Inconspicuous Ankle Foot Orthosis (AFO) for Teen

PRELIMINARY REPORT

Team Name:
Rise and Stride - Lab 001

Team Members:
Lucy Hockerman (Team Leader)
Presley Hansen (BSAC)
Madison Michels (Communicator)
Kate Hiller (BPAG)
Sadie Rowe (BWIG)

Client:
Debbie Eggleston

Advisor:
Doctor John Puccinelli; University of Wisconsin - Biomedical Engineering Department
Lizzie Maly; University of Wisconsin - Biomedical Engineering Department

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Abstract

Facioscapulohumeral Dystrophy (FSHD) is one of the most common types of muscular dystrophy, affecting approximately 4-10 in 100,000 individuals. This genetic disorder leads to progressive muscle weakness, and while there is currently no cure, physical therapy, orthotics, and surgery can help manage symptoms. [1] There is limited clinical research focusing on children with FSHD, leaving gaps in understanding and addressing their specific needs. This project aims to raise awareness of FSHD and explore the benefits of discrete ankle-foot orthoses (AFOs) for individuals with progressive muscle weakness.

Current devices that provide the flexibility the patient seeks include flexible-dynamic, jointed, and passive-dynamic AFOs. However, these designs fail to meet key patient needs, such as discreteness, sufficient flexibility, and ankle inversion prevention. To address this, a discrete AFO for the right foot will be fabricated for a teenager diagnosed with FSHD. The design aims to support dorsiflexion to prevent foot drop, provide flexibility for daily activities, and prevent ankle inversion. The current rigid support design balances appearance and functionality. It will be made from carbon fiber reinforced PLA (CF-PLA), include a gel pad to minimize comfort, and be attached to the foot with elastic straps. The bungee cord system from the Fall 2024 design team will be incorporated with the new rigid support design to allow for adjustable tension, facilitating dorsiflexion. Current plans for testing this design include Finite Element Analysis, Comfortability Testing, and IMU and MoCap Testing.

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Introduction

Motivation & Global Impact

Currently, the majority of AFOs are rigid, bulky, and unappealing. The patient is a teenager in high school who has FSHD, and is in need of an AFO for their right foot. Current devices are not aesthetically appealing and the patient does not want to draw attention from unwanted peers. The goal is to create a comfortable and flexible AFO that the patient will wear without feeling self-conscious. This will allow the patient to go about their normal day-to-day activities without worrying about their safety or about peers' opinions.

Additionally, there are currently limited clinical trials for FSHD in young individuals. The device will raise awareness for FSHD affecting young individuals, and increase the amount of research on how FSHD affects children.

On a global scale, the device can be made customizable to other young individuals who need an AFO but do not want to draw attention to their condition. The device could help other children with FSHD who are feeling self-conscious about their condition. This device can also potentially meet other markets, such as adults who also want an inconspicuous AFO. Additionally, it could be worn by individuals who have a different type of muscular dystrophy, or simply need extra support in their ankle.

Existing Devices & Current Methods

Current orthotics use the Three-Point Pressure system. This is where the force on the corrected joint is countered by forces above and below the joint so the sum of all forces is zero. This relieves discomfort for the patient [2].

Pediatric Supra Malleolar Orthosis (SMOs) are made from thin and flexible thermoplastic that provides support just above the ankle bones (malleoli). SMOs are primarily used to control subtalar joint alignment to maintain a vertical or neutral heel to help improve mediolateral movement. They are comfortable to wear in shoes due to their thin and minimally restrictive design [3].

Figure 1: Supra Malleolar Orthosis (SMO) [4]

Jointed AFOs, as seen in Figure 2, are designed with a hinged joint that allows for a full range of motion; however, some limitations to this device are that it is bulky and difficult to fit in standard footwear. This device can be noisy due to the hinge mechanism and may break more easily. The patient is looking for an orthosis that allows for some range of motion; however, due to the bulkiness of this device, it does not meet the criterion the patient is looking for [5].

Figure 2: Jointed AFO [6]

The Passive-Dynamic AFO (PD-AFO), as seen in Figure 3, consists of a calf shell and a foot plate. This AFO provides flexibility by allowing both dorsiflexion and plantarflexion. As the calf shell bends in the stance phase, elastic potential energy is stored. The energy is later released during the push-off phase, supporting the user throughout the gait cycle. More commonly, PD-AFOs are made from 3D-printed materials; however, due to the flexibility of this device, it should be worn by individuals with less severe foot drop [7]. This device meets the flexibility requirements of the patient, but may not support the patient medially, so it is not a viable option.

Figure 3: Front View of Passive-Dynamic AFO [8]

Variable Stiffness Orthoses (VSOs), as shown in Figure 4, are powered and feature a customizable cam-based transmission able to specify any torque-angle and change the magnitude of its overall stiffness in real time. VSOs are found to lead to reduced foot drop and increased total ankle moments. VSOs are currently in the research stage and not on the market [9].

Figure 4: Variable Stiffness Orthosis [10]

Problem Statement

AFOs are designed to provide dorsiflexion support during the swing phase of walking. These devices are primarily used to treat muscular dystrophies. This project aims to raise awareness of FSHD and explore the benefits of discrete AFOs for individuals with progressive muscle weakness. The team aims to design a discreet, flexible brace that supports natural gait, enhances walking safety, and allows for a functional range of ankle motion. The brace will be tailored specifically for the patient. The key objectives of this device include positioning the ankle in adequate dorsiflexion, restricting medio-lateral ankle motion, maintaining a narrow, thin, and discrete design, and ensuring sufficient flexibility to minimize any restriction of movement.

Background

The team was tasked with creating an AFO for the client, Debbie Eggleston, and her patient. The patient has FSHD, and the disease has progressed to the point of needing an AFO. The client explored traditional AFOs but found them too bulky and restrictive for the patient's needs. The patient is a sophomore in high school, and is concerned about the questions and judgment they may receive; therefore, they are looking for a more inconspicuous AFO. An AFO will be created that is similar to an ankle brace, limiting questions the patient may receive, while still providing the necessary support for the right ankle.

Anatomy & Physiology

FSHD is a rare neuromuscular condition that causes progressive weakness of muscles in the shoulder girdle, hip girdle, and lower limbs. Therefore, FSHD patients tend to suffer from foot drop because of their weakened muscles which affects their gait cycle and increases their risk of falling. FSHD is the third most common type of muscle dystrophy, and 1 in every 15,000 people suffer from FSHD. [11] It most commonly affects females in their late twenties to early thirties. There are two types, FSHD1 and FSHD2, in which 95% of patients have FSHD1. [12]

The client specifically has FSHD1, which is an autosomal dominant muscle disorder, mapped to 4q35 on chromosome 4. The EcoRI fragment is partially deleted, less than 35 kb [kilobase] in length, instead of a normal 35-300 kb or with repeated copies. [13] Additionally, it has been found that mutations in epigenetic regulators lead to FSHD. [14] The overexpression of the DUX4 gene on chromosome 4 in the D4Z4 region is another cause of FSHD. The DUX4 protein is active at low levels during fetal development and is silenced as development progresses and in most adult cells. Hypermethylation, a large number of methyl groups attached to the DNA of the D4Z4 region on chromosome 4, silences the DUX4 protein. [15] However, if the DUX4 protein is activated again, it damages muscle cells leading to FSHD diagnosis.

The AFO's primary purpose is to support the foot in dorsiflexion, as shown below in Figure 5, in order to fix foot drop.

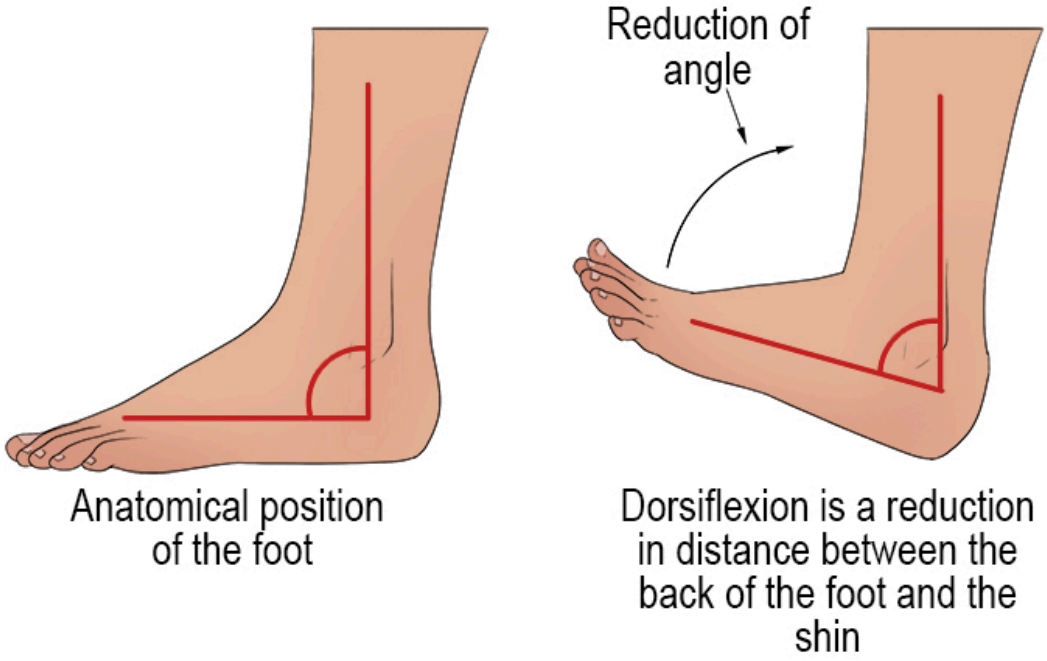


Figure 5: Foot dorsiflexion [16]

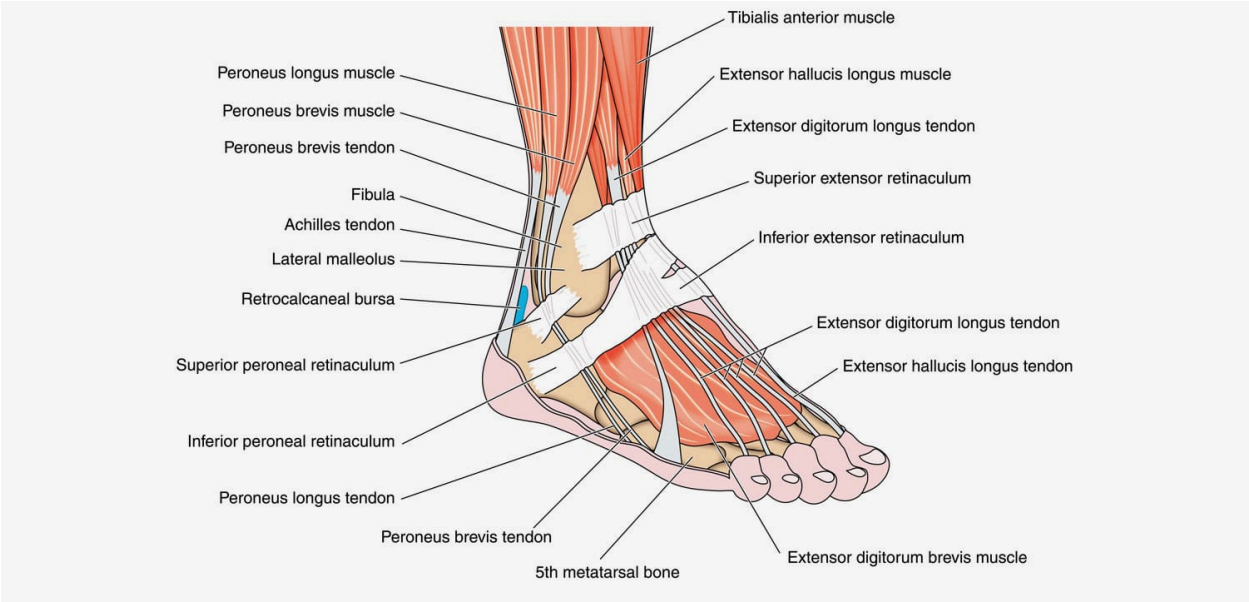


Figure 6: Ankle Muscle Anatomy [17]

Foot drop occurs when the muscles extending distally to the ankle, specifically the tibialis anterior shown above in Figure 6, are too weak to support the foot in a normal position, leading to an excess drop of the foot. This affects the initial contact or heel strike phase of the gait cycle shown in Figure 7. The patient's foot can catch on the ground, increasing the risk of fall while walking.

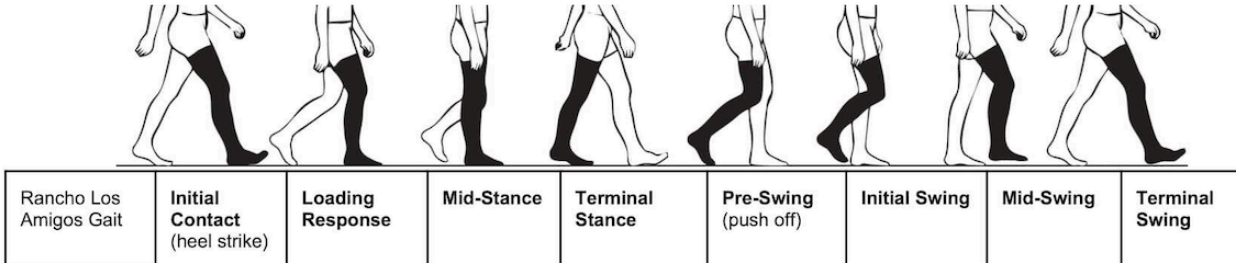
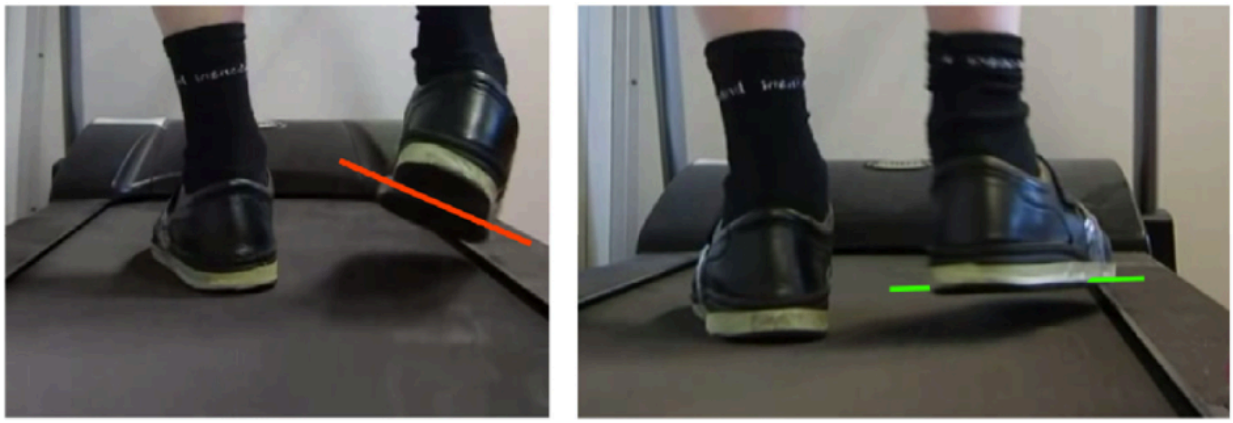


Figure 7: Normal Gait Cycle [18]

The patient also experiences ankle inversion shown in Figure 8. The medial side of the foot is rotated inward in compression, while the lateral side of the foot is in tension. This poses a risk of straining the tendons of the ankle. The patient also requires arch support in the foot, which is already implemented in the form of inserts in tennis shoes.



(d) excessive foot inversion (negative roll) (e) neutral inversion/eversion (zero roll)

Figure 8: Ankle Inversion During Gait vs. Normal Gait [19]

Client Information

The client, Debbie Eggleston, is a physical therapist and activist for FSHD. She introduced the team to the patient, who is receiving the AFO. After weeks of a lack of progress with the client, Ms. Eggleston worked closely with the University of Michigan to diagnose the patient's disorder, FSHD1, in December 2022. Ms. Eggleston has worked closely with other FSHD specialists to advocate and bring awareness to the disease. She has also joined several Facebook groups to fundraise and bring awareness to the condition. Ms. Eggleston has been advocating for FSHD patients for more than five years now, and she continues to be a driving force in advocating for FSHD patients.

This project started in the Fall 2024 semester; therefore, the team has met with Ms. Eggleston at various points over the course of the semester to provide updates regarding manufacturing of the AFO, as well as her providing updates with the patient. The patient's condition has progressed to the point of needing a professional AFO, and Ms. Eggleston provided the team with the information of the orthotist so that future groups can continue to work in tandem with the doctor and herself.

Product Design Specifications

The AFO will be custom designed to fit the patient's specific dimensions and comfort preferences. The device must withstand day-to-day usage, including horseback riding, which the patient enjoys. Additionally, the patient requests that the device has a discrete design, as they would not like to draw attention to the AFO. The device will be 31 cm in length, extending proximally from the distal end of the foot. The device will have a rigid aspect and an adjustable bungee mechanism to provide customizable mechanisms of support for dorsiflexion and ankle inversion. The client experiences foot drop during the heel strike phase of the gait cycle. Therefore, the AFO will need to support normal gait and allow for more than 30° of motion from

neutral ankle position. To support dorsiflexion, the device will provide 5-10 Nm of counteracting force for every 10° of plantar flexion [20]. The device must also prevent inversion angles greater than 25°[21] . In regards to the rigid support, it must resist 30 Nm of torsional forces and withstand a load of 266 N [22]. The budget of this project is $100, but this value could change as it is funded by the UW-Madison's Department of Biomedical Engineering. Additional details on the Product Design Specifications can be found in Appendix A.

Preliminary Designs

Design One: Pivot Pro

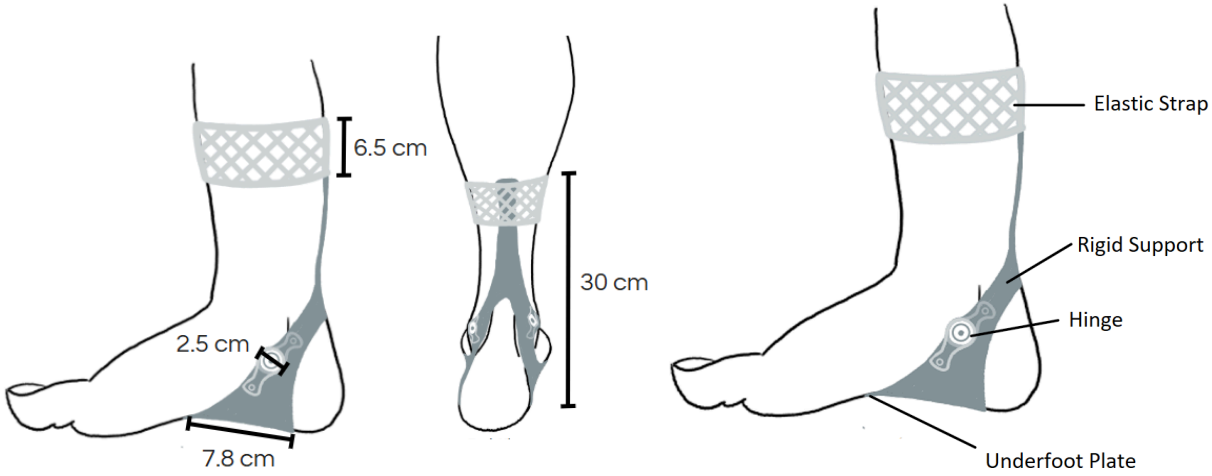


Figure 9: Pivot Pro Dimensions and Components.

The design shown above is called the Pivot Pro, named after the hinge located on the lateral and medial sides of the ankle. The design incorporates a rigid support modeled to the patient's ankle anatomy. It wraps around the back, upper portion of the heel and underneath the posterior arch of the foot. The rigid support travels up the back of the calf and connects to an elastic strap holding the design in place. The hinge allows the underfoot plate to rotate to allow for dorsiflexion and plantarflexion. The hinge will be compact to reduce bulk in the shoe and discomfort for the patient. The entirety of this design will slide underneath the bungee cord apparatus that was constructed last semester.

Design Two: Calf Hugger

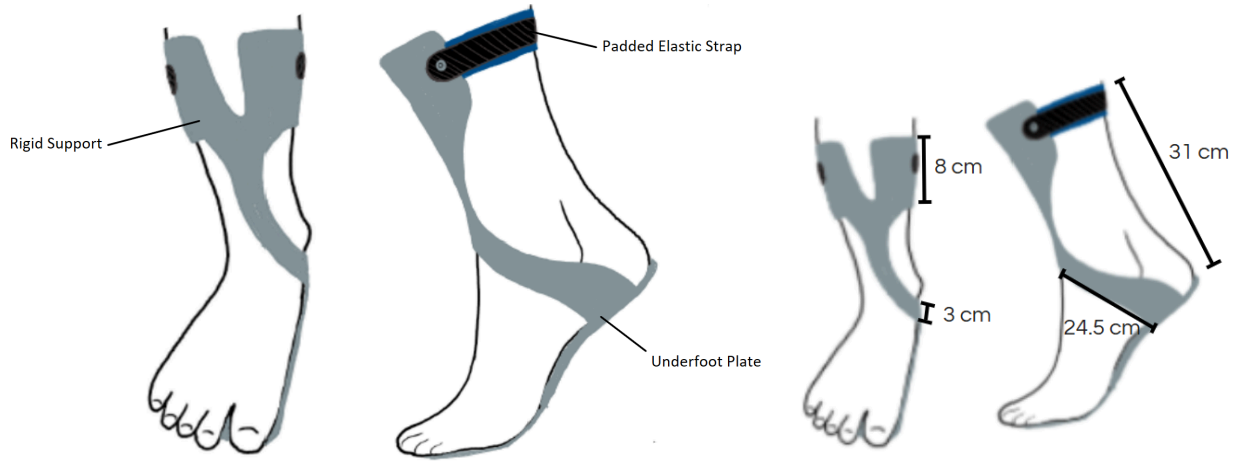


Figure 10: Calf Hugger Dimensions and Components.

The calf hugger design is modeled to wrap around the patient's calf and foot with extreme specificity. This will allow for maximum comfort and discreteness. The front piece follows the shin of the patient and wraps around the side of the foot, passing just below the ankle bone. As ankle inversion occurs on the subtalar joint below the bulk of the ankle protrusion, the design will limit rubbing on the ankle joint and prevent ankle inversion at the subtalar joint. The long rigid support is connected to a rigid plate underneath the foot that provides greater stability of the design within a shoe. Lastly, there are elastic straps connected to the top of the brace via velcro or buttons to hold the design upright. The lack of rigidity along the back of the ankle allows for comfortable dorsiflexion and plantarflexion and reduces rubbing during the gait pattern.

Design Three: We Support U

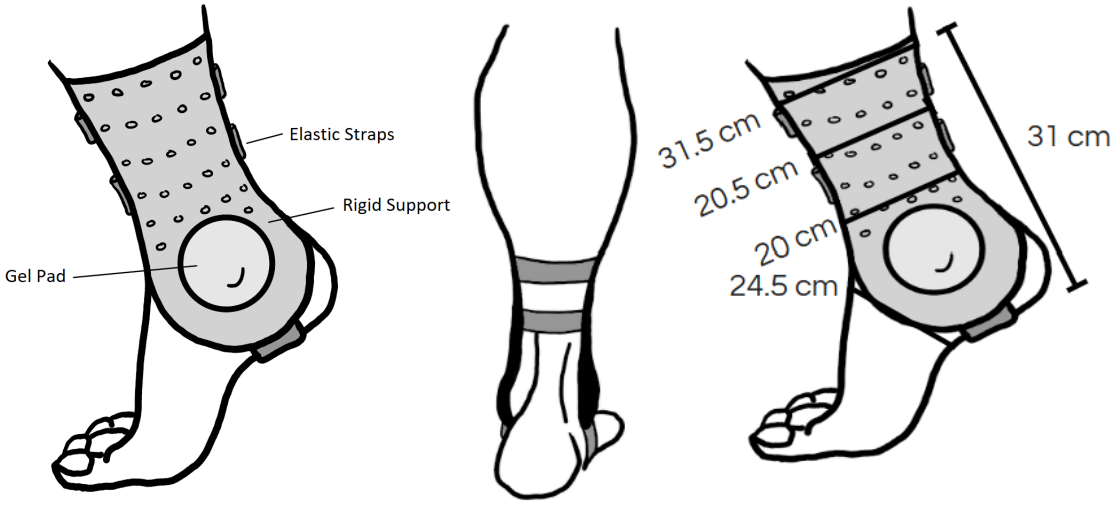
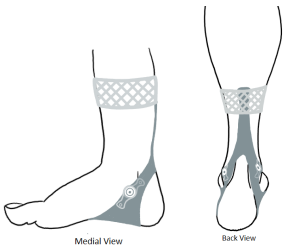
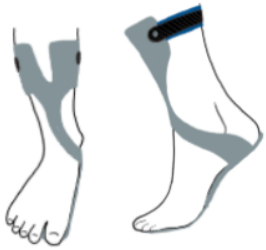
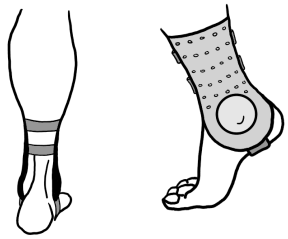


Figure 11: We Support U Dimensions and Components.

We Support U is the final design, as it resembles a “U” shape along the ankle and offers support while walking. The design consists of two rigid plates placed medially and laterally along the side of the shin to the subtalar joint. The plates may incorporate perforations to allow for breathability and airflow. There are two adjustable elastic straps along the front and back of the calf to allow for customizability and adjustability for the patient. These straps will travel through slots along the side of the brace and wrap back onto themselves. A gel pad is inserted into a cavity on the lateral sides of the brace to ensure the ankle does not rub on the rigid support. Lastly, another elastic band dives under the posterior arch of the foot to fasten the bottoms of the slabs together.

Preliminary Design Evaluation

Rigid Support Design Matrix

Criteria	 Design 1: Pivot Pro		 Design 2: Calf Hug		 Design 3: We Support U	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Dorsiflexion range of motion (20)	3/5	12/20	2/5	8/20	5/5	20/20
Mediolateral support (20)	3/5	12/20	3/5	12/20	4/5	16/20
Ease of user assembly (15)	4/5	12/15	4/5	12/15	3/5	9/15
Comfort (15)	2/5	6/15	3/5	9/15	4/5	12/15
Discreteness (10)	3/5	6/10	4/5	8/10	2/5	4/10
Ease of	1/5	2/10	2/5	4/10	4/5	8/10

Fabrication (10)						
Cost (5)	3/5	3/5	4/5	4/5	3/5	3/5
Safety (5)	4/5	4/5	5/5	5/5	5/5	5/5
Total	57/100		62/100		77/100	

Table 1: Design Matrix for Preliminary Designs.

Summary of Design Matrix

To properly evaluate the three designs, a multitude of criteria were considered. The criteria were chosen based on client-expressed desires, product design specifications, and fabrication concerns. The following criteria and constraints are outlined below:

1. **Dorsiflexion range of motion:** Dorsiflexion range of motion refers to the degree of dorsiflexion and plantarflexion motion that each design allows. This category was given a weight of 20 because one criteria of the brace is to provide the patient additional dorsiflexion support. If this motion is inhibited by the rigid support, then the overall functionality of the brace decreases. A higher score represents a design that allows for more dorsiflexion range of motion. Design 3 was ranked the highest in this category because it has nearly zero inhibition of dorsiflexion motion. The first two designs, however, both include rigid components that might inhibit the range of motion of the foot by limiting ankle motion or general foot motion.
2. **Mediolateral support:** Mediolateral support refers to how effectively each design prevents inversion (and, ideally, eversion) of the ankle. This category is also weighted 20 because the second most imported criteria provided by the client was protection against ankle inversion. A higher score represents a design that allows for more mediolateral support and prevents ankle inversion best. We Support U won this category because it includes the most material along the ankle, on both sides, providing the greatest amount of support. The Calf Hugger and the Pivot Pro both provide similar support in that they only inhibit motion at the subtalar joint. While this is location ankle inversion transpires, it does not provide nearly as much stability during the gait cycle.
3. **Discreetness:** Discreteness refers to inconspicuousness of the brace. The brace should fit underneath the patient's pants and shoes while sporting an athletic-like appearance. This category is weighted a 10 because the client is a high schooler who does not want to draw attention to her ankle. She is often ridiculed for her appearance and gait pattern at school, so the goal is to reduce the noticeability of the brace. The highest score represents the most discreet design. The Calf Hugger design was ranked the highest in discreteness because it uses the least amount of material and has the most sleek and narrow design. The Pivot Pro rigid support is designed to fit within the shoe, and the strap will fit under

the pants. It resembles a little less like an athletic brace due to the strap rising above the brace. Lastly, the We Support U design ranked the lowest because it is the bulkiest and uses the most material to provide support.

4. **Ease of user assembly:** Because the client intends to use this device everyday, it must be easy and simple to don and take off. Ease of user assembly is weighted a 15 because it is a downfall of most braces on the market currently. The highest score represents the most user-friendly brace. Pivot Pro and Cald hug won this category because both designs require the patient to simply slide her foot into the brace. The We Support U brace, however, requires the user to strap the design together upon wearing it to allow for customizability and stability.
5. **Comfort:** The comfort category considers how comfortable the brace is for the client to wear. Comfort is weighted 15 because the client intends to wear this brace during all of her daily activities. If the brace causes discomfort, the client will not wear it. A higher score represents a design that is more comfortable for the user. We Support U won this category because it has padding around the ankle and no material on the front or back of the heel, which is usually a pain point for brace wearers. Pivot Pro placed last in this category because of the hinge directly below the ankle joint and the material pressing near the achilles tendon. Lastly, the Calf Hugger placed second because it has less material on the ankle joint, but does have a piece running down the front of the shin that may cause discomfort during dorsiflexion.
6. **Ease of fabrication:** Ease of fabrication considers how easy each design is to fabricate, including the accessibility of materials needed and the time required for fabrication. Ease of fabrication is weighted a 10 because, although the design needs to be practical to produce, there is considerable flexibility in the time and fabrication processes that can be used. The We Support U design will be the easiest to fabricate because it requires the least amount of specific patient anatomy and specificity. The Calf Hugger's success relies heavily on the team's ability to accurately model the patient's foot and ankle anatomy. This adds additional fabrication challenges because the patient is currently not available in person. The Pivot Pro design is more simple in its molding, but requires a hinge to be effective. Fabricating a small, flat, thin hinge that allows for dorsiflexion and plantarflexion motion will be extremely challenging.
7. **Cost:** The cost category considers the fiscal burden of each design. Cost was ranked a 5 because each design should have a similar total cost, as they all use the same materials. Low scores indicate higher costs. The Calf Hugger will be the cheapest design, as it has the least amount of material to produce. The Pivot Pro and We Support U designs are tied in this category because the Pivot Pro requires purchasing or fabricating a hinge joint and the We Support U brace requires gel padding, elastic straps, and more material than the other two designs.
8. **Safety:** Safety refers to how safe the rigid support is when worn. This category is ranked a 5 because none of the designs have considerable safety risks. The Pivot Pro ranked

slightly lower, however, because the hinge might add a pain point or pinch point when in motion. The Calf Hugger and We Support U designs do not include any components that will lead to injury.

Proposed Final Design

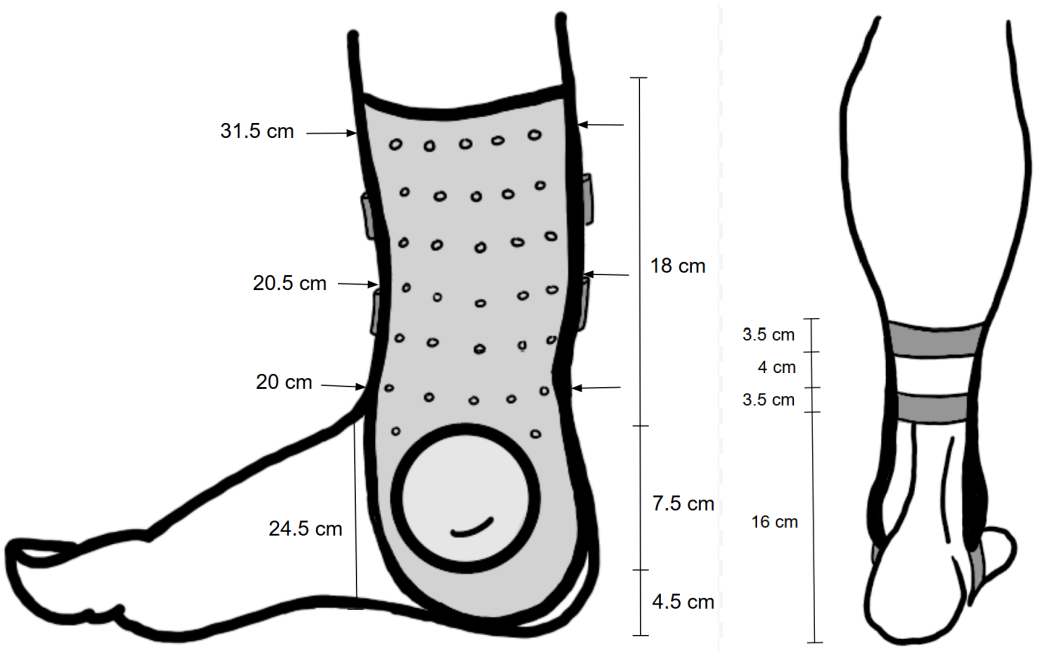


Figure 12: Proposed Final Design Dimensions.

Figure 13: We Support U Preliminary SolidWorks Model, Anterior and Lateral Views.

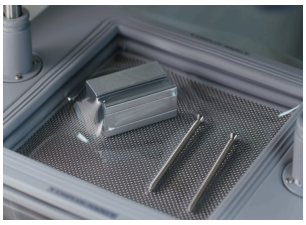
After evaluation of the three rigid support designs, the We Support U design was chosen. This design balances appearance with functionality, as the client will likely grow in her condition, needing more support over time than the other two braces can offer. The CF-PLA supports will prevent ankle inversion and eversion at the subtalar joint. The gel pad will reduce discomfort and rubbing on the ankle joint, and the elastic straps will allow for adjustability and customizability for the patient. Strap attachment methods are being considered, but will likely be composed of slots travelling along the exterior edge of the brace and one under the gel pad for the underfoot strap, as shown in Figure 13.

Fabrication and Development Process

Materials

The final design will incorporate six materials across three components of the device: the foot sleeve, bungee cord mechanism, and inversion support. Specifically for the inversion support, the team considered different materials in attempts to select the most appropriate material. The design matrix and criteria for the inversion support gives insight on our decision making process below.

Materials Design Matrix

Criteria	 Carbon Fiber reinforced PLA composite (CF-PLA)		 Fiberglass Plaster		 Thermoplastics	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Strength/rigidity (30)	5/5	30/30	4/5	24/30	4/5	24/30
Ease of Fabrication (20)	4/5	16/20	5/5	20/20	1/5	4/20

Cost (20)	5/5	20/20	3/5	12/20	4/5	16/20
Safety (20)	5/5	20/20	3/5	12/20	5/5	20/20
Environmental Impacts (10)	5/5	10/10	4/5	8/10	2/5	4/10
Total	96/100		76/100		68/100	

Table 2: Design Matrix for Inversion Support Material

Summary of Material Design Matrix

To evaluate the three materials effectively, criteria was selected to assess the mechanical properties, fabrication process, cost, safety, and environmental impacts of each considered material. The following criteria and scoring decisions are outlined below:

1. **Strength and Rigidity:** This criteria is the highest priority as it is the main determining factor of the support's functionality. Rigidity is assessed based on flexural strength because it will be subjected to bending forces that the material must effectively support the ankle and resist inversion during daily activities. CF-PLA ranks the highest, with a flexural strength of 470 MPa according to the Makerspace material reference sheet. Fiberglass and thermoplastics, while strong, have lower flexural strengths of 50 Mpa [23] and 10-50 Mpa [24].
2. **Ease of Fabrication:** This criteria evaluates the complexity and time required for fabrication, weighted at 20% because it is important to ensure practical material selection and allow for appropriate time for testing and revisions. Fiberglass plaster ranks highest due to its water-based application process, which eliminates the need for precise foot dimensions or modeling. CF-PLA has the next highest rating, as 3D printing is relatively simple but requires a 3D scan for customization. Thermoplastics rank lowest due to their complex fabrication process, which involves a heat gun and vacuum sealing.
3. **Cost:** Cost is weighted as 20% due to the $100 budget and funding through BME design. CF-PLA received the highest rating because the Makerspace offers minimal 3D printing cost compared to fiberglass plaster, which requires bulk purchasing, and thermoplastics, which are inexpensive but still more expensive than 3D printing.
4. **Safety:** The primary safety concern is skin irritation as the material will be in direct contact with the skin for an extended period of time. CF-PLA and thermoplastics scored highest due to their smooth surfaces, while fiberglass plaster ranked lower due to potential skin irritation from fiberglass dust or fragments.
5. **Environmental Impacts:** Environmental impact considers the material's effect on the Earth, particularly its recyclability. While this is an important factor, our design is customized for an individual patient and is unlikely to be mass-produced, so this criterion

is weighted at 10%. CF-PLA and fiberglass plaster have similar environmental impacts, but CF-PLA scores highest due to its high recycling rate and improved strength after remanufacturing [25]. Thermoplastics rank the lowest because non-degradable plastics can release methane and harm wildlife [26].

Inversion Support: Carbon Fiber Reinforced PLA Composite (CF-PLA)

As decided from the materials design matrix, the rigid support pieces around the ankle will be made from CF-PLA, chosen for its lightweight, high flexural strength, and sleek, low-profile design.

CF-PLA's lightweight nature will allow for ease of use, enabling better movement while reducing fatigue and pain for the user. Its sturdiness ensures resistance to everyday wear and tear, providing long-term support. With a flexural strength of 470 MPa, CF-PLA maintains its integrity under high bending loads. The ankle experiences an average force of 266 N generated mediolaterally for an individual with typical gait patterns. CF-PLA well exceeds the strength required to prevent inversion. The extra strength helps withstand higher force caused by increased inversion due to FSHD symptoms during dynamic movements and potential falls, ensuring effectiveness in real-world conditions. These combined properties optimize ankle stabilization for overall gait improvement [27].

Although this device is custom-made to fit the patient's dimensions and not intended for mass production, CF-PLA has a high recycling rate, and its mechanical properties improve after remanufacturing. Recycling CF-PLA involves reversing the 3D printing process by using a hot air gun to melt the composite and recover the carbon fiber to be used in the next printing process. Through this recycling approach, 100% of the carbon fiber and 73% of the PLA matrix are recovered and reused, requiring only 67.7 MJ/kg - significantly less energy than original CF/PLA production [25].

Additionally, CF-PLA is low in cost at $0.05 per gram of material [28]. Granted access to University of Wisconsin-Madison's Design Innovation Lab allows for fabrication processes including 3D scanning, 3D printing, and additional CF-PLA manual refinement with minimal costs.

Foot Sleeve: **Nylon, Polyester, and Latex**

The foot sleeve of the brace will be composed of a blend of nylon, polyester, and latex. These materials were chosen for their specific properties that enhance both functionality and comfort. The sleeve's breathability will absorb sweat and keep the foot dry, providing comfort during extended use. The material will also be tight and strong, ensuring that the sleeve stays securely in place without sliding. Additionally, the fabric is smooth and soft, adding comfort, while its graduated compression promotes circulation, providing support and pain relief to the user [29].

Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight [30]. Polyester,

known for its durability and strength, is ideal as it retains its shape and resists wrinkles, shrinking, and environmental elements like water and wind, which is crucial since the device will frequently be exposed to outdoor conditions [31]. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining overall strength [32]. Since this device will be worn on the foot during activities that involve sweating, these properties are essential to ensuring both the functionality of the design and the comfort of the user.

Bungee Cord Mechanism: Lock Lace, Bungee Cord, and Casing

A thin black bungee cord that is ⅛ inch in diameter and has 100 lb max tensile strength will be used. This specific cord was chosen because it is less bulky and requires less cord displacement, but still offers the patient the support needed for dorsiflexion. The bungee cord will apply adequate tension, strength, recoil, and flexibility needed for gait support.

The bungee cord is securely sewn at the base of the foot and anchored by a 3D-printed black PLA casing, which houses a spring-loaded cord lock from Lock Lace, positioned on the anterior side of the shin. This mechanism ensures consistent tension while the brace is worn.

Current Prototype

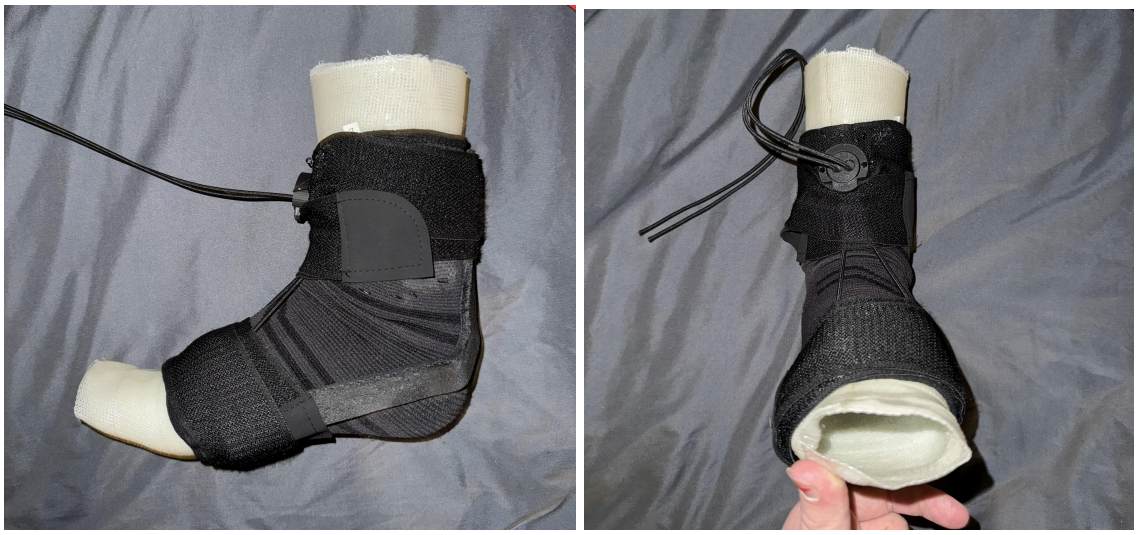


Figure 14: Bungee Brace Assembly, Lateral and Anterior Views.

The final design consists of three main components: the inner and outer compression socks, the bungee cord mechanism, and the rigid inversion support. Each element was designed to address the patient's difficulties with maintaining dorsiflexion and preventing inversion during daily activities.

The inner compression sock features strategically placed gel pads at key pressure points, including the medial malleolus and the posterior leg. These gel pads serve to cushion areas susceptible to pressure from the rigid inversion support, enhancing comfort and reducing

irritation. The gel pads are intended to accommodate individual needs by adjusting the gel placement based on personal preference. The outer compression sock secures the rigid support and anchors the bungee cord mechanism while maintaining a sleek and black “athletic brace” look. Two adjustable Velcro straps provide a customizable fit, ensuring that the brace remains secured throughout movement.

The bungee cord mechanism incorporates a Lock Lace system housed within a custom 3D-printed holder, positioned on the anterior leg. The bungee cord can be adjusted to match specific support needs. The more tension in the bungee cord will provide an increased dorsiflexion support.

The rigid inversion support extends from the posterior side of the leg and runs along the medial side of the right foot, offering stabilization against excessive inversion. The inversion component is 3D-printed from a CF-PLA composite. The design was tailored using x, y, and z coordinate measurements from a team member.

Overall, the Bungee Brace is ideally built to effectively prevent falls, minimize foot inversion, and support dorsiflexion, providing a practical and user-friendly solution for everyday wear. For additional information on current design fabrication methods, refer to Appendix B.

Strengths and Limitations of the Current Design

The current prototype incorporates good fundamental components, which were evaluated through gait analysis on a healthy individual (see the testing section for more details). Among the different components, the bungee cord mechanism proved to be the most promising as it maintained an increased dorsiflexion angle throughout gait. Additionally, the brace featured a sleek, black aesthetic, designed to resemble an athletic brace to remain discrete.

Despite these strengths, the prototype has areas that require further updates and refinements. One of the primary concerns is the rigid inversion support, which the team aims to improve this semester. Gait analysis results indicated minimal to no mediolateral change, suggesting that the current inversion support may not be effective. This could be attributed to the inaccuracies in the customized dimensions caused by the limitations in SolidWorks to build specified dimensions in three different planes. The current prototype has visible gaps along the leg where the rigid support should be flesh with the skin, causing bulkness and functional concerns. Another key challenge is the brace’s usability. With multiple components and two tight compression sleeves, the current design can be difficult and time consuming to put on and remove. Moving toward, the team aims to create a more cohesive design with improved usability that incorporates the bungee cord mechanism and updated inversion support.

Methods

The team is currently using the patient’s leg cast to obtain accurate dimensions for the updated rigid inversion support. In the previous semester, the cast was sent from the client in Michigan to the University of Wisconsin-Madison. Due to an unsuccessful attempt to create a mold of the cast’s interior, the cast has a hard epoxy coating. This semester, the team used a

dremel to cut the epoxy-coated cast in two parts, exposing the medial and lateral dimensions of the patient's right leg.

The cast provided to the team by the patient must be 3D scanned and modeled. The Creality RaptorX device in the Makerspace is the best option for 3D scanning our piece because it is readily available, does not require high definition parts, and can depict crevices in the item. This wireless blue laser scanner does not require the use of sprays, can model objects ranging from five millimeters to 157 inches long, and can fully replicate the model in color [33]. Using the device's software, both sides of the cast can be scanned into a mesh file, smoothed, simplified, and refined. After being exported as an "obj" file, the mesh will be imported into SolidWorks to build splines off of. Lastly, the splines will be lofted and the solid extruded into the desired shape and dimensions before being 3D printed.

The 3D-printed inversion support will feature side slits designed to secure the support using flexible fabric. The fabric will be threaded through the slits and fastened to the leg at two locations around the shin and one location beneath the heel. To engineer a more cohesive and user-friendly design, additional fabrication methods are needed to incorporate the bungee cord mechanism. The goal is to enhance ease of use, making the brace simpler to put on and remove while maintaining both functionality and aesthetics.

Testing

Previous Semester Testing

During the previous semester, the team conducted testing to evaluate the effect of the AFO on gait in a healthy individual using Runeasi, a device equipped with an internal measurement unit (IMU) located on the lower back to measure biomechanical data [34]. Using the acceleration of the body center of gravity, Runeasi was capable of calculating measuring four main metrics:

- Dynamic instability (%): the mediolateral movement during walking.
- Ground time contact (ms): the duration of foot to ground contact.
- Impact magnitude (G): the vertical force transmitted to the pelvis at initial contact.
- Cadence: refers to the number of steps a person takes per minute during walking or running.

Testing was performed under three conditions: walking with the brace, without the brace, and with the brace minus the rigid support. Results demonstrated that the previous semester's prototype brace had no adverse impact on gait in a healthy individual and maintained high comfort levels throughout use. However, testing revealed no improvement of dynamic instability indicating the device's limitations in mediolateral support. Additionally, despite slight slippage in the bungee cord lock mechanism, the brace successfully supported dorsiflexion by raising the resting foot angle by 38° compared to the natural resting position.

Although Runeasi provided useful insights, it is no longer available for use, necessitating alternative testing procedures to evaluate device performance requirements.

Testing Limitations

Debbie Eggleston and the patient reside in Michigan, making in-person testing a challenge. To identify necessary initial adjustments, the team plans to first test the device on an unaffected individual before conducting trials with the client.

Finite Element Analysis

To effectively evaluate the rigidity of the design and ensure its ability to meet force and torsional requirements established in the PDS, Finite Element Analysis (FEA) will be conducted via SolidWorks. SolidWorks SimulationXpress Analysis Wizard is an easy-to-use portfolio of structural analysis tools that utilize FEA to predict a design's real-world physical behavior through virtual testing of CAD models. The portfolio provides linear and non-linear static and dynamic analysis capabilities which will allow the team to evaluate design requirements without physical destruction of prototype parts. Use of SimulationXpress will help to reduce cost and time by eliminating the need for expensive and time-consuming mechanical tests.

Specifically, FEA in SolidWorks will be used to ensure that the rigid components of the support can withstand a force of 266N, as specified in the PDS and that moment-ankle characteristics remain within a torque range of ±30 Nm without causing deformation of the rigid support [35], [36].

In addition to force and torsional design specifications SolidWorks Simulation will be used for fatigue and cyclic loading testing to simulate the forces and motions experienced during the complete stance phase of walking. This motion includes the moment the heel strikes the ground to the moment the toe leaves the ground. The fatigue analysis will evaluate the effect of cyclic loads on the part, therefore providing performance characteristics of the orthotic device and ensuring that it meets the quality and safety standards outlined in the PDS and ISO Standard 2267:2024 [37], [38].

The SimulationXpress Analysis Wizard can be accessed directly from the Tools menu in SolidWorks. Before starting the analysis, the preferred unit system will be selected. Required fixtures and loads will be applied along the inside of the rigid support as per the specified design parameters. The material, CF-PLA composite, will be registered in SolidWorks, and the simulation will be executed. Based on results, further adjustments will be made to optimize the part's performance.

Comfortability Testing

To meet design and client requirements, the AFO must maintain a low profile and fit comfortably within a standard shoe without the need for specialized footwear. To assess the comfort level of the device during walking, a participant will undergo a comfortability testing protocol in which they will be asked to walk at a normal pace for 5 minutes while wearing the brace. After completing the walking session, participants will rate their comfort level on a scale of 1-10, where 1 indicates extreme discomfort and 10 represents no discomfort. Participants will

be encouraged to consider factors such as pressure points, stability, ease of dorsiflexion, ankle stiffness, and overall sensation while wearing the device.

This simple and subjective assessment will identify areas for improvement in the design and ensure that the device meets both functionality and comfort requirements prior to client evaluation. Results are expected to highlight problem areas and guide alterations to the design prior to client presentation, during which further customizations will be made as necessary.

IMU and MoCap Testing

To effectively assess the AFO design against physical performance requirements outlined in the PDS the team will conduct testing using Inertial Measurement Units (IMUs) and Motion Capture (MoCap) technology via OptiTrack. OptiTrack is a high-precision motion capture system that tracks the movement of objects in three-dimensional space using specialized software. The technology can be integrated with IMUs to provide a more comprehensive analysis of human movement, typically achieving less than 0.2 mm of measurement error across large testing areas [39]. These tests will enable quantification of specific motion parameters while wearing the orthotic, including: plantarflexion and dorsiflexion range of motion as well as ankle inversion stability.

To evaluate ankle inversion, a participant will wear the AFO and walk along a straight path toward motion capture cameras, which will track movements in the coronal plane. IMU sensors will be strategically placed on the ankle to measure the angle of inversion throughout the natural gait cycle. Results will confirm whether the angle of ankle inversion remains below the 25 degree requirement outlined in the PDS, therefore ensuring that the AFO provides adequate stability [21].

A separate test will assess the orthrotic's ability to facilitate dorsiflexion during gait. Evaluation will begin with a goniometer measurement to establish maximum allowable dorsiflexion and plantarflexion angles measured from resting foot position while wearing the ADO. Next, the participant will walk along a straight path parallel to the motion capture cameras to track natural gait movements in the sagittal plane. Optitrack software will then be used to test whether the design allows for at least 30 degrees of dorsiflexion from neutral foot position, facilitating sufficient foot clearance during the swing phase [40].

Discussion

Ethical and Safety Concerns

To address ethical concerns, the patient must be fully informed about the potential risks associated with using the prototype, as well as the various testing methods involved. This ensures the patient can make an informed decision regarding their voluntary participation. Informed consent must be obtained and is able to be retracted at any point during the project. To prioritize patient safety and well-being, pain levels will be regularly monitored throughout the testing. If

pain levels exceed a low to moderate threshold, testing must immediately stop and the prototype will be refined to further enhance comfort.

It is essential to recognize that not everyone has equal access to orthotics. Socioeconomic differences significantly influence the availability of healthcare resources, limiting many individuals' access to necessary orthotics. The treatment of rare diseases, although individually uncommon, is associated with substantial health and financial burdens globally. Custom orthotics, in particular, require a high level of expertise and resources that are not readily available. On average, the total societal burden of muscular dystrophy ranges between $80,120 and $120,910 per patient annually, increasing significantly with disease progression. The corresponding household burden is estimated to be between $58,440 and $71,900. Given the substantial costs associated with such conditions and treatment options, it is vital to consider the socioeconomic impacts of engineering design [41].

The use of advanced materials, such as carbon fiber composites, enhances the durability and performance of orthotic devices; however, these advancements come with significant expense. While the durability of the device may improve with the use of more advanced materials, the increased cost raises concerns about affordability and poses important questions about accessibility among diverse populations. To satisfy ethical considerations, it is essential to consider reducing the cost of replication to ensure broader accessibility in the case of a reproducible design.

Considering safety factors, the device must be able to withstand the cyclic loading during walking and provide proper anatomical alignment. Alignment must be maintained to avoid excessive tension, compression, or shear forces on joints, bones, and muscles to ensure long-term musculoskeletal health. The device’s use of new materials raise allergy concerns that must be considered during design analysis. There must be a protective layer between the user and the CF-PLA composite to avoid skin irritation and maximize comfort while protecting the user. In case of emergency, there must be a protocol for easy and quick removal of the designed orthotic

Given the task of manufacturing a single AFO for use, it is crucial to evaluate the environmental impact of its production, including material sourcing, energy consumption, and waste generation. While the impact of a single device may be minimal, scaling up to mass production introduces additional sustainability concerns. In analysis of such design factors, it is especially important to consider manufacturing processes. Among industry standards, additive manufacturing (AM), particularly 3D printing, has emerged as a promising alternative to traditional fabrication methods. AM enables customization to minimize material waste and reduce mass and energy consumption that contribute significantly to greenhouse gasses and global warming [42]. Consideration of these factors early in the design process ensures a more responsible approach to both individual and large-scale production.

Design Evaluation

The previous semester’s design demonstrated that the design effectively supported dorsiflexion without interfering with normal gait. However, the rigid support did not provide

adequate ankle inversion control, and proved difficult to take on and off. By refining this aspect of the design with, the We Support U design, will provide additional ankle support while preserving free range of dorsiflexion and plantar flexion. When combined with the adjustable bungee mechanism from the previous design, this updated AFO will remain easily concealable, offer sufficient ankle stability, and accommodate the client' progressive condition while also meeting her aesthetic preferences.

Potential Sources of Error

In the design and fabrication of the device, potential sources of error may arise from measurement inaccuracies and modeling discrepancies. Slight errors in capturing the client's foot dimensions or inconsistencies in the translation of the 3D-scanned mesh into SolidWorks could lead to an imperfect fit of the rigid support. To mitigate this, the team will refine the model with each prototype iteration and consult the client for necessary custom adjustments. Additionally, incorporating interior padding within the rigid support will help compensate for minor fit imperfections, ensuring better comfort and adaptability to the client's exact foot geometry. Another key source of error stems from testing limitations during the preliminary design phase.

Since the client resides in another state, the device cannot be tested directly on her patient at this stage in the design process. As a result, initial testing will be conducted on a different subject, whose biomechanics will not perfectly match the client's. While this may introduce discrepancies in testing results, it will still provide a baseline for PDS evaluation, which can be further refined once direct client testing becomes possible.

Additionally, material properties and fabrication inconsistencies may contribute to variation in the rigid support's performance. Differences incurred by 3D printing precision, carbon-fiber reinforcement distribution within the PLA composite, and bungee cord tensioning could lead to slight variations between prototypes. All of these factors have potential to affect overall rigidity, support, and ease of use. Finite Element Analysis will allow for consistent evaluation of the support despite potential discrepancies in fabrication.

Finally, qualitative user feedback and subjective assessments obtained from comfortability testing procedures may introduce variability as comfort, ease of use, and perception of support differ among test subjects.

By addressing these potential sources of error through iterative prototyping, controlled testing conditions, and direct client feedback, the team aims to strategically improve the design's accuracy, functionality, and overall effectiveness.

Conclusions

The development of this custom AFO aims to provide necessary functional support for a high school student with FSHD, while maintaining a discreet and aesthetically appealing design. Current designs fall short of the clients needs and fail to avoid drawing attention from unwanted peers. Given the client's concern regarding an inconspicuous AFO, the final preliminary design

integrates a CF-PLA composite rigid support along with a bungee lock lace mechanism, previously validated from last semester's design. This combination ensures adequate dorsiflexion assistance and ankle inversion stability while still resembling a standard athletic brace, thus minimizing visibility and social discomfort during use. By achieving a balance between functionality and subtlety, this AFO seeks to enhance mobility, confidence, and overall quality of life for the patient.

Future Work

As previously mentioned, the team's general next steps include successfully fabricating an updated inversion support and incorporating the bungee mechanism into one cohesive device. Additionally, testing will be conducted to evaluate the updated brace's comfort and effectiveness preventing mediolateral ankle movement and supporting dorsiflexion. Based on testing results and input from the client, the team will make further refinements to the design.

In the future, the team desires to increase accuracy of the braces's dimensions by directly scanning the patient's foot. This will simplify the fabrication process as the mesh 3D scan file would not require smoothing or an excessive amount of modifications. Ideally, the rigid support fabrication process will be structured and straightforward, allowing for easy remanufacturing to accommodate the patient's support needs and growth.

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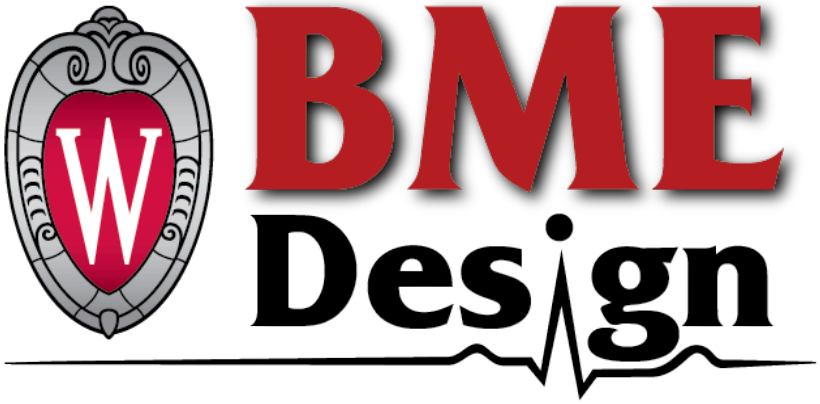
Appendices

Appendix A: Product Design Specification (PDS)



Inconspicuous Ankle Foot Orthosis (AFO) for teen

PRODUCT DESIGN SPECIFICATIONS (PDS)

Team Name:
Rise and Stride

Team Members:
Lucy Hockerman (Team Leader)
Presley Hansen (BSAC)
Madison Michels (Communicator)
Kate Hiller (BPAG)
Sadie Rowe (BWIG)

Client:
Debbie Eggleston

Advisor:
Doctor John Puccinelli; University of Wisconsin - Biomedical Engineering Department
Lizzie Maly; University of Wisconsin - Biomedical Engineering Department

February 6th, 2025

Function/Problem Statement:

Facioscapulohumeral Dystrophy (FSHD) is one of the most common types of muscular dystrophy, affecting approximately 4-10 in 100,000 individuals. This genetic disorder leads to progressive muscle weakness, and while there is currently no cure, physical therapy, orthotics, and surgery can help manage symptoms [1]. However, there is limited clinical research focusing on children with FSHD, leaving gaps in understanding and addressing their specific needs. This project aims to raise awareness of FSHD and explore the benefits of discrete ankle-foot orthoses (AFOs) for individuals with progressive muscle weakness. The team aims to design a brace for the patient to aid in natural gait for safer walking while being easily concealable and flexible enough to allow for a functional ankle range of motion. The key objectives of this device include positioning the ankle in adequate dorsiflexion, restricting medio-lateral ankle motion, maintaining a narrow, thin, and discrete design, and ensuring sufficient flexibility to minimize any restriction of movement.

Client requirements:

The client requests that the AFO supports dorsiflexion and prevents foot inversion while remaining flexible enough for the patient to carry out their daily activities. Additionally, the client prefers the AFO to be discreet, fitting inside a shoe and minimizing visibility. Functionality, however, is starting to outweigh discreteness as the patient's disease progresses.

Design requirements:

1. Physical and Operational Characteristics
    a. Performance requirements
        i. The AFO must be designed to be discrete and involve minimal material while providing strong support for ankle dorsiflexion and resist ankle inversion to prevent irregular gait [1].
        ii. The device should mimic normal gait without providing any resistive moment during dorsiflexion [2]. Additionally, it should allow a range of motion of more than 30° from the initial ankle angle to facilitate foot clearance [3].
        iii. The device should generate a resistive moment in the plantarflexion direction and should be adjustable in the range of 5-10 Nm per 10° of plantarflexion [3].

iv. Moment-angle characteristics should be maintained within a torque range of ±30 Nm. Additionally, the design must resist torsional forces that could lead to misalignment of the ankle or foot during typical activities [4].

v. The design must withstand the maximum bodyweight forces exerted by a teen. The average weight of a 16-year-old teenager in the United States is 136.2 lbs [5] and during walking, forces exerted on the AFO are estimated to be three times the body weight [6].

vi. Design must possess sufficient flexibility to allow for active concentric ankle movement, enabling the user to perform daily activities effectively, such as squatting and ascending/descending stairs.

vii. The AFO dimensions must be tailored to the client's leg geometry and customizable to ensure a secure fit. Ideally, the design should incorporate the patient's custom-made orthotic insole.

viii. The rigid inversion must support a minimum flexural strength of 266N in order to restrict unwanted mediolateral movement.

ix. AFO design must prevent inversion angles greater than 25° [8].

b. Safety

i. To prevent tripping and falling, the brace must facilitate normal gait patterns and enhance balance. Proper anatomical alignment must be maintained to avoid excessive tension, compression, or shear forces on joints, bones, and muscles to ensure long-term musculoskeletal health.

ii. In a manufactured and marketed design, the chosen material must be non-toxic and hypoallergenic to minimize the risk of skin irritation or allergic reactions. All surfaces must be smooth and free of sharp or ridged edges to prevent risk of surface wounds or abrasions.

iii. The outer surface of the AFO material must offer sufficient traction to prevent slipping when worn without shoes.

iv. Adjustable components of the design must remain secure under strong impacts while avoiding restriction of blood flow.

v. Any fastening mechanisms should prevent loosening or dislodgement during regular physical activity.

vi. The AFO must feature mechanisms for quick and easy removal in case of emergency without the need for specialized tools.

vii. The design should allow breathability to prevent overheating and moisture buildup.

c. Accuracy and Reliability

i. The AFO design must maintain structural integrity with repetitive use while consistently providing support to ensure proper anatomical alignment of the ankle and foot. Carbon fiber AFOs typically fail at the mid-shank region of the calf support under forces of 1970 N [9]. To limit the possibility of injury, the calf support should include a padding layer to protect the user in case of material failure. Additionally, the soft padding material must be easily replaceable after extended use to prevent user discomfort from padding degradation.

d. Shelf Life

i. Custom orthotics are tailored to the patient's specific measurements and support needs. They are designed for immediate and continuous use. If left unused for an extended period, the patient's measurement or support requirements could change, making the AFO ineffective. Therefore, the shelf-life should be limited, and the AFO should be regularly assessed to ensure it continues to meet the patient's evolving needs.

e. Life in Service

i. The lifespan of an AFO depends on several factors, including material composition, frequency or intensity of use, and changes to the patient's needs. Generally, it should last around 5 years [10].

ii. AFOs fabricated using semi-rigid materials like carbon fiber, fiberglass, or polyethylene may last longer than less-stiff materials [11].

iii. An orthotist should review the AFO at least once a year to ensure it continues to meet the user's needs and to check for any signs of deterioration [12].

f. Operating Environment

i. This AFO is designed for day-to-day use and must withstand transportation and frequent use. It will mainly be used around the house, during the school day, and

for horseback riding. The bulkiness of the device should be considered so that it can still be inserted into horseback riding shoes.

ii. It will be used both indoors and outdoors, exposed to varying temperatures, humidity, dirt, water, and sweat. The AFO should be cleaned with mild soap and water at least once a week to prevent bacterial build-up [13].

g. Ergonomics

i. The AFO must be capable of withstanding the maximum downward force exerted by the user's weight while distributing this force in a way that avoids excessive pressure points.

ii. The design should allow for adjustments to accommodate the growth, such as adjustable straps to ensure a secure and personalized fit for the intended product life in service.

iii. Current AFOs commonly weigh between 0.3 and 3.4 kg depending on the material and bulkiness of the device. The AFO should be as lightweight as possible while maintaining proper function to ensure normal gait patterns and reduce fatigue [14].

iv. Padding should be provided around sensitive areas, such as the Achilles tendon, ankle, and foot base, to prevent discomfort and skin irritation.

v. The orthosis should maintain a low profile and be able to fit comfortably within a standard shoe, without requiring the user to wear specialized footwear [3].

vi. Any moveable components of the design should function quietly.

vii. AFOs can increase step length and step velocity of patients which results in more fluid body movement and less energy excursion. AFOs can provide more stability during gait which improves the patient's daily life [15].

h. Size:

i. The size of the AFO must be tailored to the patient's dimensions. Measurements have been taken to closely match the leg. The orthotic should match these measurements, with minor adjustments for padding or other anti-chafing mechanisms in the design [16].

1. Length of the leg (measured bottom of foot to directly below kneecap) is 45.5cm.

2. Diameter directly below the kneecap (measured at top of the lower leg) is 31.5cm.
3. The diameter of the thickest part of the calf (measured mid-leg) is 31.5cm.
4. Diameter where the Achilles meets the calf (measured bottom of leg) is 20.5cm.
5. The diameter of the thinnest part of the ankle (measured where Achilles is felt) is 20cm.
6. Diameter across the middle of the ankle, through the joint is 30cm.
7. Diameter just in front of the ankle joint (measured low ankle) is 24.5cm
8. Arch Measurements: bony prominence to floor is 4.5cm and 6.25cm in length.
9. Length of the foot is 24-24.5cm.
10. Width of the foot (measured where the metatarsals meet the phalanges) is 8.25 cm.
11. Width of the foot (measured in midsole area) is 8cm.
12. Width of the foot (measured at the heel) is 5.5cm.

ii. Typically, an AFO's thickness will be 3.175 mm to adequately support the foot [17]. The device should deform only minimally during use while maintaining enough flexibility to avoid excessive stiffness that could cause instability [3].

iii. AFO must be small enough to fit comfortably inside of a shoe.

i. Weight

i. The orthosis will be light enough to allow a full range of motion without hindrance. The weight will not impair the patient's walking gait or velocity. It should be minimized as much as possible, ideally weighing less than 1 kg [18].

j. Materials

i. The foot sleeve of the brace as well as the bungee cord will be composed of a blend of nylon, polyester, and latex. These materials were chosen for their specific properties that enhance both functionality and comfort [19].

1. The sleeve's breathability will absorb sweat and keep the foot dry, providing comfort during extended use. The material will also be tight and

strong, ensuring that the sleeve stays securely in place without sliding [20].

2. The fabric is smooth and soft, adding comfort, while its graduated compression promotes circulation, providing support and pain relief to the user [20].
    a. Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight [20].
    b. Polyester, known for its durability and strength, is ideal as it retains its shape and resists wrinkles, shrinking, and environmental elements like water and wind, which is crucial since the device will frequently be exposed to outdoor conditions [21].
    c. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining overall strength [22].

ii. The effectiveness of preventing ankle inversion depends highly on the rigid strength of the cast. Fiberglass substrates impregnated with polyurethane resin offer a strength proportional to the square of their thickness. By wrapping the fiberglass twice, the rigid support can withstand a bending deflection of 50 N minimum. With an increase in thickness, the piece can provide exponential strength [23].

iii. The rigid supporting piece along the ankle will be constructed using fiberglass polymer tape. This material was selected for the following characteristics: lightweight, moldable, radiolucent, resistant to degradation by water, inexpensive, high strength-to-weight ratio, and thin profile [23].

iv. There is potential to include a 3D printed component within the fiberglass tape that is modeled after the patient's own anatomy and acts as a reinforcement against ankle inversion. This piece would be fabricated using PLA.

v. Fiberglass substrate's lightweight nature will allow for ease of use, enabling better movement while reducing fatigue and pain for the user. Its sturdiness ensures resistance to everyday wear and tear, providing long-term support. Additionally,

fiberglass substrate's porous nature will allow the patient comfort and breathability. These combined properties maximize the aid needed for foot-dragging prevention, ankle stabilization, and overall gait improvement.

k. Aesthetics, Appearance, and Finish
    i. The AFO will have a black, sleek design to reduce its visibility. It will resemble an athletic brace, promoting a more natural appearance when worn in public. The brace is designed to fit comfortably in tennis shoes and Converse, giving the patient the freedom to maintain their personal style.
    ii. The brace will have a smooth finish and a slim appearance, making it as inconspicuous as possible while still providing the necessary support.

2. Production Characteristics
    a. Quantity
        i. This project consists of making one right-leg AFO. However, considering mass production, the quantity would meet market demands among teens needing right-leg and/or left-leg AFOs.
    b. Target Product Cost
        i. This project is funded by Biomedical Engineering (BME) Design at the University of Wisconsin-Madison. The monetary supplementation is $100 with room for expansion where needed.
        ii. The initial prototype accounted for $189.02 of last semester's budget of $300. $8.71 was covered by the BME department, so the total spent through BME Design funding was $180.30.
        iii. The remaining budget is to be spent on fabricating a rigid support to inhibit the patient's ankle inversion. Because fiberglass substrates are relatively inexpensive, this support should cost under $50 to implement in an initial prototype [24].

3. Miscellaneous
    a. Standards and Specifications
        i. Code of Federal Regulations Title 21, Section 890.3025
            1. This device is classified as a Class I Medical Device. The device will be considered a Class II Medical Device if an electronic component is incorporated [25].
        ii. 501(k) requirements, premarket submission

1. Most class I medical devices are exempt from 501(k) requirements. The device may be exempt if the FDA determines that a 501(k) is not required to provide reasonable assurance of the safety and effectiveness of the device [26].

iii. Code of Federal Regulations Title 21, Section 890.3475

1. This defines a limb orthosis as a medical device worn on upper or lower limbs to support, correct, prevent deformities, or align body structures to improve bodily function. Examples of limb orthoses are as follows: a whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe [27].

iv. Code of Federal Regulations, Title 21, Chapter 1 Part 803

1. Manufacturers and facilities that use the device must report deaths and serious injuries that the device has caused or contributed to through a Medical Device Report (MDR) [28].

v. ISO Standard 14971:2019

1. Risk analysis through Failure Modes and Effects Analysis (FMEA) should be completed to identify potential risks for the patient, operator, and property. This includes gathering data and reviewing literature about the risks of similar medical devices. This standard states the concept of risk involves the probability of occurrence of harm and the severity of its consequences [29].

vi. ISO Standard 8549-3:2020

1. Defines orthosis as an externally applied device utilized to compensate for impairments in the structure and function of the neuromuscular and skeletal system; ankle-foot orthosis is defined as an orthosis that encompasses the ankle joint and the whole or part of the foot [30].

vii. ISO Standard 8551:2020

1. Covers functional deficiencies in prosthetics and orthotics. The standard provides guidelines for the person to be treated with an orthosis, the clinical objectives of treatment, and the functional requirements of the orthosis [31].

viii. ISO Standard 2267:2016

1. This standard outlines a specific testing procedure for ankle-foot devices and foot units used in external lower-limb prostheses.
2. Testing should be completed on how the prosthetic device performs under repeated, cyclical loading conditions that simulate the forces and motions experienced during the complete stance phase of walking. This includes the moment the heel strikes the ground to the moment the toe leaves the ground (toe-off). The testing will provide performance characteristics of the prosthetic device such as its strength, durability, and service life, ensuring the prosthesis meets quality and safety standards [32].

b. Customer [33]

i. The device is intended for everyday use by a 16-year-old teenager, who has been diagnosed with Facioscapulohumeral Dystrophy. While the orthosis will be custom-fitted to the patient's ankle, the primary target audience includes all young individuals diagnosed with Facioscapulohumeral Dystrophy or similar muscular dystrophies that require an ankle orthosis.

ii. The device must be discreet, featuring a slim and narrow design that allows it to be easily hidden under pants or remain minimally noticeable with any type of clothing, ensuring it doesn't draw attention to the individual's physical limitation.

iii. The device must be capable of holding the ankle in dorsiflexion (angle 10 degrees upwards from straight foot plane) when unweighted to ensure foot clearance and prevent gait deviations.

iv. The device must have enough flexibility to ensure that other functional activities, such as squatting or descending stairs, are minimally affected.

v. The device must minimize the need for eccentric muscle contractions while preventing foot slap to support individuals with ankle weakness.

c. Patient-related concerns

i. The device must be flexible enough to allow for natural gait movement while being sturdy enough to support the patient's ankle weakness and prevent foot drop as well as foot collapse (foot inversion specifically).

ii. The device must not interfere with daily activities or draw attention to itself or the patient.
iii. The device must be discreet to prevent drawing unwanted attention and reduce the risk of bullying at school and in other public settings.

d. Additional optional patient requests
   i. The device should be designed to fit comfortably within the patient's horse riding boot.
   ii. The device should resemble a standard athletic brace to avoid drawing attention in public settings.

e. Economic Impact
   i. Given that approximately 53,000 AFOs are fabricated each year in the United States at an average Medicare reimbursement of $417, more than $2.2 million per year are spent on them [34]. These costs may make AFOs inaccessible to low-income families.
   ii. For patients with muscular dystrophies, expenses incur in the form of direct and indirect medical costs.
      1. Direct medical costs include hospital visits, therapy, pharmaceutical treatments, and insurance coverages. The sum of these factors amounts to about $22,533 per year in the United States [35].
      2. Indirect costs include home renovations, vehicle accommodations, home relocations, professional caregiving, dietary supplements, travel expenses, and more. In total, indirect costs in the United States cost approximately $12,939 per patient per year [35].
   iii. One of the largest contributors to the loss of income in families with a member who suffers from a muscular disorder is loss of productivity. While race, age, gender, duration of disease, level of education of the primary income member, and number of adults in the family are considered, the annual loss of income for a family with a patient requiring care is $21,600 less than those who do not need care [35].
   iv. Overall, the total cost of muscular dystrophy disorders in the United States ranges from $1.07 to $1.4 billion per year [35].

v. Providing a cost-effective AFO will alleviate the long-term economic burden of FSHD and increase the productivity of individuals who have the condition, raising their income levels and allocating more funds to treating the condition.

f. Competition

When constructing AFOs, the Three-Point Force system is essential for creating an orthosis that stabilizes a joint or segment to reduce angular rotation. The force is applied either medio-laterally or anteroposteriorly, with counter forces applied above and below the primary force, all summing to zero. The longer the lever of the orthosis, the farther apart the points of force are, resulting in greater correction. This technique can also help reduce pressure and discomfort when wearing the orthosis. This system is incorporated in the majority of existing AFO designs [36].

i. Passive-Dynamic AFO (PD-AFO)
    1. Sleek and flexible design, ideal for patients with less severe ankle weakness.
    2. Have a flexible calf shell, which can absorb energy to promote dorsiflexion by releasing additional energy during the push-off phase of walking.
    3. Shown to provide better comfort and improve spatio-temporal parameters.
    4. Able to customize dimensions for the user through 3D printing but unable to adjust stiffness and support to match the patient's level of ankle impairment [1].

ii. Supramalleolar Orthosis (SMO)
    1. Pediatric SMO's are made from thin and flexible thermoplastic that provides support just above the ankle bones (malleoli).
    2. Primarily used to control subtalar joint alignment to maintain a vertical or neutral heel to help improve mediolateral movement.
    3. Comfortable to wear in shoes due to their thin and minimally restrictive design [36].

iii. Variable Stiffness Orthosis (VSO)

1. This powered AFO features a customizable cam-based transmission able to specify any torque-angle and change the magnitude of its overall stiffness in real time.
2. Found to lead to reduced foot drop and increased total ankle moments.
3. In the research stages, not currently on the market [38].

iv. Jointed AFO

1. Features a hinge at the ankle joint, allowing for motion
2. Optimizes gait patterns and allows for a full range of motion.
3. Drawbacks include being bulkier, potentially noisy, and prone to parts breaking more easily [36].

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Appendix B: Previous Fabrication Methods

The carbon fiber attachment was designed in SolidWorks and subsequently 3D printed at the UW-Makerspace using the Bambu Labs printer [43]. The material will undergo an initial testing evaluation on Solidworks prior to being printed (see testing section for more details). This preliminary testing will assess the strength, flexibility, and overall functionality of the carbon fiber component in the device.

The ankle brace and bungee cord will be purchased (see BPAG cost sheet for pricing details), but the bungee cord will be customized to meet the specific dimensions and support requirements of the patient. The cord will be cut and modified to optimize the level of tension needed to assist with walking. These modifications will be made based on assumptions and initial bungee cord testing and then fine-tuned after an in-person testing session with the patient (see the Testing and Results section for more detailed procedures). To ensure ease of adjustability, the bungee cord will be threaded through a “lock lace” plastic cord lock, which will also be purchased and integrated into the design.

The attachment for the Locklace will also be designed in SolidWorks and 3D printed at the UW-Makerspace using the Ultimaker printer [43]. It will be printed using PLA material also on the Bambu Labs printer, and the Locklace will be assembled by fitting snugly and being glued to the inside the printed piece. Both the Locklace and the 3D-printed piece, when assembled, will be sewn onto the foot brace through two holes on either side of the printed component. This design increases the surface area for improved grip, ensures the Locklace is securely positioned, and facilitates ease of use and adjustability on the brace.

To assemble all components, the gel-padded compression sock will remain separate as an additional layer of comfort and support for the user. The gel pads will be strategically sewn onto the sock at three key locations—behind the calf, around the ankle bone, and near the second attachment point of the carbon fiber support, around the ball of the foot. These placements were determined based on the pressure points identified by team members during and after testing. The carbon fiber attachment will be securely sewn onto the foot sleeve brace using purchased sheets of nylon fabric. This will hold the carbon fiber in place without adding unnecessary bulk or restricting movement. This assembly will be completed by hand using basic black nylon thread and sewing needle. The plastic cord lock and its attachment will be sewn onto the top portion of the foot sleeve, while the bungee cord, once placed under tension, will be threaded through the cord lock, ensuring adjustability. The bungee will then be covered and secured using diagonal Velcro straps, which wrap across the front of the ankle to stabilize the brace. The bottom of the bungee cord will be sewn to the front of the brace, approximately 15.24 centimeters from the top, using additional nylon fabric that will be glued down with strong fabric glue for extra support and reinforcement.

Once fully assembled, the user will be able to put on the brace by first slipping on the compressive sock, followed by sliding the brace onto their foot, both processes like a regular sock. The bungee cord can then be tightened to the user's preference using the cord lock, and the Velcro straps will be fastened as the final step. The design prioritizes simplicity, speed, and ease

of use, as the AFO will be worn daily and taken on and off frequently. This streamlined assembly and adjustment process ensures that the device will be comfortable, user-friendly, and highly functional for everyday use.

Appendix C: Past Semester Expenses

Item	Description	Manufacturer	Vendor	Date	QTY	Cost Each	Total	Link
Ankle Brace - Component 1								
Ankle Brace	Cloth brace	**Abiram**	Amazon	10/10/2024	1	$14.88	$14.88	Link
Gel padding	medical grade padding	**Shchekin**	Amazon	10/10/2024	1	$15.81	$15.81	Link
Gel sock	Compressive sock to support the carbon fiber	**KEMFORD**	Amazon	10/10/2024	1	$15.95	$15.95	Link
Plastic cord locks	End of the bungee	**Heado US**	Amazon	10/10/2024	1	$3.98	$4.20	Link
Nylon Fabric	fabric/cloth to sew carbon fiber	**MYUREN**	Amazon	11/6/2024	1	$12.61	$12.61	Link
Bungee pt 2	stronger bungee to support better dorsiflexion	**LuckyStraps**	Amazon	10/23/2024	1	18.99	$20.03	Link
Bungee	thinner bungee	**Huouoo**	Amazon	10/25/2024	1	$6.32	$6.32	Link
Mini carabiner	small sized carabiner to hold bungee	**REI**	REI	11/4/2024	1	$6.00	$6.00	**In-store**
Shock cord	thinner and stronger bungee	**REI**	REI	11/4/2024	1	$5.95	$6.61	**In-store**
Lock laces	lock laces to fix the slipping problem of the plastic cord lock	**Lock Laces**	Amazon	11/4/2024	1	$12.65	$12.65	Link
Fabric Glue	glue to attach the cord locks to the fabric	**E6000**	Amazon	11/08/2024	**1**	$8.14	$8.14	Link
Needles and Thread	Stronger needles and thread to attach various fabrics	**Basic Home**	Amazon	12/03/2024	**1**	$8.43	$8.43	Link
Carbon Fiber piece - Component 2								
3D printing prototype	3D printing of back support	**Bambu printer**	Makerspace	11/8/2024	1	1.4	$1.40	***covered by our given $50 per team**

3D printing prototype - 3 variants	3D printing of back support	**Bambu printer**	Makerspace	11/12/2024	1	3.8	$3.80	***covered by our given $50 per team**
3D printing prototype	3D printing of back support	**Bambu printer**	Makerspace	11/13/2024	1	1.71	$1.71	***covered by our given $50 per team**
Lock lace piece	3D printing the lock lace piece	**Bambu printer**	Makerspace	11/18/2024	1	0.23	$0.23	***covered by our given $50 per team**
3D Printing Final Prototype	3D printing of back support	**Shen Printer**	Makerspace	12/3/2024	1	1.57	$1.57	***covered by our given $50 per team**
Epoxy Mold - Component 3								
Epoxy	Take cast of the leg	**Easy Pour Epoxy**	Amazon	11/14/2024	1	$39.97	$39.97	Link
Mold release Agent	PVA release agent - Prevent bonding to the cast	**Mrealeazy**	Amazon	11/14/2024	1	0	$0.00	***Used the provided materials in ECB**
						TOTAL:	**$189.02**	