Inconspicuous Ankle Foot Orthosis (AFO) for Teen

FINAL REPORT

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AFO for Teen

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Abstract

This project focused on developing a discrete ankle foot orthosis (AFO) for a teenage patient with Facioscapulohumeral Muscular Dystrophy, addressing foot drop, ankle inversion, and gait instability while improving wearability compared to traditional bulky devices. The final prototype incorporated carbon fiber reinforced PLA inversion supports, dual layer mesh padding to reduce pressure along the bones of the ankle and foot, and a low profile dorsiflexion strap designed to sit comfortably along the inside of the patient's shoe without adding unnecessary bulk. In-person gait and balance testing conducted with the patient demonstrated reduced heel strike versus toe off force discrepancies, improved mediolateral stability, and increased overall comfort compared to earlier iterations developed in previous semesters. Stabilogram analysis further suggested that the prototype contributed to more controlled postural sway, particularly during single leg stance on the affected limb. Although statistical significance was limited by the single participant sample, effect size trends and visual gait improvements indicated that the design provided meaningful functional support. The device also met the patient's aesthetic requirement for discretion, an essential factor in the client and patient's wishes. While testing results confirmed promising performance, additional refinement, including improved material durability, adjustments to prevent strap slippage, and expanded clinical evaluation, is needed before the device can be considered a fully stable, ready to use product.

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Introduction

Motivation & Global Impact

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

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

Aspects of this project can affect a multitude of people on a global scale. As 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, a different kind of muscular dystrophy, or any ankle destabilization.

Existing Devices & Current Methods

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

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

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

Figure 2: Supramalleolar Orthosis (SMO) [2]

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

Figure 3: Jointed AFO [3]

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

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

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

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

Problem Statement

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

Background

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

Anatomy & Physiology

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

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

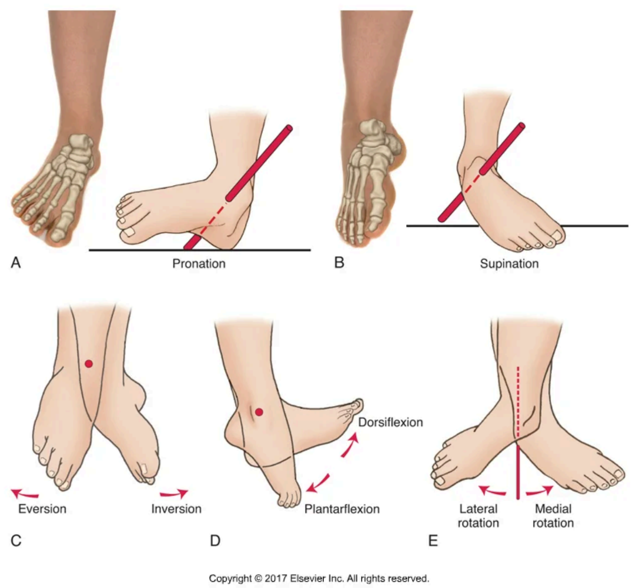


Figure 5: Illustration of various anatomical positions [9]

The primary purpose of the ankle-foot orthosis (AFO) is to provide dorsiflexion support, and in the client'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.

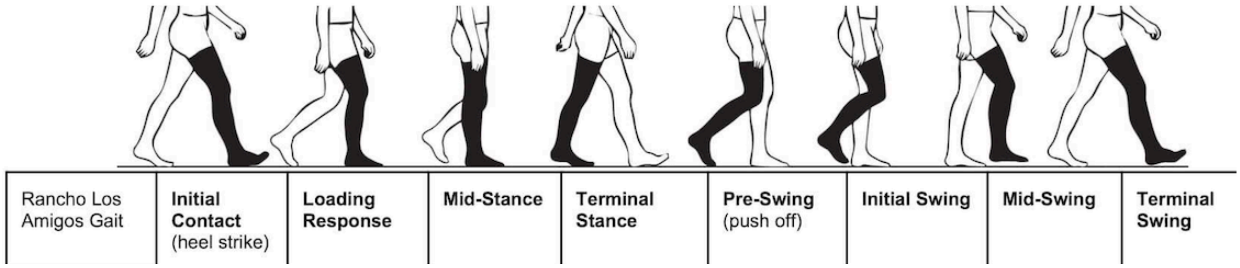


Figure 6: Normal Gait Cycle [10].

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.

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.

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. 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 measures approximately 31 cm in length, extending proximally from the distal end of the foot. Its structure will combine rigid elements 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, permitting over 30° of motion from the neutral ankle position. To achieve this, the device delivers approximately 5–10 Nm of counteracting torque for every 10° of plantarflexion [11]. Additionally, it limits inversion to angles below 25° [12] while resisting up to 30 Nm of torsional force and sustaining loads as high as 244 N [13].

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

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

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

$$F_I = 523.32 \cdot tan(25) = 244.03\ N$$

Equation 1: Calculation of Ankle Inversion Peak Force.

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

Preliminary Designs

Design 1: 24-25 Combination

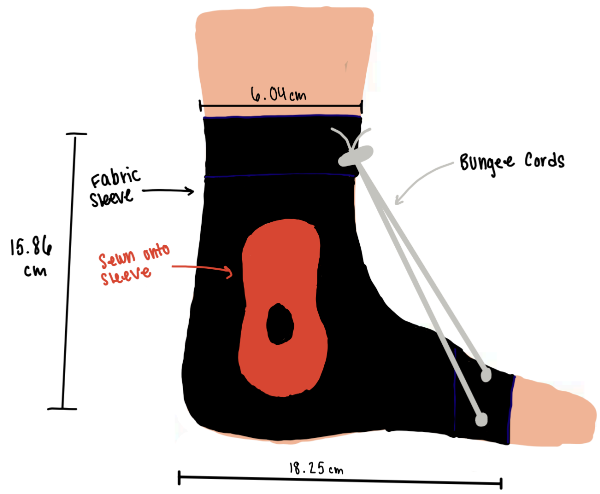


Figure 7: Drawing of Design 1

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

Design 2: Inversion Straps

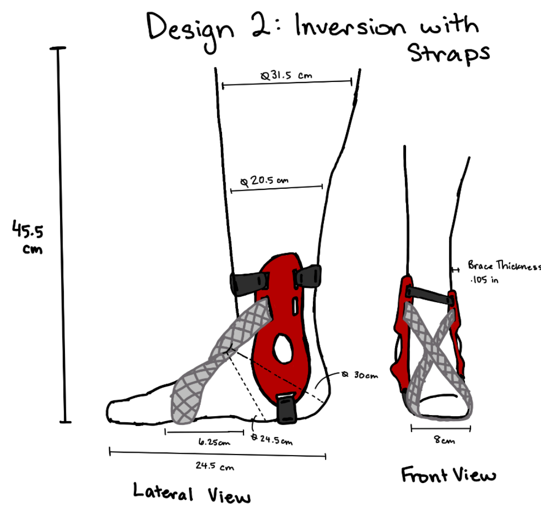


Figure 8: Drawing of Design 2

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

Design 3: Shoe Insert

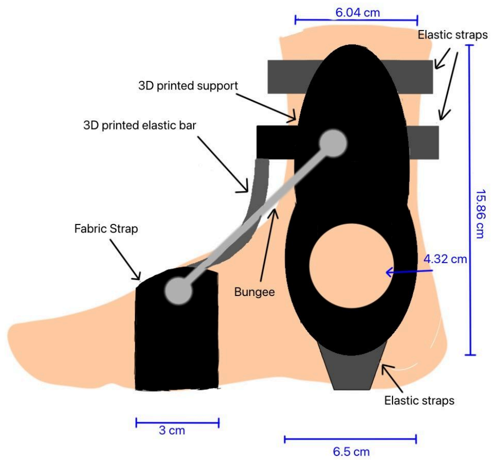


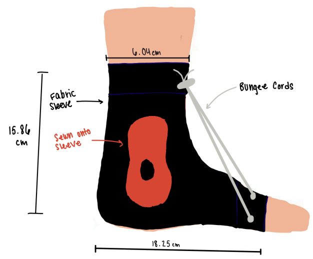
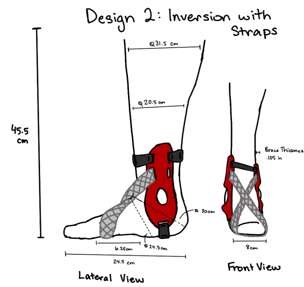
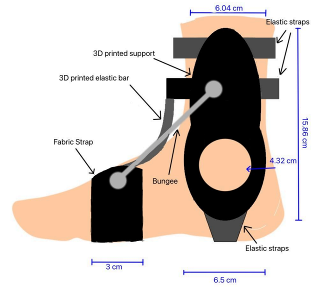
Figure 9: Drawing of Design 3

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

Preliminary Design Evaluation

Prototype Design Matrix

Table 1: Prototype Design Matrix, rated to meet the specifications from the client.

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

Summary of Design Matrix

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

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

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

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

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

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

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

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

Final Design

Figure 10: OnShape model of AFO on 3D-printed foot.

The final design of the ankle foot orthoses comes with many unique features that contribute to its success. The 3D-printed medial and lateral sides prevent ankle inversion and eversion, while the front polyester strap supports dorsiflexion when the client is walking. Two layers of padding were added to the interior to ensure maximum comfort. Finally, ballistic nylon straps were utilized for attachment and to allow for proper adjustability. This is essential as the client's condition continues to develop over time. Additional CAD drawings with measurement can be found in Appendix G.

Figure 11 : Finalized prototype to aid in dorsiflexion and prevent ankle eversion and inversion.

The final design was created taking into account all the information from testing and patient preference, creating a streamlined, finalized product. Details about fabrication and testing are continued in the fabrication process.

Fabrication and Development Process

Materials

The final design consists of 5 different materials. The inversion supports are composed of carbon fiber-reinforced PLA at 50% infill, the dorsiflexion strap is a knit elastic material, the additional straps for attachment and adjustability are ballistic nylon, attached with velcro pieces, and the padding inside the inversion supports consists of air sponge mesh fabric. These materials were chosen for their specific properties that enhance both functionality and comfort, and prices can be found in Appendix H..

The rigid inversion support pieces on either side of the ankle are made of carbon fiber reinforced PLA composite (CF-PLA), chosen for its minimal weight, high flexural strength, and sleek, low-profile design. CF-PLA's lightweight nature allows for ease of use, enabling better movement while reducing fatigue and pain for the user. Its sturdiness ensures resistance to everyday wear and tear, providing long-term durability. A carbon-fiber AFO is capable of supporting up to 1,000 N, making it highly suitable for the demands of this device [14]. Carbon fiber offers superior weight distribution and flexibility compared to materials like plastic and steel, which is crucial for the design. The support it provides is especially important given that the patient has been experiencing frequent foot inversion falls, and as their disease progresses, this support will become even more critical. CF-PLA also has a very smooth surface, which contributes to the comfort and overall sleekness of the design. Additionally, CF-PLA is low in cost at $0.05 per gram of material [15]. Granted access to University of Wisconsin-Madison's

Grainger Engineering Design Innovation Lab allowed for fabrication processes including 3D scanning, 3D printing, and additional CF-PLA manual refinement with minimal costs.

The dorsiflexion strap is made of a knit elastic consisting of 69% polyester and 31% rubber. Polyester is a strong, durable, and lightweight material, making it ideal for AFO straps that must withstand repeated use and movement. Its low moisture absorption allows it to dry quickly and resist stains, keeping the straps comfortable and hygienic during daily wear. Polyester also resists shrinking, wrinkling, and fading, maintaining its shape and appearance over time with minimal maintenance. Additionally, it is inexpensive, easy to clean, and recyclable, making it both a practical and sustainable choice for this AFO design [16].

The additional straps located in the front and back of the brace for attachment and adjustability are made of ballistic nylon. Ballistic nylon is a woven synthetic fabric known for exceptional abrasion and tear resistance. Its dense weave distributes stress across fibers, enhancing toughness and long-term wear performance [18]. In the AFO, ballistic nylon functions effectively as an adjustable strap, where durability, comfort, and repeated flexing are critical. The front strap also utilizes velcro, allowing the user to customize the tightness of the brace to their individual needs.

Finally, the inner lining of the inversion supports uses air sponge mesh fabric. This 100% polyester material promotes natural cooling, enhanced airflow, moisture wicking, and heat management, making it well-suited for applications where hygiene and longevity are essential. Its lightweight, breathable, open-knit structure allows heat and moisture to escape, keeping the skin cool and dry during use. Made from durable polyester fibers, it also provides elasticity, recovery, and resistance to wear, ensuring long-term comfort and performance [19]. These qualities make air sponge mesh fabric an ideal material choice to enhance both comfort and breathability in the AFO design.

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. In the Spring 2025 survey, she indicated that there were uncomfortable pressure points around the malleoli. The current team attempted to mitigate this problem by adding a second layer of padding, to which the client reported that the issue was successfully resolved. 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 necessity for long distance traveling. This made it so that the team could not obtain another comfortability survey with the updated final design. Additionally, limited materials were available for use. The medial and lateral sides are made from carbon fiber- reinforced PLA. Ideally, they would be made from pure carbon fiber. However, this would be extremely expensive and require extensive additional training for the whole team on handling this material. Carbon fiber could be used on a future design if there is more time available. 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 progressing.

Methods

The team reused the 3D scans of the patient's right leg from Spring of 2025 by a previous group. First, they used a dremel to cut the epoxy-coated cast into medial and lateral halves. The team then scanned the cast using the Creality RaptorX device in the Grainger Engineering Design Makerspace Lab, creating a mesh file that was smoothed, simplified, and exported as an "obj" file. The mesh was imported into SolidWorks, where splines were built, lofted and extruded into the desired shape and dimensions before being 3D printed. These scans were then used to 3D print new inversion supports.

The old design was updated by increasing the height on the superior end of both sides of the brace. Additionally another slit was added for an adjustable strap on the ventral side, removing the strap on the inferior side since the slippage of the brace made the strap irrelevant. The medial and lateral sides of the brace were 3D printed from PLA that has a 50% carbon fiber in-fill.

To fabricate the padding, the team traced the shape of the inversion supports onto the mesh padding and cut out 2 layers for each side which were then sewn together around the edges. The mesh padding was attached to the inversion supports using super glue on the concave side of the support. The excess material was then cut to about a ½ inch outside of the sewn lines to prevent discomfort due to rubbing of the support on the foot. An exacto knife was then used to cut slits in the mesh to allow the straps to be threaded through, but leaving the malleolus hole intact.

Each of the straps on the ventral side was added by cutting out about one inch thick strips of ballistic nylon, and threading the straps through the slits of the rigid supports. These straps are not able to be adjusted and were measured using the cast to achieve the most accurate fit possible to the patient. The strap across the anterior ankle joint was sewn onto the lateral side, and then threaded through the medial side, to then reconnect with the lateral side via velcro. This allows the patient to adjust the brace to their preferred tightness and take it on and off easily.

For the dorsiflexion element of the brace, an elastic polyester strap was used crossing over the front of the foot. 2 layers of polyester were sewn together across the grain in multiple directions to reduce elasticity and provide sufficient dorsiflection support. Using the cast from last semester, the strap was created to be the right length and was sewn to the slits on the top of the brace.

Once fully assembled, the user will be able to put on the brace by sliding their foot into the brace between the inversion supports, then fastening the Velcro straps to the user's preference. The design prioritizes simplicity, speed, and ease of use, as the AFO will be worn daily and taken on and off frequently. This streamlined assembly and adjustment process ensures that the device will be comfortable, user-friendly, and highly functional for everyday use.

Testing

Previous Semester Testing

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

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

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

They then carried out force-plate testing. Three conditions were tested: eyes open, eyes closed and wedge stance. Center of pressure (COP) and stabilograms were shown for black, red and no AFO. Results demonstrated that the black brace had the best stability but the differences weren't statistically significant.

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

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

Testing Limitations

Debbie Eggleston and the patient reside in Michigan, making in-person testing a challenge. 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.

Comfortability Testing

Adhering to design and client requirements, the AFO must be inconspicuous and therefore fit in a standard, everyday shoe. The patient completed a comfortability form detailing the level of pain and comfortness with both the black and red braces on, which can be viewed in Appendix E and F for both days of testing. The patient experienced less discomfort than the previous semester, indicating less discomfort in the navicular and malleolus. Further testing with the final iteration of the brace will be necessary to test all aspects of comfortability.

Force Plate Testing

To test the impact of the AFO on stability, we will conduct force plate testing. By measuring ground reaction forces during gait, this test provides insight on balance, symmetry and power across different activities, in this case, primarily, walking [24]. The client and patient came down to Madison for testing November 8th through 10th, and the team completed the gait analysis as well as the balance testing.

The gait analysis was performed with several different factors. The gait was analyzed without a brace, with the red brace, with the black brace, with and without the shoe, and with the medical AFO, for a total of seven trials. These trials were each analyzed for their heel strike forces and toe off forces, the graphs of which can be seen in Appendix D. The data was then compared to a healthy subject and then were all together subjected to a statistical analysis to determine if the brace was statistically applying appropriate forces to improve the gait.

The balance testing was performed over a series of 10 iterations, with 3 trials per iteration. The types of tests performed included balancing on the left leg, right leg, right leg with the red and black braces, with and without shoes.

- Single leg stand, left leg: this is the control for the patient, standing on the left leg for 10 seconds will allow for adequate data collection.
- Single leg stand, right leg: the patient will stand on one leg for 10 seconds, this will be done for the healthy and dropfoot impacted leg [25]. This will assess how well the device is able to support the impacted ankle.

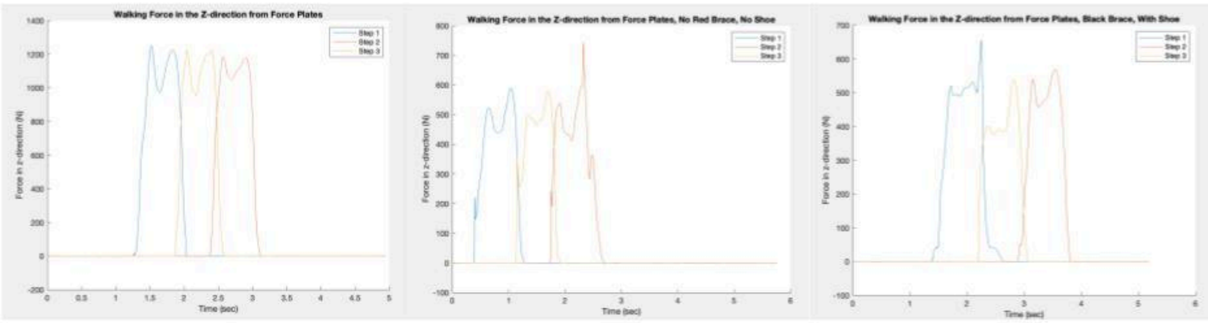


Figure 12: Gait Plots for the healthy patient compared to the affected patient with no support, compared to the affected patient with the black brace support.

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.
As shown in Figure 12, the unaffected 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.

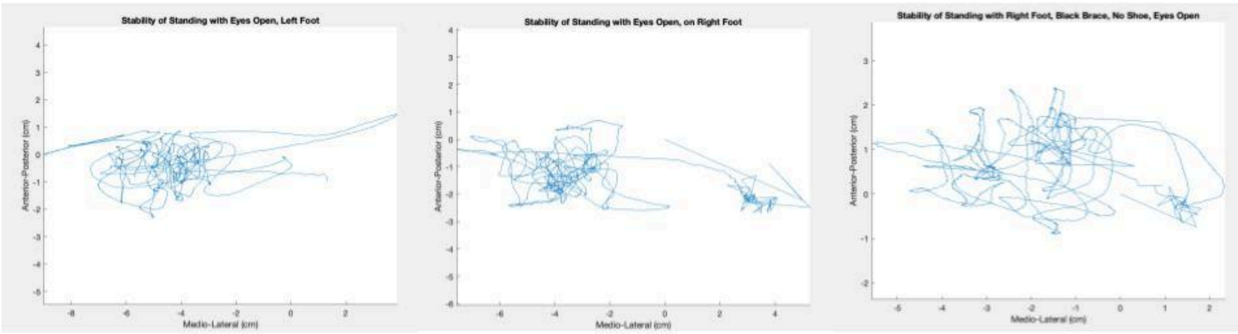


Figure 13: Stabiligrams of the Unaffected Left Foot, the Unassisted Right Foot, and the Black Brace-assisted Right Foot, eyes open

The stabilograms of the patient were generated using the matlab code, which can be seen in the testing Appendix D. The stabilograms show the path of the center of pressure, which moves in response to keeping the body stable. Overall, the stabilogram shows general instability of the patient, especially when balancing on the right foot. The path lengths increase dramatically when the eyes are closed, which is expected of the affected patient; this is also typical of an unaffected patient. The path length is greater with the eyes closed, as the patient's center of pressure moves more to prevent the body from falling over. The change in the stabilogram can be seen in Figure 13.

Statistical Analysis

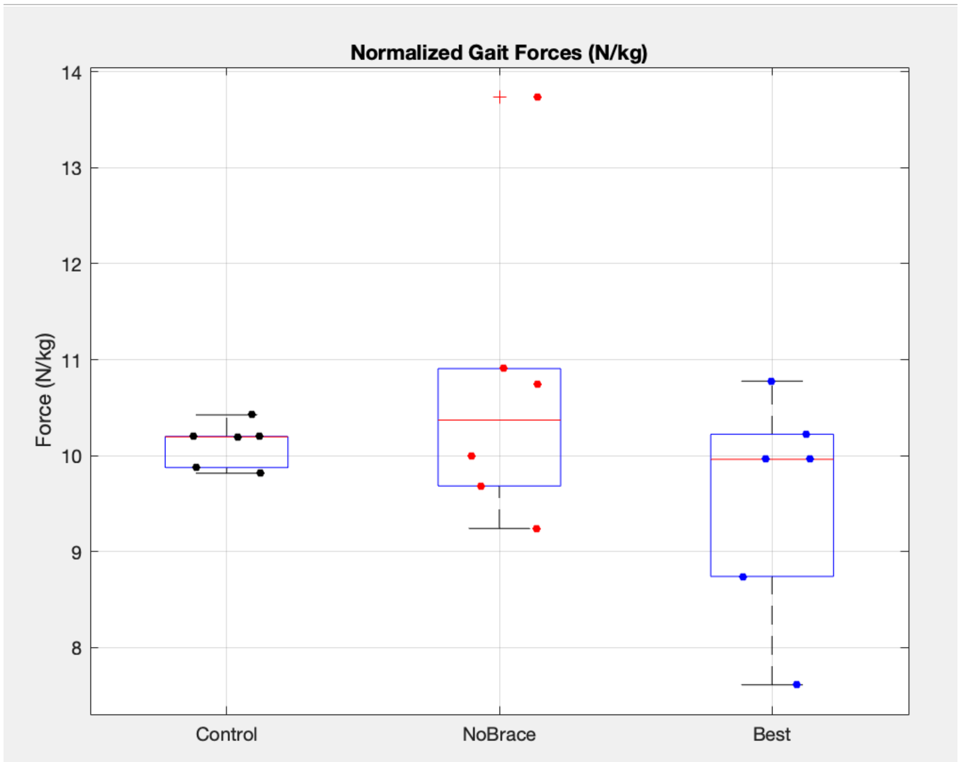


Figure 14: Normalized Gat forces Plotted against the No Brace forces and Best Brace forces

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, as seen in Figure 14. 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, the larger the Cohen's d value, the greater the effectiveness. 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.

Turning to the stabilogram analysis, the same type of analysis was used to track significant differences in path length.

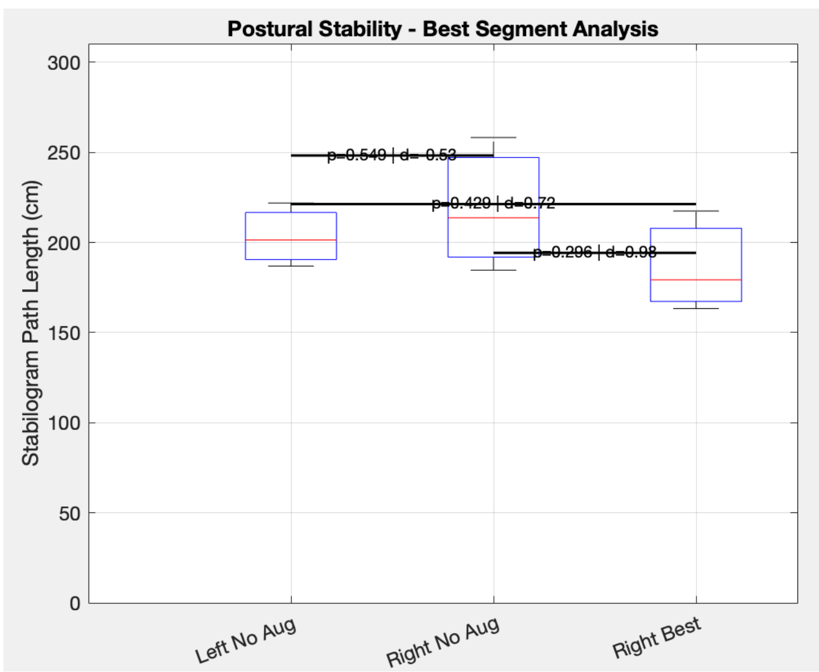


Figure 15: Best Stabilogram Plots of Data with error bars

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, which are plotted in Figure 15. 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.

Overall, the interpreted data shows that while the brace may not have shown complete statistical significance in testing, visually, it showed improvements to the patients gait, and per Cohen's analysis, provided effective treatment to foot drop.

<u>Discussion</u>

Ethical and Safety Concerns

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

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

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

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

Design Evaluation

There are 2 previous semesters of work that have been put into this project. The first semester's main focus was dorsiflexion support. Some success was achieved, but there was much improvement needed in the dorsiflexion and inversion support had also not been addressed. The second semester's main focus was inversion support. The AFO had been successful, but there were durability concerns with the braces. The goal of this semester was to improve and combine the work of the previous two semesters. The design also needed to be more concealable than it has been in the past.

Overall, the AFO has been successful, and all of the goals set for the project were 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. Last of all, 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, helping keep the brace in place without shifting. 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.

The testing done on the brace shows that the design works and provides support in the way it was intended. One of the major goals this project has achieved is that the patient feels like it is helping. 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 nobody will wear a brace that they don't feel is effective. Combined with the very sleek design, which can be hidden under shoes and pants completely, the patient is very likely to use this AFO on a daily basis.

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.

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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We would also like to thank all of the advisors for this project, providing integral information to improve the functionality of the device, Dr. Coventry from Fall 2024, Dr. Puchinelli from Spring 25', and Dr. Williams from Fall 25'. Other members of the University that helped the project include Dr. Willie from the BME department, who helped us use the lab equipment and analyze the gait data; and Jesse from the Grainger Design and Innovation lab who helped us navigate Onshape to create the brace.

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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 - Lab 311

Team Members:
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Client:
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December 9th, 2025

Function/Problem Statement:

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

Client requirements:

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

Design requirements:

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

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

v. Dimensions must be customized to the user's leg geometry to ensure a secure fit and ideally integrate with a custom orthotic insole.

vi. The rigid components must also limit inversion to less than 25° [7].

b. Safety

i. The AFO should promote normal gait mechanics to reduce the risk of tripping or falling while maintaining anatomical alignment to avoid excessive stress on joints, bones, or muscles.

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

iii. The outer surface should provide enough traction to prevent slipping when used without shoes. Adjustable parts should remain secure under impact but not restrict circulation.

iv. Fastening systems must prevent loosening during activity, yet allow for quick removal in emergencies without tools.

v. The design should allow breathability to reduce overheating and moisture buildup.

c. Accuracy and Reliability

i. The orthosis must maintain structural integrity through repeated use while continuing to provide consistent support and proper alignment. Carbon fiber AFOs, for example, typically fail at the mid-shank calf support under forces of 1970 N [8].

ii. To reduce injury risk, the design should include padding in the calf region, with soft materials that are easy to replace after extended wear.

d. Shelf Life

i. Because custom orthotics are tailored to an individual's needs, their shelf life is limited. If left unused for extended periods, changes in the user's measurements or support requirements may reduce effectiveness. For this reason, the AFO should be periodically re-evaluated to confirm fit and function.

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

i. The AFO must match the patient's specific measurements, with slight adjustments to allow for padding and anti-chafing features [15]. Key measurements are as follows:
   1. Length of the leg (measured bottom of foot to directly below kneecap) is 45.5cm.
   2. Diameter directly below the kneecap (measured at top of the lower leg) is 31.5cm.
   3. The diameter of the thickest part of the calf (measured mid-leg) is 31.5cm.
   4. Diameter where the Achilles meets the calf (measured bottom of leg) is 20.5cm.
   5. The diameter of the thinnest part of the ankle (measured where Achilles is felt) is 20cm.
   6. Diameter across the middle of the ankle, through the joint is 30cm.
   7. Diameter just in front of the ankle joint (measured low ankle) is 24.5cm
   8. Arch Measurements: bony prominence to floor is 4.5cm and 6.25cm in length.
   9. Length of the foot is 24-24.5cm.
   10. Width of the foot (measured where the metatarsals meet the phalanges) is 8.25 cm.
   11. Width of the foot (measured in midsole area) is 8cm.
   12. Width of the foot (measured at the heel) is 5.5cm.

ii. Standard AFO thickness is approximately 3.175 mm, which balances structural support with sufficient flexibility to avoid stiffness-related instability [16].

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

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

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

iii. Fiberglass substrates impregnated with polyurethane resin offer a strength proportional to the square of their thickness. By wrapping the fiberglass twice, the rigid support can withstand a bending deflection of 50 N minimum. With an increase in thickness, the piece can provide exponential strength [18].

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

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

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

vi. To enhance resistance against ankle inversion, a custom 3D-printed PLA insert may be integrated within the fiberglass. This reinforcement would be modeled directly on the patient's anatomy to improve fit and structural stability.
vii. Fiberglass provides several advantages for long-term use. Its low weight minimizes fatigue and discomfort, making it easier for the user to move naturally. At the same time, its durability ensures resistance to daily wear and tear, extending the service life of the device. The material's porous structure improves airflow, reducing heat and moisture buildup for greater comfort. Together, these characteristics maximize the orthosis' effectiveness in preventing foot drag, stabilizing the ankle, and improving gait.

k. Aesthetics, Appearance, and Finish
   i. The AFO will feature a sleek black design to minimize visibility. It will resemble an athletic brace and fit comfortably inside tennis shoes or Converse, helping the user maintain their preferred style.
   ii. The surface will be smooth, slim, and inconspicuous, while still offering the necessary support.

2. Production Characteristics
   a. Quantity
      i. This project consists of making one right-leg AFO. However, considering mass production, the quantity would meet market demands among teens needing right-leg and/or left-leg AFOs.
   b. Target Product Cost
      i. This project is funded by Biomedical Engineering (BME) Design at the University of Wisconsin-Madison. The expected cost of this semester's continuation will be $100 dollars.
      ii. In fall 2024, the initial prototype accounted for $189.02 of the $300 budget, with $8.71 covered by the BME department and $180.30 from the BME Design fund. In spring 2025, project expenses were $37.95, of which $13.60 was covered by the department. In total, project costs came to $226.97, with $22.31 supported by the department and $204.65 through the BME Design fund.

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

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

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

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

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

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

f. Competition

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

i. Passive-Dynamic AFO (PD-AFO)

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

ii. Supramalleolar Orthosis (SMO)

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

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

iii. Variable Stiffness Orthosis (VSO)

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

iv. Jointed AFO

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

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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

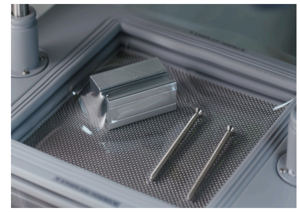
Criteria	 Carbon Fiber reinforced PLA composite (CF-PLA)		 Fiberglass Plaster		 Thermoplastics	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Strength/rigidity (30)	5/5	30/30	4/5	24/30	4/5	24/30
Ease of Fabrication (20)	4/5	16/20	5/5	20/20	1/5	4/20
Cost (20)	5/5	20/20	3/5	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	Heado US	Amazon	10/10/2024	1	$3.98	$4.20	Link
Nylon Fabric	fabric/cloth to sew carbon fiber	MYUREN	Amazon	11/6/2024	1	$12.61	$12.61	Link
Bungee pt 2	stronger bungee to support better dorsiflexion	LuckyStraps	Amazon	10/23/2024	1	18.99	$20.03	Link
Bungee	thinner bungee	Huouoo	Amazon	10/25/2024	1	$6.32	$6.32	Link
Mini caribener	small sized caribener to hold bungee	REI	REI	11/4/2024	1	$6.00	$6.00	**In-store**
Shock cord	thinner and stronger bungee	REI	REI	11/4/2024	1	$5.95	$6.61	**In-store**
Lock laces	lock laces to fix the slipping problem of the plastic cord lock	Lock Laces	Amazon	11/4/2024	1	$12.65	$12.65	Link
Fabric Glue	glue to attach the cord locks to the fabric	E6000	Amazon	11/08/2024	**1**	$8.14	$8.14	Link
Needles and Thread	Stronger needles and thread to attach various fabrics	Basic Home	Amazon	12/03/2024	**1**	$8.43	$8.43	Link
Carbon Fiber piece - Component 2								
3D printing prototype	3D printing of back support	Bambu printer	Makerspace	11/8/2024	1	1.4	$1.40	***covered by $50 budget**
3D printing prototype - 3 variants	3D printing of back support	Bambu printer	Makerspace	11/12/2024	1	3.8	$3.80	***covered by $50 budget**
3D printing prototype	3D printing of back support	Bambu printer	Makerspace	11/13/2024	1	1.71	$1.71	***covered by $50 budget**
Lock lace piece	3D printing the lock lace piece	Bambu printer	Makerspace	11/18/2024	1	$0.23	$0.23	***covered by $50 budget**

3D Printing Final Prototype	3D printing of back support	Shen Printer	Makerspace	12/3/2024	1	$1.57	$1.57	***covered by $50 budget**
Epoxy Mold - Component 3								
Epoxy	Take cast of the leg	Easy Pour Epoxy	Amazon	11/14/2024	1	$39.97	$39.97	Link
Mold release Agent	PVA release agent - Prevent bonding to the cast	Mrealeazy	Amazon	11/14/2024	1	0	$0.00	***Used the provided materials in ECB**
						TOTAL:	**$189.02**	
Spring 2025								
Category 1 - Rigid Support								
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	2/28/2025	1	$0.86	$0.86	***covered by $50 budget**
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	3/5/2025	1	$2.42	$2.42	***covered by $50 budget**
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	3/14/2025	1	$3.66	$3.66	***covered by $50 budget**
CF-PLA (red)	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	4/4/2025	1	$3.92	$3.92	***covered by $50 budget**
CF-PLA	Carbon Fiber PLA 3D Print	Shen Printer	MakerSpace	4/4/2025	1	$1.94	$1.94	***covered by $50 budget**
Category 2 - Straps and Padding								
Carpet Tape		Capitol	Menards	4/2/2025	1	$7.36	$7.36	link
Mesh Padding	3D Air Sponge Mesh Fabric	Tong Gu	Amazon	3/7/2025	1	$16.99	$16.99	link
Velcro	Velcro pieces		MakerSpace	2/28/2025	2	$0.40	$0.80	***covered by $50 budget**
						TOTAL:	**$37.95**	
						TOTAL:	**$226.97**	

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

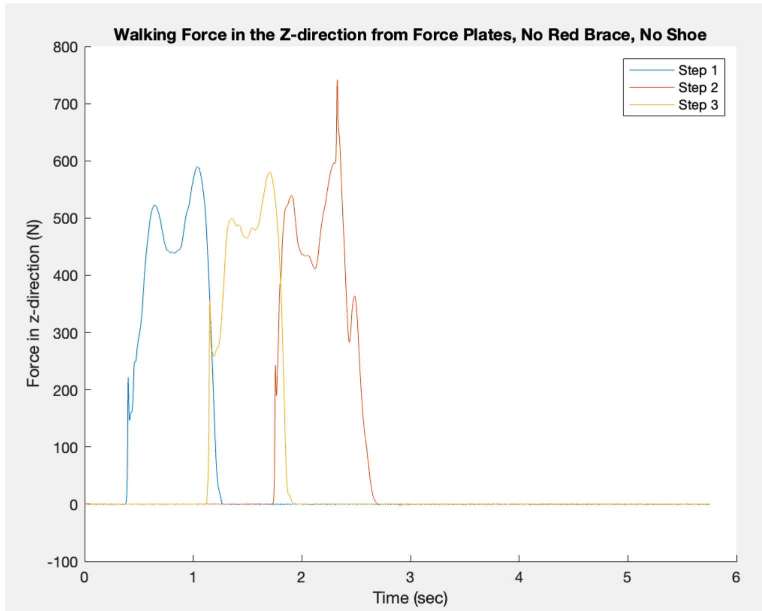


Figure 4: Walking with no brace

Test 2: Walking, No Brace, with Shoe

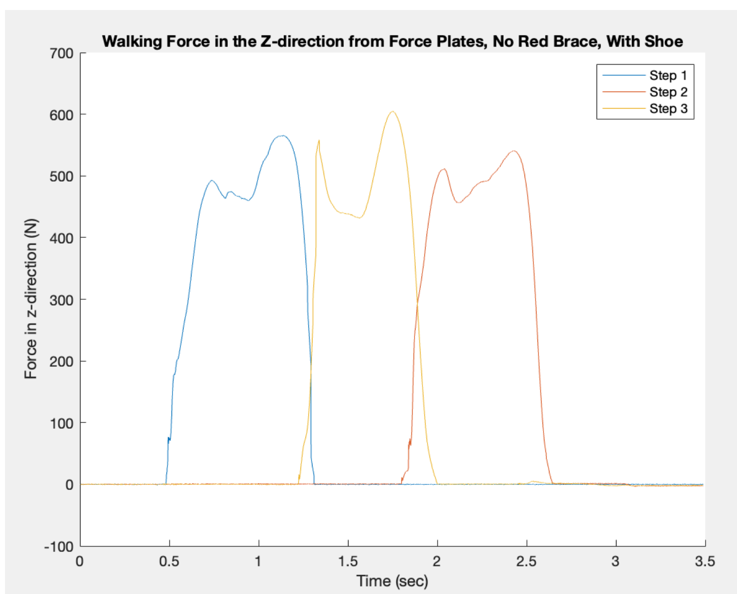


Figure 5: Walking with no brace, with shoe

Test 3: Walking, Red Brace, No Shoe

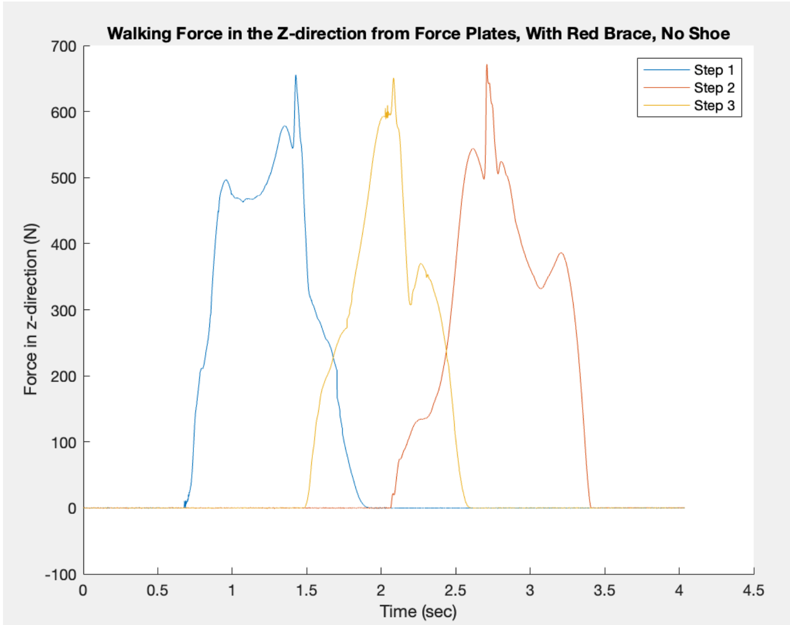


Figure 6: Walking with Red Brace, No Shoe

Test 4: Walking, Red Brace, With Shoe

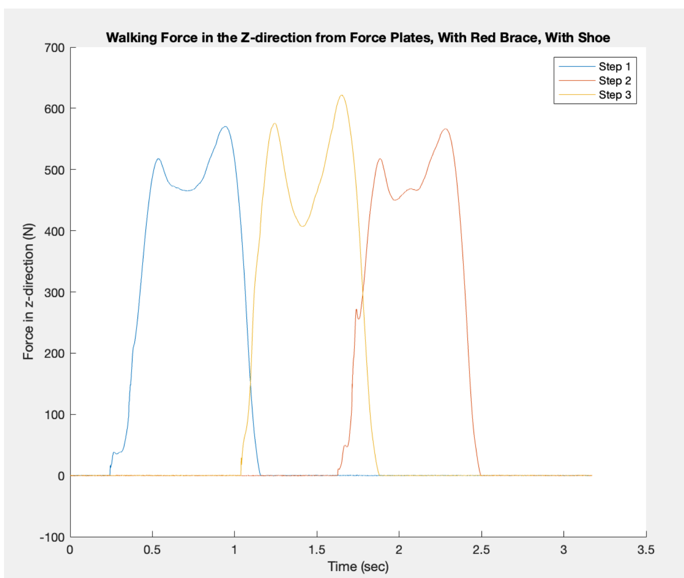


Figure 7: Walking with Red Brace, With Shoe

Test 5: Walking, Black Brace, No Shoe

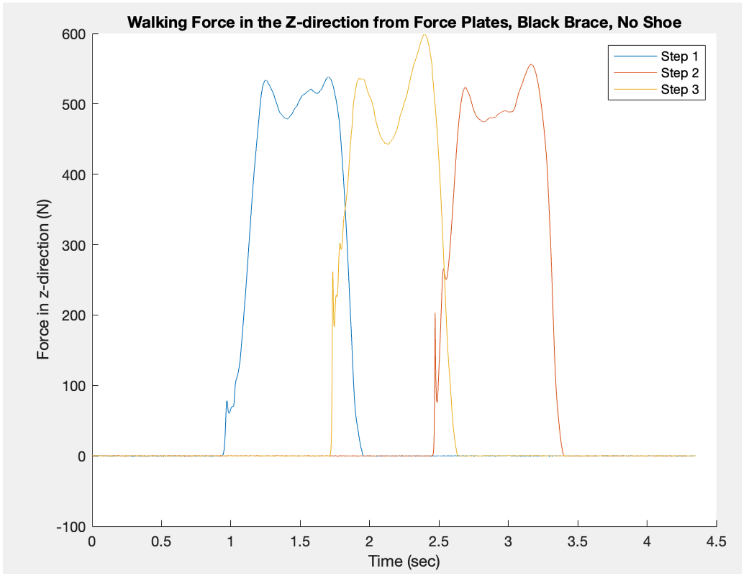


Figure 8: Walking, Black Brace, No Shoe

Test 6: Walking, Black Brace, With Shoe

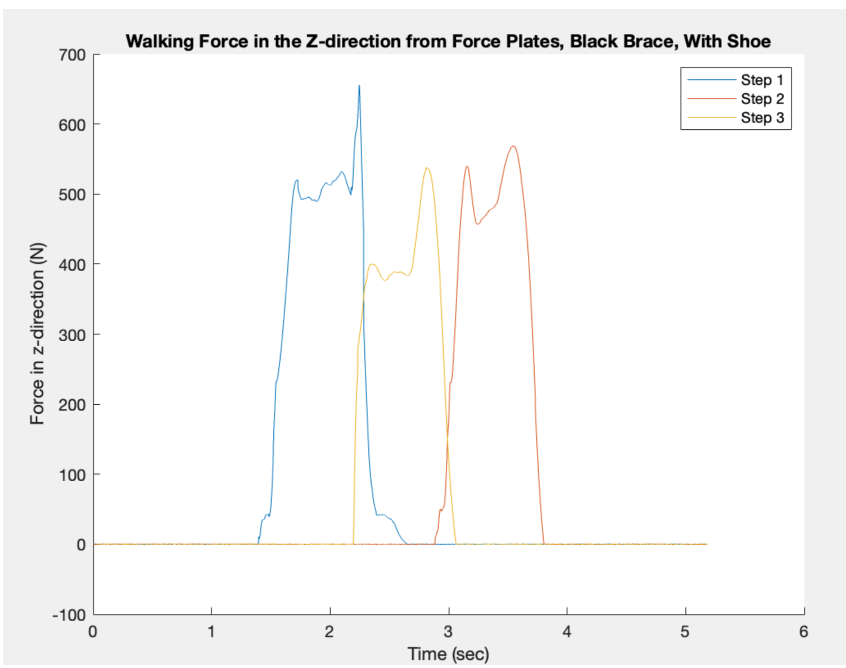


Figure 9: Walking, Black Brace, With Shoe

Test 7: Walking, AFO, With Shoe

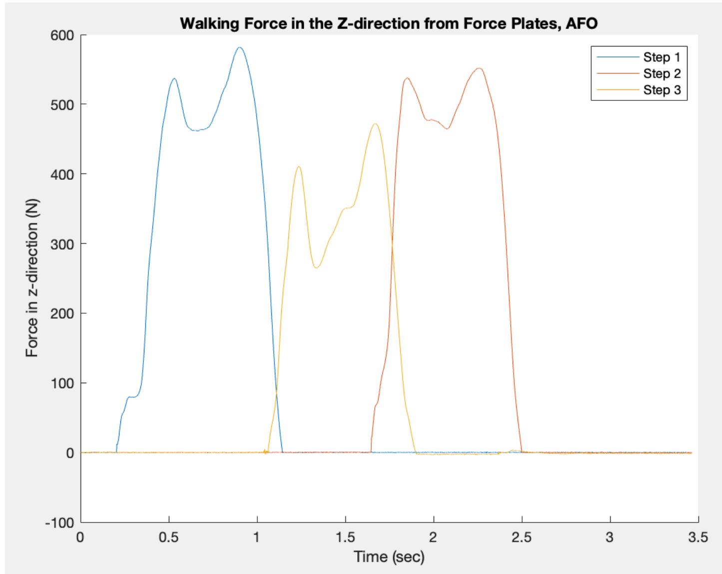


Figure 10: Walking with AFO

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.

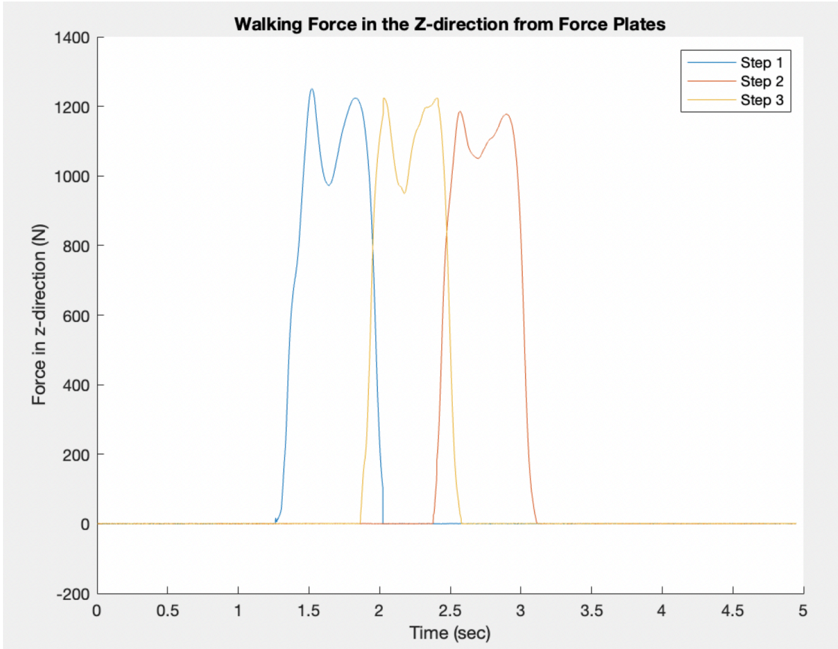


Figure 11: Normal Patient Walking

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)

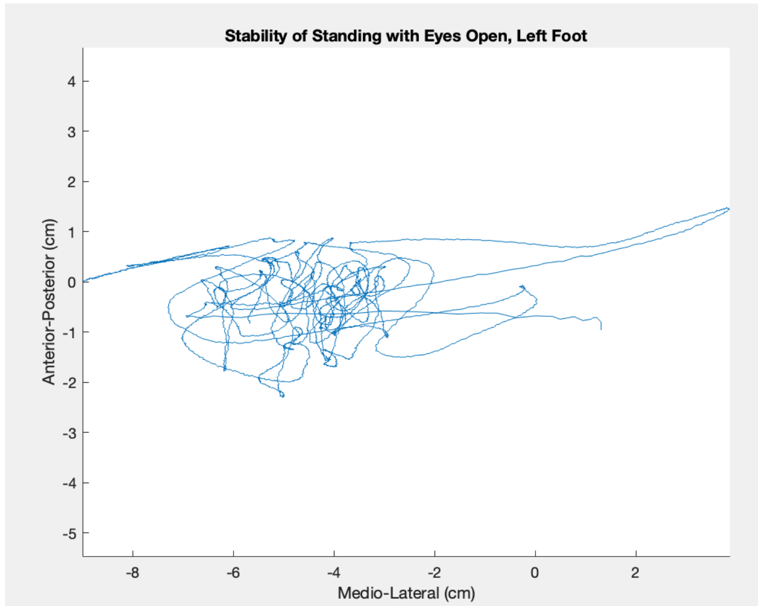


Figure 12: The patient balancing on the left foot, with her eyes open, no brace

Test 2: Right Foot, No brace

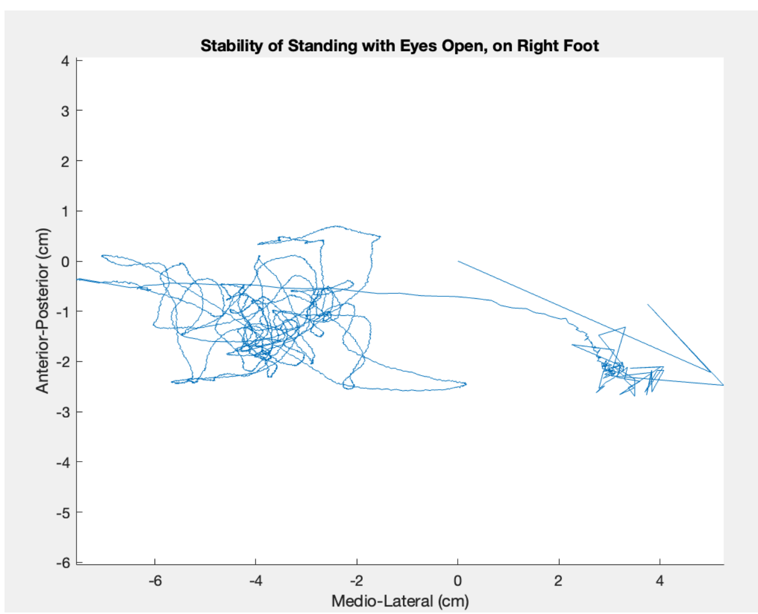


Figure 13: The patient balancing on the right foot, with her eyes open, no brace

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

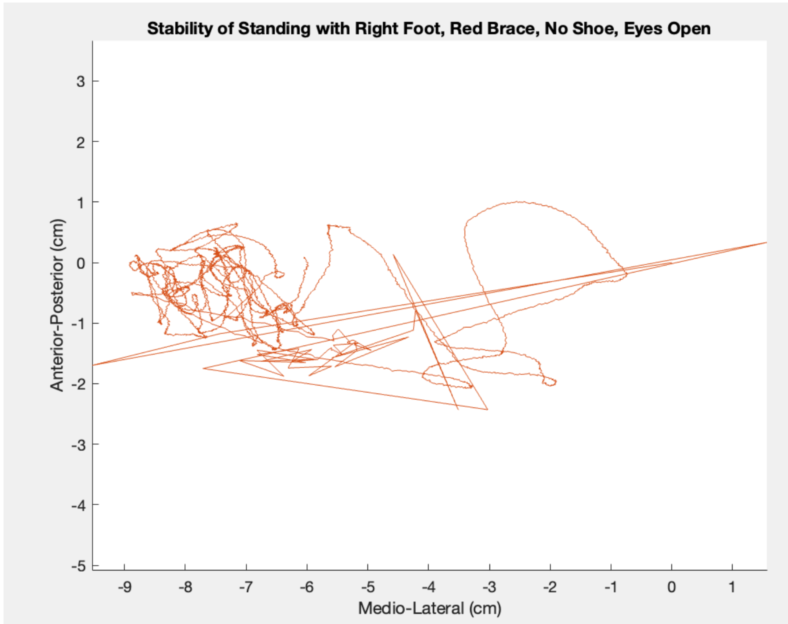


Figure 14: The patient balancing on the right foot, with her eyes **open**, red brace, **no** shoe

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

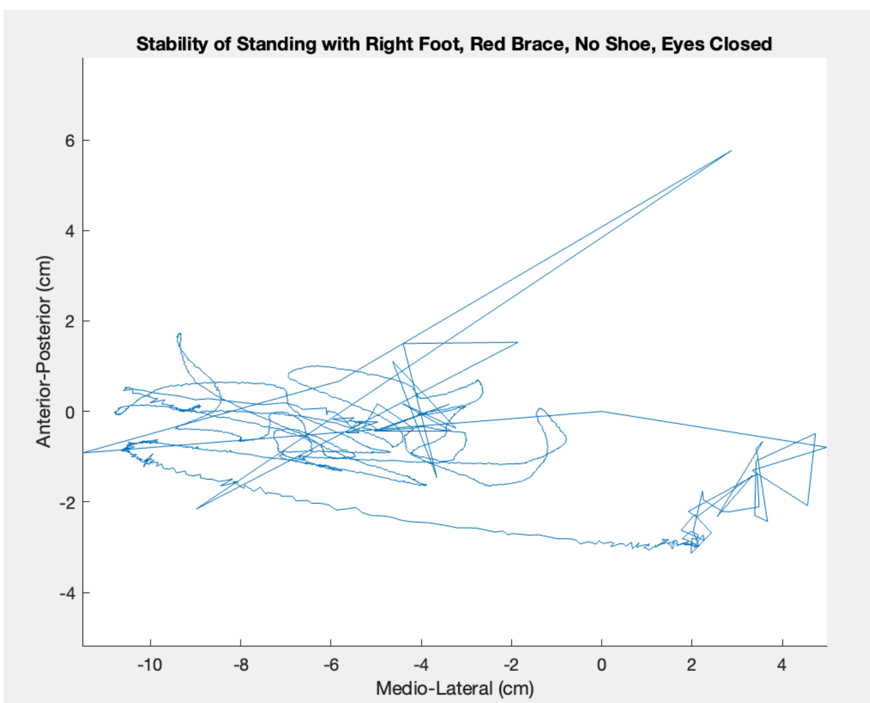


Figure 15: The patient balancing on the right foot, with her eyes **closed**, red brace, **no** shoe

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

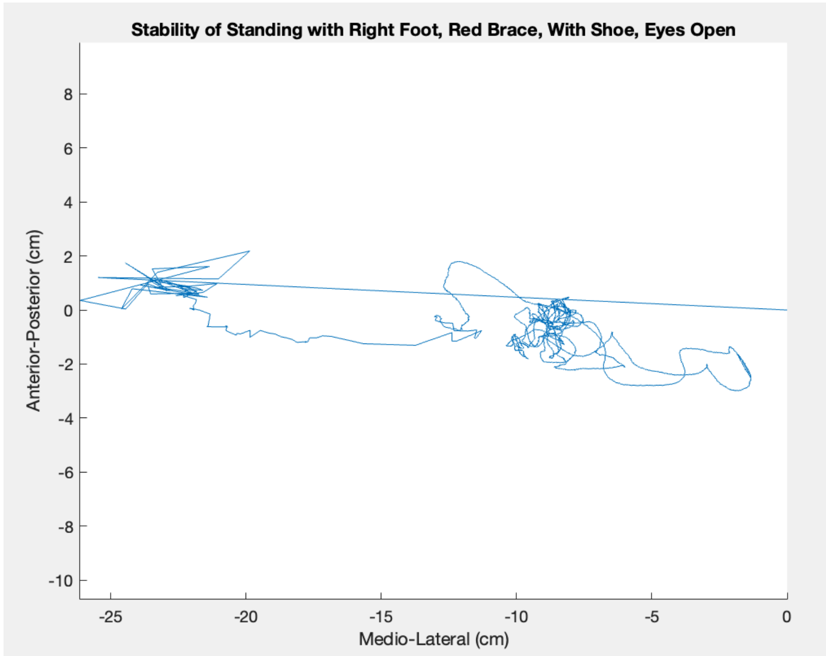


Figure 16: The patient balancing on the right foot, with her eyes **open**, red brace, **with** shoe

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

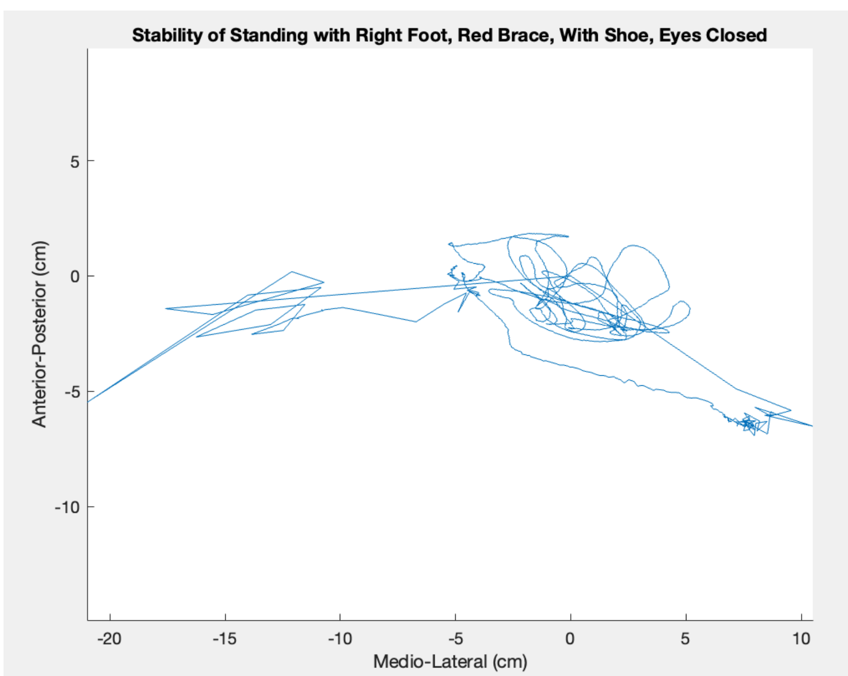


Figure 17: The patient balancing on the right foot, with her eyes **closed**, red brace, **with** shoe

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

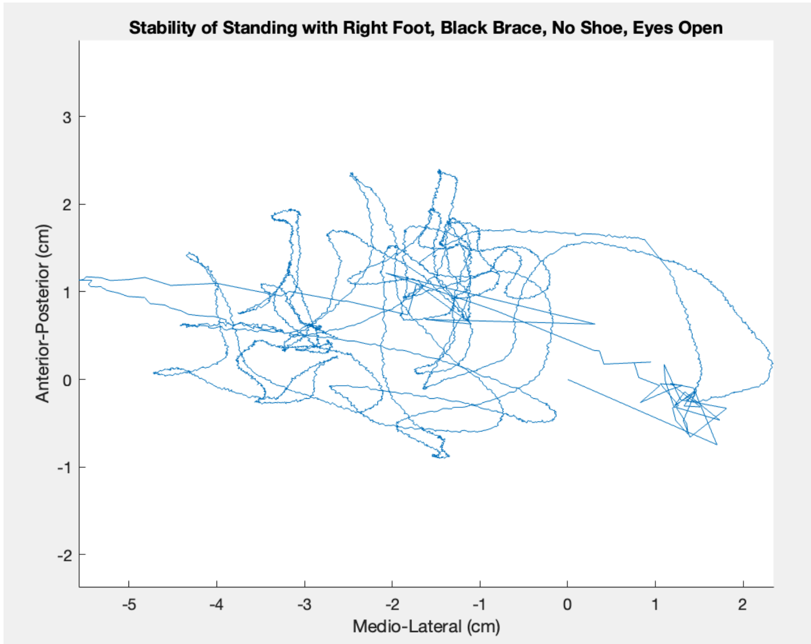


Figure 18: The patient balancing on the right foot, with her eyes **open**, black brace, **no** shoe

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

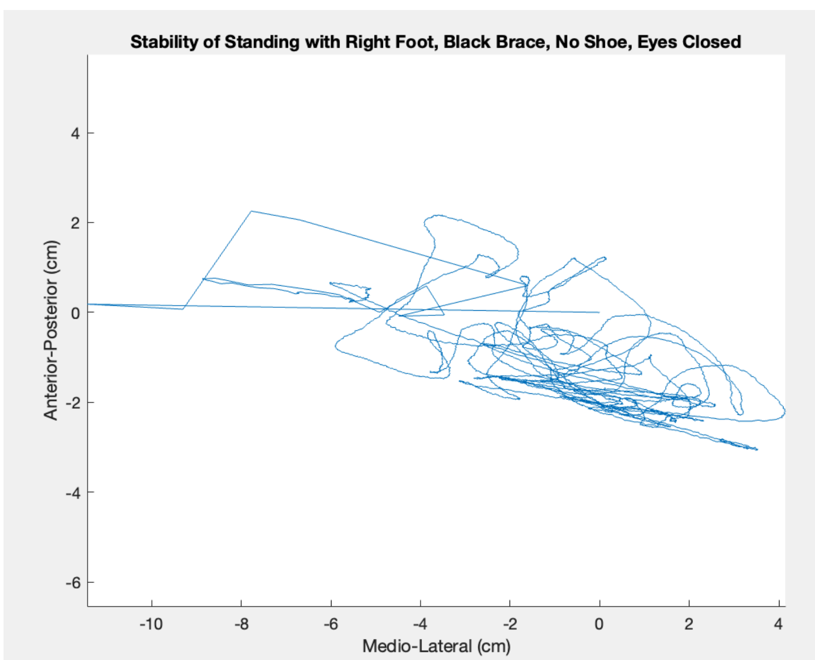


Figure 19: The patient balancing on the right foot, with her eyes **closed**, black brace, **no** shoe

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

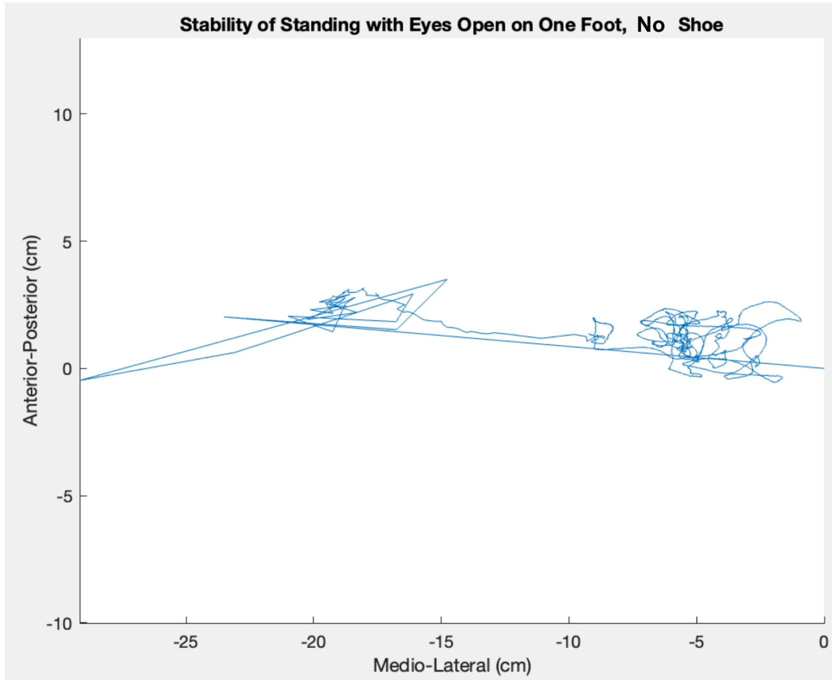


Figure 20: The patient balancing on the right foot, with her eyes **open**, black brace, **no** shoe

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

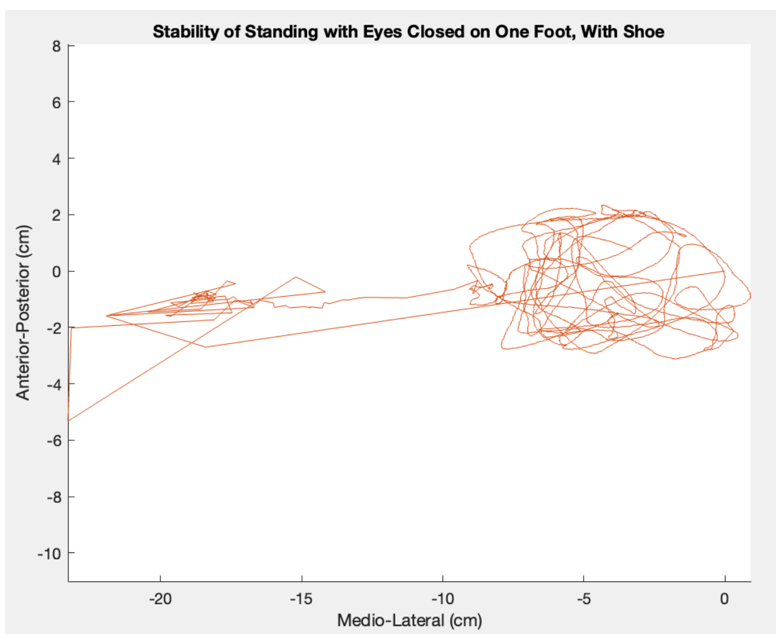


Figure 21: The patient balancing on the right foot, with her eyes **closed**, black brace, **no** shoe

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

Appendix A: 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 B: 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 C: 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 D: 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
```

```matlab
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

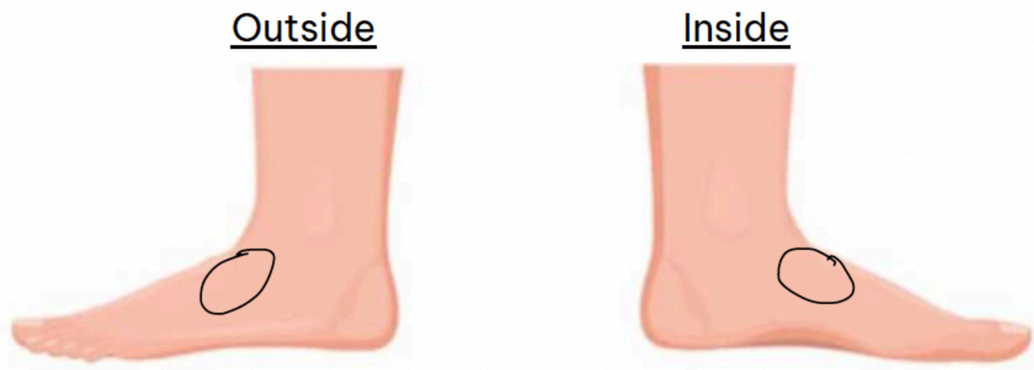
Notes: digs in to bone

Inside Support Fit:

1 2 3 4 5 6 7 8 9 10

Notes:

Please circle on the foot where you feel discomfort:



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

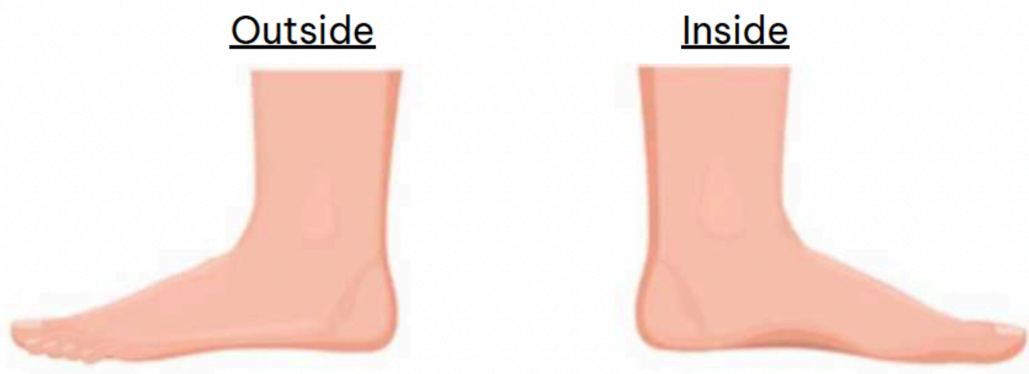
Notes:

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:



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

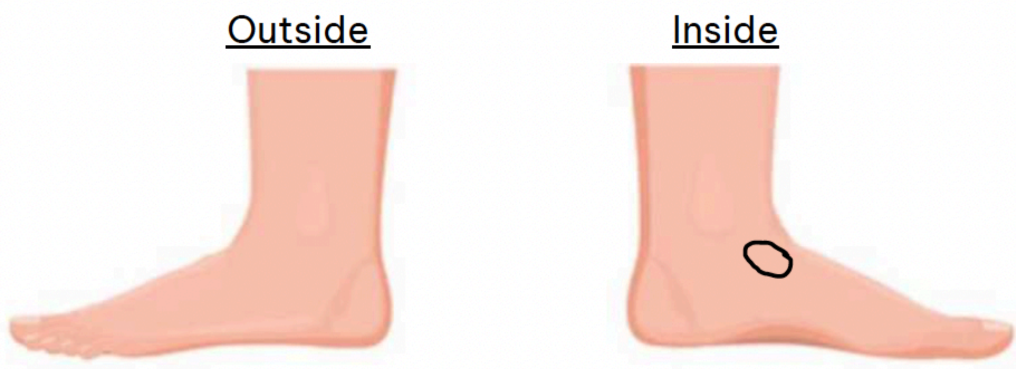
Notes:

Inside Support Fit:

1 2 3 4 5 6 7 8 9 10

Notes: digs in to my navicular bone

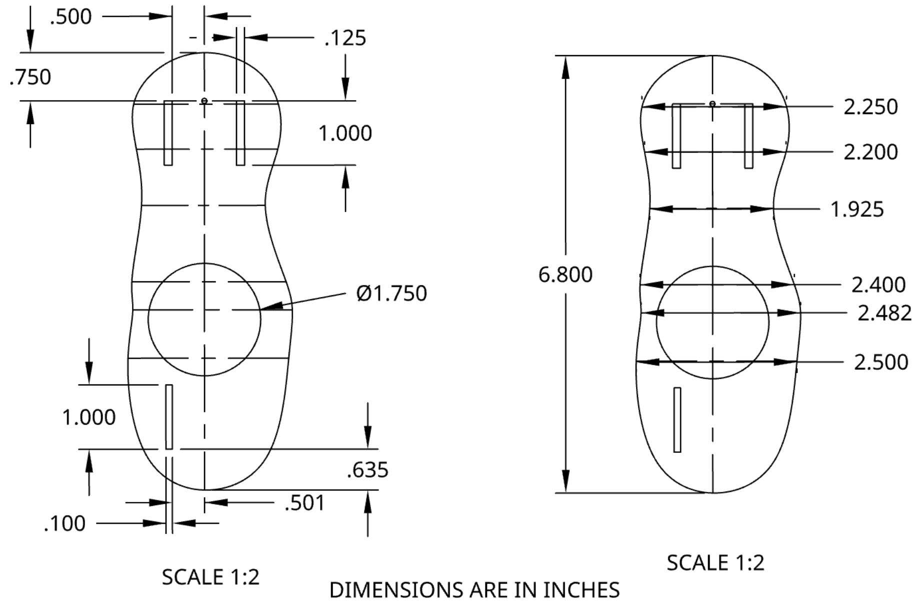
Please circle on the foot where you feel discomfort:



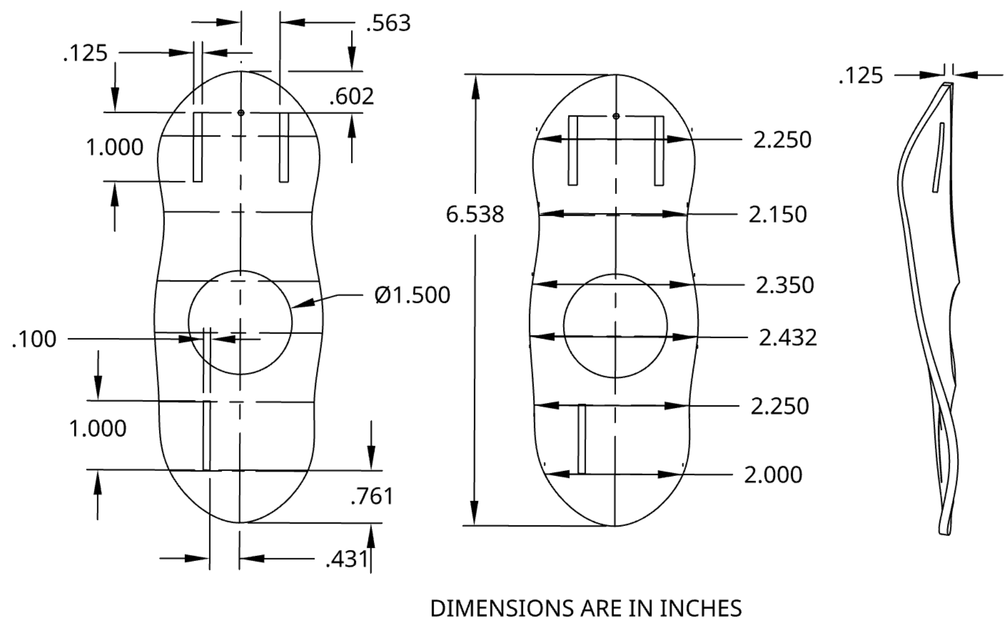
Anterior to medial malleolus

Appendix G: CAD Drawings with measurement

Lateral Side



Medial Side



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**