Inconspicuous Ankle Foot Orthosis (AFO) for Teen

PRELIMINARY REPORT

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AFO for Teen

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Client:
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Abstract

This project focuses on the design and preliminary development of an inconspicuous ankle-foot orthosis (AFO) for a 16-year-old female patient with Facioscapulohumeral Muscular Dystrophy (FSHD). The device aims to assist dorsiflexion, reduce ankle inversion, and improve gait stability, while remaining discreet enough for everyday use, particularly in social environments such as high school. Existing AFOs are typically bulky and draw unwanted attention, leading to poor compliance among adolescent users. To address this, the team designed a lightweight, low-profile brace—termed the "Inversion with Straps" model—that integrates carbon fiber-reinforced PLA supports, polyester or TPU straps, and EVA foam padding to balance flexibility, strength, and comfort. The design prioritizes biomechanical effectiveness, user independence, and aesthetic subtlety. Finite Element Analysis (FEA) and planned force-plate and comfortability testing will evaluate performance metrics including torsional stiffness, load tolerance, and user fit. The project builds upon prior semesters' work by combining effective dorsiflexion support with mediolateral stability and durable materials. Ultimately, this prototype serves as a critical step toward developing customizable, discreet orthotic solutions for the patient, emphasizing both biomechanical functionality and psychosocial well-being.

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Introduction

Motivation & Global Impact

AFOs presently on the market are bulky and unappealing to wear. The patient is a teenager who has been diagnosed with Facioscapulohumeral Muscular Dystrophy (FSHD), in need of a foot brace. Due to societal pressures and norms in high school, the patient does not want her brace to draw attention from her peers, so she often does not wear it. The end goal is to create an AFO that corrects experienced foot drop and provides comfort and flexibility to the patient. The subtlety of the AFO will allow the patient to go about her day free from the opinions of her peers, while simultaneously preventing the worst symptoms of FSHD from affecting her walking.

There is limited research done for FSHD in adolescents, so this project will be a stepping stone to advocating for adolescent FSHD awareness. Increased research on how FSHD affects young individuals specifically is desperately needed, and this project will help spread the word.

Aspects of this project can affect a multitude of people on a global scale. As our AFO will be made custom to the client's patient, other AFOs could be made custom to other young individuals with FSHD as well. This device could be modified in the future to fit into other markets, including other conditions that cause foot drop, a different kind of muscular dystrophy, or any ankle destabilization.

Existing Devices & Current Methods

Many AFO's currently exist to help patients suffering from ankle or leg weakness. The patient has expressed disdain with the current methods, as they are not inconspicuous enough to remain judgement free within the context in which she wears the brace. Nonetheless, the following existing devices provide some insight into the methods in which AFO's work, as well as reasoning to why the patient does not want to use these devices.

Figure 1: Passive Dynamic AFO (PD-AFO) [1]

Passive Dynamic AFOs (PD-AFOs) aim to combat drop-foot and assist plantar flexion with a spring-like bending in order to support walking stability [1]. This device is extremely visible and bulky, which does not align with the goals of the client.

Figure 2: Supramalleolar Orthosis (SMO) [2]

Supramalleolar Orthosis (SMOs) as seen in Figure 2 are made from a thin plastic that provides support to the malleoli just above the ankle bones. They can be worn comfortably in shoes, but they do not provide support for dorsiflexion, they only correct misaligned ankles and provide ankle stability [2].

Figure 3: Jointed AFO [3]

Jointed AFOs have a key feature of a hinge joint on the ankle that provides a full range of motion while simultaneously providing mediolateral ankle support [3]. This device is one of the most bulky out of all competing designs. This hinge system is prone to breakage, and with the noisiness and bulkiness combined, it does not match the goals of the client.

Figure 4: Variable Stiffness AFO (VSO) [4]

The Variable Stiffness Orthoses provide a middle ground between powered mechanical orthoses and passive orthoses by being a passive AFO but with an adjustable stiffness. The adjustable leaf spring assists in foot drop and reduces foot striking [4]. VSOs are not currently on the market, as they are still being researched.

Overall, the existing devices are more bulky than what the client and patient are looking for, which is why the team is moving towards a sleeker design. The team may implement ideas from these designs to enable adequate dorsiflexion, but ultimately a new design will be constructed for customizability to the patient.

Problem Statement

Ankle-foot orthoses (AFOs) help support dorsiflexion during walking. For adolescents with Facioscapulohumeral Dystrophy (FSHD), weakened ankle control can increase fall risk. Our project aims to design a brace that improves safety by assisting dorsiflexion, while staying lightweight, discrete, and flexible to allow natural movement. The primary goals of the device are to enable dorsiflexion to combat foot-drop, to minimize mediolateral movement to stabilize the foot, and to ensure the device is sleek and inconspicuous.

Background

The team has been tasked with developing a discrete ankle-foot orthosis (AFO) for Debbie Eggleston's patient, a 16-year-old female living with facioscapulohumeral muscular dystrophy (FSHD). The progression of the disease has resulted in significant muscular weakness, particularly in the lower limb, leading to limited ankle mobility and the onset of foot drop. While the clinical need for an AFO is clear, the patient's perspective adds an important consideration: as a high school student, she is highly conscious of the social and aesthetic implications of wearing a visible orthotic device. The design challenge, therefore, is not only to provide functional stabilization and improve gait mechanics but also to deliver a discreet solution that supports her confidence, independence, and quality of life.

Anatomy & Physiology

Facioscapulohumeral muscular dystrophy (FSHD) is a rare neuromuscular disorder characterized by progressive muscle weakness, primarily affecting the shoulder girdle, hip girdle, and lower limbs. As a result, many patients develop foot drop due to weakened musculature, which disrupts the gait cycle and increases the risk of falls. FSHD is the third most common form of muscular dystrophy, with an estimated prevalence of 1 in 15,000 individuals [5]. The condition most commonly presents in females during their late twenties to early thirties. There are two recognized subtypes, FSHD1 and FSHD2, with approximately 95% of cases classified as FSHD1 [5].

The patient in this case has FSHD1, an autosomal dominant muscular disorder linked to the 4q35 region of chromosome 4. In affected individuals, the EcoRI fragment is partially deleted, measuring less than 35 kb in length rather than the typical 35–300 kb with multiple repeat copies [6]. Additionally, mutations in epigenetic regulators have been associated with disease progression [7]. Another contributing mechanism is the aberrant expression of the DUX4 gene within the D4Z4 region of chromosome 4. Normally, the DUX4 protein is expressed at low levels during fetal development and silenced in most adult tissues. In healthy individuals, hypermethylation—an increased number of methyl groups attached to the DNA within the D4Z4 region—maintains this silencing [8]. In FSHD, however, reactivation of DUX4 expression damages muscle cells and drives disease pathology.

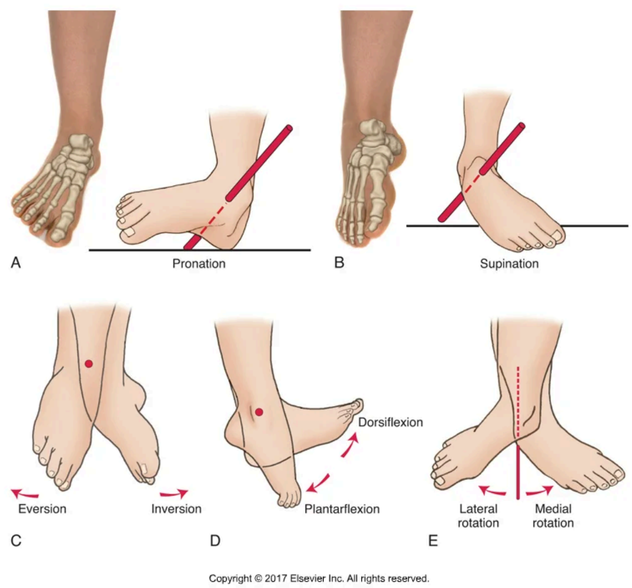


Figure 5: Illustration of various anatomical positions [9]

The primary purpose of the ankle-foot orthosis (AFO) is to provide dorsiflexion support, thereby addressing foot drop and improving gait mechanics, as illustrated in Figure X.

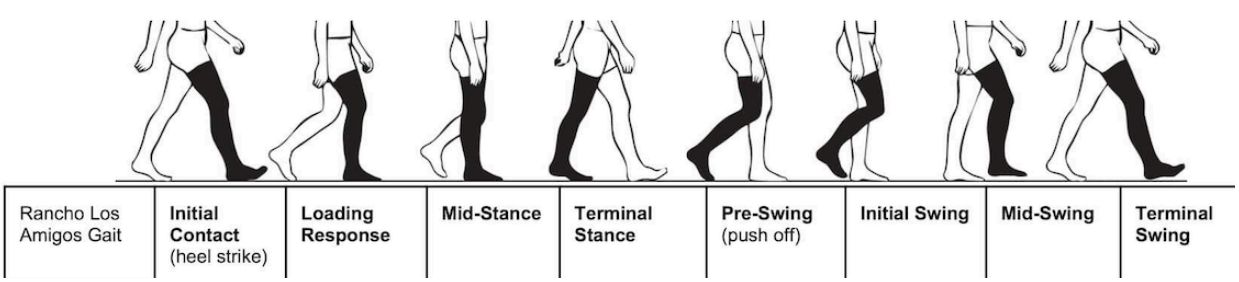


Figure 6: Normal Gait Cycle [10].

Foot drop occurs when the muscles distal to the ankle, particularly the tibialis anterior (Figure x), are too weak to maintain the foot in a neutral position, resulting in excessive plantarflexion. This impairment disrupts the initial contact, or heel-strike phase, of the gait cycle (Figure x). Consequently, the foot may catch on the ground during ambulation, significantly increasing the risk of falls.

In addition to foot drop, the patient also presents with ankle inversion (Figure x). In this condition, the medial side of the foot rotates inward under compressive forces, while the lateral side experiences tensile forces. This abnormal loading pattern increases the risk of strain or injury to the ankle tendons. Furthermore, the patient requires supplemental arch support, which is currently being addressed through the use of orthotic inserts in athletic footwear.

Client Information

The client, Debbie Eggleston, is a physical therapist as well as an advocate for individuals with facioscapulohumeral muscular dystrophy (FSHD). She first introduced the team to the patient who would be receiving the AFO. Following a period of limited progress, Ms. Eggleston collaborated with specialists at the University of Michigan to confirm the patient's diagnosis of FSHD1 in December 2022. In addition to her clinical role, Ms. Eggleston has been an active advocate for FSHD awareness for over five years. She has worked closely with FSHD specialists, engaged in community outreach, and utilized social media platforms, such as Facebook groups, to fundraise and raise awareness for the condition.

This project was initiated in the Fall 2024 semester, during which the team met with Ms. Eggleston at multiple points to provide progress updates on the AFO design and manufacturing process. In turn, she shared updates regarding the patient's condition. As the disease has advanced to the point of requiring a professional-grade AFO, Ms. Eggleston has also connected the team with the patient's orthotist, ensuring that future groups can continue development in close collaboration with both the physician and herself.

Product Design Specifications

The ankle-foot orthosis (AFO) will be custom-designed to accommodate the patient's specific anatomical dimensions and personal comfort needs. Because the patient enjoys horseback riding and other daily activities, the device must be durable enough to withstand regular use while remaining comfortable for long periods of wear. Just as importantly, the patient has expressed a desire for a discreet design that does not draw unnecessary attention, reflecting her concern with social perception as a high school student.

The device will measure approximately 31 cm in length, extending proximally from the distal end of the foot. Its structure will combine rigid elements with an adjustable bungee mechanism, allowing for personalized levels of support against both dorsiflexion weakness and ankle inversion. Since the patient experiences foot drop primarily during the heel-strike phase of gait, the AFO must both stabilize the ankle and restore a more natural gait cycle, permitting over 30° of motion from the neutral ankle position. To achieve this, the device will deliver approximately 5–10 Nm of counteracting torque for every 10° of plantarflexion [11]. Additionally, it must limit inversion to angles below 25° [12] while resisting up to 30 Nm of torsional force and sustaining loads as high as 260 N [13].

Equation 1 illustrates the mathematical analysis used to determine the peak transverse load acting on the ankle during inversion:

$$F_I = W \cdot tan(\theta)$$

- F_I is inversion force
- W is patient weight in Newtons
- θ is the angle of ankle inversion in degrees

$$F_I = 556.03 \cdot tan(25) = 259.28\, N$$

Equation 1: Calculation of Ankle Inversion Peak Force.

The project operates under a working budget of $100, provided by the University of Wisconsin–Madison Department of Biomedical Engineering. However, this budget may be adjusted as development progresses. Additional specifications can be found in Appendix A.

Preliminary Designs

Design 1: 24-25 Combination

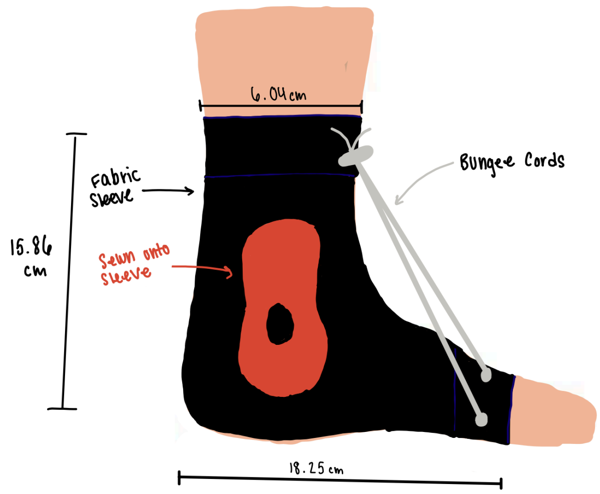


Figure 7: Drawing of Design 1

Design 1 is a combination of the final designs from Fall 2024 and Spring 2025. The Fall 2024 design included a sleeve with bungee cords attached to the outside in order to accommodate foot drop and dorsiflexion support. The Spring 2025 design did not include a sleeve, but instead focused more on inversion and mediolateral support. Design 1 brings both designs together with the bungee cords, sleeve, and inversion supports. For this reason, it scores well in dorsiflexion and mediolateral support. However, the bungee cords make this AFO difficult to conceal and fit inside of a shoe. Additionally, the sleeve may not be the most comfortable option for the client, as it could rub against the skin after many hours of wear. Finally, if a bungee cord were to break, the AFO would no longer do its job and be unsafe for the patient.

Design 2: Inversion Straps

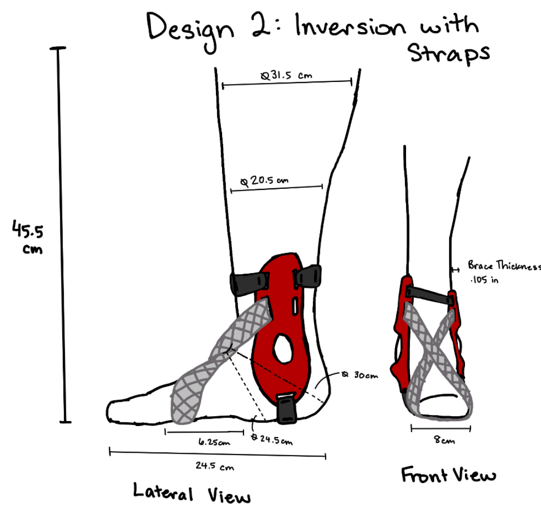


Figure 8: Drawing of Design 2

Design 2 is similar to the Spring 2025 design with its use of inversion supports. However, this design also includes straps that run in a truss-like fashion across the foot in order to negate foot drop and improve dorsiflexion support. For this reason, it scores very high in both support categories. Additionally, due to its minimalist design, it would be fast and easy for the patient to put on and wear throughout the day. Most notably, it could also fit inside nearly any shoe and go unnoticed, hence the high score in the category of discreteness. Finally, if any piece of the AFO were to unexpectedly break, there would be no immediate harm to the patient due to the durability of the straps and rounded edges of the inversion supports.

Design 3: Shoe Insert

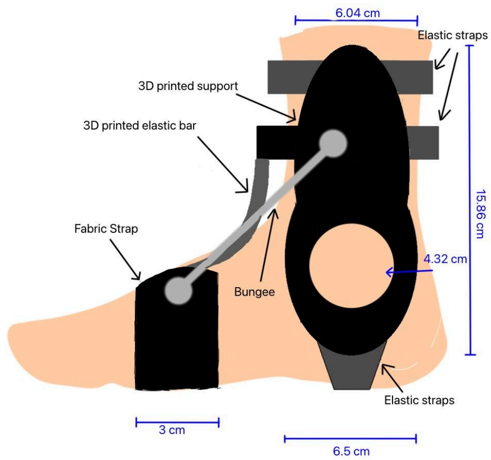
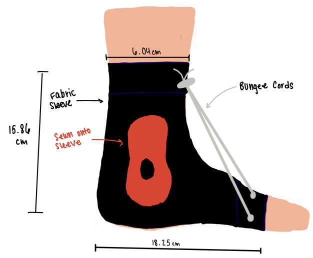
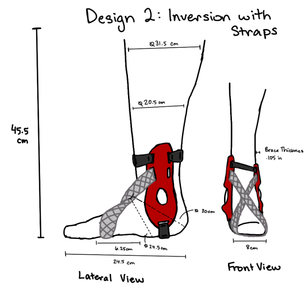
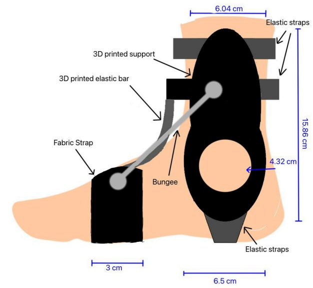


Figure 9: Drawing of Design 3

Design 3 is similar to some AFO designs that are currently on the market today. However, instead of the support bar being outside the shoe, it is inside. This not only improves discreteness, but also better protects the bar from environmental factors such as damaging weather. Additionally, with the bar inside the shoe, it is closer to the foot and ankle which may provide more support and control than the alternative. On the other hand, this would be extremely bulky and severely limit the shoes that the patient could wear with the brace. It would also not be durable and could cause unwanted pressure and tension inside the shoe. Finally, this design would be extremely difficult to fabricate, especially with the patient's increasing condition severity.

Preliminary Design Evaluation

Prototype Design Matrix

Design Criteria	 **Design 1: Combination Design 24-25**		 **Design 2: Inversion with Straps**		 **Design 3: In the Shoe**	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Dorsiflexion Support (20)	3/5	12/20	4/5	16/20	5/5	20/20
Mediolateral support (20)	4/5	16/20	4/5	16/20	4/5	16/20
Ease of user assembly (15)	2/5	6/15	4.5/5	13.5/15	3/5	9/15
Comfort (15)	3.5/5	10.5/15	4/5	12/15	4/5	12/15
Durability (10)	4/5	8/10	4/5	8/10	3.5/5	7/10
Discreteness (10)	2/5	4/10	4/5	8/10	3.5/5	7/10
Fabrication Quality (5)	3/5	3/5	4/5	4/5	3/5	3/5
Cost (5)	3/5	3/5	3/5	3/5	2/5	2/5
Total	62.5/100		80.5/100		76/100	

Summary of Design Matrix

Dorsiflexion Support (20%): Dorsiflexion support is one of the most important aspects of this design. The patient is experiencing foot drop, which is when the foot experiences a constant negative angle from the neutral position, meaning excess dorsiflexion, when the foot is set at a neutral position. The device needs to eliminate the excess dorsiflexion by assisting in plantar flexion, the upward movement of the foot. This part of the support will help maintain proper gait and help reduce excessive heel strike.

Mediolateral Support (20%): Mediolateral support, crucial for any orthosis that aims to lessen the symptoms of FSHD, is the stabilizing force and support from the side-to-side axis of a body or joint. FSHD causes severe weakness in the muscles, leading to foot drop and problems with inversion of the ankle. This support helps maintain proper foot and ankle alignment during the stance and swing phases of gait.

Ease of User Assembly (15%): This criteria is important to consider when designing the AFO because our patient has FSHD, causing weakness in their right arm and a significant loss of function in the left. Therefore, the AFO needs to be easy to assemble to ensure they can use it independently without relying on others. If the device has intricate assembly steps, they will be less likely to use it consistently. By prioritizing ease of user assembly, the AFO is more practical for daily use making it more effective in the long run.

Comfort (15%): Comfort is an important criterion because the orthosis will be worn throughout the day for extended periods of time. The AFO must minimize pressure points, prevent skin irritation, and distribute forces evenly across the foot and ankle. If the device causes pain, rubbing, or excessive heat buildup, the user will be less likely to wear it consistently, therefore reducing its effectiveness. A higher score represents a design that avoids irritation and feels natural to the user.

Durability (10%): Durability is an important aspect of the AFO because it needs to withstand repeated daily use and exposure to different environments. The AFO needs to support the users gait without wearing down too quickly or losing effectiveness over time. A durable AFO reduces the risk of breakage or frequent repairs, which is especially important because breakage during use can put the user at risk of falling and injuring themselves.

Discreteness (10%): The discreteness of the AFO has proven to be an important aspect of the design over the last semester's work due to the age of the patient. The AFO needs to draw no more attention than a regular ankle brace for an ordinary injury would. The patient has demonstrated that they will not wear the brace if it is bulky, highlighting their FSHD. One of the goals of this design is to make it discrete enough that it can be covered with loose pants.

Fabrication Quality (5%): The fabrication quality of the AFO is key to its functionality. If it breaks like in previous years, it is crucial to ensure that there would be no sharp edges that could cause harm to the patient. Additionally, rough edges would need to be sanded and deburred to avoid discomfort during everyday wear. The AFO would also need to withstand many years of wear so that the patient does not need a new one to be fabricated immediately when the project is finished.

Cost (5%): The cost of the AFO is an important factor to consider in the choice of design. The materials chosen should not only perform their own functionality adequately, but also be within the scope of our budget of $100. This budget should account for not only upfront costs of fabrication of the AFO, but also any maintenance costs that may be needed for the design to continue to perform sufficiently.

Proposed Final Design

The proposed final design is Design 2, the “Inversion with Straps”. The client expressed that the three most important aspects for the AFO are dorsiflexion support, mediolateral support, and discreteness. This design scored very highly in all of these categories, most notably discreteness. The biggest factor in determining if the patient will wear the brace in everyday life, including her high school environment, is if the brace is truly inconspicuous. Design 2 accomplishes this much more than the other two design options. The inversion supports in this design will be made with carbon fiber PLA with 50% infill, as done in Spring 2025. The straps go along the front of the foot, forming a truss. These will either be sewn onto the supports and made with polyester, or 3D-printed with TPU filament.

Fabrication and Development Process

Materials

The final design will consist of 4 different materials. The inversion supports will be composed of carbon fiber-reinforced PLA at 50% infill, the straps will be either polyester or TPU filament, and the padding inside the inversion supports will consist of closed cell EVA foam with a layer of polyester mesh on top. These materials were chosen for their specific properties that enhance both functionality and comfort.

The rigid inversion support pieces on either side of the ankle will be made from carbon fiber reinforced PLA composite (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 durability. A carbon-fiber AFO is capable of supporting up to 1,000 N, making it highly suitable for the demands of this device [14]. Carbon fiber offers superior weight distribution and flexibility compared to materials like plastic and steel, which is crucial for the design. The support it provides is especially important given that the patient has been experiencing frequent foot inversion falls, and as their disease progresses, this support will become even more critical. CF-PLA also has a very smooth surface, which will contribute to the comfort and overall sleekness of the design. Additionally, CF-PLA is low in cost at $0.05 per gram of material [15]. 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.

The straps will be either polyester or TPU filament. Polyester is a strong, durable, and lightweight material, making it ideal for AFO straps that must withstand repeated use and movement. Its low moisture absorption allows it to dry quickly and resist stains, keeping the straps comfortable and hygienic during daily wear. Polyester also resists shrinking, wrinkling, and fading, maintaining its shape and appearance over time with minimal maintenance. Additionally, it is inexpensive, easy to clean, and recyclable, making it both a practical and sustainable choice for the AFO design [16]. TPU is an excellent material choice because of its rubber-like flexibility and high durability, allowing parts to bend and return to shape without cracking. It performs well under repeated stress, is resistant to abrasion and oils, and maintains its properties even at low temperatures. Its strong layer adhesion during 3D printing ensures durable, long-lasting components suitable for medical and wearable applications [17].

Finally, the inner lining of the inversion supports will be made out of closed cell EVA foam lined with polyester mesh. Closed-cell EVA foam is a lightweight, durable material known for its water resistance, cushioning, and pressure absorption. Because its cells are tightly sealed, it does not absorb moisture, making it ideal for applications where hygiene and longevity are important. It offers a balance of flexibility and structural support, providing comfort while maintaining shape under repeated pressure [18]. These properties make closed-cell EVA foam an excellent choice for padding inside the AFO. The foam padding will be lined with polyester mesh and is a lightweight, breathable fabric. Its open-knit structure promotes airflow and allows heat and moisture to escape, helping keep the skin cool and dry during use. Made from durable polyester fibers, it offers excellent elasticity, recovery, and resistance to wear, ensuring long-term comfort and performance [19]. These qualities make polyester mesh an ideal inner lining for EVA foam padding, enhancing both comfort and breathability in the AFO design .

Current Prototype

The team has not yet fabricated an initial prototype. Some materials have been ordered and fabrication will begin in the coming week.

Strengths and Limitations of the Current Design

The current prototype does a good job of building off of designs from previous semesters while incorporating key adjustments that strengthen those designs' weak points. This current design includes straps that run across the foot in order to negate foot drop and improve dorsiflexion support. The AFO also has a very minimalistic design that makes it fast and easy for the patient to put on and wear throughout the day. This design also features a very sleek design that can fit into almost any shoe and resembles an athletic brace to fulfill the patient's wish for a discrete AFO.

Despite these strengths, this design has areas that weaknesses that could be areas for potential improvements. While the EVA foam and polyester provide good comfort and moisture resistance, they may compress with prolonged use, reducing cushioning effectiveness. In addition, because the foam would be permanently adhered to the inversion supports, there isn't a good way to remove the padding for cleaning. In addition, although the slim design fulfills the client's request for a discreet AFO that resembles an athletic brace, this minimal structure may not provide the same level of support as traditional AFOs that extend under the foot and higher up the calf. However, the addition of strategically placed straps is intended to help counteract foot drop and provide sufficient dorsiflexion support, balancing aesthetics with functional performance.

Overall, this prototype represents a strong foundation that balances functionality, comfort, and aesthetics. While certain aspects such as support distribution and material durability will require further testing and refinement, the design demonstrates clear progress toward creating an effective, user-friendly, and visually appealing AFO that meets the client's needs.

Methods

The team will be using the 3D scans of the patient's right leg that were made in the Spring of 2025 by a previous group. This team started out by using a dremel to cut the epoxy-coated cast into two parts, exposing the medial and lateral dimensions of the patient's right leg. The team then used the Creality RaptorX device in the Grainger Engineering Design Makerspace Lab to scan a cast of the patient's leg. Using the device's software, both sides of the cast were scanned into a mesh file, smoothed, simplified, and refined. After being exported as an "obj" file, the mesh was imported into SolidWorks to build splines off of. Lastly, the splines were lofted and the solid extruded into the desired shape and dimensions before being 3D printed. Using these scans, this team will 3D print new CF-PLA inversion supports.

To fabricate the padding, the team will trace the shape of the inversion supports onto the closed cell EVA foam and cut out the 2 pieces. They will then cut out 2 pieces of the polyester mesh, large enough to cover the exterior side of the foam pads, and ensuring there are slits in both the foam and the mesh to allow the straps to be threaded through, but leaving the malleolus hole intact. The mesh will be sewn to the foam pad, and excess material will be cut to about 1 mm outside of the sewn lines. The padding will be attached to the inversion supports using liquid adhesive, Weld-On 4. The adhesive will be applied to the concave side of the rigid support and the padding will be firmly adhered with the smooth foam side on the adhesive.

Each of the straps will be added to the design by cutting out about one inch thick strips of polyester, and threading the straps through the slits of the rigid supports. The strap around the top of the ankle will have an adhesive velcro square attached to it so that the patient can adjust the brace to their preferred tightness. The remaining straps, including the straps crossing the front of the foot, the back of the foot, and the strap underneath the heel will all have predetermined lengths, so after threading the strap through the brace, the polyester strap will be sewn to itself. If TPU filament is used for the the straps the cross in front and behind the foot, a heat gun could be used to melt the material and bond it to itself.

Once fully assembled, the user will be able to put on the brace by sliding their foot into the brace between the inversion supports, then fastening any Velcro straps to the user’s preference. 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.

Testing

Previous Semester Testing

In Fall 2024, the team tested the AFO on a healthy participant using Runeasi, an internal measuring unit (IMU) that determines asymmetries and compensation in an individual's gait [20]. The device was placed on the lower back to measure: dynamic instability (%), ground contact time (ms), impact magnitude (G), cadence (steps/min). They compared three conditions: with the brace, without the brace and with the brace but without the rigid support.

Testing revealed that the prototype did not worsen gait, but it also did not improve dynamic instability which indicates the AFO had limited mediolateral support. Despite minor slippage in the bungee-lock, the device successfully supported dorsiflexion, increasing the resting foot angle by 38° from the resting position.

In Spring 2025, the team performed a MTS three point bend test for the rigid support. Carbon fiber PLA (CF-PLA) at 15%, 35% and 50% infill was tested to withstand 260 N at 25° inversion. All three infills passed so 15% infill was chosen.

They then carried out force-plate testing. Three conditions were tested: eyes open, eyes closed and wedge stance. Center of pressure (COP) and stabilograms were shown for black, red and no

AFO. Results demonstrated that the black brace had the best stability but the differences weren't statistically significant.

Comfort testing was also carried out. The client completed a comfort evaluation form, rating the comfort of different components on a scale from one to 10. Testing revealed discomfort on the medial side of the foot and slippage in the red support with the compression sleeve and straps presenting the biggest challenge.

Lastly the team carried out motion capture testing using OpenCap. They collected videos of the patient's gait to estimate hip flexion, knee flexion and subtalar inversion/eversion. Testing was done for no AFO, client's existing AFO and red prototype AFO. Knee and hip angles looked similar across the different conditions however, the inversion ankle results were inconclusive.

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 verify the design's rigidity and demonstrate it meets the force and torsion targets stated in the PDS, we will run a finite element analysis in SOLIDWORKS Simulation. We will first define the problem statement in relation to stress, stiffness and stability, apply fixed supports and distributed loads, mesh the model, and check mesh convergence and reactions [21].

We will use SOLIDWORKS Simulation to evaluate the assembly interaction, contact and stability of the device. Additionally, the wizard interface in SimulationXpress will be used for quick single part screening to confirm that peak stress and displacement remain within material limits [22], [23]. Through the analysis wizard we can select the preferred unit system, assign the CF-PLA composite material, apply the specified loads and support along the interior of the rigid support according to the specified design parameters, mesh and solve. And then modify the thickness or support placement based on the results to optimize performance [23].

Using SOLIDWORKS Simulation we can predict real life behavior of the CAD model, reducing costly and time consuming tests. Through the FEA, we will verify that the rigid AFO components withstand the PDS specified 260 N vertical force and maintain ankle moment response within ±30 Nm, without permanent deformation of the support [13].

Comfortability Testing

Adhering to design and client requirements, the AFO must be inconspicuous and therefore fit in a standard, everyday shoe. To test comfort of the device under daily use, healthy participants will complete a structured comfortability test in which they will wear the AFO over a thin sock and close-toed shoes. The participant will then walk at a normal pace for 5 minutes. Immediately after, the participants will provide a comfort rating where 1 = extreme discomfort and 10 = no discomfort. Participants will also be encouraged to provide qualitative information regarding pressure points, stability felt, ease of dorsiflexion and ankle stiffness.

Fit and function will also be recorded: if the shoe fits normally without excessive bulging, any strap or rigid support slippage and visible skin redness. Safety measures include having a spotter present and the option to stop the trial if the pain becomes unbearable.

This short trial will highlight problem areas and usability issues allowing us to make changes before the client evaluation and ensure the AFO meets functionality and comfort requirements. The results will confirm the AFO is low profile which will allow us to focus on prioritizing comfort driven changes.

Force Plate Testing

To test the impact of the AFO on stability, we will conduct force plate testing. By measuring ground reaction forces during gait, this test provides insight on balance, symmetry and power across different activities, in our case, primarily, walking [24]. We are coordinating with the client to come down to Madison for lab testing, allowing for a client specific evaluation of the AFO's effectiveness, something that has not been possible in previous years.

We will perform within-subject trials under three conditions: no AFO, the client's current AFO, our prototype AFO. Comparing the three conditions will help quantify the prototype's stability benefits relative to unassisted gait and to the device the patient already uses. If it is safe and the patient is comfortable, we will carry out the following static balance stances:

- Quiet stand: the patient will stand feet shoulder width apart, aiming to maintain a steady stance with eyes open and closed for 30 seconds each [25].
- Single leg stand: the patient will stand on one leg for 30 seconds, this will be done for the healthy and dropfoot impacted leg [25]. This will assess how well the AFO is able to support the impacted ankle.
- Tandem balance: the patient will stand with one leg directly in front of the other for 30 seconds. This stance targets the ability to balance in a less stable stance making it useful for testing if the AFO will provide sufficient support [25].

Discussion

Ethical and Safety Concerns

Ethical concerns are of great importance during the design and testing phases of this project. To satisfy these concerns, the patient must have full disclosure of any possible risks during the testing phase of the device. They should be aware that the device is still in development and expect some discomfort and possibly device failure. It is important that testing only proceeds with the consent of the patient, which can be retracted at any time. Testing must also be immediately stopped at any notification of pain from the patient to prevent any injury.

In regards to the safety concerns, it is important to note that the device is intended for daily use and horseback riding. Therefore, safety must be prioritized during the design. The most serious concern is that the device worsens the patient's condition by further misaligning the foot or that the device fails in a way that injures the patient. To prevent these possible outcomes, it is necessary that extensive testing be conducted to find all possible points of failure and that these issues be addressed.

As the device being manufactured is a prototype, it is expected that there will be some flaws, but this makes transparency and communication with the client extremely important. It is crucial that upon receival that the client is aware of all aspects of the device, including the benefits, limitations, and all possible failures. This creates realistic expectations of what the device is capable of, and failure to do this would be unsafe and unethical.

It is also important to consider socioeconomic factors when designing the device. Recognizing that not everyone is in a position that allows them access to custom made orthoses is necessary in the design process. While this prototype is made to help a specific patient, it should be held in mind that they are not the only ones suffering from this type of issue and that others could greatly benefit from this design. Therefore, it is important to keep in mind the cost of the device including materials, manufacturing, labor, and the customization of it. Keeping in mind these factors allows for the creation of a device that is accessible for more people.

Design Evaluation

There are 2 previous semesters of work that have been put into this project. The first semester’s main focus was dorsiflexion support. Some success was achieved, but there was much improvement needed in the dorsiflexion and inversion support had also not been addressed. The second semester’s main focus was inversion support. The design has been successful, but there are durability concerns with the braces. The goal of this semester is to improve and combine the work of the previous two semesters. Extensive testing will be performed and using these results, design changes will be made to fix the durability issues and the effectiveness of the design. The changes that occur can range from material selection to altering the design itself.

Potential Sources of Error

There are many potential sources of error that must be kept in mind during the design and fabrication process of the device. One potential source of error is the measurements of the client’s foot. A lot of the manufacturing and design details of this project heavily rely on correct foot measurements, but it must also be recognized that some error in measurements is expected due to the patient living in Michigan and not being able to take in-person measurements. There have been measurements taken using patients previous cast, but there is possibility of error due to the translation of the 3D mesh into SolidWorks.

Comfortability is also a point of concern during the design. Due to the patient living in Michigan, there are very few chances to receive user feedback on the comfortability of the device. There will be padding added, but there are also other factors like tightness that affect comfortability. Comfortability testing will be conducted on someone with similar foot anatomy as the patient, but it will not completely match the patients comfortability due to this type of testing being subjective. It would be ideal to have a working prototype that the client is able to try on to get the device to be as comfortable as possible.

Due to the previous semester's inversion support design fracturing, the material durability has become a point of concern. Testing will occur using the material for the support, but there is potential error due to the difference of forces acting on the device during controlled testing and actual use. There is also the potential for error during fabrication. There are many precise measurements used during the fabrication of the device, and it is important that they are all precise so that it is able to withstand the amount of force expected. Keeping track of these potential sources of error is a necessity to producing a safe device that the client is able to use for a long time.

Conclusions

The goal of this project is to develop a custom Ankle-Foot Orthosis to provide support to a teenager with Facioscapulohumeral Dystrophy, while remaining discreet so that it does not draw attention to the AFO. The design features a rigid support made of carbon fiber PLA with a connected elastic strap. This design is aimed at assisting with the dorsiflexion of the foot and fixing the patient's current foot inversion. It also remains relatively slim and simple to remain discreet. This AFO is a continuation of the previous semester's work and aims to address the previous problems in order to provide a functional device that assists the patient.

Future Work

The future work for this project will include the finalization of material selection, customization and fitting the device, and testing. There has been some material research in selection done, but before the final decision is made, testing will be conducted to find the best choices. As stated previously, material orders have been made so that preliminary material testing can be conducted. There will also be some customization work that needs to be done to the final preliminary design so that it fits the patient's foot before fabrication begins. Fabrication will then be able to proceed according to the methods stated above. Finally, testing will be conducted, including Finite Element Analysis, Comfortability Testing, and Force Plate Testing. Using the data from these tests, adjustments will be made before the device is ready to be sent to the patient.

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Appendices

Appendix A: Product Design Specification (PDS)

Inconspicuous Ankle Foot Orthosis (AFO) for teen

PRODUCT DESIGN SPECIFICATIONS (PDS)

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September 18th, 2025

Function/Problem Statement:

Ankle-foot orthoses (AFOs) are designed to support dorsiflexion during the swing phase of walking. They are commonly used in managing muscular dystrophies, and for this project, our focus is specifically on adolescents with Facioscapulohumeral Dystrophy (FSHD), the most prevalent form of muscular dystrophy [1]. Our goal is to create a brace that helps teens achieve safer walking by assisting ankle dorsiflexion, while remaining discreet, lightweight, and flexible enough to allow natural ankle motion. The main design priorities are to position the ankle in proper dorsiflexion, keep the brace slim and unobtrusive, and provide enough flexibility to reduce movement restrictions.

Client requirements:

The client requests an AFO to be created to help support dorsiflexion of the right foot, as well as prevent excessive inversion. It should be flexible enough for daily activities, and be simple to wear. Additionally, the client prefers the AFO to be discreet, fitting inside a shoe and minimizing visibility. Functionality is becoming more prevalent as the disease increases.

Design requirements:

1. Physical and Operational Characteristics
   a. Performance requirements
      i. The AFO should be designed to remain discreet and lightweight, using minimal material while still providing strong support for ankle dorsiflexion and resisting ankle inversion to prevent gait irregularities [1]. It must allow a natural walking pattern without generating resistive moments during dorsiflexion [2].
      ii. The device should permit more than 30° of motion from the initial ankle angle to ensure proper foot clearance [3].
      iii. In plantarflexion, the orthosis should generate an adjustable resistive moment ranging from 5–10 Nm per 10° of motion [3]. Overall, moment-angle performance should stay within ±30 Nm of torque. The brace must also resist torsional forces that could cause misalignment of the ankle or foot during regular activity [4].
      iv. The AFO should withstand forces equal to at least three times the user's bodyweight, reflecting the peak loads experienced during walking [6]. For a 16-year-old weighing approximately 136.2 lbs (61.8 kg), this translates into

supporting a maximum force of 266 N [5], [6]. At the same time, the device must allow active concentric ankle movement so the user can perform daily activities such as squatting or climbing stairs.

v. Dimensions must be customized to the user's leg geometry to ensure a secure fit and ideally integrate with a custom orthotic insole.
vi. The rigid components must also limit inversion to less than 25° [7].

b. Safety
    i. The AFO should promote normal gait mechanics to reduce the risk of tripping or falling while maintaining anatomical alignment to avoid excessive stress on joints, bones, or muscles.
    ii. Chosen materials must be non-toxic, hypoallergenic, and free of sharp edges to prevent irritation or injury.
    iii. The outer surface should provide enough traction to prevent slipping when used without shoes. Adjustable parts should remain secure under impact but not restrict circulation.
    iv. Fastening systems must prevent loosening during activity, yet allow for quick removal in emergencies without tools.
    v. The design should allow breathability to reduce overheating and moisture buildup.
c. Accuracy and Reliability
    i. The orthosis must maintain structural integrity through repeated use while continuing to provide consistent support and proper alignment. Carbon fiber AFOs, for example, typically fail at the mid-shank calf support under forces of 1970 N [8].
    ii. To reduce injury risk, the design should include padding in the calf region, with soft materials that are easy to replace after extended wear.
d. Shelf Life
    i. Because custom orthotics are tailored to an individual's needs, their shelf life is limited. If left unused for extended periods, changes in the user's measurements or support requirements may reduce effectiveness. For this reason, the AFO should be periodically re-evaluated to confirm fit and function.

e. Life in Service
    i. The expected lifespan of an AFO is about five years, though actual service life depends on the material, usage patterns, and patient needs [9].
    ii. Semi-rigid materials such as carbon fiber, fiberglass, and polyethylene generally last longer than softer materials [10].
    iii. Annual reviews by an orthotist are recommended to assess wear and ensure the device continues to meet the user's needs [11].
f. Operating Environment
    i. The AFO is intended for everyday use and must withstand frequent wear and transport. The user will rely on it at home, during school, and while horseback riding. Size and bulk should be minimized so it can fit inside riding boots.
    ii. It must withstand exposure to varying temperatures, humidity, dirt, water, and sweat. To prevent bacterial buildup, the device should be cleaned weekly with mild soap and water [12].
g. Ergonomics
    i. The device must tolerate the user's full weight while distributing pressure evenly to avoid discomfort. It should include adjustable features, such as straps, to accommodate growth.
    ii. Weight should remain below 1 kg to minimize fatigue, as most AFOs weigh between 0.3–3.4 kg [13].
    iii. Padding should be included around sensitive areas like the Achilles tendon, ankle, and foot base. The design should be slim enough to fit into standard shoes without requiring specialty footwear [3].
    iv. Any moving parts must operate quietly.
    v. By supporting dorsiflexion, the AFO can improve step length, walking speed, and overall gait stability, helping the user move more efficiently in daily life [14].
h. Size:

i. The AFO must match the patient's specific measurements, with slight adjustments to allow for padding and anti-chafing features [15]. Key measurements are as follows:
   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. Standard AFO thickness is approximately 3.175 mm, which balances structural support with sufficient flexibility to avoid stiffness-related instability [16].

i. Weight
   i. The orthosis should remain lightweight enough to allow free movement without affecting gait or speed. Ideally, total weight will stay under 1 kg [17].

j. Materials
   i. The AFO design is working away from the fully covered iterations of the previous semesters, and instead, is working towards a more breathable design to maintain discreetness and comfortability.

ii. The material of the design will be a material well suited to prevent inversion of the ankle. The effectiveness of preventing ankle inversion depends highly on the rigid strength of the cast.

iii. 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 [18].

iv. The dorsiflexion aspect of the brace will be either a polyester fabric, or a stretchy PLA, such as TPU filament. Either of these materials will need to withstand forces from the patient walking, so around 266 N of force.

    1. 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 [19].
    2. Thermoplastic polyurethane (TPU) exhibits high elongation capacity in bulk form, often several hundred percent, but 3D-printed parts generally demonstrate reduced elasticity and are prone to creep under sustained loading, leading to gradual sag or deformation over time [20]. To mitigate premature failure, the orientation of the printed layers is critical, as strength in the Z-direction is significantly weaker; tensile loads should therefore be aligned in-plane with the filament paths [20]. Under dynamic conditions, such as cyclic loading during gait, TPU components may accumulate fatigue damage, making conservative design margins and fatigue testing essential. Despite these limitations, TPU provides excellent abrasion resistance, which enhances durability in applications like straps positioned beneath the ball of the foot, where constant rubbing and contact stresses occur.

v. The rigid ankle support will be constructed from fiberglass polymer tape, selected for its lightweight profile, moldability, radiolucency, water resistance, affordability, high strength-to-weight ratio, and thin structure [18].

vi. To enhance resistance against ankle inversion, a custom 3D-printed PLA insert may be integrated within the fiberglass. This reinforcement would be modeled directly on the patient's anatomy to improve fit and structural stability.

vii. Fiberglass provides several advantages for long-term use. Its low weight minimizes fatigue and discomfort, making it easier for the user to move naturally. At the same time, its durability ensures resistance to daily wear and tear, extending the service life of the device. The material's porous structure improves airflow, reducing heat and moisture buildup for greater comfort. Together, these characteristics maximize the orthosis' effectiveness in preventing foot drag, stabilizing the ankle, and improving gait.

k. Aesthetics, Appearance, and Finish

i. The AFO will feature a sleek black design to minimize visibility. It will resemble an athletic brace and fit comfortably inside tennis shoes or Converse, helping the user maintain their preferred style.

ii. The surface will be smooth, slim, and inconspicuous, while still offering 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 expected cost of this semester's continuation will be $100 dollars.

ii. In fall 2024, the initial prototype accounted for $189.02 of the $300 budget, with $8.71 covered by the BME department and $180.30 from the BME Design fund. In spring 2025, project expenses were $37.95, of which $13.60 was covered by the department. In total, project costs came to $226.97, with $22.31 supported by the department and $204.65 through the BME Design fund.

iii. Goals for fall 2025 include creating a working prototype; reprinting the brace created spring 2025 with minor tweaks, as well as printing the final dorsiflexion method should be completed in under $100.

3. Miscellaneous
   a. Standards and Specifications
      i. CFR Title 21, Section 890.3025: This regulation classifies the device as a Class I medical device. If electronics are added, it would fall under Class II [21].
      ii. 501(k) requirements: Most Class I devices are exempt from 501(k) submission. This AFO may be exempt if the FDA determines that additional review is not needed to ensure safety and effectiveness [22].
      iii. CFR Title 21, Section 890.3475: Defines a limb orthosis as a medical device worn on the upper or lower limbs to support, correct, or prevent deformities. Examples include braces, splints, elastic stockings, and corrective shoes [23].
      iv. CFR Title 21, Part 803: Manufacturers and facilities must report any deaths or serious injuries linked to the device through a Medical Device Report (MDR) [24].
      v. ISO 14971:2019: Outlines risk management requirements. A Failure Modes and Effects Analysis (FMEA) should be done to identify possible risks for patients, users, and property. The standard defines risk as the combination of the chance of harm and the severity of the outcome [25].
      vi. ISO 8549-3:2020: Defines an orthosis as an external device used to compensate for problems in the neuromuscular or skeletal system. An ankle-foot orthosis specifically covers the ankle joint and all or part of the foot [26].
      vii. ISO 8551:2020: Provides guidelines for evaluating functional deficiencies in patients and setting clinical objectives when prescribing orthoses [27].
      viii. ISO 2267:2016: Specifies testing methods for ankle-foot devices under repeated loading. Testing simulates the stance phase of walking, from heel strike to toe-off, to evaluate strength, durability, and service life [28].
   b. Customer [29]
      i. This device is designed for daily use by a 16-year-old with Facioscapulohumeral Dystrophy (FSHD). Although it will be custom-fitted, the target group also

includes other young patients with FSHD or related muscular dystrophies who require ankle support.

c. Patient-related concerns
    i. The orthosis must hold the ankle in dorsiflexion (approximately 10° above the neutral foot plane) when unweighted, ensuring proper foot clearance and reducing gait deviations. At the same time, it must allow enough flexibility for functional tasks such as squatting or descending stairs.
    ii. The device should minimize the need for eccentric muscle contractions while preventing foot slap, thereby supporting patients with weakened ankle muscles.
    iii. The AFO must balance flexibility and stability: flexible enough to allow natural gait, but strong enough to prevent foot drop and inversion. It should not interfere with daily activities and should remain discreet to avoid drawing attention.
    iv. A slim profile that can be hidden under clothing is essential to reduce the risk of stigma or bullying in social settings such as school.
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. Each year, approximately 53,000 AFOs are fabricated in the United States, with an average Medicare reimbursement of $417, totaling more than $2.2 million annually [30]. For many families, these costs present a barrier to access.
    ii. For patients with muscular dystrophies, additional expenses accumulate through both direct and indirect medical costs. Direct costs include hospital visits, therapy, pharmaceuticals, and insurance coverage, averaging $22,533 annually in the U.S. [31].
    iii. Indirect costs such as home modifications, vehicle accommodations, caregiving, dietary needs, and travel add approximately $12,939 per patient each year [31].
    iv. Loss of income is another significant burden.

v. Families with a member requiring care for a muscular disorder experience an annual income reduction of about $21,600 compared with unaffected households, even after accounting for demographic and socioeconomic variables [31].

vi. Overall, the economic burden of muscular dystrophy disorders in the U.S. is estimated at $1.07–1.4 billion annually [31]. Developing a cost-effective AFO can help ease this financial strain by improving mobility, enabling greater independence, and supporting long-term productivity for individuals living with FSHD.

f. Competition

Most AFO designs incorporate the three-point force system, a fundamental biomechanical principle for stabilizing joints and limiting angular rotation. This system applies a primary force in either the medio-lateral or anteroposterior direction, countered by two opposing forces applied above and below the main force. Together, the forces balance to zero. Increasing the lever length of the orthosis allows greater spacing between these force points, which enhances corrective effectiveness. This approach also helps distribute pressure more evenly, reducing discomfort for the user [32].

i. Passive-Dynamic AFO (PD-AFO)

1. The PD-AFO features a sleek, flexible design suited for patients with mild ankle weakness.
2. It incorporates a flexible calf shell that absorbs energy during stance and releases it at push-off, promoting dorsiflexion. Studies have shown that PD-AFOs improve patient comfort and spatiotemporal gait parameters.
3. Dimensions can be customized for individual users through 3D printing; however, stiffness and support cannot currently be tailored to match varying levels of ankle impairment [1].

ii. Supramalleolar Orthosis (SMO)

1. Pediatric SMOs are constructed from thin, flexible thermoplastic and extend just above the ankle bones (malleoli).
2. They primarily provide control of subtalar joint alignment, maintaining a neutral heel to improve mediolateral stability.

3. Their lightweight, low-profile design makes them comfortable for daily wear and compatible with most shoes [33].

iii. Variable Stiffness Orthosis (VSO)

1. The VSO is a powered AFO currently in the research phase. It uses a customizable cam-based transmission system that can define specific torque-angle relationships and adjust stiffness in real time.
2. Early results suggest it reduces foot drop and increases overall ankle moments. However, VSOs are not yet commercially available [34].

iv. Jointed AFO

1. Jointed AFOs include a hinge at the ankle joint, allowing controlled motion and enabling a more natural gait with a full range of movement.
2. While they optimize gait patterns, drawbacks include greater bulk, potential noise during use, and a higher likelihood of mechanical component failure [32].

Resources

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Appendix B: Previous Fabrication Methods

Fall 2024 [27]:

Materials

The final design will consist of six different materials. 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 [10].

Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight [11]. 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 [12]. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining overall strength [13]. 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.

The supporting piece on the medial end of the ankle brace will be constructed from PLA reinforced with carbon fiber, selected for its exceptional properties including being lightweight, sturdy, having a high strength-to-weight ratio, thin profile, and superior energy return capabilities. Carbon fiber'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, carbon fiber's ability to store and release energy will improve the user's gait by reducing the effort required for movement.

These combined properties maximize the aid needed for foot-dragging prevention, ankle stabilization, and overall gait improvement [14].

A carbon-fiber AFO (Ankle Foot Orthosis) is capable of supporting up to 1,000 N, making it highly suitable for the demands of this device [15]. Carbon fiber offers superior weight distribution and flexibility compared to materials like plastic and steel, which is crucial for the design. Since the material is not entirely made of carbon fiber but is reinforced with it, we assume the support to be less than this value, yet still largely adequate to meet the patient's needs.The support it provides is especially important given that the patient has been experiencing foot inversion falls that have been progressively increasing in frequency, and as their disease progresses, this support will become even more critical.

Although carbon fiber is more expensive than many alternative materials, the benefits—such as its strength, flexibility, and energy return—far outweigh the higher cost, making it the optimal choice for this project. Additionally, all prototypes were made using PLA to save costs prior and the final design was printed using PLA reinforced with carbon fiber which was additionally less expensive.

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, requires less cord displacement, but still offers our patient the support needed for dorsiflexion. The bungee cord will apply adequate tension, strength, recoil, and flexibility needed for support. It is made of nylon, polyester, and latex, see above material specifications for more details on the material's properties.

Methods

The carbon fiber attachment was designed in SolidWorks and subsequently 3D printed at the UW-Makerspace using the Bambu Labs printer [16]. 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 [16]. 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.

Spring 2025 [28]:

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

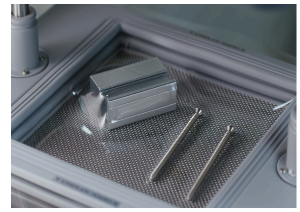
Criteria	 Carbon Fiber reinforced PLA composite (CF-PLA)		 Fiberglass Plaster		 Thermoplastics	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Strength/rigidity (30)	5/5	30/30	4/5	24/30	4/5	24/30
Ease of Fabrication (20)	4/5	16/20	5/5	20/20	1/5	4/20
Cost (20)	5/5	20/20	3/5	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.

Appendix C: Past Semester Expenses

Item	Description	Manufacturer	Vendor	Date	QTY	Cost Each	Total	Link
Fall 2024								
Ankle Brace - Component 1								
Ankle Brace	Cloth brace	Abiram	Amazon	10/10/2024	1	$14.88	$14.88	Link
Gel padding	medical grade padding	Shechekin	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 caribener	small sized caribener 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 $50 budget**
3D printing prototype - 3 variants	3D printing of back support	Bambu printer	Makerspace	11/12/2024	1	3.8	$3.80	***covered by $50 budget**
3D printing prototype	3D printing of back support	Bambu printer	Makerspace	11/13/2024	1	1.71	$1.71	***covered by $50 budget**
Lock lace piece	3D printing the lock lace piece	Bambu printer	Makerspace	11/18/2024	1	$0.23	$0.23	***covered by $50 budget**
3D Printing Final Prototype	3D printing of back support	Shen Printer	Makerspace	12/3/2024	1	$1.57	$1.57	***covered by $50 budget**
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**	
Spring 2025								
Category 1 - Rigid Support								
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	2/28/2025	1	$0.86	$0.86	***covered by $50 budget**
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	3/5/2025	1	$2.42	$2.42	***covered by $50 budget**
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	3/14/2025	1	$3.66	$3.66	***covered by $50 budget**
CF-PLA (red)	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	4/4/2025	1	$3.92	$3.92	***covered by $50 budget**
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	4/4/2025	1	$1.94	$1.94	***covered by $50 budget**
Category 2 - Straps and Padding								
Carpet Tape		Capitol	Menards	4/2/2025	1	$7.36	$7.36	link
Mesh Padding	3D Air Sponge Mesh Fabric	Tong Gu	Amazon	3/7/2025	1	$16.99	$16.99	link
Velcro	Velcro pieces		MakerSpace	2/28/2025	2	$0.40	$0.80	***covered by $50 budget**
						TOTAL:	**$37.95**	
						TOTAL:	**$226.97**	