Inconspicuous Ankle Foot Orthosis (AFO) for Teen

PRELIMINARY REPORT

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AFO for Teen

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Abstract

Facioscapulohumeral muscular dystrophy (FSHD) causes progressive lower limb muscle weakness which can lead to foot drop and restricted ankle mobility that disrupts the natural gait and increases risks of falling. While ankle-foot orthoses (AFO) are usually prescribed in order to manage stated symptoms, available AFO are generally unappealing to highschoolers due to their unaesthetic look. This often leads to highly decreased compliance of wearing the AFO due to peer judgment. This project aims to design and fabricate a custom inconspicuous AFO that mitigates peer judgment for a 16 year old female patient who is diagnosed with FSHD. It is engineered to keep proper dorsiflexion, inversion, and eversion while remaining discrete and light-weight allowing for normal motion.

The current design features low profile carbon fiber mediolateral supports that are elongated to be snug with the floor or the bottom of a shoe. These structural components are paired with 3D printed TPU straps that thread through the supports providing dorsiflexion support while presenting as an ankle brace. Along with the gait improvement materials, padding is lined along the carbon fiber supports to help provide comfort for the daily use of the product. These parts are all configured to provide a lightweight inconspicuous device.

Biomechanical testing indicated that the Fall 2025 prototype positively influenced the patient gait but the data was not significant for dorsiflexion support. Patient testing showed reduced difference in the heel strike and toe-off forces producing loading patterns closer to a typical gait. Refinements to the device aim to further balance the loading patterns of the patient's gait in order to provide significant data which proves the impact of the AFO.

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Introduction

Motivation & Global Impact

In the United States alone, approximately 2 million individuals use lower-limb orthosis to assist them in daily activities such as balance or walking [1]. Typically, these orthotic devices are prescribed to patients who are experiencing a loss of typical function in their muscles due to a variety of conditions, such as muscular dystrophy. Weakening of lower limb muscles can negatively impact an individual's gait, and pose hazards such as tripping. Ankle-foot orthoses (AFOs) are specifically used to support weakened muscles in the ankle and foot regions, and aid in achieving a natural gait. Due to the rise in neurological and musculoskeletal conditions in the global population, the global AFO market is expected to grow to $330 million by 2034 [2].

Current AFOs that are available on the market are bulky and unaesthetic to wear. Studies have shown that patients, especially women, did not wear their prescribed AFOs due to their poor aesthetics [3]. This creates a need for AFOs that are both effective in supporting muscles as well as visually appealing.

The patient is a teenager who has been diagnosed with Facioscapulohumeral Muscular Dystrophy (FSHD), and is in need of a redesigned orthotic device. Due to societal pressures and norms in high school, the patient does not want her device to draw attention from her peers. This has resulted in a lack of use in her current AFO that was prescribed by her doctors, which is large and bulky. The end goal is to create an AFO that corrects foot drop and provides comfort and flexibility to the patient, while also remaining low profile so as to not draw attention from her peers.

Currently, 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 the 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, other forms of muscular dystrophy, or any condition that causes ankle instability.

Existing Devices & Current Methods

Many AFOs 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.

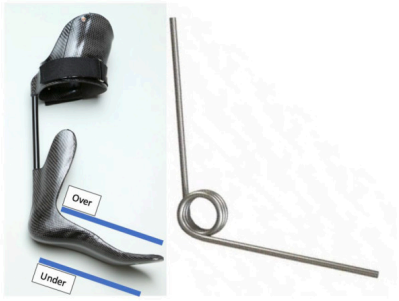


Figure 1: Passive Dynamic AFO (PD-AFO) [4]

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 [4]. This device, as seen in Figure 1, is the type of AFO the patient currently has. It is extremely visible and bulky, leading to a lack of usage.

Figure 2: Supramalleolar Orthosis (SMO) [5]

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 [5].

Figure 3: Jointed AFO [6]

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 [6]. This device, as seen in Figure 3, is one of the most bulky out of all competing designs. This hinge system is prone to breakage, making it an unreliable option for long-term usage.

Figure 4: Variable Stiffness AFO (VSO) [7]

The Variable Stiffness Orthoses provide a middle ground between powered mechanical orthoses and passive orthoses. This is a passive AFO, but with an adjustable stiffness, as seen in Figure 4. The adjustable leaf spring assists in foot drop and reduces foot striking [7]. 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, further emphasizing the need for a newly designed AFO that is more minimalistic in nature.

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. For this project, the focus is specifically on aiding adolescents with Facioscapulohumeral Dystrophy (FSHD). The goal is to create a device that helps teens achieve safer walking by assisting ankle dorsiflexion, as well as preventing ankle inversion and eversion, but also 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. This project has been ongoing throughout three semesters, and this semester, Spring 2026, will be the final semester of the project; the team is hoping to create a device that fulfills all requests, as well as displays significant data following the completion of testing.

Background

The Spring 2026 team has been tasked with designing and fabricating an ankle-foot orthosis (AFO). This product is for Debbie Eggleston's patient, a 16-year-old high school student living with facioscapulohumeral muscular dystrophy (FSHD). This disease leads to facial and lower limb muscular weakness. The team is focusing on the lower limb weakness, specifically managing the limited ankle mobility from inversion and onset of foot drop in dorsiflexion of the patient's gait. These symptoms warrant an AFO, but current market AFOs garner attention from peers. As a high school student, the patient is conscious of the aesthetic implications of an AFO that also lead to social implications. This guides the project to provide significant support in the

patients gait while delivering it as a discreet solution to bolster confidence, independence and quality of life.

Client Information

The client, Debbie Eggleston, is a physical therapist as well as an advocate for individuals with 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.

Anatomy & Physiology

Facioscapulohumeral muscular dystrophy (FSHD) is a rare neuromuscular disorder characterized by progressive muscle weakness, primarily affecting the shoulder girdle, hip girdle, facial muscles 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 [8]. 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 [8].

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 [9]. Additionally, mutations in epigenetic regulators have been associated with disease progression [10]. 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 [11]. In FSHD, however, reactivation of DUX4 expression damages muscle cells and drives disease pathology.

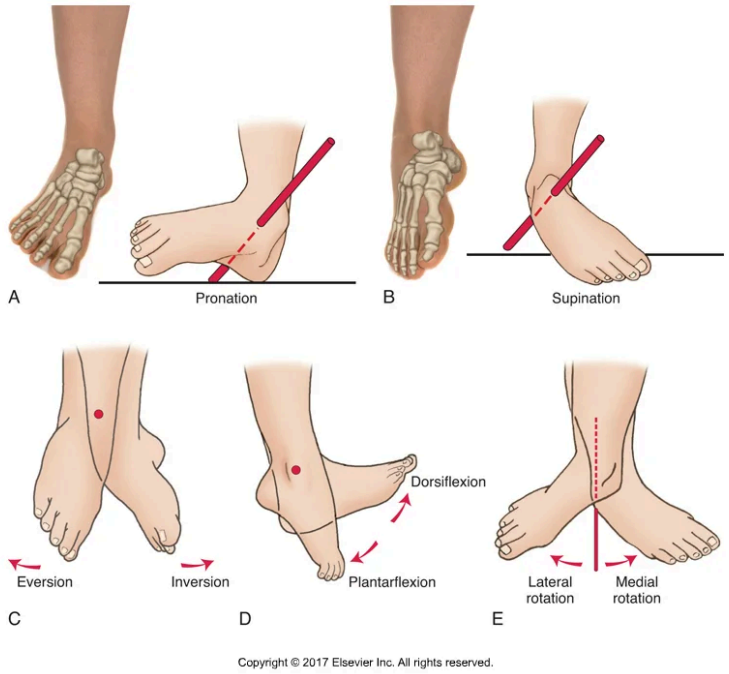


Figure 5: Illustration of various anatomical positions [12]

The primary purpose of the ankle-foot orthosis (AFO) is to provide dorsiflexion support, and in the patient's case, prevent ankle inversion and eversion. The movements are shown above in Figure 5. Because of the foot drop, the gait of the patient is also affected, so the AFO must also address the weaknesses seen while walking. The gait cycle is illustrated below in Figure 6.

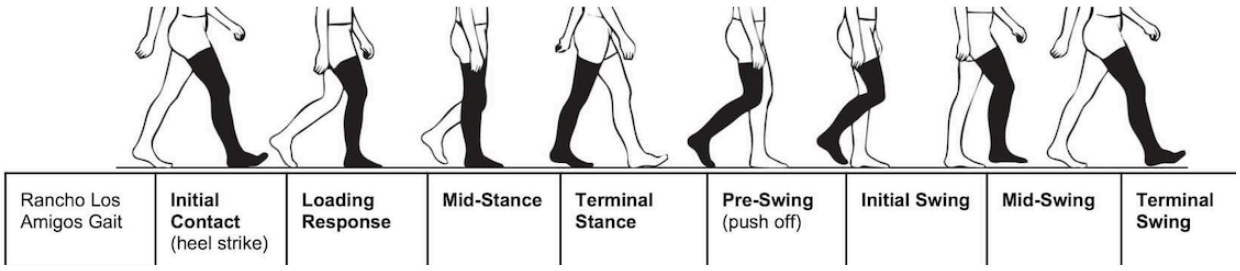


Figure 6: Normal Gait Cycle [13].

Foot drop occurs when the muscles distal to the ankle, particularly the tibialis anterior in Figure 5 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 in Figure 6. Consequently, the foot may catch on the ground during walking, significantly increasing the risk of falls.

In addition to foot drop, the patient also presents with ankle inversion, as seen in Figure 5. 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.

Previous Work

As previously mentioned, this project has been in progress for three previous semesters. The first iteration of the design was the Bungee Brace (Figure 7), which was composed of a compression sock combined with nylon-reinforced carbon fiber support. It also included a Locklace and bungee cord system to adjust the support of the brace. Although effective at supporting dorsiflexion of the foot, this design lacked a rigid inversion support.

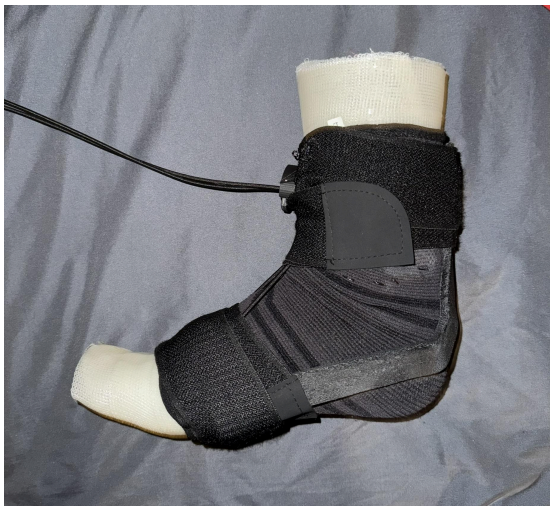


Figure 7: The Bungee Brace final prototype from Fall 2024.

Efforts from the Spring 2025 semester mainly focused on creating rigid supports to prevent ankle inversion and eversion. This resulted in 3D-printed carbon fiber PLA inversion supports. This concept was slightly modified and then implemented in the final design from Fall 2025 (Figure 7) along with elastic straps to aid in dorsiflexion.

Figure 8: The final AFO design from Fall 2025

The final prototype from Fall 2025 was shipped to the client and patient in Michigan. Currently, it is being tested by having the patient wear it for a day and then providing the team with verbal feedback on the effectiveness as well as noting any discomforts. So far, the patient has noted the increase in comfort of this prototype compared with previous ones. However, it was also mentioned that the dorsiflexion strap slips from the distal portion of the bottom of the foot towards the ball of the foot after extended use. The team will take this into consideration when implementing changes in this semester's prototype.

Product Design Specifications

The ankle-foot orthosis (AFO) was 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. In order to maximize comfort, padding will be implemented into various areas of the device based on user feedback. 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 currently measures approximately 31 cm in length, extending proximally from the distal end of the foot. Its structure combines rigid elements on the medial and lateral sides, with a strap truss mechanism, allowing full 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, not permitting more than 30° of foot drop from the neutral ankle position. To achieve this, the device delivers approximately 5–10 Nm of counteracting torque for every 10° of plantarflexion [14].

Additionally, it limits inversion to angles below 25° [15]. The AFO must withstand the forces placed upon by the user walking, as calculated using the equation below (Equation 1). The equation yields a vertical force of 439.7 N which is created by the user based on their specific height and weight. However, due to a standard medical device factor of safety of 4, the force that the device needs to withstand becomes 1758.78 N [16].

Equation 1 [16]: $F_{vertical} = mg - (m(v_x)^2)/L$

*Assumes a velocity of 1.2 m/s and a leg length of 0.914 m

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.

Current Design

The current design features a mediolateral shell that has been 3D-printed using carbon fiber-reinforced polylactic acid (CF-PLA). There are slits along each side for the support straps. A strip of ballistic nylon was sewn into the lateral side, threaded through the medial side, then reconnected to the lateral side via velcro. A strip of elastic polyester was sewn to the slits at the top of the brace, and wrapped around the bottom of the foot for dorsiflexion support. Finally, two layers of mesh padding were sewn together and super-glued to each side of the brace to ensure maximum comfortability.

Preliminary Materials

The preliminary designs for the Spring 2026 semester are not traditional prototype designs, but rather material designs for both the front dorsiflexion trap and the mediolateral side pieces. The strap needs to increase the amount of force applied to the foot and mitigate slippage. A different material than the elastic polyester currently being used may have better strengths for this element of the design. The inversion and eversion aspects of the design can be upgraded further from carbon fiber-reinforced PLA using another material of choice, hence the second design matrix.

Dorsiflexion Material 1: Elastic Polyester

Elastic polyester is a synthetic material that is majorly composed of polyethylene terephthalate (PET) [18]. It includes high-stretch fibers such as spandex. The most notable properties include low moisture absorbency, low density, abrasion resistance, high ductility, and high tensile strength [19].

Dorsiflexion Material 2: TPU

Thermoplastic Polyurethane, also known as TPU, is a type of thermoplastic elastomer that is most well known for its uses in 3D printing. It is often used as an additive to modify the

properties of another material. Its most notable properties include excellent durability, high ductility, resistance to impact, abrasion, chemicals, extreme temperatures, and high tensile strength [20].

Dorsiflexion Material 3: Ballistic Nylon

Ballistic nylon is a type of nylon fabric that was originally engineered during World War II to protect soldiers against flying shrapnel and bullets. It was created to improve traditional nylon fabric in both abrasion resistance and durability. The process includes creating a very tight 2x2 basket weave, termed a “ballistic weave”, with any nylon fabric, which immediately enhances its protective properties [21]. Other notable properties include elasticity, shock absorption, moderate water resistance, low density, and high ultimate tensile strength [22].

Inversion/Eversion Material 1: Carbon Fiber

Carbon fiber is a material composed of crystalline filaments of pure carbon that are tightly bonded together. Each of the fibers are very thin, having diameters of approximately five to ten micrometers. The pure carbon has almost no impurities, making it an excellent material for performance purposes. Notable properties include high stiffness, low density, fatigue resistance, and corrosion resistance [23].

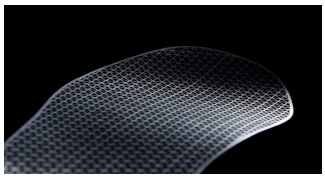
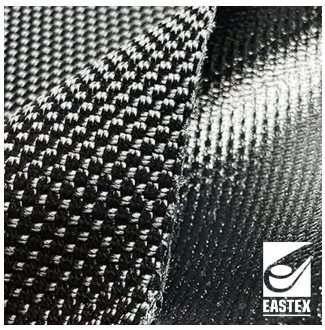
Inversion/Eversion Material 2: 50% Infill CF-PLA

Carbon fiber-reinforced PLA with a 50% infill is a 3D printing composite material. This material is sufficiently strong and rigid to handle heavy loads without failure due to its carbon fiber composition. It is slightly more elastic, more environmentally friendly, and significantly less expensive than traditional carbon fiber due to its PLA composition [24].

Material Evaluation

Dorsiflexion Material Design Matrix

Table 1: Dorsiflexion Material Design Matrix

Design Criteria	 **Material 1: Elastic Polyester**		 **Material 2: TPU**		 **Material 3: Ballistic Nylon**	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Dorsiflexion Support (25)	3/5	15/25	4/5	20/25	5/5	25/25
Durability (15)	4/5	12/15	3/5	9/15	4/5	12/15
Flexibility (15)	5/5	15/15	4/5	12/15	2/5	6/15
Fabrication Quality (15)	3/5	9/15	4/5	12/15	3/5	9/15
Comfort (10)	5/5	10/10	4/5	8/10	3/5	6/10
Discreetness (10)	4/5	8/10	4/5	8/10	4/5	8/10
Cost (10)	3/5	6/10	5/5	10/10	2/5	4/10
Total	75/100		79/100		70/100	

Dorsiflexion Support (25%): The material chosen needs to be able to provide ample dorsiflexion support in order to improve the swing, heel strike, and mid-stance phases for the

consumer's gait. This ultimately corrects the body's adaptive strategies that deal with the compromised gait such as early heel rise, foot dragging, circumduction, and steppage gait. Ballistic nylon was ranked best in this category due to having the largest ultimate tensile strength of the three materials at 60-80 MPa [25].

Durability (15%): The material chosen needs to be durable and strong enough to withstand the forces applied during walking, which can be up to 1500 Newtons. The material should also be able to withstand creep and general wear and tear of the design. The material needs to be able to be used for several years before needing to be replaced. Elastic polyester was ranked best in this category due to its versatility, abrasion resistance, and high ultimate tensile strength of 55 MPa [25].

Flexibility (15%): The material must exhibit enough flexibility for the patient to be able to move comfortably through a multitude of motions, including but not limited to stairs, sitting in a car seat, and walking. The material must hold the foot with adequate support in dorsiflexion to return the gait to normal, while also maintaining this element of flexibility. Elastic polyester ranked best in this category due to its high elongation, shape retention, and elasticity.

Fabrication Quality (15%): The fabrication quality of the material should withstand the stresses of everyday use for an extended period of time. There should be no evidence of fraying, snagging, loss of elasticity, or odor retention. It should maintain original shape, texture, and structural integrity to ensure that it continues to meet the project goals. TPU was ranked the best due to its unique combination of rubber-like elasticity and extreme durability when it comes to chemicals, abrasion, and everyday wear-and-tear [20].

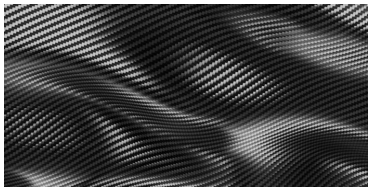
Comfort (10%): The goal of the AFO is for it to be worn all day excluding sleeping. This means that it must be extremely comfortable for the user to encourage consistent use. Rubbing, chafing, pinching, poking, excessive tightness, and any other causes of discomfort are unacceptable. Additionally, these symptoms could start new, unwanted problems such as circulation issues, cramping, and blisters. Elastic polyester ranked the best due to its tendency to be softer against skin compared to the other materials, elasticity, and breathability.

Discreteness (10%): It is important to the client and patient that the design of the AFO is discrete in nature. AFOs that are currently available on the market are bulky in design, and extremely noticeable to others when worn. A discrete design ensures that the user will not receive any unwanted attention, and will feel comfortable wearing it in public. TPU ranked the best because it can be printed in a variety of colors. One option is printing it in black, matching the other AFO components and potentially creating a sleek and athletic look. Another would be to print it in a color similar to the patient's skin tone, making it less visible to passerbys.

Cost (10%): Although this project is being generously funded through the Department of Biomedical Engineering, the cost of the design must still be considered. If this design were to be duplicated by another party, it should be cost-friendly in order to make it accessible to as many users as possible. The price of the materials incorporated into the design should be reasonable, ensuring that the price of buying the device is not a barrier for patients. TPU ranked the best because it is the least expensive of the three materials, coming in at $1.12 per ounce [26].

Inversion/Eversion Materials Design Matrix

Table 2: Medial/Lateral Material Design Choice

Design Criteria	**Material 1: Carbon Fiber [27]** 		**Material 2: PLA-CF 50% infill [28]** 	
	Raw Score	Weighted Score	Raw Score	Weighted Score
Strength (25)	5/5	25/25	3/5	15/25
Durability (15)	5/5	15/15	3/5	9/15
Flexibility (15)	3/5	9/15	3/5	9/15
Fabrication Quality (15)	5/5	15/15	4/5	12/15
Comfort (10)	3/5	6/10	3/5	6/10
Discreetness (10)	4/5	8/10	4/5	8/10
Cost (10)	2/5	4/10	5/5	10/10
Total	82/100		69/100	

Strength (25%): The material should be strong enough to provide sufficient mediolateral (side-to-side) support. The foot and ankle should be kept in alignment with the rest of the body. The material should also be strong enough to withstand the mechanical loads of daily weight-bearing activities. There should be no evidence of structural failure. Carbon fiber ranked best due to its incredibly high tensile strength of 5407 MPa [29].

Durability (15%): The material chosen needs to be durable and strong enough to withstand the forces applied during walking, which can be up to 1500 Newtons. The material should also be able to withstand creep and general wear and tear of the design. The material needs to be able to be used for several years before needing to be replaced. Carbon fiber ranked best due to its low density of 1.79 g/cm^3, high chemical resistance, and high temperature tolerance [29].

Flexibility (15%): The material must exhibit enough flexibility for the patient to be able to move comfortably through a multitude of motions, including but not limited to stairs, sitting in a car seat, and walking. The material must hold the foot with adequate support in mediolateral support to return the gait to normal, while also maintaining this element of flexibility. Carbon fiber and carbon fiber-reinforced PLA ranked equally due to their similar elongations of 1.75% and 2%, respectively [29].

Fabrication Quality (15%): The fabrication quality of the material should withstand the stresses of everyday use for an extended period of time. There should be no evidence of fraying, snagging, loss of strength and stability, or odor retention. It should maintain original shape, texture, and structural integrity to ensure that it continues to meet the project goals. Carbon fiber ranked best due to its excellent strength-to-weight ratio of 1847 ($MPa/g/cm^3$) and precise manufacturing techniques [29].

Comfort (10%): The goal of the AFO is for it to be worn all day excluding sleeping. This means that it must be extremely comfortable for the user to encourage consistent use. Rubbing, chafing, pinching, poking, excessive tightness, and any other causes of discomfort are unacceptable. Additionally, these symptoms could start new, unwanted problems such as circulation issues, cramping, and blisters. Carbon fiber and carbon fiber-reinforced PLA ranked equally due to their similar density and rigidity.

Discreteness (10%): It is important to the client and patient that the design of the AFO is discrete in nature. AFOs that are currently available on the market are bulky in design, and extremely noticeable to others when worn. A discrete design ensures that the user will not receive any unwanted attention, and will feel comfortable wearing it in public. Carbon fiber and carbon fiber-reinforced PLA ranked equally due to their similar athletic looks and aesthetic appeal.

Cost (10%): Although this project is being generously funded through the Department of Biomedical Engineering, the cost of the design must still be considered. If this design were to be duplicated by another party, it should be cost-friendly in order to make it accessible to as many users as possible. The price of the materials incorporated into the design should be reasonable, ensuring that the price of buying the device is not a barrier for patients. Carbon fiber-reinforced PLA ranked best in this category due to its much lower cost in comparison to pure carbon fiber. PLA-CF costs $0.84 per ounce and carbon fiber costs $2.00-10.00 per ounce [26][30].

Final Material Choice

Figure 9: Finalized prototype to aid in dorsiflexion and prevent ankle eversion and inversion.

Following the testing of the new materials chosen in the design matrices, the team will move forward to fabricate the device with minor changes from Figure 9, which was the final design from Fall 2025. The team will likely implement the TPU filament in the dorsiflexion strap, and continue to work with the Design Innovation Team in ECB to fabricate the carbon fiber pieces.

Fabrication and Development Process

Materials

The final AFO design incorporates five primary materials selected to optimize strength, durability, comfort, and cost-effectiveness (see Appendix H for full costs). The inversion supports are 3D printed using carbon fiber–reinforced PLA (CF-PLA) at 50% infill, chosen for its lightweight structure, high flexural strength, smooth finish, and low-profile design. CF-PLA provides strong mediolateral support while minimizing fatigue, and carbon-fiber AFOs are capable of supporting loads up to 1,000 N [31]. Compared to plastic or steel, carbon fiber offers improved weight distribution and flexibility, which is especially important as the patient experiences frequent inversion falls. Additionally, CF-PLA is cost-effective at approximately

$0.05 per gram, and access to the University of Wisconsin-Madison Grainger Engineering Design Innovation Lab enables low-cost fabrication through 3D scanning and printing [26].

The dorsiflexion strap is constructed from a knit elastic composed of 69% polyester and 31% rubber, providing durable, lightweight, and moisture-resistant support while maintaining elasticity and creep-resistant shape retention [32]. Polyester's low moisture absorption, resistance to shrinking and fading, and ease of cleaning make it well suited for daily wear. Adjustable attachment straps are fabricated from ballistic nylon, a densely woven synthetic fabric known for high abrasion and tear resistance, ensuring durability under repeated loading and flexion [33]. Velcro integration allows customizable tightness for user comfort. To enhance wearability, the inversion supports are lined with 100% polyester air sponge mesh fabric, which promotes airflow, moisture wicking, and heat management while maintaining durability and elasticity [34]. Together, these materials balance structural support and breathability, reinforcing both functional performance and long-term comfort.

To learn more about the fabrication of the design from previous semesters, see Appendix B.

Strengths and Limitations of the Current Design

The final design has exhibited success in both client feedback and testing. A comfortability survey was given to the patient for both Spring 2025 and Fall 2025 models, which can be seen in Appendix E and Appendix F. In the Spring 2025 survey, the patient indicated that there were uncomfortable pressure points around the malleoli. The Fall 2025 team attempted to mitigate this problem by adding a second layer of padding, to which the patient reported that the issue was successfully resolved, leading to no additional discomfort. Additionally, both the client and the patient approved of the new aesthetic appeal to the design. Testing displayed that foot drop during gait decreased, dorsiflexion was improved, and increased standing stability. Finally, it was confirmed that the brace comfortably fit inside of the desired shoes, and that the shoe even prevented the front strap from slipping back.

Though the design has been proven initially successful, the team did face some limitations. First, testing with the patient was limited to one weekend due to the long travel distance from Michigan. This limitation prevented the team from acquiring another comfortability test during the semester. The teams also had difficulty manufacturing the medial and lateral aspects of the design; the desire to work with carbon fiber was quenched with the difficulty of manufacturing. Working with carbon fiber would have required extensive training and research to create a finalized product. Finally, the front polyester strap is prone to slippage. While wearing the brace with a shoe mitigates this problem, a further improved design would involve further modifications to ensure that there would be no slippage without a shoe.

Overall, the final design is very strong and displays success. It balances functionality, comfort, and aesthetics to give the client a product that truly works and could help to prevent the FSHD from negatively impacting the patients everyday life.

Methods

The Fall 2025 team reused 3D scans of the patient's right leg from Spring 2025 to guide the updated brace design, created in OnShape. In spring 2025, the team cut the epoxy-coated cast into medial and lateral halves using a Dremel, scanned the cast with the Creality RaptorX, and refined the resulting mesh before importing it into Onshape for modeling. After this model was uploaded, the Fall 2025 Team recreated the side pieces from scratch. Splines were created, lofted, and extruded to achieve the desired geometry, and the updated inversion supports were 3D printed using PLA with 50% carbon fiber infill for added strength. The design was modified by increasing the superior height on both sides of the brace and adding an additional ventral slit for an adjustable strap, while removing the inferior strap due to previous slippage issues.

Padding was fabricated by tracing and cutting two layers of mesh for each side, sewing them together, and attaching them to the concave surface of the rigid supports with super glue. Excess material was trimmed to reduce friction, and slits were carefully cut to allow the strap to travel through while preserving the malleolus opening. Ventral straps made from ballistic nylon were measured using the cast for accuracy, and an anterior ankle strap with Velcro allows adjustable tightness and quick and easy application and removal.. For dorsiflexion support, a reinforced elastic polyester strap was sewn across the front of the foot to reduce overstretching while maintaining assistance. The final design emphasizes simplicity, durability, and ease of daily use, ensuring the brace remains comfortable, functional, and practical for long-term wear.

The Spring 2026 team is aiming to update the design to create optimal levels of comfort, dorsiflexion support, and minimum slippage. The design will be updated in OnShape to extend the medial and lateral aspects to the base of the foot, eliminating downward slippage while in the shoe; the material will hypothetically change from PLA-CF to true Carbon Fiber, with the assistance of the team lab. The dorsiflexion element of the brace will be modified, with the team testing various materials to increase the support of the foot during walking.

Testing

Previous Semester Testing

In Fall 2024, the team evaluated the AFO prototype on a healthy participant using the Runeasi IMU system to measure gait metrics including dynamic instability, ground contact time, impact magnitude, and cadence across three conditions: with the brace, without the brace, and with the brace minus the rigid support. Results showed that while the device did not negatively impact gait, it also did not significantly improve dynamic instability, suggesting limited

mediolateral support. However, the brace effectively assisted dorsiflexion, increasing the resting foot angle by 38°. Minor slippage was observed in the bungee-lock system. In Spring 2025, mechanical testing using a three-point bend test assessed carbon fiber PLA (CF-PLA) at 15%, 35%, and 50% infill under a 260 N load at 25° inversion. All configurations passed, and 50% infill was selected for its added structural robustness.

Further evaluation included force-plate testing under eyes open, eyes closed, and wedge stance conditions to analyze center of pressure and stabilograms across three brace types. The black brace demonstrated the best overall stability, though differences were not statistically significant. Comfort testing revealed medial foot discomfort and slippage in the red support, with the compression sleeve and straps identified as key issues. Finally, motion capture analysis using OpenCap compared no AFO, the client's existing AFO, and the red prototype. Hip and knee kinematics were consistent across conditions, while subtalar inversion/eversion results were inconclusive, indicating the need for further ankle-specific analysis.

Testing was conducted in person during the Fall 2025 semester with both the client and patient to ensure technical accuracy and allow for minor brace adjustments. The team evaluated the Spring 2025 brace model with the newly sewn elastic polyester dorsiflexion strap, performing three gait trials for each condition (red, black, taped, and untaped) along with stabilogram balance testing. Raw data and graphical results are documented in the testing analysis document, Appendix D. Comfort testing was also repeated using the newly printed medial and lateral components to assess pressure points and overall wearability. The patient reported improved comfort compared to the previous semester, particularly reduced irritation at the navicular and malleolus.

Force plate gait analysis demonstrated that both braces reduced the difference between heel strike and toe-off forces compared to no brace, with the black brace performing best and producing loading patterns closer to a typical gait. After normalizing for body weight differences, the best brace condition showed lower average loading and improved consistency, though statistical significance was not achieved due to small sample size. Effect size analysis (Cohen's d) indicated large practical improvements, and stabilogram data showed trends toward reduced sway in the affected limb. Overall, while results were not statistically significant, the combined biomechanical data, effect sizes, and observed gait improvements suggest the brace positively influences stability and walking mechanics, with further refinements planned to strengthen outcomes in Spring 2026.

Testing Limitations

Debbie Eggleston and the patient reside in Michigan, making in-person testing a challenge. The device hadn't been tested in person in any of the previous semesters, but after communication with both parties, testing was able to be performed in person in November. The

team also wanted to test with TPU filaments, however, upon printing and MTS testing, the filament was not long or stretchy enough to test with the patient.

The team in Spring 2026 has received the phone number of the patient, looking to directly communicate with her to receive updates about the fit of the final prototype from the Fall semester. The communication remains in a closed channel, and takes patient safety and privacy into account.

Current Testing

The Spring 2026 team has performed MTS testing of the three materials, TPU, elastic polyester, and ballistic nylon. Each material had three samples ready for testing, and were tested through a range of tensile testing at various speeds. Each material sample was 1 inch in width, 1/32 inch in thickness, and on average, 7 inches in length.

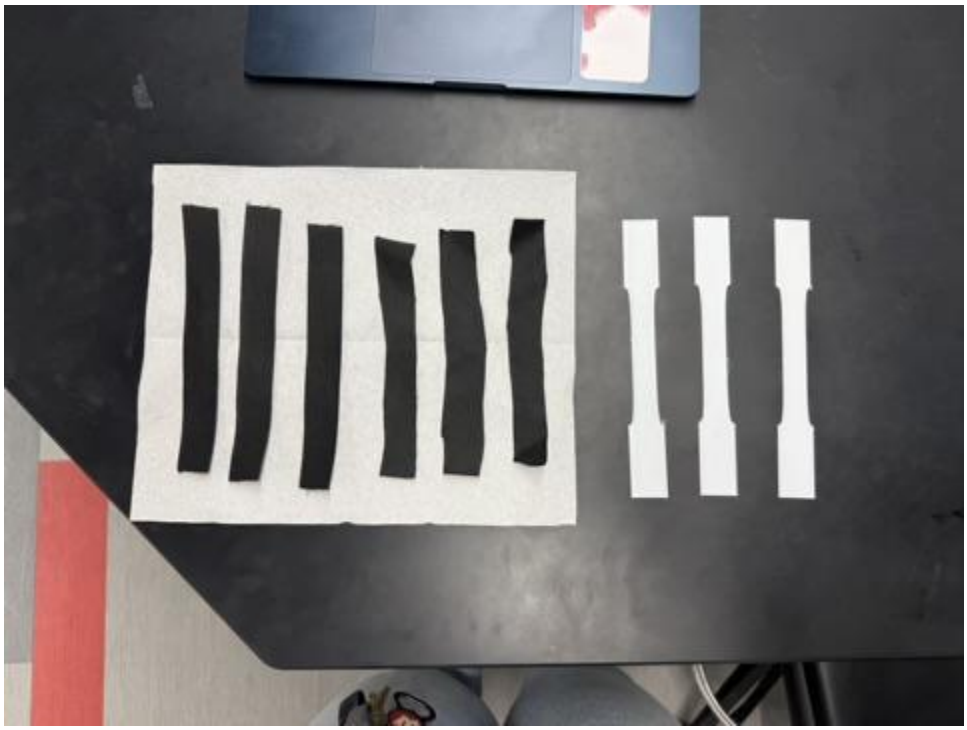


Figure 10: Elastic Polyester, Ballistic Nylon, and TPU filament samples for MTS testing

Each sample was placed in the grips of the machine and stretched to determine the elastic modulus and other material properties. In Figure 10, each of the samples can be seen. The elastic polyester is the cleanest cut material, as that was only cut with scissors and on a straight cut. The ballistic nylon was also cut into strips using scissors, but without a straight edge or other device to ensure straight cuts; therefore, each strip is slightly variable along the length when concerning width, but on average, remains the same. The TPU material was printed at the Design and Innovation Lab in Wendt commons, which used the same white filament for each print; this resulted in slight variations on the surface of each material, but no changes to the structural integrity of each print.

Figure 11: TPU filament in the grips of the MTS machine

The team tested each material in the MTS machine, and in Figure 11 one can see the TPU being tested in the grips. Each material was tested in this manner, and the data collected will be analyzed and presented in an upcoming progress report.

The team has also communicated with the patient, receiving text confirmation that the brace feels like it works, raising the foot during walking to help eliminate the footdrop, and therefore excessive falling. The patient also confirmed the design changes eliminated the rubbing against the malleoli, and is comfortable and easy to wear.

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.

Due to the difference in location between the team and the client, there has been significant use of virtual communication via Zoom, email, and text messaging. This means that the team must consider the ethics behind remote communication. These include ensuring that the communication systems in use are accessible to the client, ensuring there are no privacy concerns, using language that is clearly understood and does not contain any difficult health-jargon, and eliminating any barriers to communication between the team and the patient herself, such as using her phone number versus email. All of these methods have been implemented to ensure precaution and the best possible care for both the client and the patient [35].

Design Evaluation

There are 3 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 third semester's goals were to improve concealability, updating means for dorsiflexion, and inversion support. The current AFO is concealable as an ankle brace, but has problems with significant data to support dorsiflexion. The goal for spring 2026 is to modify the AFO and materials in order to gain significant data for dorsiflexion and create a polished final product. These goals align with the deadline for this project to conclude at the end of the semester.

Overall, the AFO has been successful with improving the patients gait, but significant data has not been achieved. The inversion support braces were slightly modified to make them more comfortable and sturdier. Additionally, the bungee cord was changed to polyester straps that go around the balls of the feet. This offers increased dorsiflexion support that had been lacking in previous designs. Lastly, the design of the straps used to secure the brace were changed. The placement of the straps have been adjusted so that the straps are even between the two sides of the brace on the foot which helps keep the brace more stable, but there are still concerns with brace slippage down the ankle. Overall, the most noticeable change in the AFO has been its appearance. By changing the dorsiflexion support straps and no longer using the compression sock from the previous semester's design, the current AFO is much more sleek and concealable while still offering increased support.

A major takeaway from the past design is the patient's recognition of gait improvement. They report increased ankle stability and can notice a difference in heel strike and push-off during their gait. This is a major success, because the improvement along with the minimalistic design encourages the patient to wear the AFO at a more consistent rate.

Potential Sources of Error

There are many potential sources of error that were identified during the design and fabrication of the device. One potential source of error was the measurement of the client's foot. Much of the manufacturing and design work relied heavily on accurate foot measurements, but it must also be acknowledged that some measurement error was expected because the patient lives in Michigan and could not participate in regular testing while the changes were being made. The initial measurements were taken using the patient's previous cast, but there is also a possibility of error introduced during 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 were very few chances to receive user feedback on the comfortability of the device. There was padding added, but there were also other factors like tightness and correct positioning that affect comfortability. Luckily, because the client and patient were able to come to Madison for testing, the team was able to receive feedback on the comfort and fit of the design. Ideally, this comfort testing would have been repeated after the changes were made, but the team was not able to do that, which is a potential source of error.

Due to the previous semester's inversion support design fracturing, material durability has become a point of concern. The inversion brace design was altered so that there were fewer thin parts, but because the brace is 3D-printed, there are still concerns about breakage along the

grain. This limitation in material options creates a significant potential source of error. Due to the organic shape of the braces, 3D printing is the only material that the team was trained to use for making the brace. Some tensile strength testing was performed in previous semesters to determine the best percent infill of the CP-PLA, but the data from that testing won't be perfect because there will be some differences in the forces compared to the actual use of the AFO.

One of the last potential sources of error was the actual 3D printing of the device. 3D printing is not always perfect, there are occasional printing errors that can make the device more susceptible to breaking. There could also be small mistakes during the print that make the brace less comfortable. Overall, while many of these potential sources of error are fairly unlikely, they are still possible and could have contributed to issues in the AFO design.

Conclusions

The goal of this project was 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 polyester strap. This design was aimed at assisting with the dorsiflexion of the foot and fixing the patient's current foot inversion. It also remained relatively slim and simple to remain discreet. This AFO was 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. The testing showed that the AFO helped the patient, and it is likely that they will wear it since it is comfortable and discreet.

Future Work

Moving forward, the team aims to enhance the stability and functional performance of the brace through several targeted improvements. First, the medilateral supports will be extended to the floor to reduce downward slippage and provide a more consistent foundation while walking. The team also plans to look into integration of a TPU strap instead of polyester, as MTS testing suggested that TPU is more durable than polyester in terms of long-term wear and fatigue resistance. The team will also evaluate the effectiveness of different TPU strap lengths and thicknesses to identify a combination that offers strength and security without compromising comfort or range of motion. Continued testing with various strap combinations will help to refine this balance and make the test results even more statistically significant as well as improve slippage of the dorsiflexion support.

Given that the client and patient reside in Michigan, just 15 minutes from Ann Arbor, the team would like to explore a collaboration with the University of Michigan's Department of Biomedical Engineering. Working with a nearby institution would allow for streamlined prototype updates, reduced turnaround time for repairs, and enable more frequent testing and data collection. This collaboration would make it significantly easier to gain meaningful feedback from the patient and make more frequent adjustments to the design.

Acknowledgements

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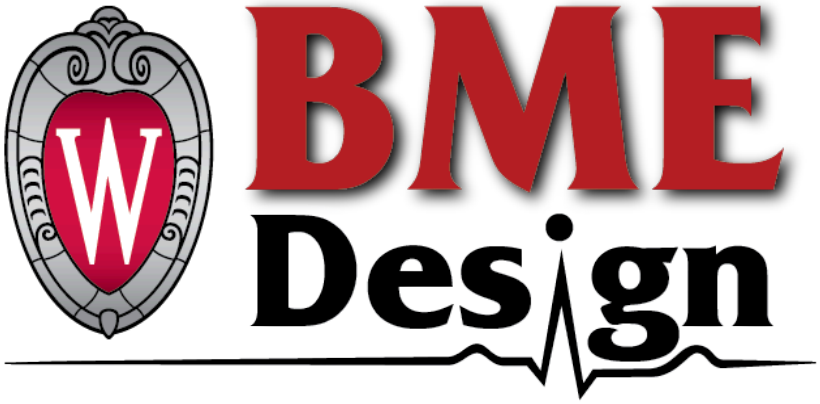
Appendices

Appendix A: Product Design Specification (PDS)



Inconspicuous Ankle Foot Orthosis (AFO) for teen

PRODUCT DESIGN SPECIFICATIONS (PDS)

Team Name:
Team AFO

Class: *BME 301, Section 304*

Team Members:
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Client:
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Advisor:
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February 25th, 2026

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. This project has been ongoing throughout three semesters, and this semester, spring 2026, will be the final semester of the project; the team is hoping to create a device that fulfills all requests, as well as displays significant data.

Client requirements:

- An AFO to help support dorsiflexion of the right foot
- Should also prevent excessive inversion of the ankle
- Flexible enough for daily activities
- Be simple to put on and take off
- The client prefers the AFO to be discreet, fitting inside a shoe and minimizing visibility
- The functionality of this device is becoming more prevalent as the disease progresses

Design requirements:

1. Physical and Operational Characteristics
    a. Performance requirements
        i. The AFO is 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]. Ideally, the device will weigh approximately 1kg, and not more than 3.4kg, which is comparable to current AFOs on the market [2]. It allows a natural walking pattern without generating resistive moments during dorsiflexion [3].
        ii. The device permits more than 30° of motion from the initial ankle angle to ensure proper foot clearance [4].

iii. In plantarflexion, the orthosis generates an adjustable resistive moment ranging from 5–10 Nm per 10° of motion [4]. Overall, moment-angle performance should stay within ±30 Nm of torque. The brace also resists torsional forces that could cause misalignment of the ankle or foot during regular activity [5].

iv. The AFO withstands 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 118 lbs (53.4 kg), with a height of 1.72 m this translates into supporting a maximum force of 1758 N after including a factor of safety of 4 [6]. The normal force exerted by the patient is 439 N. 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, the dimensions of the leg are detailed below.

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 also maintaining anatomical alignment to avoid excessive stress on joints, bones, or muscles.

ii. Chosen materials should be non-toxic, hypoallergenic, and free of sharp edges to prevent irritation or injury.

iii. Adjustable parts must secure under impact but not restrict circulation to the foot and ankle areas.

iv. Fastening systems should be secured to prevent loosening during activity, but allow for quick removal in emergencies without tools.

v. The device must withstand the forces put on it by the user as outlined in the performance requirements. Carbon fiber AFOs, for example, typically fail at the mid-shank calf support under forces of 1970 N [8].

vi. The design should emphasize breathability to prevent a buildup of moisture and overheating of the user.

vii. To reduce injury risk and maximize comfort, the device will include mesh padding in the calf region and around any areas of discomfort as noted by the user during testing.

c. Accuracy and Reliability
    i. The AFO must maintain structural integrity through repeated use while continuing to provide consistent dorsiflexion support. The device will be used for up to 16 hours at a time while the user is awake, and must provide consistent results throughout the entire duration of use. The device will be used up to 7 days a week.
    ii. The device should be made with durable materials. Ideally, the materials should not degrade over time, or can be easily replaced to provide consistent results.
    iii. The device should also provide consistent mediolateral support, but this is not currently the client's highest priority currently.
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 must be periodically re-evaluated to confirm fit and function, ideally up to twice per year.
e. Life in Service
    i. The expected lifespan of a custom AFO is typically 2-5 years, though actual service life depends on the material, usage patterns, and patient needs [9]. Individuals who are experiencing rapid periods of growth, such as children, may need the AFO replaced as often as every 9-18 months [10].
    ii. Regular cleaning and upkeep of the device could help to increase the life in service.
    iii. Semi-rigid materials such as carbon fiber, fiberglass, and polyethylene generally last longer than softer materials as they are more resistant to damage [11]. Softer materials often need to be replaced more frequently than rigid materials.
    iv. Annual reviews by an orthotist are recommended to assess wear and ensure the device continues to meet the user's needs [12].

f. Operating Environment

   i. The primary intention for the AFO is everyday use. As such, it must be able to withstand everyday activities without deteriorating. Main uses will be at school, home, and horseback riding. In order for the AFO to be worn for these everyday activities it must be unobtrusive and unassuming to the eye.

   ii. The AFO must withstand exposure to varying environmental factors including temperatures, humidity, dirt, water, and sweat. To prevent infections due to bacterial buildup, the device needs to be cleaned weekly with mild soap and water [13].

g. Ergonomics

   i. The device must distribute the user's weight evenly to avoid discomfort. This distribution of weight will be analyzed though force plate testing. Adjustable features such as straps and bands should allow for modularity of the AFO. This will help the device fit the user through growth and activity needs.
   ii. As most AFOs weigh between 0.3–3.4 kg [14], the inconspicuous design should weigh under 1kg. This will allow for a low profile brace that improves dorsiflexion gait without altering step due to extraneous weight.
   iii. Extra padding must be introduced around sensitive areas such as the base of the foot, ankle, and achilles tendon. The design must be low profile enough to fit into shoes so that there is no need for shoes tailored to the device [4].
   iv. Moving parts must function quietly so it does not draw attention to the AFO. The device should not create more than 50 decibels of sound while walking, which is the approximate noise level created during normal walking [15].
   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 [16].

h. Size:

   i. The AFO must match the patient’s specific measurements, with slight adjustments to allow for padding and anti-chafing features [17]. Key measurements are as follows:

1. The length of the leg (measured bottom of foot to directly below the kneecap) is 45.5 centimeters.
2. The diameter directly below the kneecap (measured at top of the lower leg) is 31.5 centimeters.
3. The diameter of the thickest part of the calf (measured mid-leg) is 31.5 centimeters.
4. The diameter where the Achilles meets the calf (measured bottom of leg) is 20.5 centimeters.
5. The diameter of the thinnest part of the ankle (measured where Achilles is felt) is 20 centimeters.
6. The diameter across the middle of the ankle, through the joint is 30 centimeters.
7. The diameter just in front of the ankle joint (measured low ankle) is 24.5 centimeters.
8. Arch Measurements: bony prominence to floor is 4.5 centimeters and 6.25 centimeters in length.
9. The length of the foot is 24-24.5 centimeters.
10. The width of the foot (measured where the metatarsals meet the phalanges) is 8.25 centimeters.
11. The width of the foot (measured in midsole area) is 8 centimeters.
12. The width of the foot (measured at the heel) is 5.5 centimeters.
13. The patient weighs 53.4 kilograms.
14. The patient's height is 1.724 meters.
15. The patient's shoe size is 8.5-9 on a U.S. scale.

ii. A standard AFO thickness is approximately 3.175 millimeters, which balances structural support with sufficient flexibility to avoid stiffness-related instability [18].

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 kilogram [19].

j. Materials

i. The AFO design will be finalized this semester. It should be a discrete, minimally visible, and comfortable design that accomplishes the project goals.

ii. The main material of this design will be a carbon fiber-reinforced (PLA-CF) or a pure carbon fiber.

1. PLA-CF material properties include high ultimate tensile strength, high Young's modulus, high flexure stress, and low ductility [20].
2. Pure carbon fiber properties include high tensile and compressive strengths, high Young's modulus, low density, and high temperature tolerance [21].

iii. The dorsiflexion component of the brace will be made of either TPU filament or polyester fabric. Either of these materials will need to withstand forces from the patient walking, which can be up to 1758 N for this specific patient when a factor of safety of 4 is implemented in the design.

1. The notable properties of polyester include ductility, durability, mechanical strength, and moisture resistance [22].
2. 3D-printed thermoplastic polyurethane (TPU) exhibits lower elasticity when compared to the material in bulk. 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 [23]. Fatigue testing for TPU is vital due to its tendency to fail under continuous cyclic loads. Despite these limitations, TPU provides excellent abrasion resistance and environmental resistance, which enhances durability in applications like straps for both upper and lower body use [24].

iv. The padding should be made of two layers of mesh that are sewn together. These are then attached to the inside of the AFO via superglue [25].

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. The brace is similar to the look offered by an athletic brace.

2. Product Characteristics
   a. Quantity
      i. The project consists of designing and fabricating one right-leg AFO. However, with considerations of bringing the product to market, the design has to be easily fabricated in order to mass produce the inconspicuous AFO.
   b. Target Product Cost
      i. This project is funded by Biomedical Engineering Design at the University of Wisconsin-Madison. The expected cost of this semester's continuation is $50 with a possible increase with materials like carbon fiber for strong and light weight material options.
      ii. As of Fall 2025, the prototypes have accounted for $272.39. The semesterly breakdown of the budget is $189.02 for fall 2024, $37.95 for spring 2025, and $45.42 for Fall 2025. If the team stays under $77.61 then the project will be within $350 for all semesters.
      iii. The goal for spring 2026 is creating a final working prototype; reworking the Fall 2025 design based on data produced by the client, improving material selection for dorsiflexion gait and medial lateral support, and solidifying significant data to prove effectiveness. As the previous prototype does not have fully significant results a new design will be made within the constraints of the budget.

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 [26].
      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 [27].
      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 [26].

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) [28].

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 [29].

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 [30].

vii. ISO 8551:2020: Provides guidelines for evaluating functional deficiencies in patients and setting clinical objectives when prescribing orthoses [31].

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 [32].

b. Customer [33]

i. This device is designed for daily use by a 16-year-old with Facioscapulohumeral Dystrophy (FSHD) that requests the device be as unnoticeable as possible. It should be able to be worn both with and without shoes. Although it is custom-fitted, the target group also includes other young patients with FSHD or related muscular dystrophies who require ankle inversion, eversion, and dorsiflexion 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. The AFO should have

a Young's modulus between 2,400 MPa and 50,000 MPa which is comparable to various AFOs available on the market, depending on the material they are made out of [8]. It should not interfere with daily activities and should remain discreet to avoid drawing attention.

1. There has been minimal recovery of the ankle movement in the inversion and eversion aspect, leading the brace to focus more on dorsiflection support and less on eversion and eversion prevention.

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, if possible.
   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 [34]. AFOs can cost over $1000 and, for many families, these costs present a barrier to access [35][36].
   ii. The global AFO market is expected to grow to over $330 million by 2034 as demand for mobility aids increases due to rises in neurological and musculoskeletal conditions [37]. This emphasizes the need for a cost-friendly, yet effective AFO.
   iii. 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. [38]. Indirect costs such as home modifications, vehicle accommodations, caregiving, dietary needs, and travel add approximately $12,939 per patient each year [38].
   iv. Loss of income is another significant burden in situations where the condition worsens to the point of the patient not being able to work. 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 [38].

v. Overall, the economic burden of muscular dystrophy disorders in the U.S. is estimated at $1.07–1.4 billion annually [38]. 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

i. Most ankle–foot orthoses (AFOs) are based on the three-point force system, a common biomechanical approach used to control joint motion and limit unwanted movement. In this system, one main corrective force is applied in either the mediolateral or anteroposterior direction, while two opposing forces act above and below it to provide balance. Together, these forces stabilize the joint. Increasing the length of the orthosis spreads these force points farther apart, which improves how effectively the brace controls motion. This wider spacing also helps spread pressure over a larger area, making the device more comfortable for the user [39].

ii. 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].

iii. 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 [40].

iv. 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 [41].

v. 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 [39].

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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 the 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.

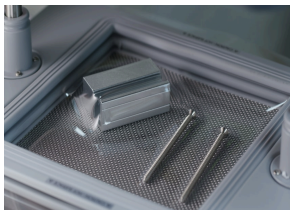
Once fully assembled, the user will be able to put on the brace by first slipping on the compressive sock, followed by sliding the brace onto their foot, both processes like a regular sock. The bungee cord can then be tightened to the user's preference using the cord lock, and the Velcro straps will 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 the 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, the 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	Headо 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**	

Appendix D: Testing Analysis of the Patient

Testing Analysis: Stability and Gait

Prototypes

Figure 1: The prototypes, from left to right, the TPU brace on the mold, the black brace (taped) on the patient, and the red brace on the patient's ankle.

Image 1 shows both versions of the prototypes that were tested on Saturday and Monday. The TPU was too small to use in actual testing, but dorsiflexion was tested after removing the strip from the actual side components. The black brace in the middle was taped for support, and was crucial to the dorsiflexion testing. The red brace on the right was tested on Saturday, and after learning about the slippage on the foot, the team implemented the taping that occurred on Monday, which held the brace in place and allowed for more accurate data collection.

The comfortability of each brace dug into the malleolus and navicular bone, with both braces, indicating the design needs to be changed to ensure comfortability with the patient. The exact testing of the comfortability can be seen in Appendices C and D.

Degrees of Support

Figure 2: Patient's Relaxed Foot

The patient, when sitting in the chair with a 90 degree bend in the hips and knees, and a completely relaxed foot, had a resting foot angle of 145 degrees as seen in image 2, which is 55 degrees below 90 degrees. The normal degree of a relaxed foot is around 15-20 degrees below 90 degrees, meaning the patient suffers from significant weakness in the ankle muscles [1].

Figure 3: Patient's foot supported by the black brace

With the addition of the elastic support, the relaxed state of the foot decreased to 106 degrees, as seen in Figure 3. The decrease of 55 degrees below parallel to 16 degrees below parallel indicates a significant aid. This indicates a good level of force being applied to the foot, alleviating some of the stress to the muscle, and aiding in helping prevent foot drop.

With the addition of the TPU support, the relaxed state of the foot decreased to 109 degrees, which is still within the 15-20 degrees below parallel, indicating a significant amount of force being applied to the foot to help prevent foot drop. However, the TPU filament was not long enough to test in the actual prototype, and therefore we only tested with the elastic filament.

Gait Analysis

Test 1: Walking, No Brace, No Shoe

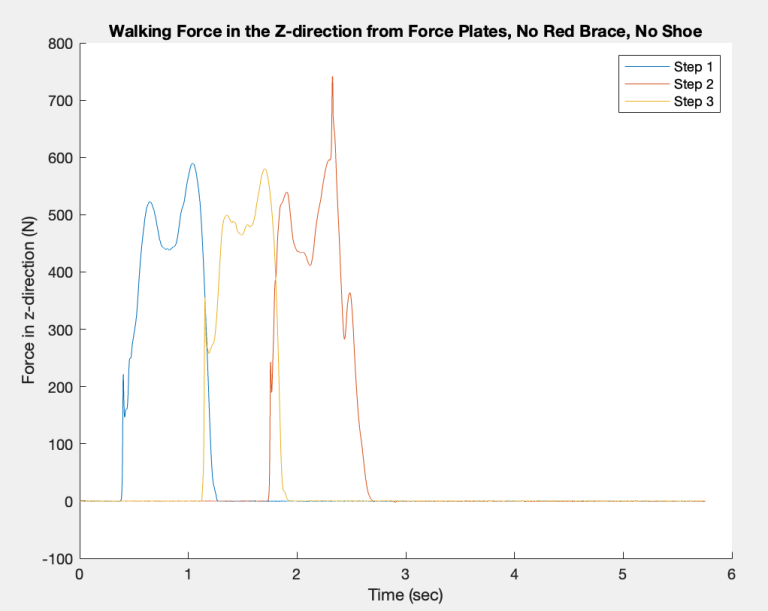


Figure 4: Walking with no brace

Test 2: Walking, No Brace, with Shoe

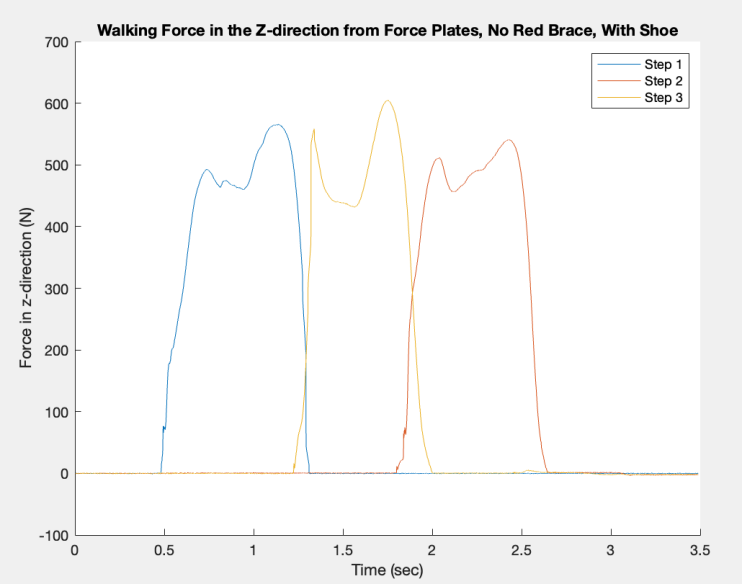


Figure 5: Walking with no brace, with shoe

Test 3: Walking, Red Brace, No Shoe

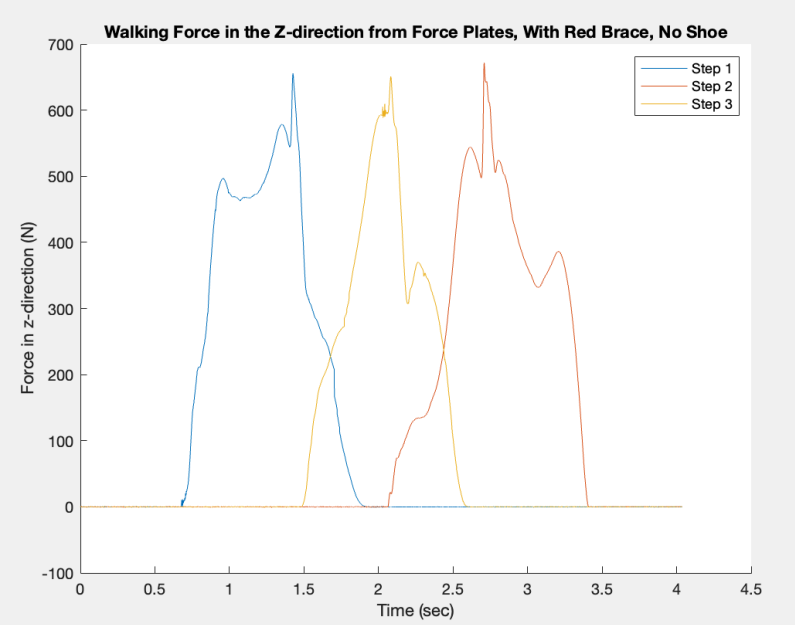


Figure 6: Walking with Red Brace, No Shoe

Test 4: Walking, Red Brace, With Shoe

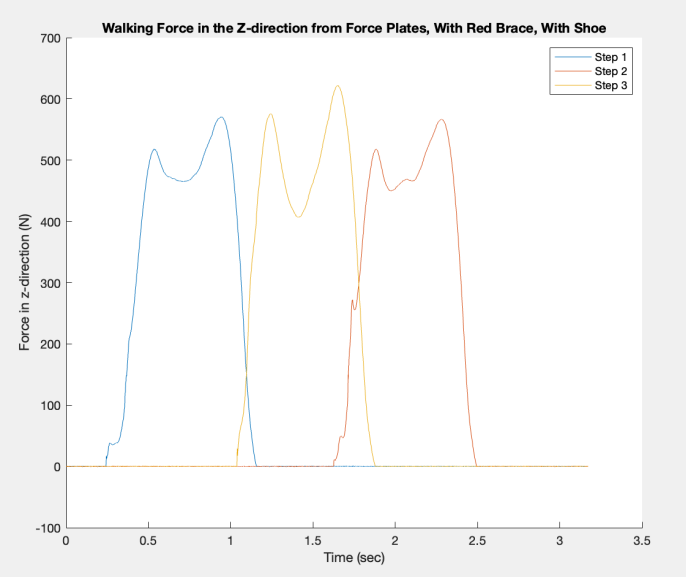


Figure 7: Walking with Red Brace, With Shoe

Test 5: Walking, Black Brace, No Shoe

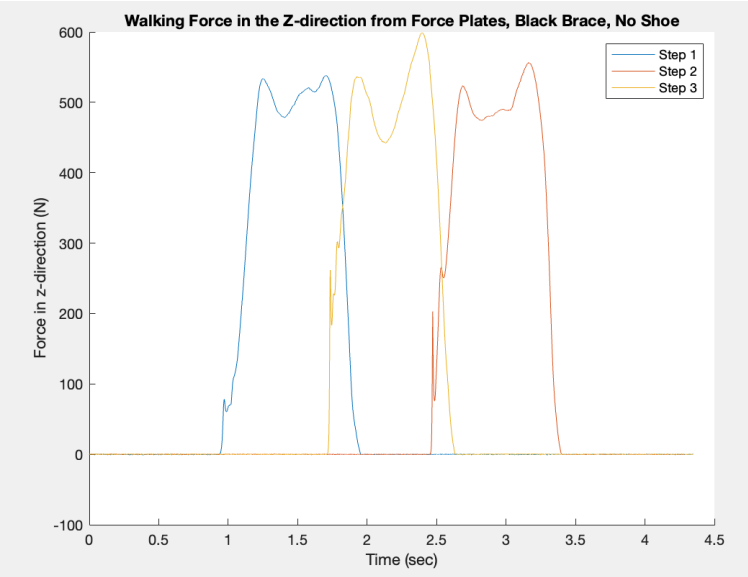


Figure 8: Walking, Black Brace, No Shoe

Test 6: Walking, Black Brace, With Shoe

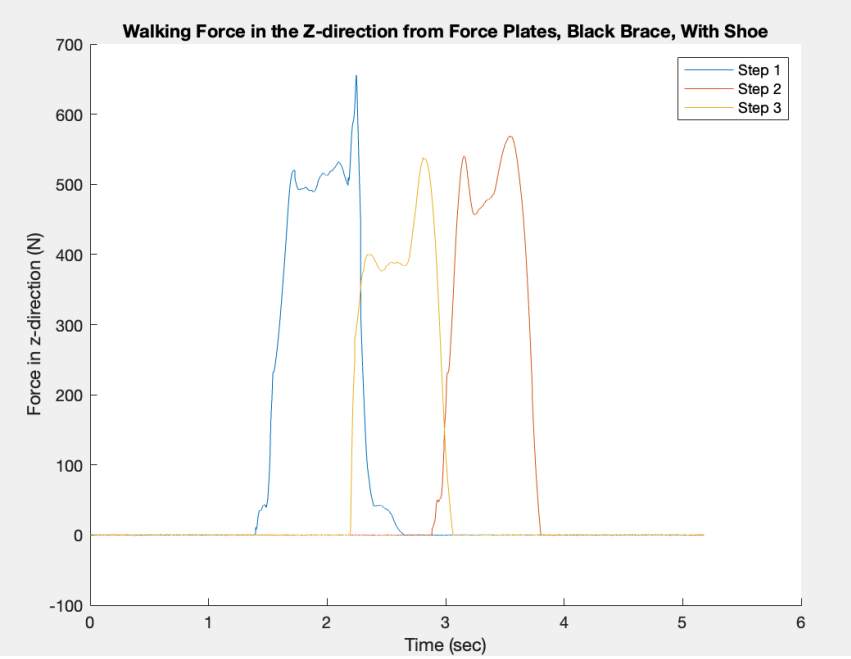


Figure 9: Walking, Black Brace, With Shoe

Test 7: Walking, AFO, With Shoe

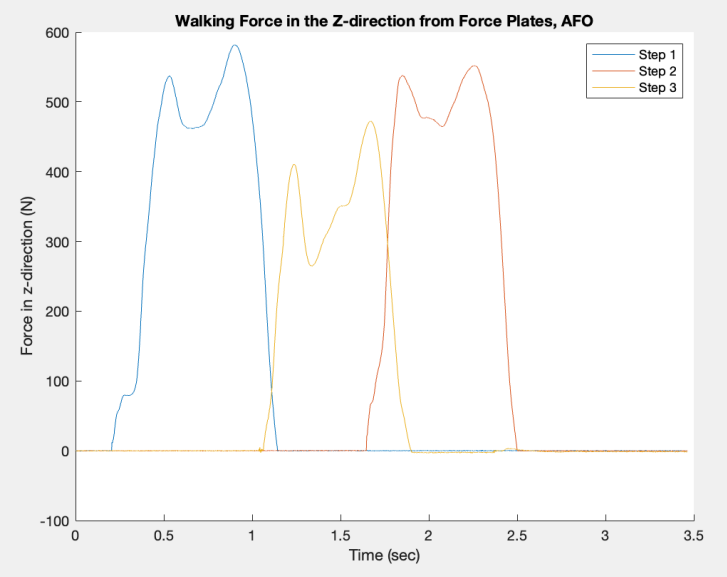


Figure 10: Walking with AFO

Data Analysis: Heel strike vs toe strike

Table 1: Heel Strike vs Toe Strike

Trial	Step 1: Heel Strike (N)	Step 1: Toe Off (N)	Step 2: Heel Strike (N)	Step 2: Toe Off (N)	Step 3: Heel Strike (N)	Step 3: Toe Off (N)
Walking, No Brace, No Shoe Trial 1	523	589	499	742	540	580
Trial 2	536	687	561	720	456	808
Trial 3	489	598	315	777	595	733
Walking, No Brace, Shoe Trial 1	493	565	558	604	511	540
Trial 2	508	575	557	615	536	544
Trial 3	511	581	560	586	538	591
Walking, Red Brace,	497	655	370	650	671	386

No Shoe Trial 1						
Trial 2	485	658	363	644	553	677
Trial 3	530	598	556	674	471	656
Walking, Red Brace, With Shoe 1	518	571	576	621	518	566
Trial 2	518	570	576	621	518	566
Trial 3	498	577	575	613	510	562
Walking, Black Brace, No Shoe Trial 1	534	538	536	599	523	557
Trial 2	511	569	509	622	527	569
Trial 3	531	579	514	650	512	561
Walking, Black Brace, With Shoe Trial 1	522	571	477	584	518	538
Trial 2	547	566	540	639	553	574
Trial 3	520	656	400	538	540	569
Walking, AFO, with Shoe Trial 1	538	582	411	472	538	552
Trial 2	523	577	539	652	539	572
Trial 3	511	535	539	575	548	554

On average, the client experienced a major difference between heel strike and toe-off when not wearing any brace, and experienced less of a difference when walking with a brace. The red brace, on average, shows a small difference with both the shoe on and off, of about 80 N. The black brace, on average, shows a smaller difference than the red brace, on average around 50 N. This proves that the brace, on average, brings the forces from the heel strike and toe off closer together, which is a lot closer to the “typical” step force for a normal gait.

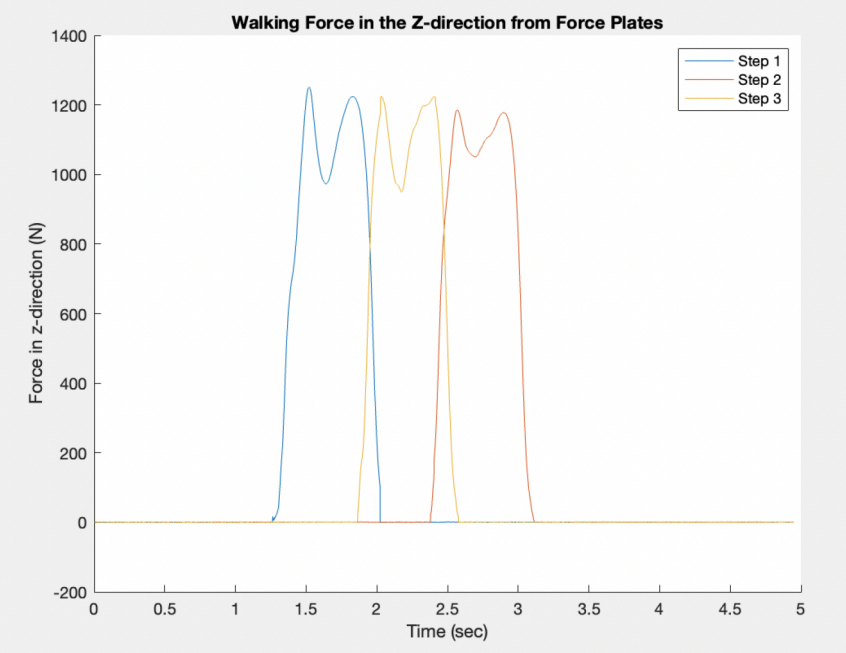


Figure 11: Normal Patient Walking

As shown in figure 11, the normal gait has a much closer force between heel strike and toe off, with the heel strike force surpassing the toe-off force. Decreasing the force between the heel strike and toe-off with the brace is a great first step to regaining normal movement with the patient. If the brace were to fit better, and not slip, it might help bring the forces closer together. Or using another type of dorsiflexion assistance, a stronger, less flexible material, might be helpful. Retesting with TPU filament might be a good next step to take.

Table 2: Control Data from Normal Patient Walking

Trial	**Step 1: Heel Strike (N)**	**Step 1: Toe Off (N)**	**Step 2: Heel Strike (N)**	**Step 2: Toe Off (N)**	**Step 3: Heel Strike (N)**	**Step 3: Toe Off (N)**
Control Data	1251	1224	1185	1178	1223	1224

The healthy subject weighs ~120 kg, and the affected patient weighs 54 kg. This significant difference in mass means the data had to be normalized for the results to be comparable. After normalization, the control walking condition showed an average force of **10.118 N/kg**. The "no brace" walking condition showed the highest forces at **10.719 N/kg**, which indicates the patient is loading the limb more during unassisted walking. With the best bracing condition, the average normalized force dropped to **9.546 N/kg**, which was the lowest of the three conditions. This suggests that the assistive brace helped reduce loading demands during gait.

Even though the differences were not statistically significant (No Brace vs Best p = **0.1779**, No Brace vs Control p = **0.3862**, Best vs Control p = **0.2632**), the direction of the change supports the idea that the brace has a beneficial effect. The patient walked with slightly lower impact forces and a more controlled loading pattern when using the brace. Visually, one could see the differences in the patient's foot angle was increased, as well as the gait being improved with both braces being worn.

Cohen's d was used to evaluate effect size. This effect size analysis showed moderate to large differences between conditions, even when the p-values were above 0.05. The best brace condition upon analysis was the black brace with the shoe test. The best brace condition showed a meaningful reduction in loading compared to walking without a brace (**d = 0.837**). This indicates that the brace did influence gait mechanics in a positive way, even if the sample size was too small to show significance.

A 95% confidence interval was used to analyze the data further. The confidence intervals show the same trend. The no-brace walking condition had the largest variability (**CI = 9.432 to 12.006 N/kg**), while the best condition was more consistent (**CI = 8.619 to 10.474 N/kg**). Walking with the brace produced the most stable and lowest average loading.

Overall, these results show that once the team accounted for differences in body weight, the brace helped the patient walk with reduced loading and improved consistency. While the statistics did not reach traditional significance levels due to small sample size, the data still supports that the brace promoted a more controlled and potentially safer gait pattern, which ultimately fulfills the patient and client's goals.

Stabilogram Generation - Balance Analysis

Test 1: Left Foot (Control)

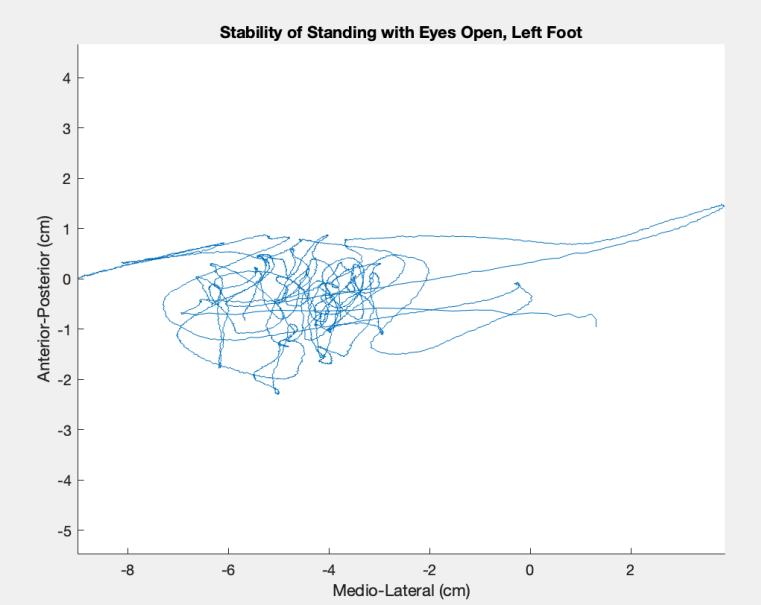


Figure 12: The patient balancing on the left foot, with her eyes open, no brace

Test 2: Right Foot, No brace

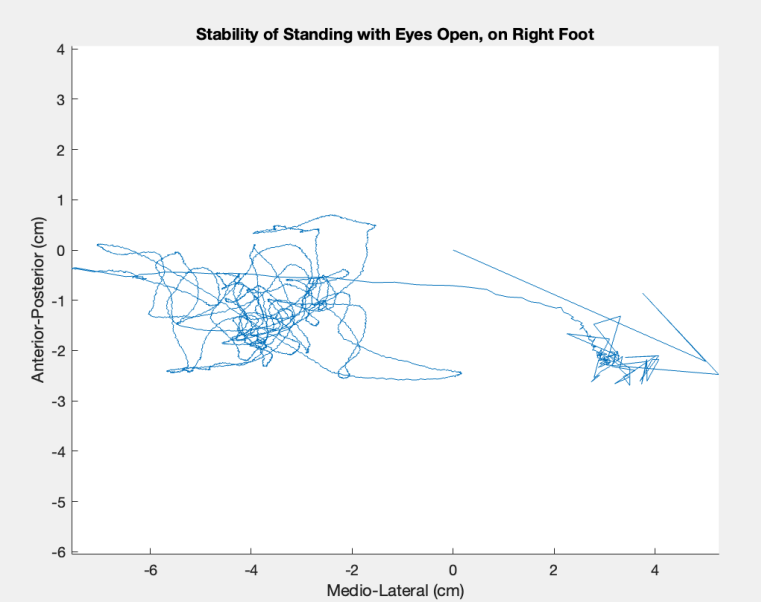


Figure 13: The patient balancing on the right foot, with her eyes open, no brace

Test 3: Right Foot, Red Brace, No Shoe, Eyes Open

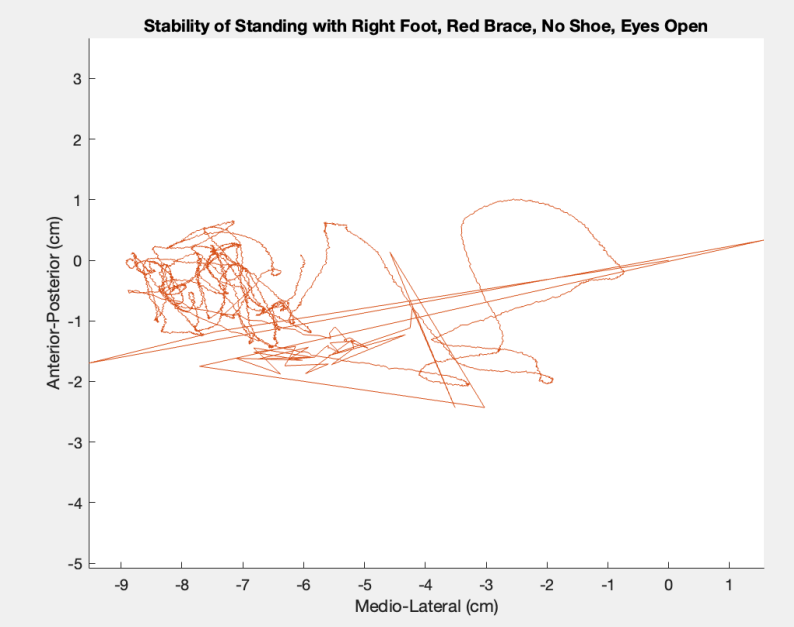


Figure 14: The patient balancing on the right foot, with her eyes **open**, red brace, **no** shoe

Test 4: Right Foot, Red Brace, No Shoe, Eyes Closed

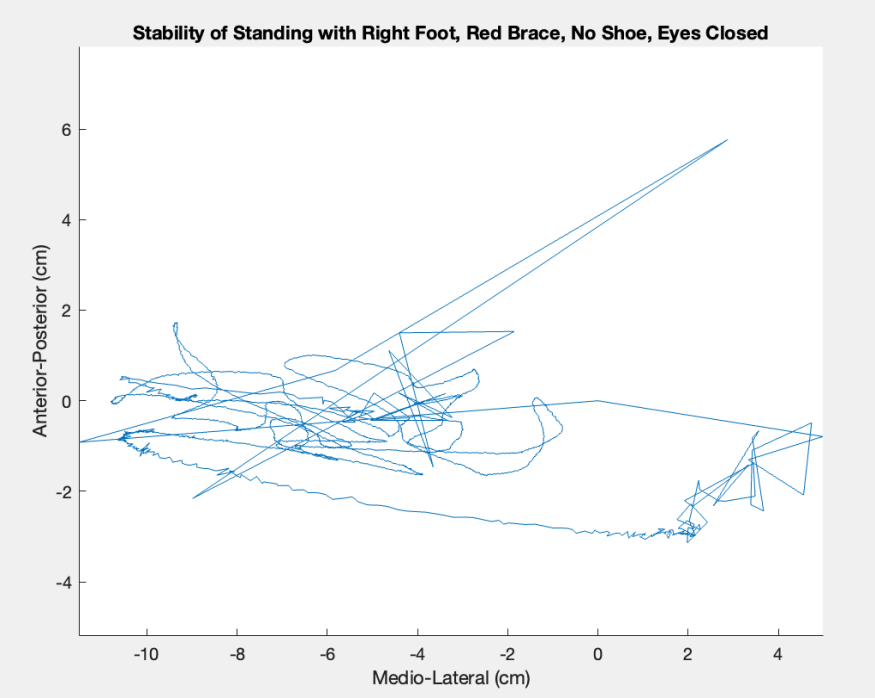


Figure 15: The patient balancing on the right foot, with her eyes **closed**, red brace, **no** shoe

Test 5: Right Foot, Red Brace, With Shoe, Eyes Open

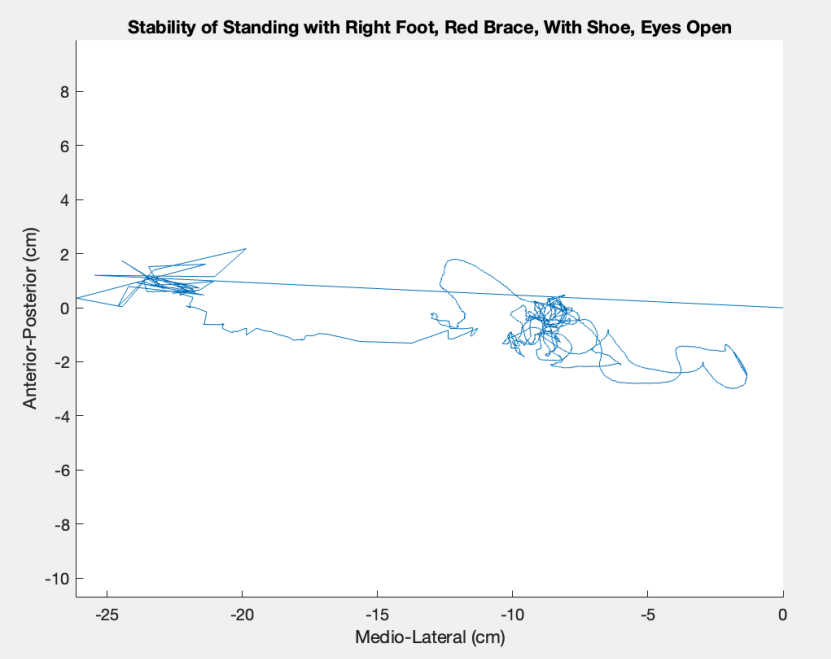


Figure 16: The patient balancing on the right foot, with her eyes **open**, red brace, **with** shoe

Test 6: Right Foot, Red Brace, With Shoe, Eyes Closed

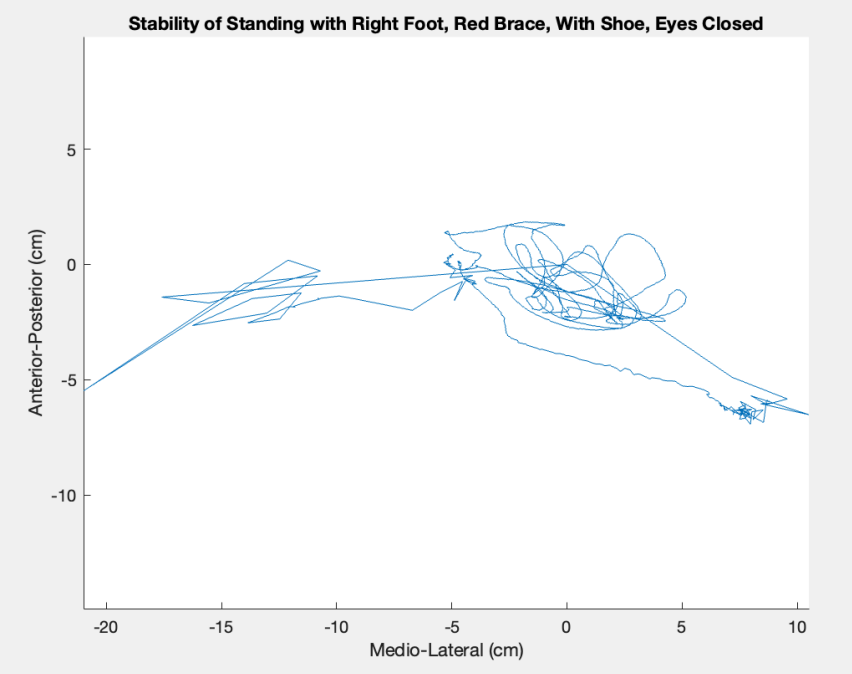


Figure 17: The patient balancing on the right foot, with her eyes **closed**, red brace, **with** shoe

Test 7: Right Foot, Black Brace, no Shoe, Eyes Open

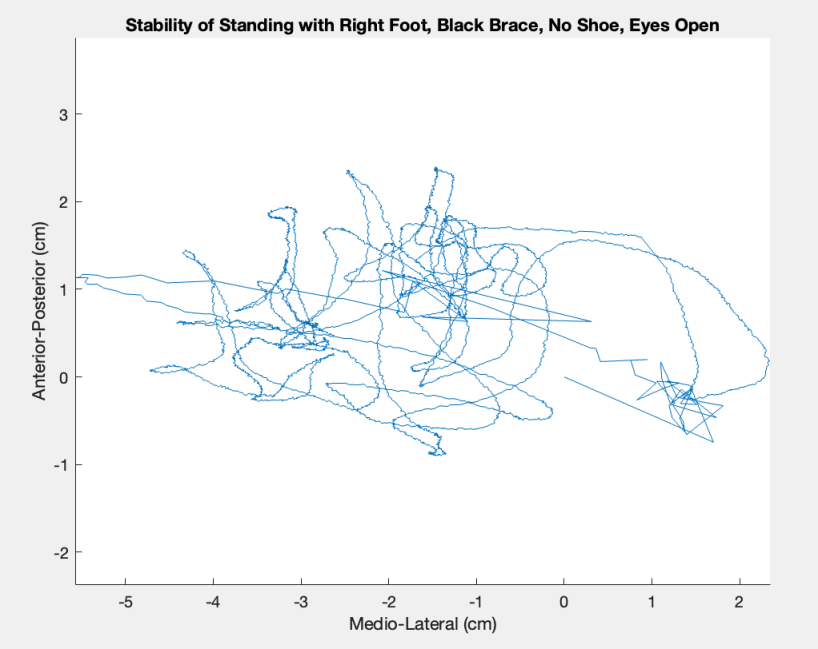


Figure 18: The patient balancing on the right foot, with her eyes **open**, black brace, **no** shoe

Test 8: Right Foot, Black Brace, no Shoe, Eyes Closed

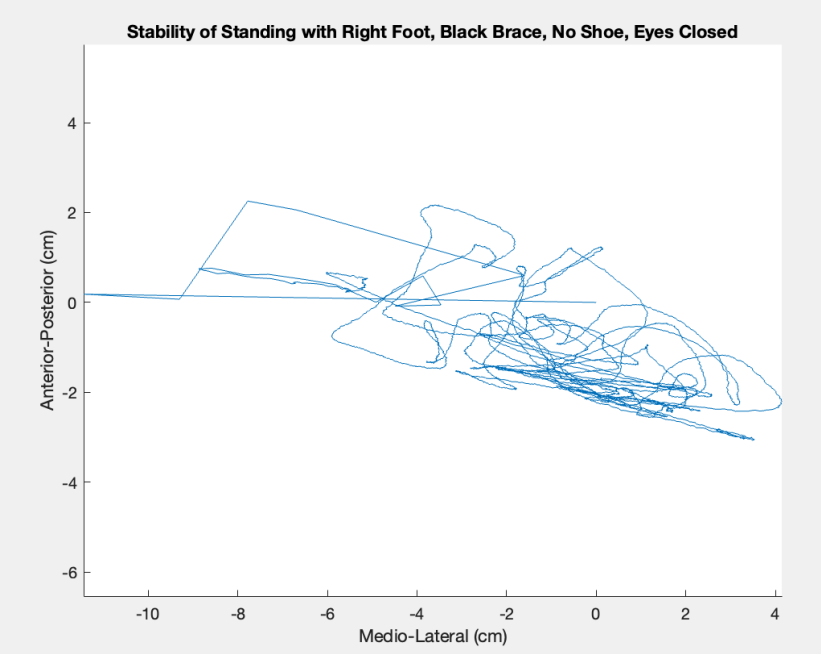


Figure 19: The patient balancing on the right foot, with her eyes **closed**, black brace, **no** shoe

Test 9: Right Foot, Black Brace, with Shoe, Eyes Open

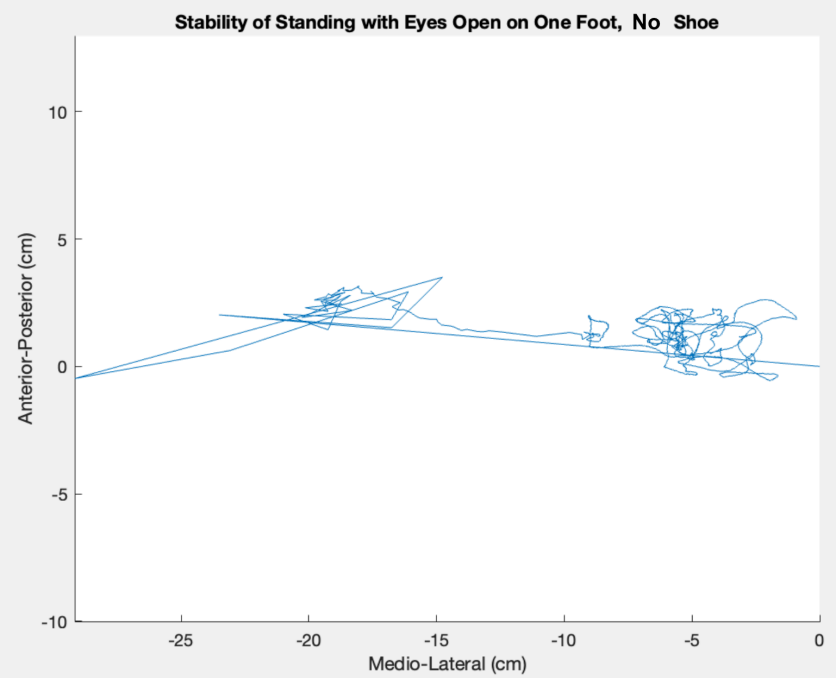


Figure 20: The patient balancing on the right foot, with her eyes **open**, black brace, **no** shoe

Test 10: Right Foot, Black Brace, with Shoe, Eyes Closed

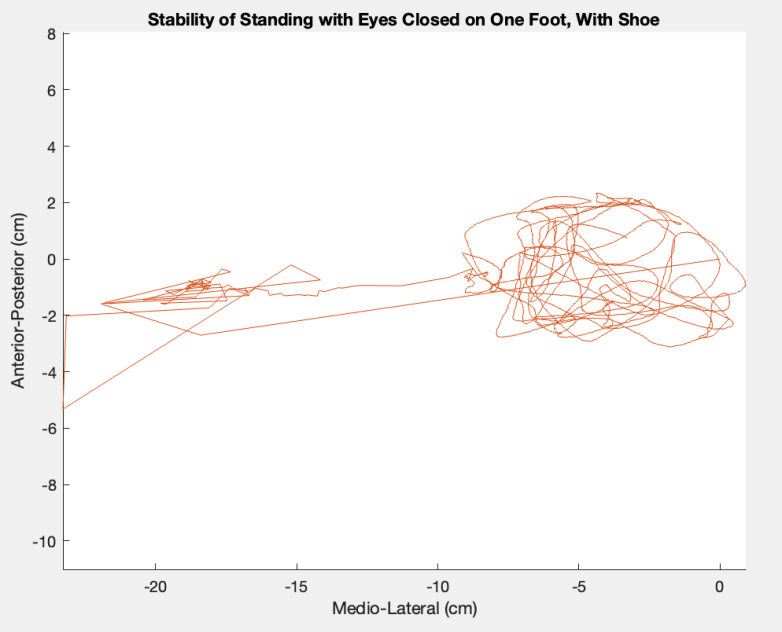


Figure 21: The patient balancing on the right foot, with her eyes **closed**, black brace, **no** shoe

Data Analysis: Stabilograms

Table 3: Stabilogram Path Length Data

Data Point (Leg, type of bracing, eyes)	Path Length 1	Path Length 2	Path Length 3	Average Path Length
Left Foot (Control)	221.89 cm	186.95 cm	201.37 cm	203.40 cm
Right Foot, No Brace	258.33 cm	184.62 cm	213.73 cm	218.89 cm
Right Foot, Red Brace, No Shoe, Eyes Open	184.62 cm	221.89 cm	208.14 cm	204.88 cm
Right Foot, Red Brace, No Shoe, Eyes Closed	204.25 cm	258.33 cm	308.75 cm	257.11 cm
Right Foot, Red Brace, With Shoe, Eyes Open	217.46 cm	246.99 cm	224.09 cm	229.51 cm
Right Foot, Red Brace, With Shoe, Eyes Closed	246.99 cm	217.46 cm	342.84 cm	269.10 cm
Right Foot, Black Brace, No Shoe, Eyes Open	163.39 cm	179.31 cm	217.46 cm	186.72 cm
Right Foot, Black Brace, No Shoe, Eyes Closed	244.67 cm	250.58 cm	262.99 cm	252.75 cm
Right Foot, Black Brace, With Shoe, Eyes Open	219.22 cm	250.92 cm		235.07 cm
Right Foot, Black Brace, With Shoe, Eyes Closed	305.88 cm	305.85 cm	414.60 cm	342.11 cm

Stabilogram path length was used as an indicator of postural stability across three conditions: left leg (control), right leg without augmentation, and right leg with a black ankle brace during eyes-open stance. Although none of the comparisons reached statistical significance (all p >

0.05), large variability in the data likely contributed to insufficient statistical power. However, the observed effect sizes provide important insight into practical differences between conditions.

The comparison between the left (control) and right leg without augmentation demonstrated a moderate effect size (Cohen's d = 0.52), suggesting asymmetry in postural stability between limbs, with the right side showing slightly greater sway overall. When the right ankle brace was applied, sway decreased, as reflected by a very small effect size when compared to the unbraced right limb (d = 0.08). This indicates that the brace did not negatively impact stability and may have helped normalize medio-lateral sway. The largest effect was observed when comparing the left leg to the braced right leg (d = 0.72), suggesting that the brace condition may enhance postural stability beyond the baseline left-leg performance.

While statistical significance was not achieved, the practical differences demonstrated by the effect sizes suggest that the black ankle brace provides a meaningful improvement in stability during quiet stance. The results should therefore be interpreted cautiously: the observed improvements are promising but require confirmation with a larger sample. Given that the study used only three trials per condition, future data collection with more participants and additional repetitions would increase confidence in the findings and may reveal significant differences that align with the effect size trends already present.

References

1. "Ankle joint," Kenhub. Accessed: Nov. 20, 2025. [Online]. Available: https://www.kenhub.com/en/library/anatomy/the-ankle-joint

Appendices for Testing Analysis of the Patient

Appendix D1: Walking MATLAB Code

Walking Analysis of each set of data, path changes dependent on what data is being analyzed.

```
%Force Plate
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking no brace/MaggieWALKINGWObrace.csv');
walk_accel_z_fp_1 = walk_data_fp(:,6);
```

```
walk_accel_z_fp_2 = walk_data_fp(:,28);
walk_accel_z_fp_3 = walk_data_fp(:,17);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
figure(2)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, No Brace'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 1-1', 'Step 1-2', 'Step 1-3')
hold off
%
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
%Force Plate
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking no
brace/MaggieWALKINGWObrace.csv');
walk_accel_z_fp_1 = walk_data_fp(:,6);
walk_accel_z_fp_2 = walk_data_fp(:,28);
walk_accel_z_fp_3 = walk_data_fp(:,17);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
figure(3)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, No Brace, Trial 2'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 2-1', 'Step 2-2', 'Step 2-3')
hold off
%
```

```
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
%Force Plate
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking no
brace/Maggie3WALKINGWObrace.csv');
walk_accel_z_fp_1 = walk_data_fp(:,6);
walk_accel_z_fp_2 = walk_data_fp(:,28);
walk_accel_z_fp_3 = walk_data_fp(:,17);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
figure(4)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, No Brace, Trial 2'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 3-1', 'Step 3-2', 'Step 3-3')
hold off
%
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
```

Analyzing Data From 11/08 - extra column in the data:

```
%Force Plate
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking with
afo/MaggieWALKINGOG.AFOWshoe.csv');
walk_accel_z_fp_1 = walk_data_fp(:,7);
walk_accel_z_fp_2 = walk_data_fp(:,29);
walk_accel_z_fp_3 = walk_data_fp(:,18);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
```

```
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
figure(2)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, AFO'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 1', 'Step 2', 'Step 3')
hold off
%
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
```

Analyzing the 3 AFO trials:

```
%Force Plate
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking with
afo/MaggieWALKINGOG.AFOWshoe.csv');
walk_accel_z_fp_1 = walk_data_fp(:,6);
walk_accel_z_fp_2 = walk_data_fp(:,28);
walk_accel_z_fp_3 = walk_data_fp(:,17);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
figure(2)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, With AFO, With Shoe'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 1', 'Step 2', 'Step 3')
hold off
%
```

```
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
%Force Plate Trial 2
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking with
afo/Maggie2WALKINGOG.AFOWshoe.csv');
walk_accel_z_fp_1 = walk_data_fp(:,6);
walk_accel_z_fp_2 = walk_data_fp(:,28);
walk_accel_z_fp_3 = walk_data_fp(:,17);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
figure(3)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, With AFO, With Shoe, Trial 2'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 1', 'Step 2', 'Step 3')
hold off
%
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
%Force Plate Trial 3
walk_data_fp = readmatrix('/Users/alexconover/Downloads/Walking data 11:8/walking with
afo/Maggie3WALKINGOG.AFOWshoe.csv');
walk_accel_z_fp_1 = walk_data_fp(:,6);
walk_accel_z_fp_2 = walk_data_fp(:,28);
walk_accel_z_fp_3 = walk_data_fp(:,17);
walk_time_fp = walk_data_fp(:,1);
walk_time_fp_adjust = (1:1:size(walk_time_fp))/1000;
% Plot your data
% Create a new figure with subplots so it is easy to look at what time take-off and landing occurred.
% You could also make an overlay plot with two different axes.
% Be sure axis labels and plot titles accurately represent your data.
```

```
figure(4)
hold on
plot(walk_time_fp_adjust, walk_accel_z_fp_1)
plot(walk_time_fp_adjust, walk_accel_z_fp_2)
plot(walk_time_fp_adjust, walk_accel_z_fp_3)
title 'Walking Force in the Z-direction from Force Plates, With AFO, With Shoe, Trial 3'
xlabel 'Time (sec)'
ylabel 'Force in z-direction (N)'
legend('Step 1', 'Step 2', 'Step 3')
hold off
%
max1 = max(walk_accel_z_fp_1);
max2 = max(walk_accel_z_fp_2);
max3 = max(walk_accel_z_fp_3);
max_values_fp = [max1, max2, max3];
mean_max_fp = mean(max_values_fp);
std_max_fp = std(max_values_fp);
hold on
```

Appendix D2: Gait Analysis MATLAB

```
%% ============================================================
%  GAIT DATA: 3 trials × 6 values (HS1 TO1 HS2 TO2 HS3 TO3)
% ============================================================
NB_NS = [523 589 499 742 540 580;
         536 687 561 720 456 808;
         489 598 315 777 595 733];
NB_S  = [493 565 558 604 511 540;
         508 575 557 615 536 544;
         511 581 560 586 538 591];
R_NS  = [497 655 370 650 671 386;
         485 658 363 644 553 677;
         530 598 556 674 471 656];
R_S   = [518 571 576 621 518 566;
         518 570 576 621 518 566;
         498 577 575 613 510 562];
B_NS  = [534 538 536 599 523 557;
         511 569 509 622 527 569;
         531 579 514 650 512 561];
B_S   = [522 571 477 584 518 538;
         547 566 540 639 553 574;
         520 656 400 538 540 569];
AFO_S = [538 582 411 472 538 552;
         523 577 539 652 539 572;
         511 535 539 575 548 554];
%% ============================================================
%  EXTRACT HEEL STRIKE (cols 1,3,5) AND TOE OFF (cols 2,4,6)
%  and vectorize (9 values per condition)
% ============================================================
```

```
extractHS = @(M) M(:, [1 3 5]);
extractTO = @(M) M(:, [2 4 6]);
% Heel strike
tmp = extractHS(NB_NS); HS_NB_NS = tmp(:);
tmp = extractHS(NB_S ); HS_NB_S  = tmp(:);
tmp = extractHS(R_NS ); HS_R_NS  = tmp(:);
tmp = extractHS(R_S  ); HS_R_S   = tmp(:);
tmp = extractHS(B_NS ); HS_B_NS  = tmp(:);
tmp = extractHS(B_S  ); HS_B_S   = tmp(:);
tmp = extractHS(AFO_S); HS_AFO   = tmp(:);
% Toe off
tmp = extractTO(NB_NS); TO_NB_NS = tmp(:);
tmp = extractTO(NB_S ); TO_NB_S  = tmp(:);
tmp = extractTO(R_NS ); TO_R_NS  = tmp(:);
tmp = extractTO(R_S  ); TO_R_S   = tmp(:);
tmp = extractTO(B_NS ); TO_B_NS  = tmp(:);
tmp = extractTO(B_S  ); TO_B_S   = tmp(:);
tmp = extractTO(AFO_S); TO_AFO   = tmp(:);
% Put into structs for convenience (clearing grouping, less matricies
% overall)
HS.NB_NS = HS_NB_NS;  HS.NB_S = HS_NB_S;  HS.R_NS = HS_R_NS;
HS.R_S   = HS_R_S;    HS.B_NS = HS_B_NS;  HS.B_S  = HS_B_S;
HS.AFO   = HS_AFO;
TO.NB_NS = TO_NB_NS;  TO.NB_S = TO_NB_S;  TO.R_NS = TO_R_NS;
TO.R_S   = TO_R_S;    TO.B_NS = TO_B_NS;  TO.B_S  = TO_B_S;
TO.AFO   = TO_AFO;
condNames = {'NB_NS','NB_S','R_NS','R_S','B_NS','B_S','AFO'};
%% ============================================================
%  UNPAIRED T-TESTS (optional)
% ============================================================
fprintf('\n====== HEEL STRIKE T-TESTS ======\n');
HS_pvals = nan(7);
for i = 1:7
   for j = 1:7
       if i ~= j
           v1 = HS.(condNames{i});
           v2 = HS.(condNames{j});
           [~, p] = ttest2(v1, v2);
           HS_pvals(i,j) = p;
       end
   end
end
HS_table = array2table(HS_pvals, 'VariableNames', condNames, 'RowNames',
condNames)
fprintf('\n====== TOE OFF T-TESTS ======\n');
TO_pvals = nan(7);
for i = 1:7
   for j = 1:7
       if i ~= j
```

```
            v1 = TO.(condNames{i});
            v2 = TO.(condNames{j});
            [~, p] = ttest2(v1, v2);
            TO_pvals(i,j) = p;
        end
    end
end
TO_table = array2table(TO_pvals, 'VariableNames', condNames, 'RowNames',
condNames)
%% ============================================================
%  BOX & WHISKER PLOTS
% ============================================================
HS_data = {HS_NB_NS, HS_NB_S, HS_R_NS, HS_R_S, HS_B_NS, HS_B_S, HS_AFO};
TO_data = {TO_NB_NS, TO_NB_S, TO_R_NS, TO_R_S, TO_B_NS, TO_B_S, TO_AFO};
labels  = {'NB-NS','NB-S','R-NS','R-S','B-NS','B-S','AFO'};
% Heel Strike boxplot
figure;
boxplot(cell2mat(HS_data'), repelem(1:7, cellfun(@numel, HS_data)));
set(gca,'XTick',1:7,'XTickLabel',labels);
xlabel('Condition');
ylabel('Heel Strike Force (N)');
title('Heel Strike Forces');
xtickangle(45);
grid on;
% Toe Off boxplot
figure;
boxplot(cell2mat(TO_data'), repelem(1:7, cellfun(@numel, TO_data)));
set(gca,'XTick',1:7,'XTickLabel',labels);
xlabel('Condition');
ylabel('Toe Off Force (N)');
title('Toe Off Forces');
xtickangle(45);
grid on;
```

Appendix D3: Stabilogram MATLAB

```
%%
%standing balance with shoe
ec1 = readmatrix('/Users/alexconover/Downloads/AFO Balance with shoe/MaggieOG.AFOWshoe.csv');
ec1_cop_x = -((ec1(:,10)))*100;
ec1_cop_y = (ec1(:,11))*100;
figure (1)
hold on
plot(ec1_cop_y, ec1_cop_x)
axis equal
title 'Stability of Standing with Eyes Closed on One Foot, With AFO'
xlabel 'Medio-Lateral (cm)'
```

```
ylabel 'Anterior-Posterior (cm)'
hold off
%%
ec2 = readmatrix('/Users/alexconover/Downloads/shoe, eyes closed, taped, black
brace/AFO-SHOE-balance-eyesclosed-2-TAPE.csv');
ec2_cop_x = -((ec2(:,10)))*100;
ec2_cop_y = (ec2(:,11))*100;
figure (2)
hold on
plot(ec2_cop_y, ec2_cop_x)
axis equal
title 'Stability of Standing with Eyes Closed on One Foot, With Shoe'
xlabel 'Medio-Lateral (cm)'
ylabel 'Anterior-Posterior (cm)'
hold off
%%
eo1 = readmatrix('/Users/alexconover/Downloads/shoe, eyes open, taped, black
brace/AFO-SHOE-balance-eyesopen-1-TAPE.csv');
eo1_cop_x = -((eo1(:,10)))*100;
eo1_cop_y = (eo1(:,11))*100;
figure (3)
hold on
plot(eo1_cop_y, eo1_cop_x)
axis equal
title 'Stability of Standing with Eyes Open on One Foot, With Shoe'
xlabel 'Medio-Lateral (cm)'
ylabel 'Anterior-Posterior (cm)'
hold off
%%
eo2 = readmatrix('/Users/alexconover/Downloads/shoe, eyes open, taped, black
brace/AFO-SHOE-balance-eyesopen-2-TAPE.csv');
eo2_cop_x = -((eo2(:,10)))*100;
eo2_cop_y = (eo2(:,11))*100;
figure (4)
hold on
plot(eo2_cop_y, eo2_cop_x)
axis equal
title 'Stability of Standing with Eyes Open on One Foot, With Shoe'
xlabel 'Medio-Lateral (cm)'
ylabel 'Anterior-Posterior (cm)'
hold off

%%
eo1 = readmatrix('/Users/alexconover/Downloads/shoe, eyes open, taped, black
brace/AFO-SHOE-balance-eyesopen-1-TAPE.csv');
eo1_cop_x = -((eo1(:,10)))*100;
eo1_cop_y = (eo1(:,11))*100;
figure (3)
hold on
```

```
plot(eo1_cop_y, eo1_cop_x)
axis equal
title 'Stability of Standing with Eyes Open on One Foot, With Shoe'
xlabel 'Medio-Lateral (cm)'
ylabel 'Anterior-Posterior (cm)'
hold off
%%
eo2 = readmatrix('/Users/alexconover/Downloads/shoe, eyes open, taped, black
brace/AFO-SHOE-balance-eyesopen-2-TAPE.csv');
eo2_cop_x = -((eo2(:,10)))*100;
eo2_cop_y = (eo2(:,11))*100;
figure (4)
hold on
plot(eo2_cop_y, eo2_cop_x)
axis equal
title 'Stability of Standing with Eyes Open on One Foot, With Shoe'
xlabel 'Medio-Lateral (cm)'
ylabel 'Anterior-Posterior (cm)'
hold off
```

Appendix D4: Stabilogram Analysis MATLAB

```
%% ============================================
%  Stabilogram Path Length Analysis
%  Unpaired t-tests + Box/Whisker Plots
%  ============================================
clear; clc; close all;
%% ----------------------------
%  Raw Stabilogram Path Length Data
%  ----------------------------
% Left Foot (Control)
CTL = [221.89, 186.95, 201.37];
% Right Foot – No Brace
NB = [258.33, 184.62, 213.73];
% Red Brace – No Shoe – Eyes Open
RB_NS_EO = [184.62, 221.89, 208.14];
% Red Brace – No Shoe – Eyes Closed
RB_NS_EC = [204.25, 258.33, 308.75];
% Red Brace – With Shoe – Eyes Open
RB_WS_EO = [217.46, 246.99, 224.09];
% Red Brace – With Shoe – Eyes Closed
RB_WS_EC = [246.99, 217.46, 342.84];
% Black Brace – No Shoe – Eyes Open
BB_NS_EO = [163.39, 179.31, 217.46];
% Black Brace – No Shoe – Eyes Closed
BB_NS_EC = [244.67, 250.58, 262.99];
% Black Brace – With Shoe – Eyes Open
```

```
BB_WS_EO = [219.22, 250.92];
% Black Brace – With Shoe – Eyes Closed
BB_WS_EC = [305.88, 305.85, 414.60];
% Calculate means
mean_CTL      = mean(CTL);
mean_NB       = mean(NB);
mean_RB_NS_EO = mean(RB_NS_EO);
mean_RB_NS_EC = mean(RB_NS_EC);
mean_RB_WS_EO = mean(RB_WS_EO);
mean_RB_WS_EC = mean(RB_WS_EC);
mean_BB_NS_EO = mean(BB_NS_EO);
mean_BB_NS_EC = mean(BB_NS_EC);
mean_BB_WS_EO = mean(BB_WS_EO);
mean_BB_WS_EC = mean(BB_WS_EC);
%% Display means
disp('=== Stabilogram Path Length Means ===')
fprintf('Control: %.2f cm\n', mean_CTL);
fprintf('No Brace: %.2f cm\n', mean_NB);
fprintf('Red Brace No Shoe EO: %.2f cm\n', mean_RB_NS_EO);
fprintf('Red Brace No Shoe EC: %.2f cm\n', mean_RB_NS_EC);
fprintf('Red Brace With Shoe EO: %.2f cm\n', mean_RB_WS_EO);
fprintf('Red Brace With Shoe EC: %.2f cm\n', mean_RB_WS_EC);
fprintf('Black Brace No Shoe EO: %.2f cm\n', mean_BB_NS_EO);
fprintf('Black Brace No Shoe EC: %.2f cm\n', mean_BB_NS_EC);
fprintf('Black Brace With Shoe EO: %.2f cm\n', mean_BB_WS_EO);
fprintf('Black Brace With Shoe EC: %.2f cm\n', mean_BB_WS_EC);
%% ----------------------------
%  Unpaired t-tests
%  ----------------------------
% Control vs No Brace
[h_CTL_NB, p_CTL_NB] = ttest2(CTL, NB);
% No Brace vs Red Brace (Eyes Open)
[h_NB_RBEO, p_NB_RBEO] = ttest2(NB, RB_NS_EO);
% No Brace vs Red Brace (Eyes Closed)
[h_NB_RBEC, p_NB_RBEC] = ttest2(NB, RB_NS_EC);
% Red Brace EO vs Red Brace EC (No Shoe)
[h_RB_EO_EC_NS, p_RB_EO_EC_NS] = ttest2(RB_NS_EO, RB_NS_EC);
% Red Brace EO vs Red Brace EC (With Shoe)
[h_RB_EO_EC_WS, p_RB_EO_EC_WS] = ttest2(RB_WS_EO, RB_WS_EC);
% Black Brace EO vs EC (No Shoe)
[h_BB_EO_EC_NS, p_BB_EO_EC_NS] = ttest2(BB_NS_EO, BB_NS_EC);
% Black Brace EO vs EC (With Shoe)
[h_BB_EO_EC_WS, p_BB_EO_EC_WS] = ttest2(BB_WS_EO, BB_WS_EC);
% Red Brace vs Black Brace (Eyes Open)
[h_RB_BB_EO, p_RB_BB_EO] = ttest2([RB_NS_EO RB_WS_EO], ...
                                  [BB_NS_EO BB_WS_EO]);
% Shoes vs No Shoes (Pooled)
NO_SHOE = [RB_NS_EO RB_NS_EC BB_NS_EO BB_NS_EC];
WITH_SHOE = [RB_WS_EO RB_WS_EC BB_WS_EO BB_WS_EC];
```

```
[h_SHOE, p_SHOE] = ttest2(NO_SHOE, WITH_SHOE);
%% ----------------------------
%  Box & Whisker Plot
%  ----------------------------
% Combine all data
all_data = [
   CTL, NB, ...
   RB_NS_EO, RB_NS_EC, ...
   RB_WS_EO, RB_WS_EC, ...
   BB_NS_EO, BB_NS_EC, ...
   BB_WS_EO, BB_WS_EC
];
% Create matching group labels
groups = [
   repmat("Control",1,3), ...
   repmat("NoBrace",1,3), ...
   repmat("RB_NS_EO",1,3), ...
   repmat("RB_NS_EC",1,3), ...
   repmat("RB_WS_EO",1,3), ...
   repmat("RB_WS_EC",1,3), ...
   repmat("BB_NS_EO",1,3), ...
   repmat("BB_NS_EC",1,3), ...
   repmat("BB_WS_EO",1,2), ...
   repmat("BB_WS_EC",1,3)
];
figure;
boxplot(all_data, groups);
title('Stabilogram Path Length Across Bracing Conditions');
ylabel('Path Length (cm)');
xtickangle(45);
```

Appendix E: 11/8 Comfortability Testing

Appendix I: Blank Comfort Testing Form

Short Outside and Long Inside (Red Brace)

Ease of Putting On:

1 2 3 4 (5) 6 7 8 9 10

Notes: -

Strap Comfort:

1 2 3 4 5 6 7 8 (9) 10

Notes:

Foam Comfort:

1 2 3 4 5 6 7 8 (9) 10

Notes:

Outside Support Fit:

1 2 3 (4) 5 6 7 8 9 10

Notes: digs in to bone

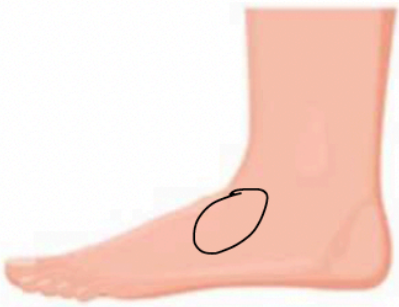
Inside Support Fit:

1 2 3 (4) 5 6 7 8 9 10

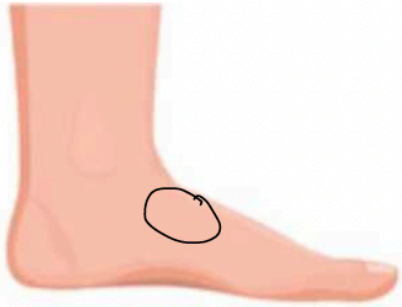
Notes:

Please circle on the foot where you feel discomfort:

Outside



Inside



Anterior to medial malleolus

Long Outside and Short Inside (Black Brace)

Ease of Putting On:

(hard)1 2 3 4 5 6 7 8 9 10 (easy)

Notes:

Strap Comfort:

1 2 3 4 5 6 7 8 9 10 (most comfort)

Notes:

Foam Comfort:

1 2 3 4 5 6 7 8 9 10

Notes:

Outside Support Fit:

1 2 3 4 5 6 7 8 9 (10)

Notes:

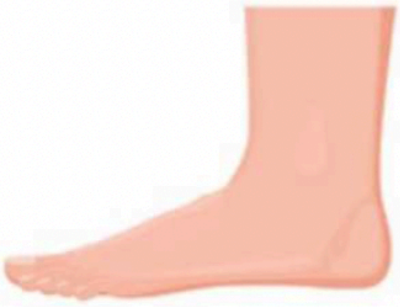
Inside Support Fit:

1 2 3 4 5 6 7 (8) 9 10

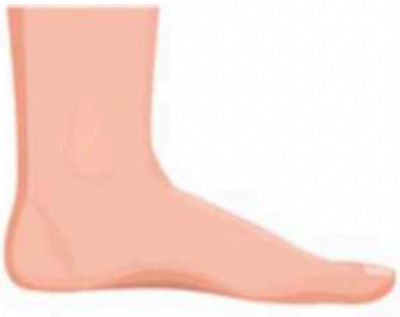
Notes: hole for malleolus too low

Please circle on the foot where you feel discomfort:

Outside



Inside

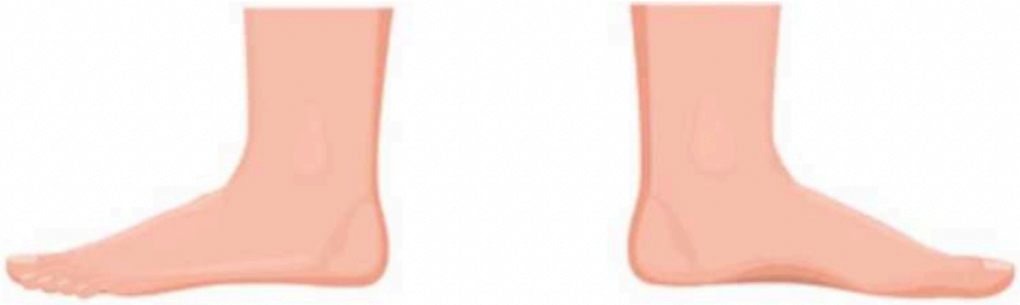


Anterior to medial malleolus

Appendix F: 11/10 Comfortability Testing

Please circle on the foot where you feel discomfort:

Outside Inside



Anterior to medial malleolus

Long Outside and Short Inside (Black Brace)

Ease of Putting On:

(hard)1 2 3 4 5 6 (7) 8 9 10 (easy)

Notes:

Strap Comfort:

1 2 3 4 5 6 7 (8) 9 10 (most comfort)

Notes:

Foam Comfort:

1 2 3 4 5 6 7 8 9 (10)

Notes:

Outside Support Fit:

1 2 3 4 5 6 7 8 **9** 10

Notes:

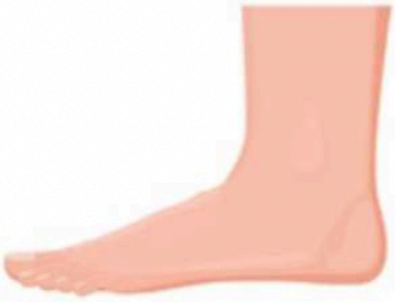
Inside Support Fit:

1 2 3 4 5 6 **7** 8 9 10

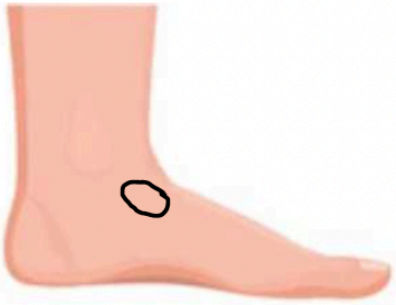
Notes: digs in to my navicular bone

Please circle on the foot where you feel discomfort:

Outside

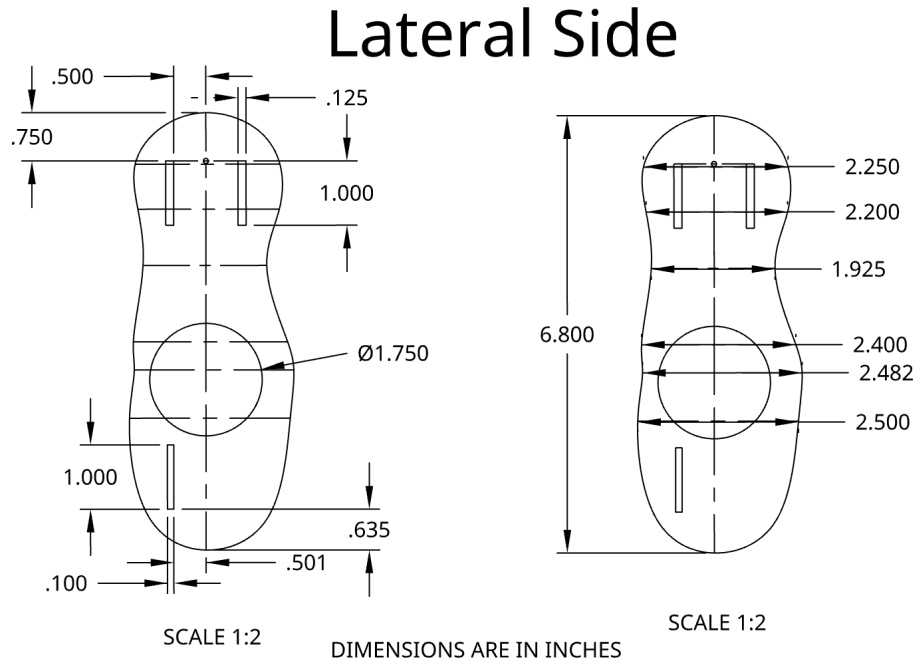


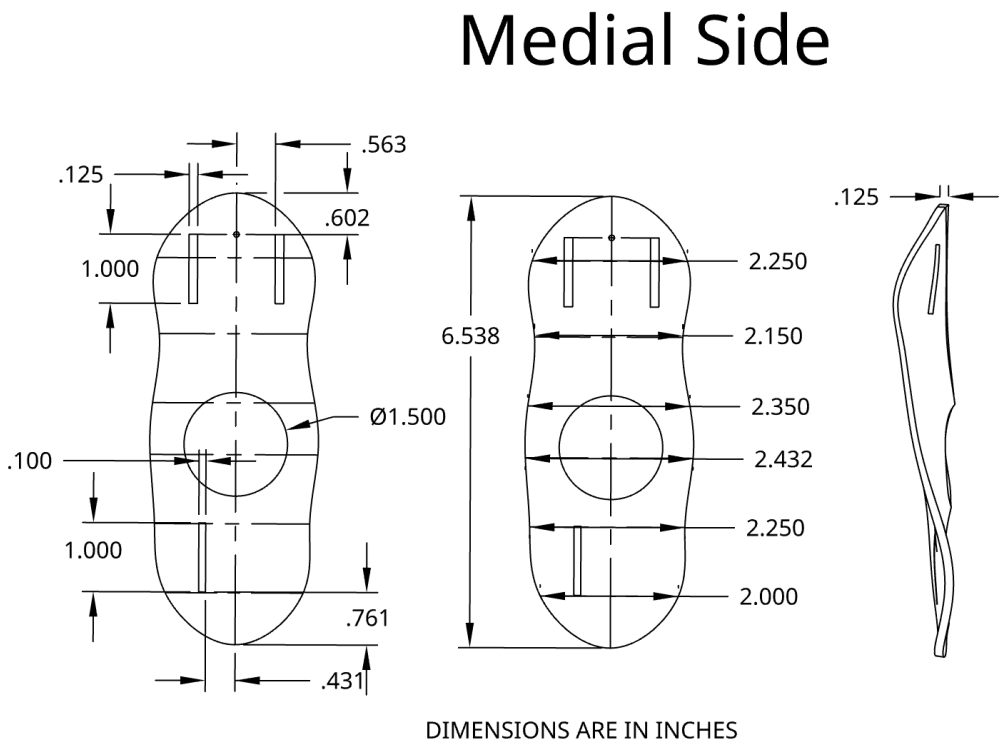
Inside



Anterior to medial malleolus

Appendix G: CAD Drawings with measurement





Appendix H: Fall 2025 Costs

Item	Description	Manufacturer	Vendor	Date	QTY	Cost Each	Total
Category 1 - Rigid Support							
CF-PLA	3D printing for testing	Bambu Lab Printer	Design Innovation Lab	10/27/2025	2	$2.25	$4.50
CF-PLA	3D printed for testing of mediolateral support	Bambu Lab Printer	Design Innovation Lab	10/27/2025	2	$2.25	$4.50
CF-PLA	3D printing for final product	Bambu Lab Printer	Design Innovation Lab	11/17/2025	1	$1.90	$1.90
CF-PLA	3D printing for final product	Bambu Lab Printer	Design Innovation Lab	11/17/2025	1	$2.18	$2.18
CF-PLA	3D printing for final product	Bambu Lab Printer	Design Innovation Lab	11/19/2025	1	$2.17	$2.17
CF-PLA	3D printing for final product	Bambu Lab Printer	Design Innovation Lab	11/19/2025	1	$2.50	$2.50
Category 2 - Straps and Padding							
Elastic Strap link	1 inch wide Polyester and Rubber blend. 10 yd in length	Cisone	Amazon	10/10/2025	1	$7.99	$7.99
TPU	TPU Test Strip for testing apparatus	Makerspace	Makerspace	10/22/2025	1	$0.39	$0.39
Padding link	Air Sponge Mesh Fabric	Tong Gu	Amazon	10/24/2025	1	$16.99	$16.99
Superglue	Superglue for fabrication	Makerspace	Makerspace	11/4/2025	1	$1.15	$1.15
Superglue	Superglue for fabrication	Makerspace	Makerspace	11/5/2025	1	$1.15	$1.15
Nylon Fabric link	Fabric used for straps and padding	Xtreme Sight Line	Amazon	11/20/2025	1	$0.00	$0.00
Velcro link	Velcro pieces	Myuren	Amazon	11/20/2024	1	$0.00	$0.00
						Total:	**$45.42**