearing an orthotic device or orthopedic shoes: A systematic review. *Journal of Bodywork and Movement Therapies*, *19*(4), 759–770. https://doi.org/10.1016/j.jbmt.2015.06.008
Swinnen, E., Lafosse, C., Van Nieuwenhoven, J., Ilsbroukx, S., Beckwee, D., & Kerckhofs, E. (2017). Neurological patients and their lower limb orthotics: An observational pilot study about acceptance and satisfaction. *PROSTHETICS AND ORTHOTICS INTERNATIONAL*, *41*(1), 41–50. https://doi.org/10.1177/0309364615592696
Swinnen, E., Lefeber, N., Werbrouck, A., Gesthuizen, Y., Ceulemans, L., Christiaens, S., … Kerckhofs, E. (2018). Male and female opinions about orthotic devices of the lower limb: A multicentre, observational study in patients with central neurological movement disorders. *NeuroRehabilitation*, *42*(1), 121–130. https://doi.org/10.3233/NRE-172214
Tan, J. L., Thomas, N. M., & Johnston, L. M. (2017). Reproducibility of Muscle Strength Testing for Children with Spina Bifida. *Physical & Occupational Therapy in Pediatrics*, *37*(4), 362–373.
Telfer, S., Pallari, J., Munguia, J., Dalgarno, K., McGeough, M., & Woodburn, J. (2012). Embracing additive manufacture: implications for foot and ankle orthosis design. *BMC Musculoskeletal Disorders*, *13*(1), 84. https://doi.org/10.1186/1471-2474-13-84
U.S. Consumer Product Safety Commission. (2015). Childrens Apparel Product Trifold. Retrieved May 10, 2019, from https://www.cpsc.gov/PageFiles/185629/ChildrensApparelProductsTrifold22014LinkUpdated82015.pdf
Van Der Wilk, D., Hijmans, J. M., Postema, K., & Verkerke, G. J. (2018). A user-centered qualitative study on experiences with ankle-foot orthoses and suggestions for improved design. *Prosthetics and Orthotics International*, *42*(2), 121–128.
Velazquez, M. (2016). 3 Safety Tests For Designing Children’s Products. Retrieved May 10, 2019, from https://makersrow.com/blog/2016/08/3-safety-tests-for-designing-childrens-products/
Wade, D. (1992). Measurement in neurological rehabilitation Oxford University Press. *New York*.

Wheely1996. (2016). Can I safely stop wearing my AFO's (ankle braces)? [Online Forum]. *Youreable*. Retrieved from https://www.youreable.com/forums/showthread.php?15246-Can-I-safely-stop-wearing-my-AFO-s-(ankle-braces)

Whitehume. (2013). Dressing up an AFO advice. *MS World*. Retrieved from https://msworld.org/forum/showthread.php?124822-Dressing-up-an-AFO-advice

Williams, E. N., Carroll, S. G., Reddihough, D. S., Phillips, B. A., & Galea, M. P. (2005). Investigation of the timed 'up & go'test in children. *Developmental Medicine and Child Neurology*, *47*(8), 518–524.

Yun, C.-K., Kim, W., & Kim, S.-G. (2016). Partial correlation between lower muscle thickness, 10-meter walk test, and the timed up & go test in children with spastic cerebral palsy. *Journal of Physical Therapy Science*, *28*(5), 1611–1613.

Zamst. (n.d.-a). A1. Retrieved December 20, 2018, from https://www.zamst.us/product/a1.2.html

Zamst. (n.d.-b). A2-DX. Retrieved December 20, 2018, from https://www.zamst.us/product/a2-dx.1.html

Zifchock, R. A., & Davis, I. (2008). A comparison of semi custom and custom foot orthotic devices in high and low arched individuals during walking. *Clin Biomech*, *23*. https://doi.org/10.1016/j.clinbiomech.2008.07.008

Appendix A

SUPPLEMENTAL MATERIALS

.

A.1 Summary of Non-Orthotic Brace Attributes

Name	Active Ankle T2 Rigid Multi-Sport Ankle Brace	McDavid 195 Ankle Brace w/ Straps	Zamst A2 DX Ankle Brace	Shock Doctor Ultra Wrap Lace Ankle Brace	Shock Doctor Ultra Gel Lace Ankle Support	P-TEX Ankle Brace With Stabilizers	Shock Doctor Compression Knit Ankle Sleeve w/ Gel Support	Zamst A1 Ankle Brace	Copper Fit Advanced Compression Ankle Sleeve	Shock Doctor Compression Knit Ankle Sleeve	Shock Doctor Ultra Knit Ankle Brace with Figure-6 Strap	Active Ankle AS1 Pro Lace-Up Ankle Brace with Straps	P-TEX PRO Knit Compression Ankle Sleeve	P-TEX Kinetic Lace-up Ankle Brace
Image														
Compression		X		X	X	X	X	X	X	X	X	X	X	X
Adjustable	X	X	X	X	X	X		X			X	X		X
Simulates Figure 8/ X taping		X	X	X				X			X	X		
Lacing		X		X	X	X						X		X
Seamless Knitting							X	X	X	X	X		X	
Horizontal Strap at top	X	X		X								X		
Grips on bottom			X	X	X							X		
Gel Cushion at ankle					X		X	X						
Plastic	X		X											
Nylon		X										X		
Padded Lining	X	X												
Neoprene			X									X		
Mesh												X		X
Lateral Stabilizers						X		X						
U-Shaped Design	X													
Hinge	X													
Arch Support		X												
Antimicrobial				X										
Inspired by Kinesio Taping														X
Internal Grip								X						
L- Strapping								X						

(Active Ankle, n.d.-a, n.d.-b, DICK'S Sporting Goods, n.d.-a, n.d.-d, n.d.-b, n.d.-c; McDavidUSA, n.d.; Shock Doctor, n.d.-a, n.d.-e, n.d.-b, n.d.-d, n.d.-c, Zamst, n.d.-a, n.d.-b)

A.2 Clothing Design for Individuals With Special Clothing Needs – Fitting Interview Questions

Name: ____

Date: __________________________________

Relationship of person completing the form to the user (if not self):

____

1)How easy is the brace to put on?

1=Very Difficult, 2=Difficult, 3=Neutral, 4=Easy, 5=Very Easy

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

2)How easy is the brace to take off?

1=Very Difficult, 2=Difficult, 3=Neutral, 4=Easy, 5=Very Easy

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

3)What changes to the brace would make it easier to put it on and take it off?

4)How would you rate comfort level in the brace?

1=Very Uncomfortable, 2=Uncomfortable, 3=Neutral, 4=Comfortable, 5=Very Comfortable

In the first 5 minutes: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ na ☐

After 15 minutes: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ na ☐

After 1 hour: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ na ☐

5) Was there any noticeable discomfort during or after use? YES ☐ NO ☐ If yes, please describe.

6) What changes to the brace would you recommend to make it more comfortable?

7)How do you think wearing the brace may impact the way others see and treat you?

8)How would you rate the overall appearance of the brace?

1=Very Unattractive, 2=Unattractive, 3=Neutral, 4=Attractive, 5=Very Attractive

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ na ☐

9)Please list any suggestions for improved appearance.

10) Please rank the following in order of importance (1,2,3,4,5) to you in relation to brace(s) (1 = Most Important; 5 = Least Important):

_____ Function - Ability to help you move

_____ Appearance – Something that is not noticeable or that looks nice

_____ Ease of Use – Something that fits within your everyday life and is easy to use

_____ Comfort – Something you can wear comfortably for long periods of time

_____ Cost – Affordability of the device

11) Does this brace meet your expectations?

1=Far below, 2=Somewhat below, 3=Just at, 4=Somewhat exceeded, 5=Far exceeded

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ na ☐

12) Please list any suggestions for helping the brace meet your expectations.

Appendix B

UNIVERSITY OF DELAWARE’S IRB APPROVED RESEARCH

B.1 [704060-5] Clothing Design for Individuals with Adaptive Clothing Needs

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	February 5, 2019
TO:	Michele Lobo, PT, PhD
FROM:	University of Delaware IRB
STUDY TITLE:	[704060-7] Clothing Design for Individuals with Adaptive Clothing Needs
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	February 5, 2019
EXPIRATION DATE:	February 22, 2020
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # (4,7)

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Renee Stewart at (302) 831-2137 or stewartr@udel.edu. Please include your study title and reference number in all correspondence with this office.