Inconspicuous Ankle Foot Orthosis (AFO) for teen

FINAL REPORT

Fall 2024 BME 200/300 Lab 304

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AFO Group

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Client:

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Abstract

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

To address the lack of inconspicuous AFO designs, a discrete AFO for the right foot was fabricated for a teenager diagnosed with FSHD. The design aims to support dorsiflexion to prevent foot drop, provide flexibility for daily activities, and prevent ankle inversion. The prototype features a compression sleeve with neoprene straps securing a carbon fiber-reinforced medial ankle support. A bungee cord, attached to the straps above the metatarsals using fabric glue and patchwork, connects to a lace lock mechanism positioned above the ankle. This drawstring mechanism allows for adjustable tension, facilitating dorsiflexion. The AFO underwent testing to evaluate its safety for continuous use and its impact on gait pattern, with promising results indicating its potential to improve mobility discreetly and effectively.

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Introduction

The team is designing an ankle foot orthosis to support the right ankle of a teen with facioscapulohumeral dystrophy. The device will be used to help facilitate normal gait patterns by positioning the ankle in dorsiflexion and preventing ankle inversion. Compared to existing AFOs, this design will be more discreet to prevent unwanted attention from others. The current objective of the team is to design an ankle-foot orthosis while maintaining its discreetness. In the future, this device will be repeatable and can be made customizable to other young individuals wanting an inconspicuous ankle foot orthosis.

Motivation & Global Impact

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

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

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

Existing Devices & Current Methods

Current orthotics use the Three-Point Pressure system. This is where the force on the corrected joint is countered by forces above and below the joint so the sum of all forces is zero. This relieves discomfort for the patient [2]. For existing devices, there are three different kinds that offer the flexibility that our client is looking for: flexible-dynamic, jointed, and passive-dynamic AFOs.

The flexible-dynamic AFO, seen in Figure 1, provides flexibility around the ankle while improving natural gait patterns. However, this device should be used by patients with good mediolateral stability. The patient is struggling with medial instability, so this device would not be suitable for them [3].

Figure 1: Side View of a Flexible AFO [4]

Looking at jointed AFOs, seen in Figure 2, are made with a moving part that hinges at the joint which offers a full range of motion. However, some limitations to this device is that it is bulky and hard to fit in standard footwear. This device can also be noisy due to the hinge mechanism and may break more easily. The patient is looking for an orthosis that allows for some range of motion; however, due to the bulkiness of this device, it does not meet the criterion the patient is looking for. [5].

Figure 2: Back Angled View of a Jointed AFO [6]

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

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

Problem Statement

Ankle foot orthoses (AFOs) are designed to provide dorsiflexion support during the swing phase of walking. These devices are primarily used to treat muscular dystrophies. This project focuses on young individuals diagnosed with Facioscapulohumeral Dystrophy (FSHD), the most common type of muscular dystrophy. The team aims to design a brace for teens that assists with ankle dorsiflexion, promoting safer walking while remaining easily concealable and flexible enough to allow for functional ankle movement. The brace will be tailored specifically for the patient. Key objectives for the device include positioning the ankle in adequate dorsiflexion, preventing inversion, maintaining a slim, discreet design, and ensuring sufficient flexibility to minimize movement restriction.

Background

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

Anatomy & Physiology

When working with AFOs, the focus will be on the lower half of the body, particularly the legs and feet. The AFOs' primary purpose is to support the foot in dorsiflexion and fix foot drop. Foot drop occurs when the foot's muscles are too weak to support the foot in a normal

position, leading to an excess drop of the foot, which affects the gait when walking. This also increases the risk of falling, especially during the gait cycle. The muscles leading to the ankle, specifically the tibialis anterior, are much weaker [9].

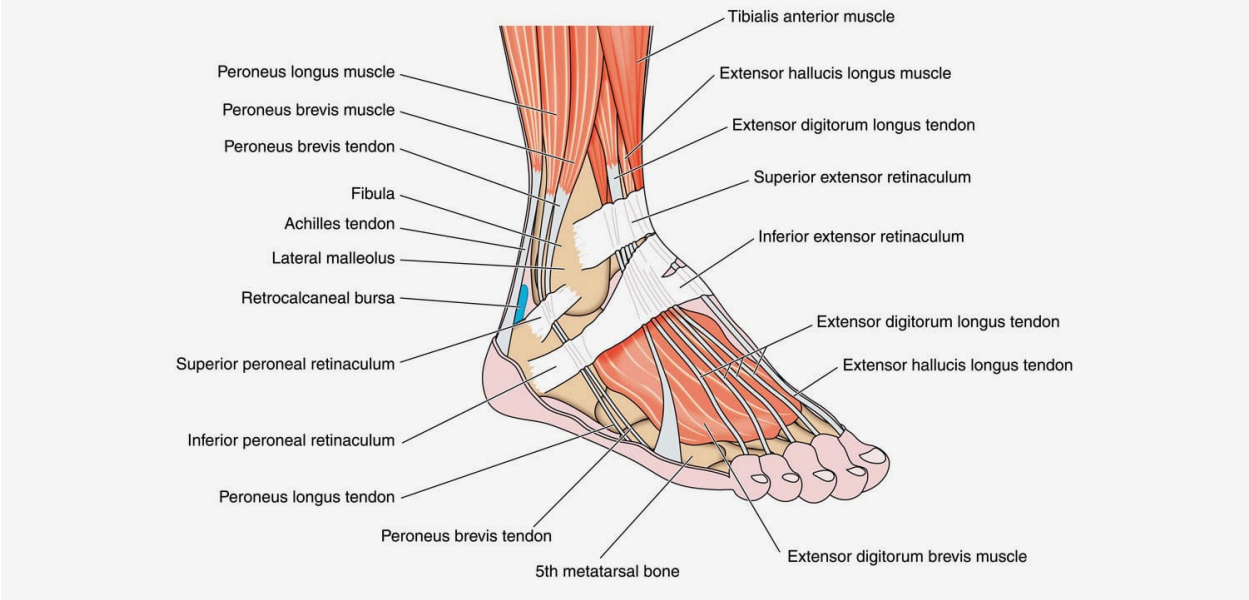


Figure 4: Ankle Muscle Anatomy [9]

The patient also experiences ankle inversion, which is where the foot rolls inwards and is potentially harmful to the tendons of the ankle. The medial side of the ankle is squished together, while the lateral side is stretched, creating further weakness in the ankle. The patient also has weakened calf muscles, so there will be a support that protects against ankle inversion. There will also be support to aid in dorsiflexion. The patient also requires arch support in the foot, which is already implemented in the form of inserts in tennis shoes.

Client Information

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

The team met with Ms. Eggleston at various points over the course of the semester to provide updates to the manufacturing of the AFO, as well as her providing updates with the patient. The patient’s condition has progressed to the point of needing a professional AFO, and

Ms. Eggleston provided us with the information of the orthotist so that future groups can continue to work in tandem with the doctor and herself.

Product Design Specifications

The goal of the AFO is to design a supportive device catered to the needs of our patient and client. The device will support dorsiflexion with an adjustable bungee mechanism to provide customizable levels, and a carbon fiber medial support to protect against ankle inversion. The AFO should be easy to take on and off due to daily usage. The thickness of the back support will be 3.175mm to adequately support the foot. The AFO initial prototype budget is 300 dollars, which should be within reason despite the price of carbon fiber; however, if the AFO is incredibly useful to the patient, the client is prepared to up the budget to create a fully operational device with full capabilities and a polished finish.

Preliminary Designs

Design One: Hinge Design

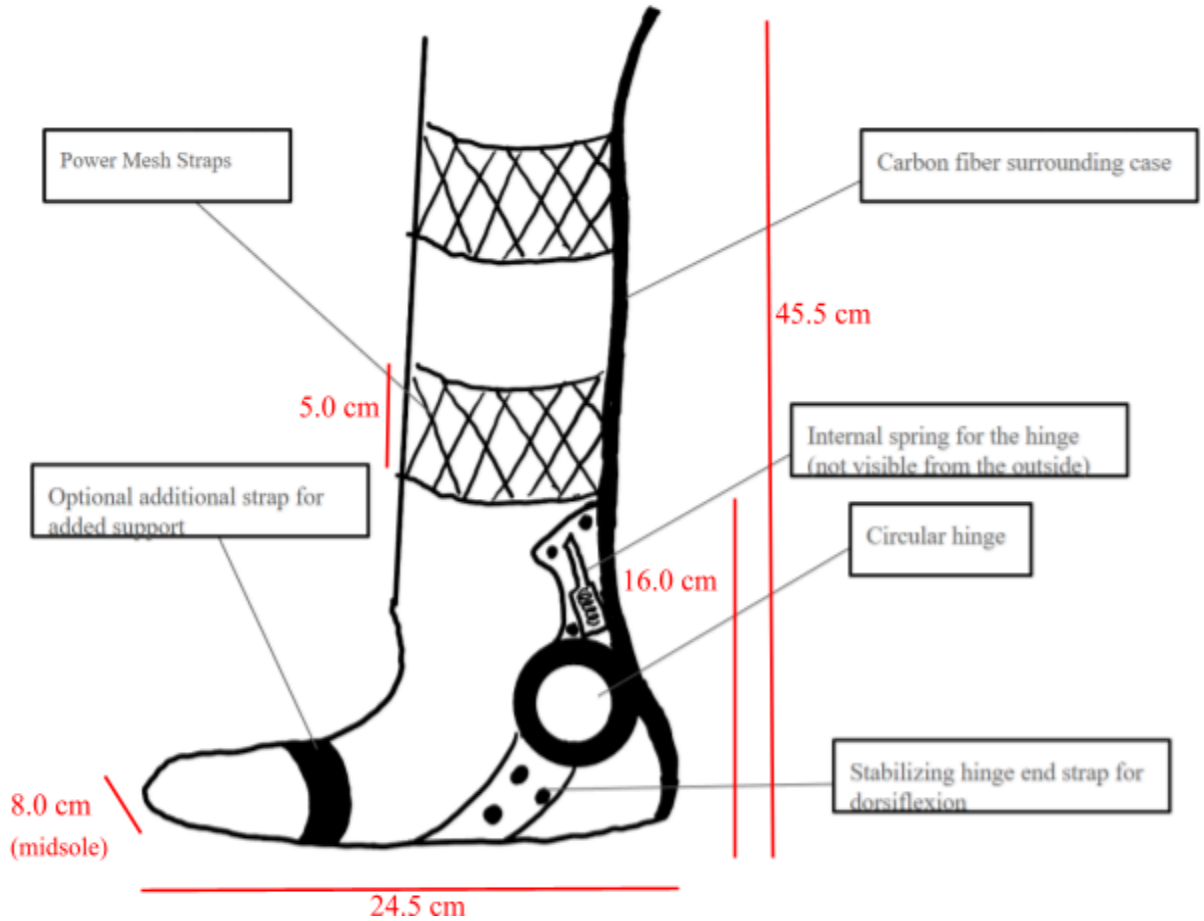


Figure 5: Hinge Design Sketch, Medial View

This design is called the “Hinge Design”, named after its key component: a circular hinge that sits on the medial side of the ankle, making it more discreet. The advantage of this hinge is that it allows for a full range of motion, unlike most commonly available fully rigid AFO designs, which restrict movement. The circular hinge is more compact than most standard hinge designs which reduces overall bulk. Additionally, a spring inside the hinge will facilitate dorsiflexion, springing back into place with each step. To further enhance the design's discretion, clear mesh straps are used. Power mesh, a stretchy, breathable, strong, and elastic material with a sheer appearance, will be utilized for this purpose. The surrounding casing of the AFO, which will secure the straps and hinge in place, will run along the back of the patient’s ankle. This casing will be constructed from carbon fiber, a rigid material that offers the necessary support to prevent foot drop.

Design Two: Bungee Brace

Figure 6: Bungee Brace Design Sketch, Medial View

This design is called the “Bungee Brace”, which consists of a rotator dial with a bungee cord that tightens to a favorable level of ankle dorsiflexion. The brace consists of adjustable velcro straps and a non-rigid material like neoprene, a synthetic rubber because it provides flexibility and comfort for the user. The client emphasized the importance of a discreet design that is also comfortable, so the bungee cord moving along the top of the foot inside the shoe is one of the main aspects. In addition, this design looks similar to an athletic brace which could limit questions regarding its functionality and improve discreteness. This design is comfortable and supports dorsiflexion, but does not support ankle inversion.

Design Three: Strap Brace Design

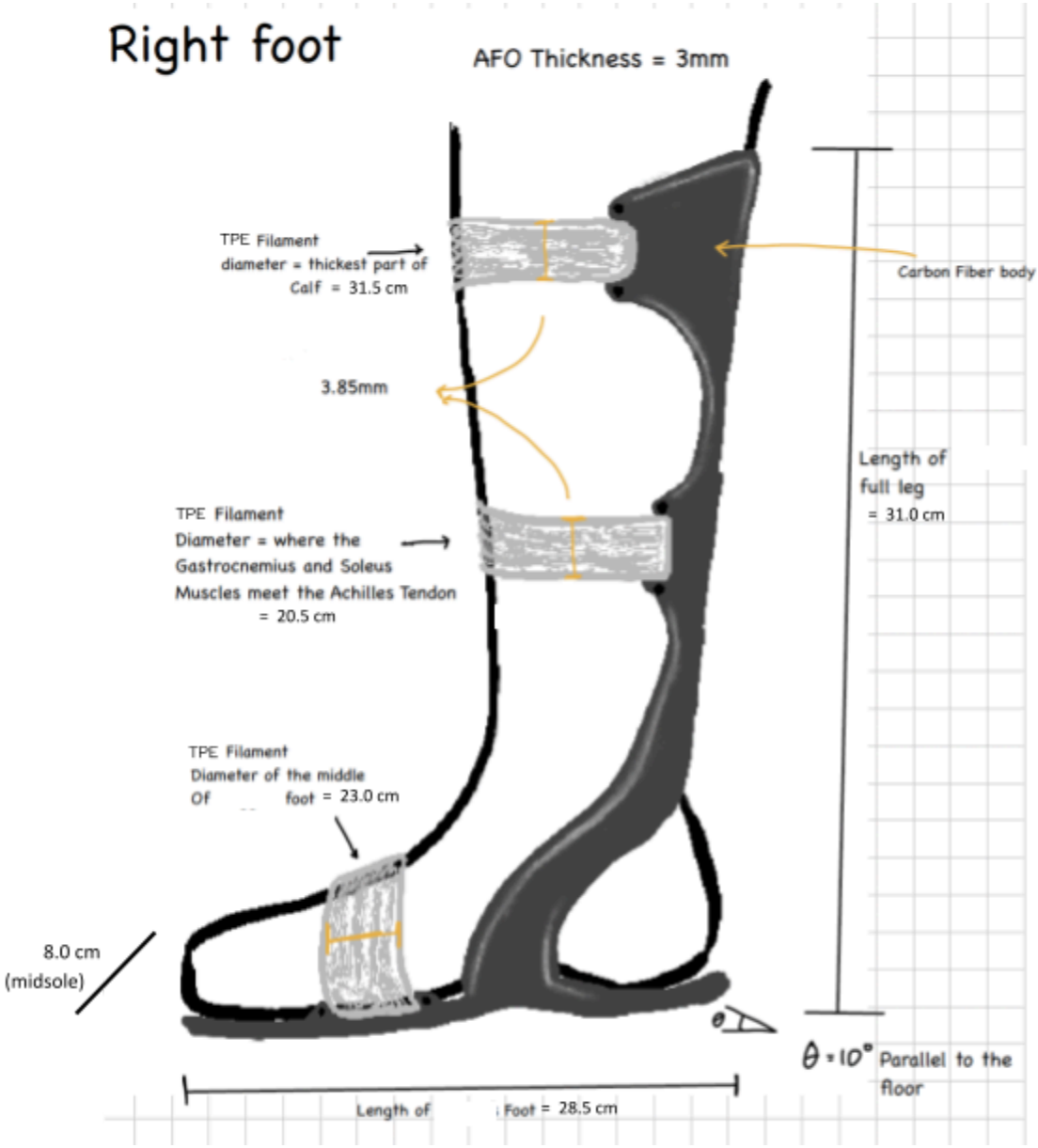


Figure 7: Strap Brace Design Sketch, Medial View

This design is called the “Strap Brace”, which consists of a carbon fiber body and straps made of Thermoplastic Elastomer (TPE) Filament, a type of rubber that can be 3D printed. In addition to their flexibility, these straps can be clear which improves the discreteness of the design. Carbon fiber is more flexible than other plastics, but more rigid than other materials like in the Bungee Brace design. This could be slightly less comfortable for the user but increases support and functionality. The carbon fiber base is angled at 10 degrees to promote ankle dorsiflexion. The carbon fiber body wraps around to the inside of the foot to provide medial support from ankle instability.

Preliminary Design Evaluation

Design Matrix

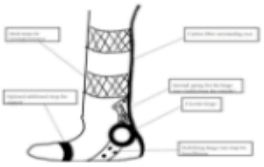
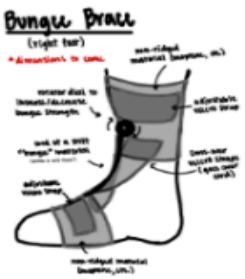
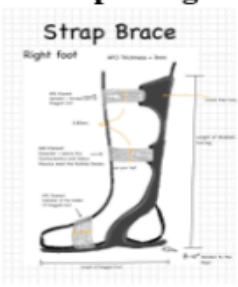
Criteria	Weight	Design 1 Hinge Design  Score |	Weighted Score	Design 2 Bungee Brace Design  Score |	Weighted Score	Design 3 Strap Design  Score |	Weighted Score
Support	20	3/5	12	3/5	12	5/5	20
Discreetness	20	3/5	12	5/5	20	4/5	16
Safety	15	3/5	9	4/5	12	4/5	12
Flexibility	15	4/5	12	5/5	15	3/5	9
Customizability	10	4/5	8	5/5	10	3/5	6
Ease of Attachment and Removal	10	2/5	4	3/5	6	4/5	8
Cost	5	4/5	4	5/5	5	4/5	4
Ease of Manufacture	5	5/5	5	4/5	4	3/4	3
Total	100	66		84		78	

Table 1: Design Matrix for Preliminary Designs

Summary of Design Matrix

In order to effectively evaluate each of the preliminary designs, a comprehensive design matrix was created. This matrix analyzes several factors related to the application of designs through the use of each criteria. Each design is scored on a scale from 1 to 5 with a score of 1 being unsatisfactory and 5 being very satisfactory. Six different criteria are defined as follows:

Support (20%) - The design must support the position of the foot and ankle. The orthosis must support the heel and allow for heel strike while also providing some mobility. A higher score represents a design that offers more support for the foot and ankle.

Discreetness (20%) - The client emphasized the importance of a discreet ankle-foot orthosis. The patient is in high school and does not want to draw attention to their ankle. The AFO should fit inside a shoe and underneath jeans or leggings. A higher score represents a more discreet design.

Safety (15%) - Depending on the materials chosen for the design, there may be potential safety hazards. It is important that the AFO is made from durable materials. If the AFO were to break, it must be ensured that it would not harm the user. Additionally, the effects of microplastics or any skin irritation that could be caused by the device must be considered. A higher score represents a design that is likely to be safer for the user.

Flexibility (15%) - The design and material used should be flexible enough to allow for a functional ankle range of motion. It must be flexible enough to ensure that other activities, such as squatting or descending stairs, are minimally impacted. A higher score represents a more flexible design.

Ease of Attachment and Removal (10%) - Since this device will be used daily, it is important that it is easy for the user to put on and take off. A higher score represents a design that is easier to attach and remove.

Customizability (10%) - A customizable AFO ensures a proper, comfortable fit. Customizability helps prevent discomfort and enhances functionality for ankle range of motion. An adjustable design ensures it remains effective as the user's needs evolve. A higher score represents a more customizable design.

Cost (5%) - Considers the amount of money needed to fabricate and maintain each design. Low scores indicate a higher cost and higher scores indicate a lower cost.

Ease of Manufacture (5%) - Considers how easy each design is to fabricate, including the accessibility of materials, machinery, and the time required for fabrication. A higher score indicates greater ease of manufacture.

The Bungee Brace Design won the design matrix because it is the most discreet, safe, flexible, customizable, and cheap. It will easily fit inside a shoe and underneath pants, and the straps give a sock-like appearance, increasing inconspicuousness. This design is safe and flexible because of the soft material; the bungee system allows for plantar flexion which also increases flexibility. The Bungee Brace can be tightened to various levels of support while still maintaining an inconspicuous profile, and it would be color-customizable.

Proposed Final Design

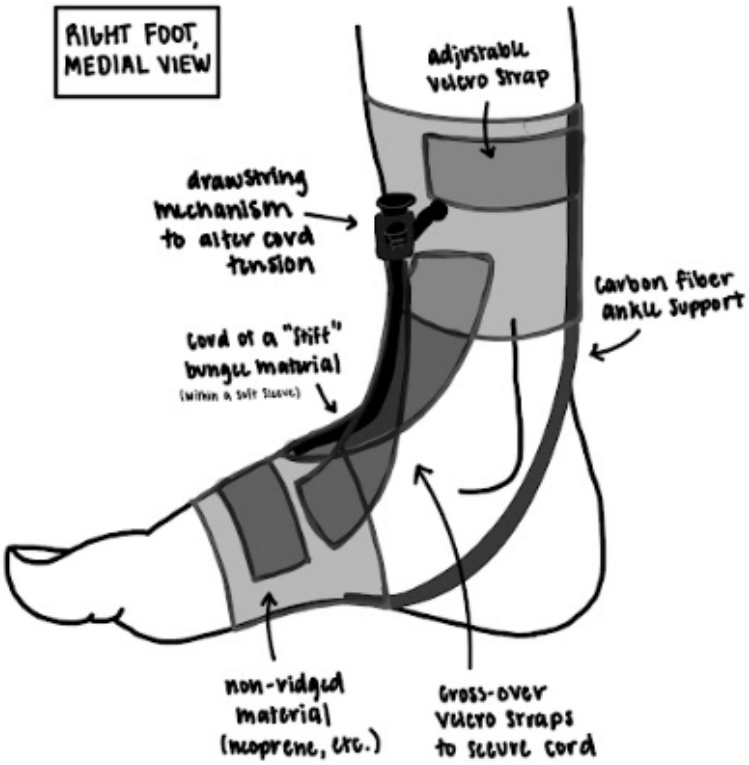


Figure 8: Proposed Final Design Sketch

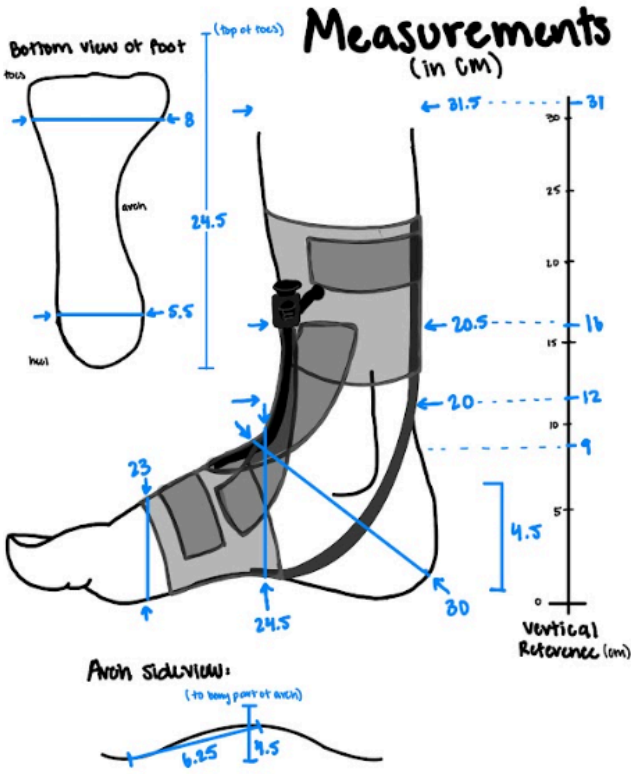


Figure 9: Proposed Final Design Sketch with Dimensions

After reviewing the three preliminary designs, it was decided to combine the Bungee Brace and Strap Brace designs to balance discreteness and comfort with support. The patient is currently struggling with inversion of the ankle so a carbon fiber support was added that runs from the calf down along the inside of the foot. The lateral and medial views of the carbon fiber

support designed in Solidworks can be seen in Figures 10 and 11. Currently, a small footplate is attached to the carbon fiber support; however, in order to limit bulkiness, this may not be necessary. The patient currently has a foot insert so further work will be done to determine if there is a way to incorporate this into the design. If the carbon fiber footplate is not necessary, the patient could possibly wear their custom insoles along with the AFO. In addition, the rotator dial seen in the Bungee Brace design was switched to a drawstring mechanism to improve ease of manufacture, at least for an initial prototype.

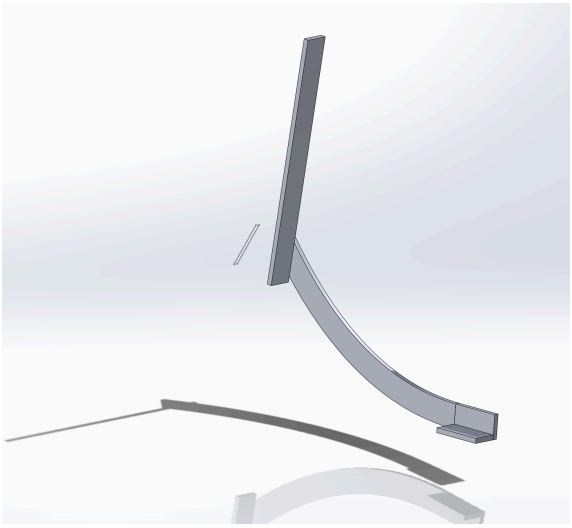


Figure 10: Lateral View of Carbon Fiber Support in Solidworks

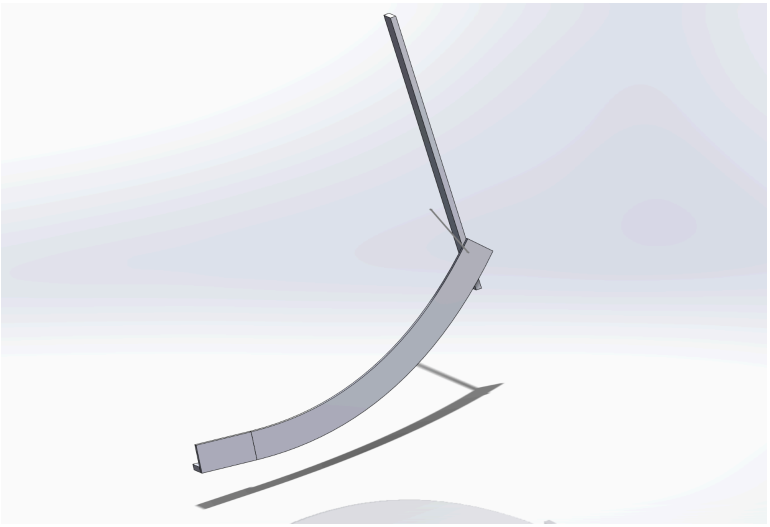


Figure 11: Medial View of Carbon Fiber Support in Solidworks

Fabrication and Development Process

Materials

The final design will consist of six different materials. The foot sleeve of the brace will be composed of a blend of nylon, polyester, and latex. These materials were chosen for their specific properties that enhance both functionality and comfort. The sleeve's breathability will absorb sweat and keep the foot dry, providing comfort during extended use. The material will also be tight and strong, ensuring that the sleeve stays securely in place without sliding. Additionally, the fabric is smooth and soft, adding comfort, while its graduated compression promotes circulation, providing support and pain relief to the user [10].

Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight [11]. Polyester, known for its durability and strength, is ideal as it retains its shape and resists wrinkles, shrinking, and environmental elements like water and wind, which is crucial since the device will frequently be exposed to outdoor conditions [12]. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining

overall strength [13]. Since this device will be worn on the foot during activities that involve sweating, these properties are essential to ensuring both the functionality of the design and the comfort of the user.

The supporting piece on the medial end of the ankle brace will be constructed from PLA reinforced with carbon fiber, selected for its exceptional properties including being lightweight, sturdy, having a high strength-to-weight ratio, thin profile, and superior energy return capabilities. Carbon fiber's lightweight nature will allow for ease of use, enabling better movement while reducing fatigue and pain for the user. Its sturdiness ensures resistance to everyday wear and tear, providing long-term support. Additionally, carbon fiber's ability to store and release energy will improve the user's gait by reducing the effort required for movement. These combined properties maximize the aid needed for foot-dragging prevention, ankle stabilization, and overall gait improvement [14].

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

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

A thin black bungee cord that is ⅛ inch in diameter and has 100 lb max tensile strength will be used. This specific cord was chosen because it is less bulky, requires less cord displacement, but still offers our patient the support needed for dorsiflexion. The bungee cord will apply adequate tension, strength, recoil, and flexibility needed for support. It is made of nylon, polyester, and latex, see above material specifications for more details on the material's properties.

Methods

The carbon fiber attachment was designed in SolidWorks and subsequently 3D printed at the UW-Makerspace using the Bambu Labs printer [16]. The material will undergo an initial testing evaluation on Solidworks prior to being printed (see testing section for more details). This preliminary testing will assess the strength, flexibility, and overall functionality of the carbon fiber component in the device.

The ankle brace and bungee cord will be purchased (see BPAG cost sheet for pricing details), but the bungee cord will be customized to meet the specific dimensions and support

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

The attachment for the Locklace will also be designed in SolidWorks and 3D printed at the UW-Makerspace using the Ultimaker printer [16]. It will be printed using PLA material also on the Bambu Labs printer, and the Locklace will be assembled by fitting snugly and being glued to the inside the printed piece. Both the Locklace and the 3D-printed piece, when assembled, will be sewn onto the foot brace through two holes on either side of the printed component. This design increases the surface area for improved grip, ensures the Locklace is securely positioned, and facilitates ease of use and adjustability on the brace.

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

Once fully assembled, the user will be able to put on the brace by first slipping on the compressive sock, followed by sliding the brace onto their foot, both processes like a regular sock. The bungee cord can then be tightened to the user's preference using the cord lock, and the Velcro straps will be fastened as the final step. The design prioritizes simplicity, speed, and ease of use, as the AFO will be worn daily and taken on and off frequently. This streamlined assembly and adjustment process ensures that the device will be comfortable, user-friendly, and highly functional for everyday use.

Final Prototype

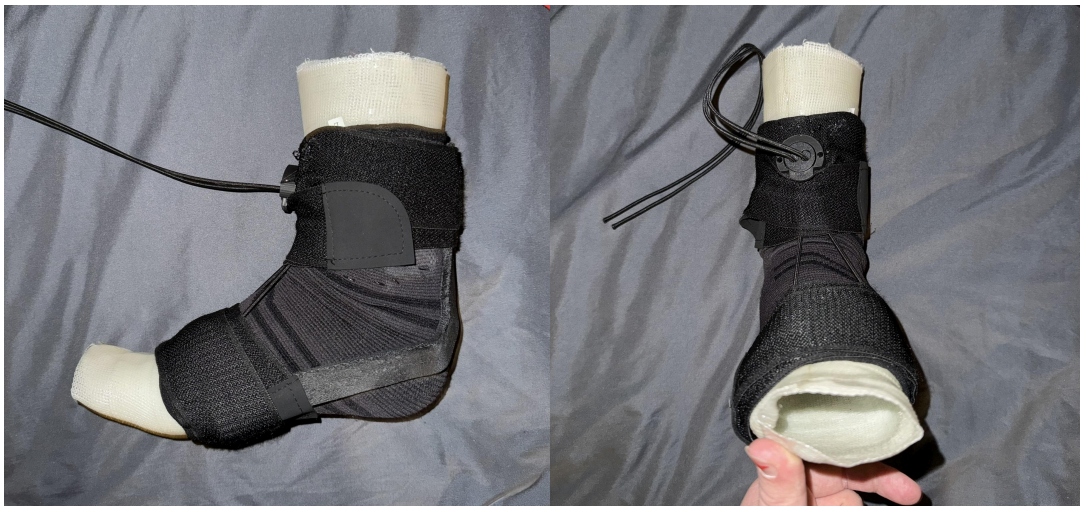


Figure 12: *Bungee Brace*

The final design is the *Bungee Brace* design, which aligns well with the design criteria provided by both our client and our team. The design consists of two main components. The first is a compression sock, featuring gel pads at key pressure points to enhance comfort during use. The second is the foot brace, which incorporates a nylon-reinforced carbon fiber support for added stability. The foot brace also includes a Locklace system on the front, with a bungee cord threaded through it. The bungee cord can be adjusted to provide as much or as little support as the user requires, and any excess cord can be tucked discreetly into the fabric on the side to avoid discomfort and maintain a clean appearance.

This design is intended to be easy to use, recognizing that the brace will be taken on and off frequently. To use it, the patient first puts on the compression sock, followed by the foot brace, and adjusts the bungee cords and nylon straps to achieve the desired level of support. Although the current design does not fit into most shoes, it is ideal for indoor use, allowing the patient to move comfortably around the house without relying on a bulky, uncomfortable AFO (Ankle-Foot Orthosis). The Bungee Brace is built to ideally effectively prevent falls, minimizes foot inversion, and supports dorsiflexion, providing a practical and user-friendly solution for everyday wear.

Testing and Results

Initial Testing

The team conducted initial tests to determine the appropriate bungee cord strength for effective dorsiflexion support. Two types of bungee cords were tested: a thicker cord with a maximum tensile strength of 176 lbs and a thinner cord with a maximum tensile strength of 100

lb. Each cord was secured around the top of the foot, just below the footpad, and tension was increased manually by vertical pulling. The cord displacement needed to achieve a 10° foot angle was measured, along with the participant's natural resting foot angle before attaching the bungee cord. The protocol was repeated over four trials using both types of bungee cords.

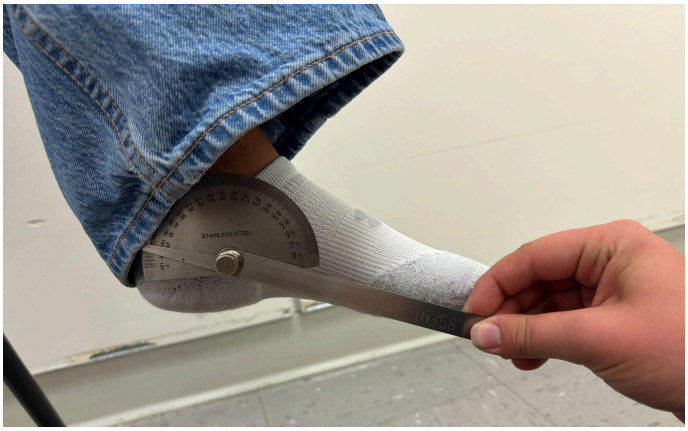


Figure 13: Resting Foot Angle Measurement with Protractor

Figure 14: Cord Displacement Measurement

Results

Overall, the thicker purple bungee cord required more displacement than the thinner black cord. Variability in results between participants suggests that cord displacement may need to be adjusted to meet individual patient needs. Regarding the most suitable bungee cord strength for the final prototype, testing showed that both types of cords were able to achieve a 10° resting foot angle. However, to minimize bulk and reduce the average cord displacement required, the thinner bungee cord with a maximum tensile strength of 100 lbs was deemed the most appropriate choice for the final prototype.

			Black Cord:	Purple Cord:
	Normal resting angle (°)	**Bungee resting angle (°)**	**Cord displacement (cm)**	**Cord displacement (cm)**
Participant 1	-11	10	11.43	7.62
Participant 2	-15	10	11.43	19.05
Participant 3	-20	10	13.97	18.42
Participant 4	-16	10	19.05	10.16

Black Cord: Thin diameter, max tensile load of 100 lb
Purple Cord: Thick diameter, max tensile load of 176 lb

Table 2: Bungee Cord Testing Results

Testing: SimulationXPress Analysis Wizard

The SimulationXpress Analysis Wizard in SolidWorks was utilized to evaluate the structural integrity of the 3D-printed PLA + CF prototype. This simulation aimed to identify

potential failure points and optimize the rigid support design for durability and performance prior to patient use. Fixtures were added to the top and bottom of the part to simulate its interaction with other components of the final design. A 200 N load was applied to the face of the part that aligns with the inside of the foot, reflecting the forces expected during ankle inversion. In addition, PLA reinforced with carbon fiber was selected as the material for analysis. Figure 15 illustrates the SolidWorks model, with red regions indicating areas where the factor of safety (FoS) is below 2. The recommended FoS for plastic components typically ranges between 1.5 and 2 [17], ensuring sufficient safety margins under anticipated loading conditions. The singular red region has a FoS of 1.7 which still falls within the recommended FoS range. Due to inversion at the ankle, the majority of the load is concentrated near the center of the piece, reducing stress around the edge while increasing it near the midpoint. The analysis showed that a 200 N force results in minimal areas of concern, with the majority of the structure maintaining a FoS above the recommended threshold; the likelihood of failure under these conditions appears low.

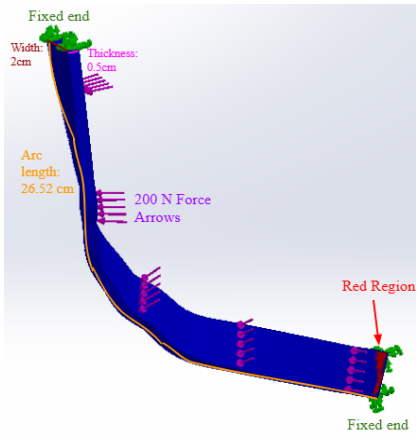


Figure 15: SolidWorks part showing red region where factor of safety is below 2

Testing and Results: Assessing Effects on a Healthy Individual

To assess the brace effect on the gait on a healthy individual, the team utilized Runeasi, a device equipped internal measurement unit (IMU) located on the lower back to measure biomechanical data [18]. Using the acceleration of the body center of gravity, Runeasi is capable of calculating three main metrics:

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

Testing involved three conditions: walking intervals with the brace, without the brace and with the brace minus the rigid support. Since the brace incorporates a customizable component, the rigid support was 3D printed to match the dimensions of a team member, Grace, who participated in the study. Grace walked on a treadmill for three minute intervals with the Runeasi device for each condition, with three trials for each.

Bar graphs in figure x show the relative difference between the left and right foot for each biomechanical data metric averages. Through statistical analysis using the Bayesian method, there was no significant difference between the right and left feet for dynamic instability, ground contact time and impact magnitude across all three testing conditions.

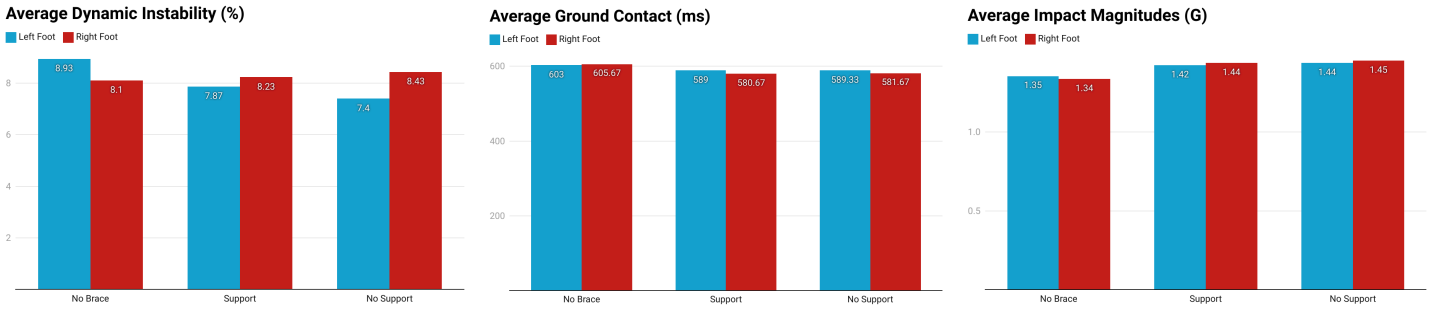


Figure 16: Average Dynamic Instability, Average Ground Contact and Average Impact Magnitude across Testing Conditions

To explore how the brace influenced gait over time, the team graphed the average percent differences between the left and right feet over the duration of each trail. Across dynamic instability, ground contact time and impact magnitudes, there was similar or reduced variability between feet comparing the control (no brace condition) and the trails wearing the brace (blue lines). Runeasi software includes a color-coded scaling system to classify gait performance: excellent, typical, elevated, high, or very high. The majority of Grace's gait data fell between "elevated" and "excellent," with the exception of higher variability in dynamic instability during the no-brace trials. This variability was likely due to initial treadmill acclimation, as dynamic instability improved over the walking interval.

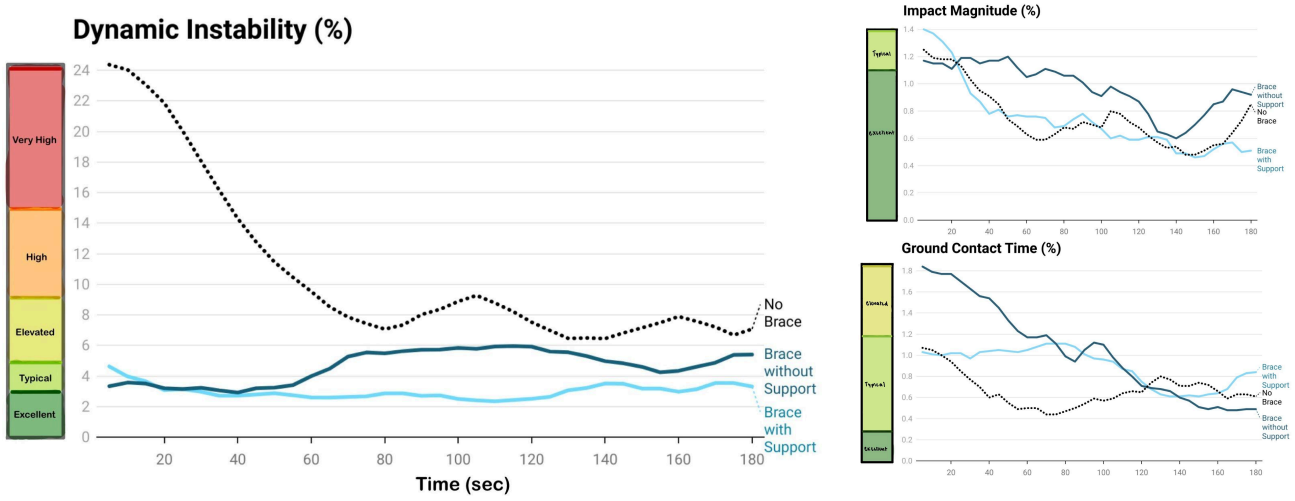


Figure 17: Graph of Dynamic Instability over Time for Three Testing Conditions

Additionally, the dorsiflexion angle was measured before and after testing trials to assess the effectiveness of the bungee cord lock mechanism. Before testing, the bungee cord raised the resting foot angle to 92° as compared to the natural resting foot angle of 130°. Immediately after testing, the measured dorsiflexion angle was 100°. This increase in 8° indicates that the cord lock slightly slipped throughout testing while maintaining the majority of bungee tension.

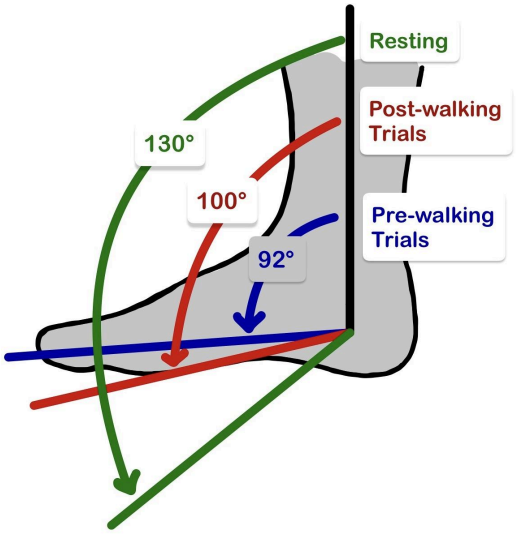


Figure 18: Dorsiflexion Angles: Resting (green), Post-walking trials (red), and Pre-walking trials (blue)

To assess the comfort of the brace, Grace walked for 10 minutes while rating her pain levels on a scale 0 (no pain) - 10 (unbearable pain). Pain levels consistently remained at 1 or below, indicating high brace comfort. The mild discomfort reported was attributed to the tightness of the compression sock rather than the brace itself.

The testing demonstrated that the prototype brace had no adverse impact on gait in a healthy individual and maintained high comfort levels throughout use. Despite slight slippage in the bungee cord lock mechanism, the brace successfully supported dorsiflexion by raising the resting foot angle by 38° compared to the natural resting position. The brace provided consistent stabilization, as shown by reduced gait variability in conditions involving the brace compared to walking without it. The Runeasi system's rating confirmed that most gait metrics were in the "excellent" to "elevated" categories, highlighting the brace's effectiveness in maintaining typical biomechanical performance.

Bayesian Estimation Statistics Test

To assess the significance of our test results, the team ran a Bayesian estimation analysis using the average values of each measured parameter: dynamic instability, ground contact time, impact magnitude, and cadence under three conditions—no brace, brace with support, and brace without support. The left and right feet for each of these conditions were assessed separately. Bayesian estimation is a statistical approach that uses observed data to update prior beliefs about a parameter, resulting in a posterior distribution that reflects the probability of various parameter values. This method provides a more intuitive understanding of uncertainty compared to traditional frequentist approaches [22].

In our analysis, credible intervals were calculated to evaluate the significance of differences between conditions. A credible interval represents the range within which a specified percentage (e.g., 95%) of the posterior distribution lies, providing a probabilistic statement about where the true value of the parameter likely falls. Significance was determined using a decision rule based on these intervals: if the 95% credible interval of the surrogate distribution of the differences in means ($\mu 1 - \mu 2$) does not include zero, the difference between the two conditions is considered significant. This method allowed us to identify whether the brace or support conditions had a measurable impact on the gait parameters assessed. More information about this test and our graphs/results can be found in the Appendix.

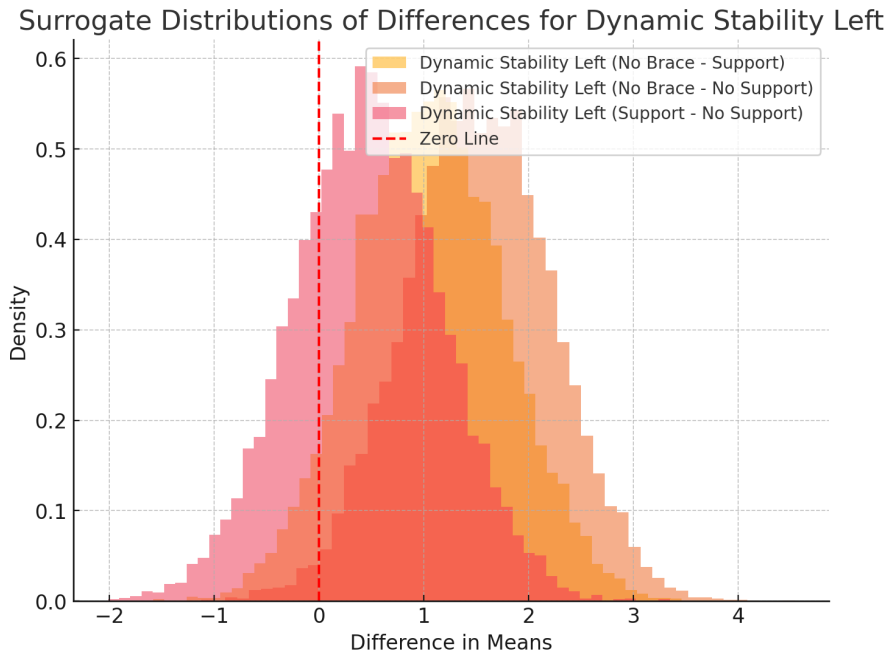


Figure 19: Surrogate distribution of differences for dynamic stability in the left leg.

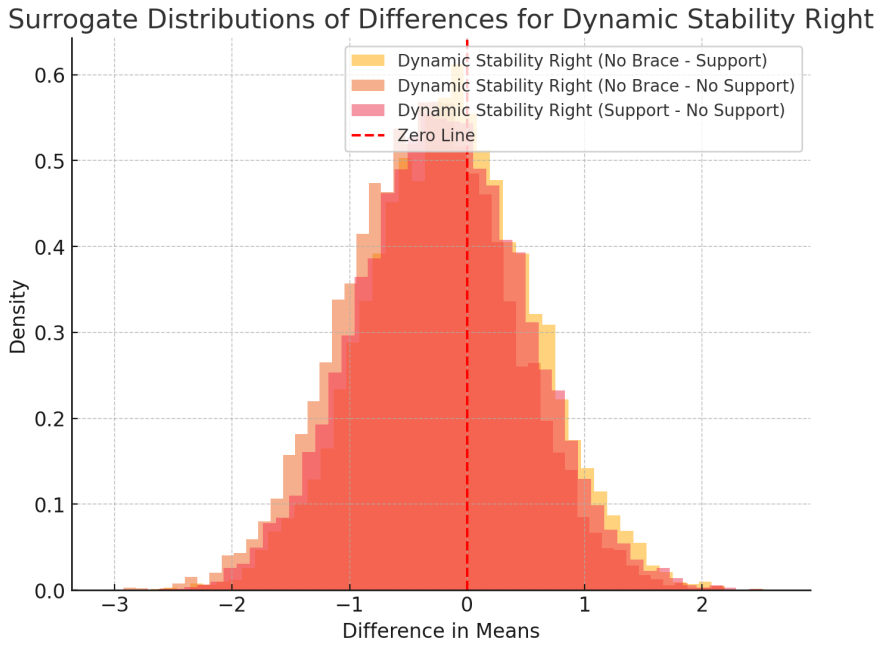


Figure 20: Surrogate distribution of differences for dynamic stability in the right leg.

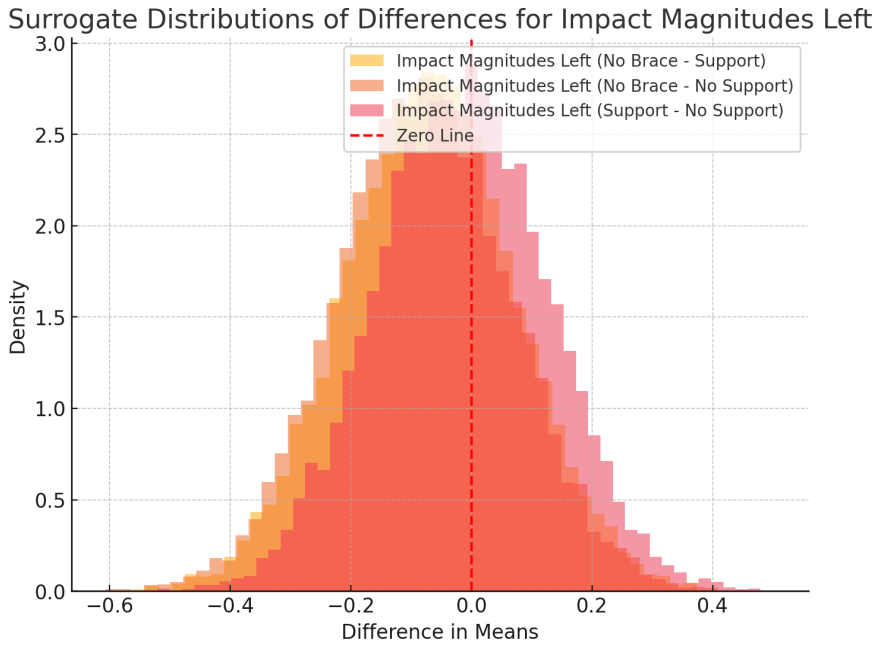


Figure 21: Surrogate distribution of differences for impact magnitudes in the left leg.

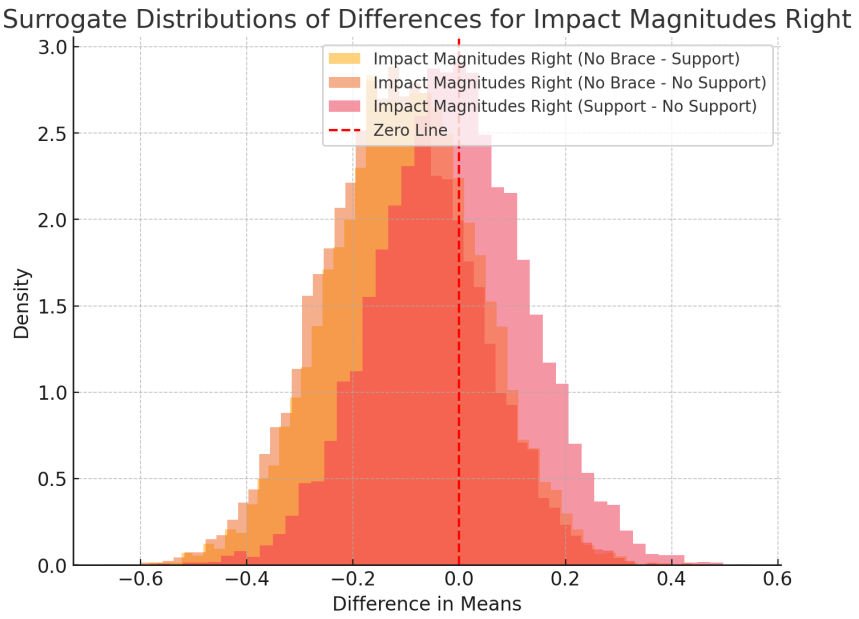


Figure 22: Surrogate distribution of differences for impact magnitudes in the right leg.

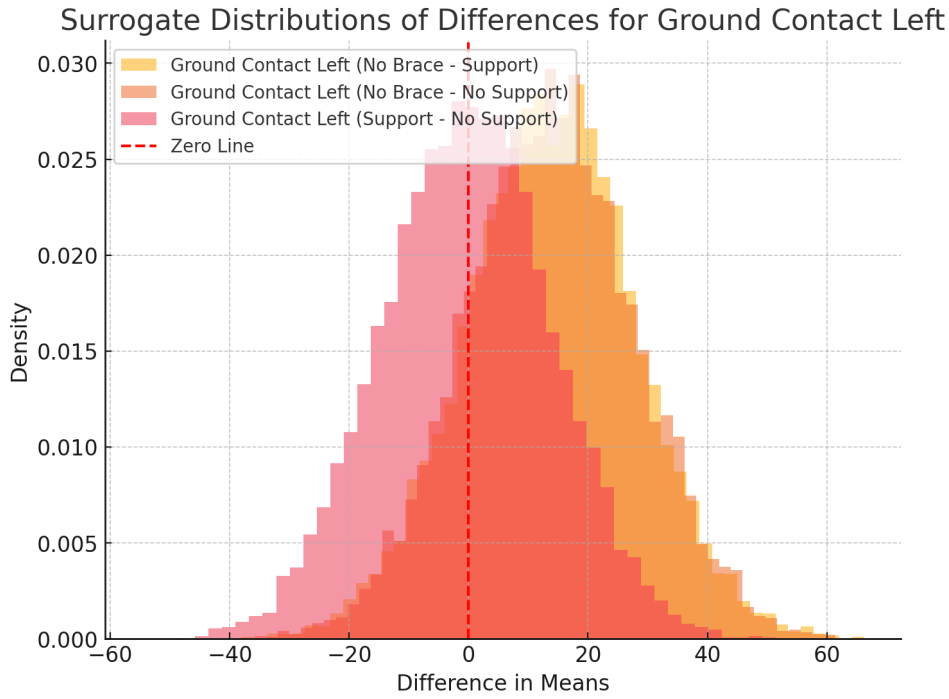


Figure 23: Surrogate distribution of differences for ground contact in the left leg.

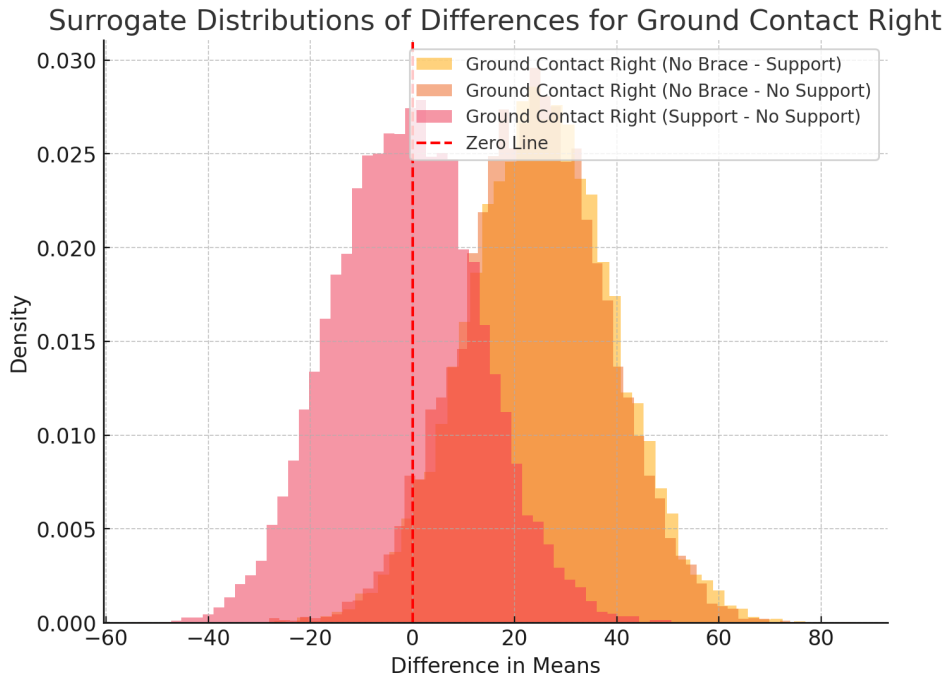


Figure 24: Surrogate distribution of differences for ground contact in the right leg.

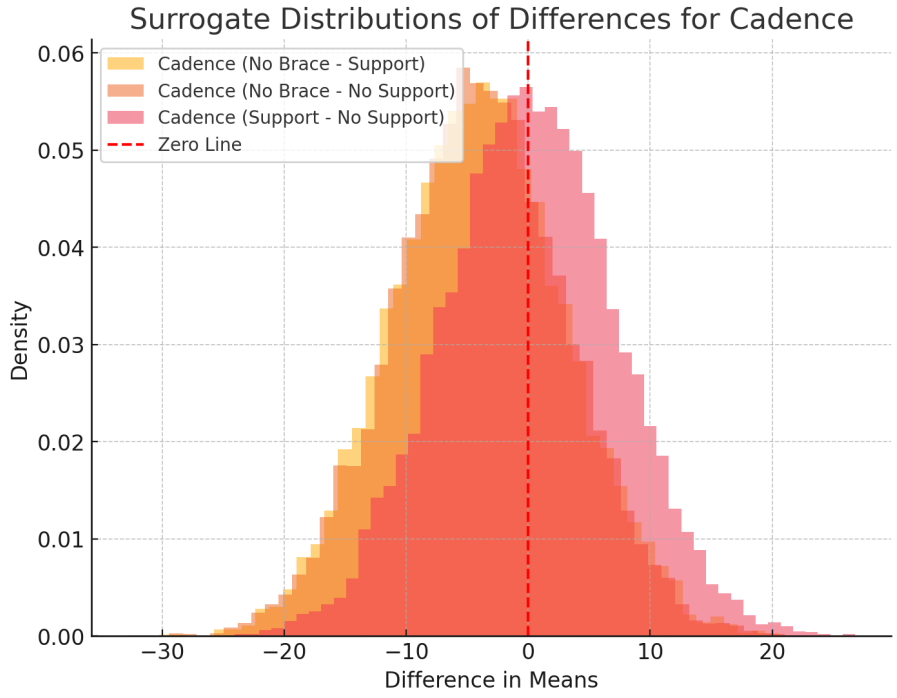


Figure 25: Surrogate distribution of differences for cadence in both legs combined.

Results

For dynamic stability on the left side, a significant difference was observed only between the "No Brace - No Support" conditions, as the credible interval did not include zero. All other comparisons, including "No Brace - Support" and "Support - No Support," were not significant. On the right side, no significant differences were found across all comparisons for dynamic stability.

Impact magnitudes, ground contact times, and cadence showed no significant differences across all conditions for both the left and right sides.

These findings align with our hypothesis that the brace would not substantially alter gait mechanics in Grace, who does not have foot drop. The results confirm that the brace did not negatively affect her dynamic stability, impact magnitudes, or overall gait patterns. This supports the expectation that the brace would neither hinder nor significantly enhance gait parameters in individuals without gait impairments.

Discussion

Ethical and Safety Concerns

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

It is essential to recognize that not everyone has equal access to orthotics. Socioeconomic differences significantly influence the availability of healthcare resources, limiting many individuals' access to necessary orthotics. Custom orthotics, in particular, require a high level of expertise and resources that are not readily available.

The use of advanced materials, such as carbon fiber, enhances the durability and performance of orthotic devices, however, these advancements are greatly more expensive. While the durability of the device may improve, the increased cost raises concerns about affordability. Consequently, advancing technology poses questions about affordability and accessibility amongst a diverse population.

Considering safety factors, the device must be able to withstand the cyclic loading during walking and provide proper anatomical alignment. Alignment must be maintained to avoid excessive tension, compression, or shear forces on joints, bones, and muscles to ensure long-term musculoskeletal health. The device’s use of nylon, polyester, and latex poses allergy concerns that must be considered. There must be a protective layer between the user and the carbon fiber support in order to maximize comfort and to protect the user if the support were to fail. In case of emergency, there must be a protocol for easy and quick removal. Lastly, while the materials

selected for the final prototype do not possess properties that significantly minimize environmental impacts, the device is reusable and does not require mass production.

Testing Limitations

Debbie Eggleston and the patient live in Michigan, so in-person testing is a challenge to conduct. The group prepared alternate testing plans due to travel not being logical for our client. The gait cycle testing using Runeasi was done on a patient without FSHD, so the results cannot be directly correlated to an FSHD population. However, it was concluded that the final prototype did not hinder gait patterns for a healthy individual which is what the team expected.

Conclusions

The patient, a teenager in high school with FSHD, needs a right ankle foot orthosis. Current devices are not aesthetically appealing and the patient does not want to draw attention from unwanted peers. Balancing this with the functionality of the device is an important aspect that must be considered. The final prototype, consisting of a carbon fiber reinforced support, neoprene straps, and a bungee lock lace mechanism, will support ankle dorsiflexion, and ankle inversion. It will also be discreet by looking similar to an athletic brace, limiting questions regarding the device's function.

Future Work

The team will need to order an ankle brace to replace the neoprene straps and compression sleeve for a slimmer and more cohesive appearance. The support should be fabricated entirely using carbon fiber, and the team will need to look into custom molding this to uniquely fit to each individual accurately. Material testing will need to be done on the carbon fiber support, and the team will determine the minimal amount of material needed while still optimizing support of the ankle. Then, the team will need to assemble the full prototype including the ankle brace, carbon fiber support, the bungee cord mechanism with the bungee cords flush to the ankle brace, and gel padding attached to pressure points. In addition, the patient currently has a foot insert so further work will be done to determine if there is a way to incorporate this into the design.

Once the full prototype is fabricated, the patient will travel to Madison for Runeasi testing. The team will conduct relatively the same protocol as done on the healthy individual, except the team will also do a trial with the full prototype inside a shoe. The current design may not be able to fit inside a shoe, so this is an additional challenge the team will have to find a solution to in the future, although the current option still provides a less bulky and more comfortable support for the patient to wear around the house. This will help the team gain more concrete results to whether or not the device improves gait patterns, mediolateral stability, and dorsiflexion for an individual with FSHD.

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Appendix

Product Design Specifications

Function/Problem Statement:

Ankle foot orthoses (AFOs) are engineered to provide dorsiflexion support during the swing phase of walking. This device is mainly used for the treatment of muscular dystrophy and this project in particular is focused on young individuals diagnosed with Facioscapulohumeral Dystrophy (FSHD), the most common kind of muscular dystrophy. The team aims to design a brace for the patient to aid in ankle dorsiflexion for safer walking while being easily concealable and flexible enough to allow for a functional ankle range of motion. The key objectives of this device include positioning the ankle in adequate dorsiflexion, maintaining a narrow, thin, and discreet design, and ensuring sufficient flexibility to minimize any restriction of movement.

Client requirements:

The client requests that the AFO (Ankle-Foot Orthosis) supports dorsiflexion while remaining flexible enough for the patient to carry out their daily activities and live a typical teenage life. Additionally, the client prefers the AFO to be discreet, fitting inside a shoe and minimizing visibility. The AFO should also enable heel strike, prevent foot drop, and reduce the risk of falls for the patient.

Recommended additional requirements:

The AFO will be designed to accommodate teenagers as there are currently no clinical trials available for young individuals.

Design requirements:

1. Physical and Operational Characteristics
    a. Performance requirements
        i. The AFO must be designed to be discrete and involve minimal material while providing strong support for ankle dorsiflexion and resist ankle inversion to prevent irregular gait [1]. It should mimic normal gait, allowing for a 20° range of ankle dorsiflexion to facilitate foot clearance [2], with moment-angle characteristics maintained within a torque range of ±30 Nm. Additionally, the

design must resist torsional forces that could lead to misalignment of the ankle or foot during typical activities [3].

ii. The design must withstand the maximum bodyweight forces exerted by a teen. The average weight of a 15-year-old teenager in the United States is 128 lb [4] and during walking, forces exerted on the AFO are estimated to be three times the body weight [5]. Therefore, the AFO must be able to withstand a minimum of 570 N.

iii. In addition to ensuring durability and structural integrity, the design must possess sufficient flexibility to allow for active concentric ankle movement, enabling the user to perform daily activities effectively, such as squatting and ascending/descending stairs.

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

b. Safety

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

ii. In a manufactured and marketed design, the chosen material should ideally be non-toxic and hypoallergenic to minimize the risk of skin irritation or allergic reactions. The surface of the AFO must be smooth, with no sharp or ridged edges, to prevent any risk of surface wounds.

iii. Adjustable components of the design must remain secure under strong impacts without restricting blood flow.

iv. In cases of emergency, the AFO must have mechanisms for quick and easy removal.

c. Accuracy and Reliability

i. The AFO design must maintain structural integrity with repetitive use while consistently providing support to ensure proper anatomical alignment of the ankle and foot. Carbon fiber AFOs typically fail at the mid-shank region of the calf

support under forces of 1970 N [6]. To limit the possibility of injury, the calf support should include a padding layer to protect the user in case of material failure. Additionally, the soft padding material must be easily replaceable after extended use to prevent user discomfort from padding degradation.

d. Shelf Life
    i. Custom orthotics are designed for immediate and continuous use, as they are tailored to the patient's specific measurements and support needs. If left unused for an extended period, changes in the patient's measurement or support requirements could change and cause the AFO to become ineffective. Therefore, the shelf-life should be limited, and the AFO should be regularly assessed to ensure it continues to meet the patient's evolving needs.
e. Life in Service
    i. The lifespan of an AFO depends on several factors, including its materials and how frequently and actively it is used. Generally, it should last around 5 years [7].
    ii. AFOs made from semi-rigid materials like graphite or carbon fiber may last longer than softer ones [8].
    iii. An orthotist should review the AFO at least once a year to ensure it continues to meet the user's needs and to check for any signs of deterioration [9].
f. Operating Environment
    i. This AFO is designed for day-to-day use and must withstand transportation and frequent use. It will mainly be used during the school day and also for horseback riding. The bulkiness of the device should be considered so that it can still be inserted into horseback riding shoes.
    ii. It will be used both indoors and outdoors, exposed to varying temperatures, humidity, dirt, water, and sweat. The AFO should be cleaned with mild soap and water at least once a week to prevent bacterial build-up [10].
g. Ergonomics
    i. The AFO must be capable of withstanding the maximum downward force exerted by the user's weight while distributing this force in a way that avoids excessive pressure points.

ii. Current AFOs commonly weigh between 0.3 and 3.4 kg depending on the material and bulkiness of the device. The AFO should be as lightweight as possible while maintaining proper function to ensure normal gait patterns and reduce fatigue [11].
iii. Padding will be provided around sensitive areas, such as the Achilles tendon, ankle, and foot base, as a gel cushion to prevent discomfort and skin irritation.
iv. The orthosis should fit comfortably within a standard shoe, without requiring the user to wear specialized footwear.

h. Size
   i. The size of the AFO will be tailored to the patient's dimensions. Measurements will be taken, and the size will closely match their leg, with minor adjustments for padding or other anti-chafing mechanisms in the design [12].
   ii. Length of the leg (bottom of foot to directly below kneecap) 45.5cm
   iii. Diameter Directly Below the kneecap (Top of the leg) 31.5cm
   iv. The diameter of the Thickest part of the calf (Middle-leg) 31.5cm
   v. Diameter Where the Achilles meets the calf (bottom leg) 20.5cm
   vi. The diameter of the thinnest part of the ankle (where you can feel the Achilles) is 20cm
   vii. Diameter Across the middle of the ankle, through the joint 30cm
   viii. Diameter just in front of the ankle joint (low ankle) 24.5cm
   ix. Arch Measurements - bony prominence to floor 4.5cm, and 6.25cm in length
   x. Length of the foot 24-24.5cm
   xi. Width of the foot (where the metatarsals meet the phalanges) 8.25 cm
   xii. Width of the foot (midsole area) 8cm
   xiii. Width of the foot (at the heel) 5.5cm
   xiv. Typically, an AFO’s thickness will be 3.175 mm to adequately support the foot [13]. The device should deform only slightly during use.
   xv. Additionally, the AFO will be small enough to fit comfortably inside a shoe

i. Weight

i. The orthoses will be light enough to allow a full range of motion without hindrance. The weight will not impair the patient's walking gait or velocity. It should be minimized as much as possible, ideally weighing less than 1 kg [14].

j. Materials

i. AFO durability is highly dependent on the material used. A carbon-fiber AFO can support up to 1,000 N, while a thermoplastic AFO can support up to 150 N before deforming [15].

ii. Carbon fiber is increasingly popular due to its superior weight and flexibility compared to plastic and steel.

iii. The foot sleeve of the brace as well as the bungee cord will be composed of a blend of nylon, polyester, and latex. These materials were chosen for their specific properties that enhance both functionality and comfort.[16]

1. The sleeve's breathability will absorb sweat and keep the foot dry, providing comfort during extended use. The material will also be tight and strong, ensuring that the sleeve stays securely in place without sliding. [17]
2. The fabric is smooth and soft, adding comfort, while its graduated compression promotes circulation, providing support and pain relief to the user [17]
    a. Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight [17].
    b. Polyester, known for its durability and strength, is ideal as it retains its shape and resists wrinkles, shrinking, and environmental elements like water and wind, which is crucial since the device will frequently be exposed to outdoor conditions [18].
    c. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining overall strength [19].

iv. 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[20].

v. 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 [20].

k. Aesthetics, Appearance, and Finish

i. The AFO will fit underneath the shoe or be worn around the house without a shoe and will be black to mimic the look of an athletic brace and avoid drawing attention to the public eye.

ii. The brace will have a smooth finish and a slim appearance, making it as inconspicuous as possible while still providing the necessary support.

2. Production Characteristics

a. Quantity

i. This project consists of making one right-leg AFO. However, considering mass production, the quantity would meet market demands among teens needing right-leg and/or left-leg AFOs.

b. Target Product Cost

i. The initial budget for this project is $300; however, the budget is flexible. The client is willing to increase the budget if the design is functional and will be used by the client.

ii. The initial prototype ended up being $189.02 in total costs. $8.71 was covered by BME department, so our total spent through BME funding was $180.30.

3. Miscellaneous

a. Standards and Specifications

i. The device will be classified as a Class 1 Medical Device. The device does require pre-market approval from the FDA [17].

ii. The device will need to fall under Code of Federal Regulations Title 21, Section 890.3475. [18]
    1. This defines a limb orthosis as a medical device worn on either upper or lower limbs to support, correct, prevent deformities, or to align body structures to improve bodily function. Examples of limb orthoses are as follows: a whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.
iii. ISO Standard 8549-3:2020
    1. Defines orthosis as an externally applied device utilized to compensate for impairments in the structure and function of the neuromuscular and skeletal system; ankle-foot orthosis is defined as an orthosis that encompasses the ankle joint and the whole or part of the foot [19].
iv. ISO Standard 8551:2020
    1. Covers functional deficiencies in prosthetics and orthotics. The standard provides guidelines for the person to be treated with an orthosis, the clinical objectives of treatment, and the functional requirements of the orthosis [20].
v. When testing the AFO, the team must abide by ISO Standard 2267:2016.
    1. This standard outlines a specific testing procedure for ankle-foot devices and foot units used in external lower-limb prostheses. This standard tests how the prosthetic device performs under repeated, cyclical loading conditions that simulate the forces and motions experienced during the complete stance phase of walking—from the moment the heel strikes the ground to the moment the toe leaves the ground (toe-off). The testing will provide performance characteristics of the prosthetic device such as its strength, durability, and service life, ensuring the prosthesis meets quality and safety standards [21].

b. Customer [22]
    i. The device is intended for everyday use by a 16-year-old teenager, who has been diagnosed with Facioscapulohumeral Dystrophy. While the orthosis will be custom-fitted to the patient's ankle, the primary target audience includes all young

individuals diagnosed with Facioscapulohumeral Dystrophy or similar muscular dystrophies that require an ankle orthosis.

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

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

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

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

c. Patient-related concerns

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

ii. The device must not interfere with daily activities or draw attention to itself or the patient.

iii. The device must be discreet to prevent drawing unwanted attention and reduce the risk of bullying at school and in other public settings.

d. Additional optional patient requests

i. The device should be designed to fit comfortably within the patient’s horse riding boot.

ii. The device should resemble a standard athletic brace to avoid drawing attention in public settings.

e. Competition

When constructing AFOs, the Three-Point Force system is essential for creating an orthosis that stabilizes a joint or segment to reduce angular rotation. The force is applied either medio-laterally or anteroposteriorly, with counter forces applied above and below the primary force, all summing to zero. The longer the lever of the orthosis, the farther apart the points of

force are, resulting in greater correction. This technique can also help reduce pressure and discomfort when wearing the orthosis [23].

i. Flexible AFO
    1. Provides flexibility around the ankle area.
    2. Ideal for individuals with increased uncontrolled movement in the ankle joint but good mediolateral stability.
    3. Promotes a natural gait pattern, making it easier to rise from chairs, navigate stairs, and for children to play on the floor and move freely.
    4. Effective for those with drop foot, as it corrects the foot to a plantigrade position while allowing movement through midstance, resulting in a more natural gait and enabling the foot to clear the ground.
    5. Drawback: It reduces the surface area around the ankle by cutting away part of the device, which diminishes the effectiveness of the Three-Point Pressure system.

ii. Rigid AFO
    1. A completely rigid orthotic device that restricts all movement.
    2. Typically used in more severe cases or conditions with mediolateral instability, where the Three-Point Pressure system can function optimally.

iii. Ground Reaction AFO
    1. Similar to a rigid AFO but includes an anterior shell that distributes the load to the front of the shin, extending the knee and maintaining the ankle in a plantigrade position.

iv. Jointed AFO
    1. Features a hinge at the ankle joint, allowing for motion while still providing correction through the Three-Point Pressure system.
    2. Optimizes gait patterns and allows for a full range of motion.
    3. Drawbacks include being bulkier, potentially noisy, and prone to parts breaking more easily [23].

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Bayesian Estimation Statistics

Average values from raw data:

Condition	Dynamic Stability Left	Dynamic Stability Right	Impact Magnitudes Left	Impact Magnitudes Right	Ground Contact Left	Ground Contact Right	Cadence
No Brace	8.93	8.10	1.353	1.336	603.00	605.67	111.67

Support	7.867	8.233	1.423	1.436	589.00	580.67	115.67
No Support	7.40	8.433	1.436	1.450	589.33	581.67	115.67

Bayesian posterior distributions:

Bayes' theorem:

$P(\theta \mid D) \propto P(D \mid \theta) \cdot P(\theta)$

Prior Distribution ($P(\theta)$): Represents initial beliefs about the parameter (ex mean Dynamic Stability).

Likelihood ($P(D \mid \theta)$): Describes how likely the observed data is, given the parameter.

Posterior Distribution ($P(\theta \mid D)$): Combines the prior and the likelihood to give the updated belief about the parameter after observing the data.

Posterior mean:

$$\mu_{\text{posterior}} = \frac{\mu_{\text{prior}}/\sigma^2_{\text{prior}} + \sum \text{data}/\sigma^2_{\text{likelihood}}}{1/\sigma^2_{\text{prior}} + n/\sigma^2_{\text{likelihood}}}$$

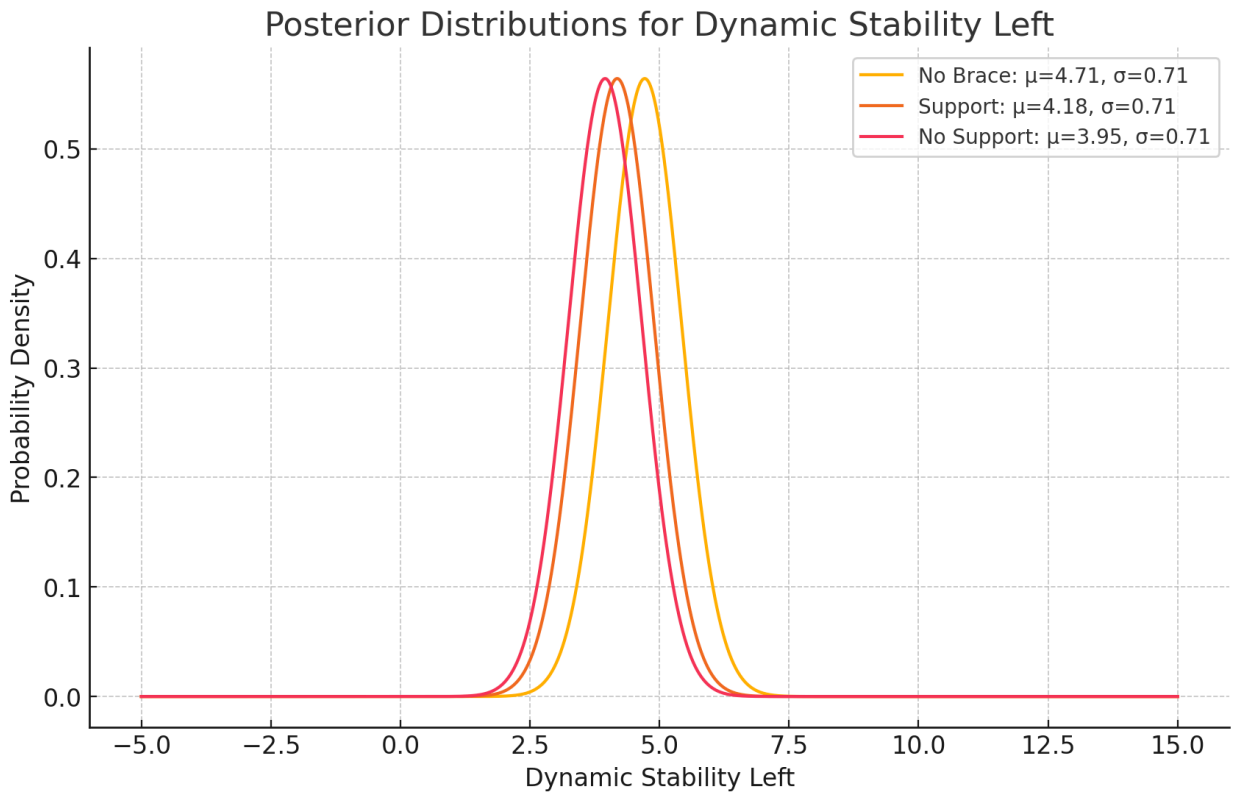
Posterior variance:

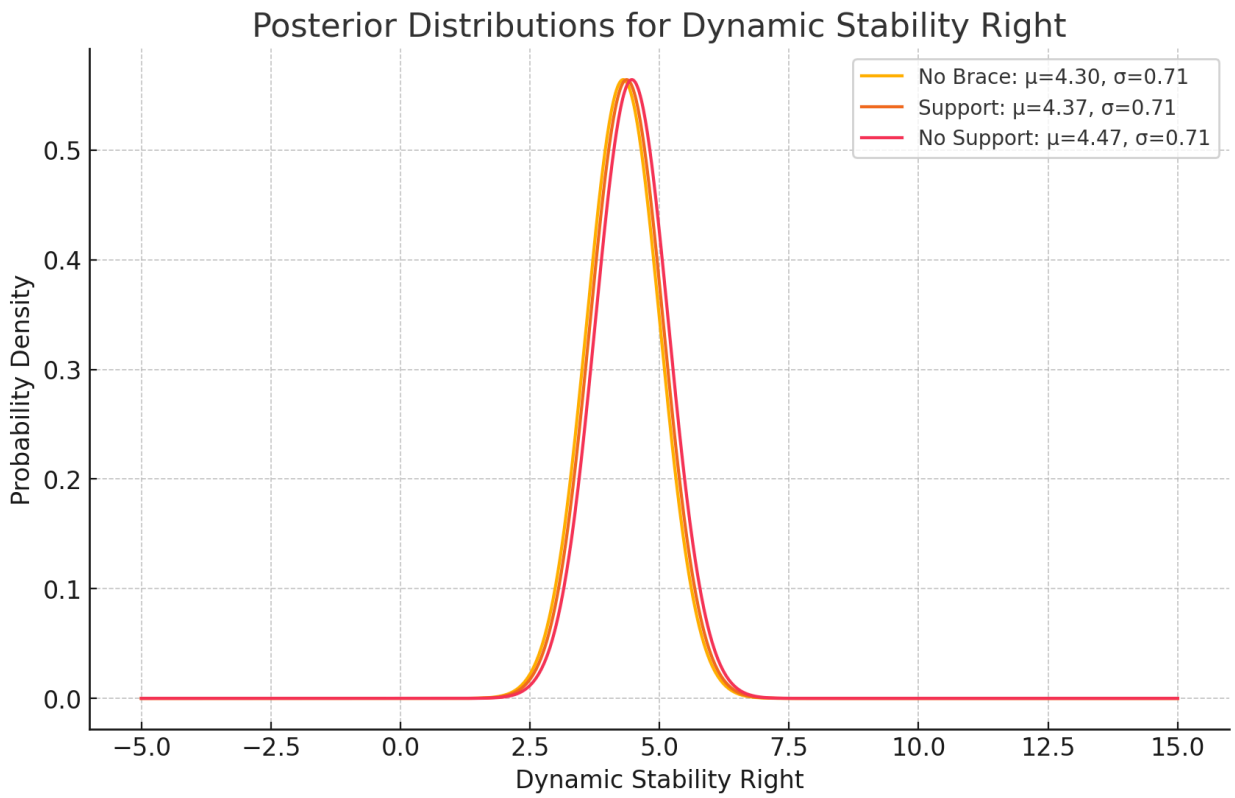
$$\sigma^2_{\text{posterior}} = \frac{1}{1/\sigma^2_{\text{prior}} + n/\sigma^2_{\text{likelihood}}}$$

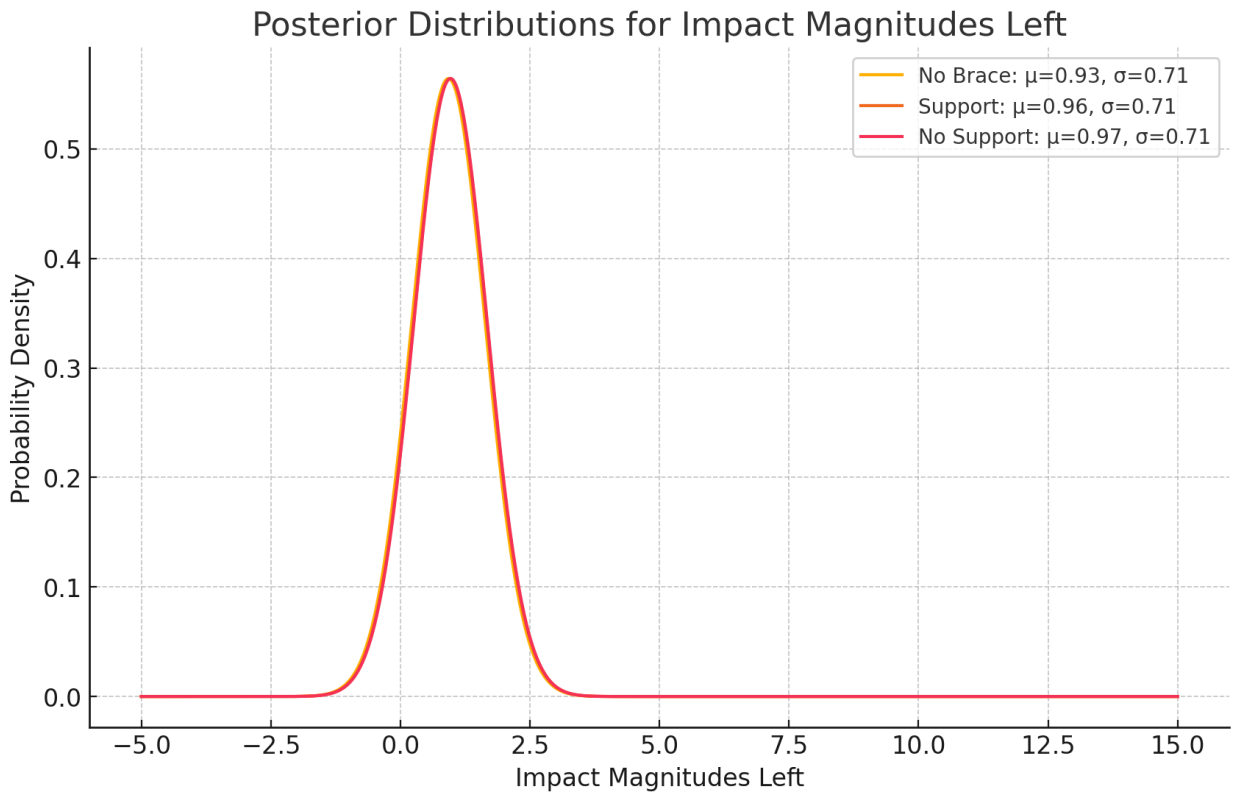
Posterior standard deviation:

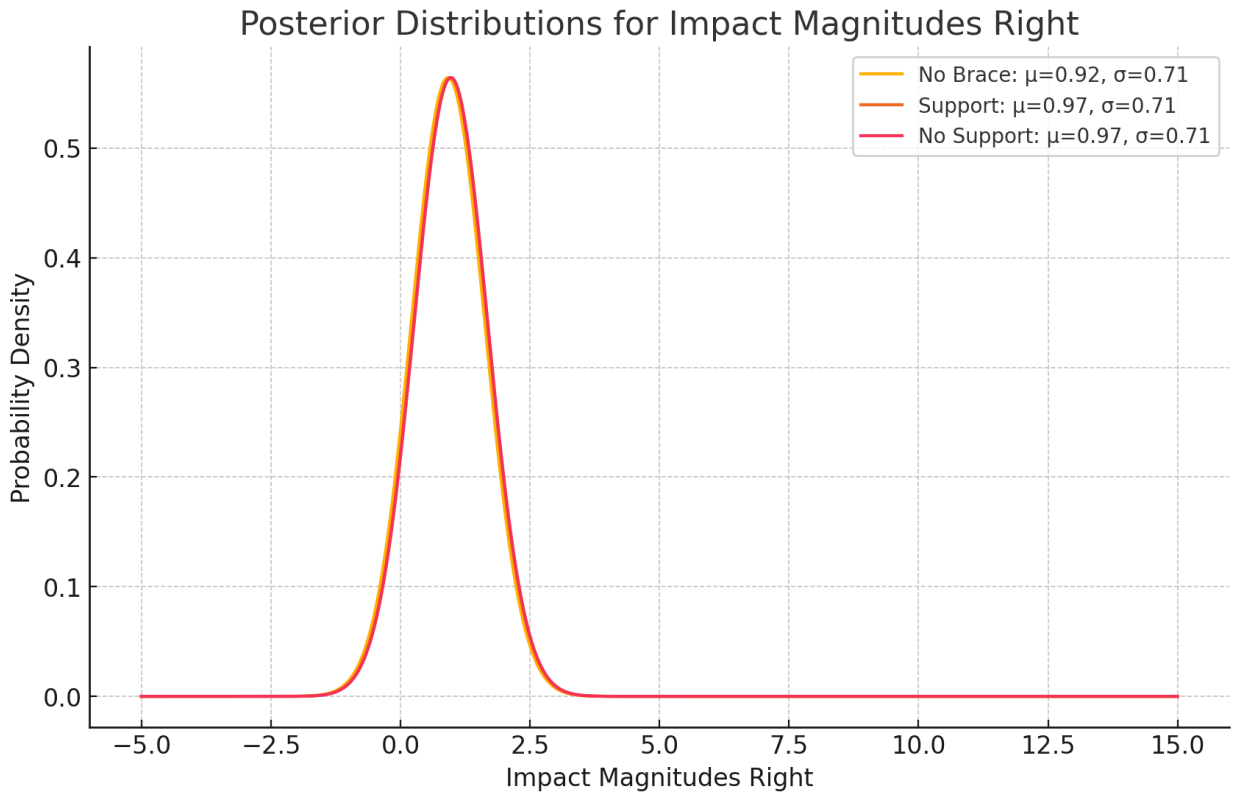
$$\sigma_{\text{posterior}} = \sqrt{\sigma^2_{\text{posterior}}}$$

Prior Mean (μprior): 0.5 (represents an initial neutral belief).
Prior Standard Deviation (σprior): 1 (indicates uncertainty in our initial belief).
Likelihood Standard Deviation (σlikelihood): 1 (assumes observed averages are not highly variable)


Posterior Distributions for Dynamic Stability Left
No Brace: μ=4.71, σ=0.71
Support: μ=4.18, σ=0.71
No Support: μ=3.95, σ=0.71
Probability Density
0.0
0.1
0.2
0.3
0.4
0.5
−5.0
−2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
Dynamic Stability Left

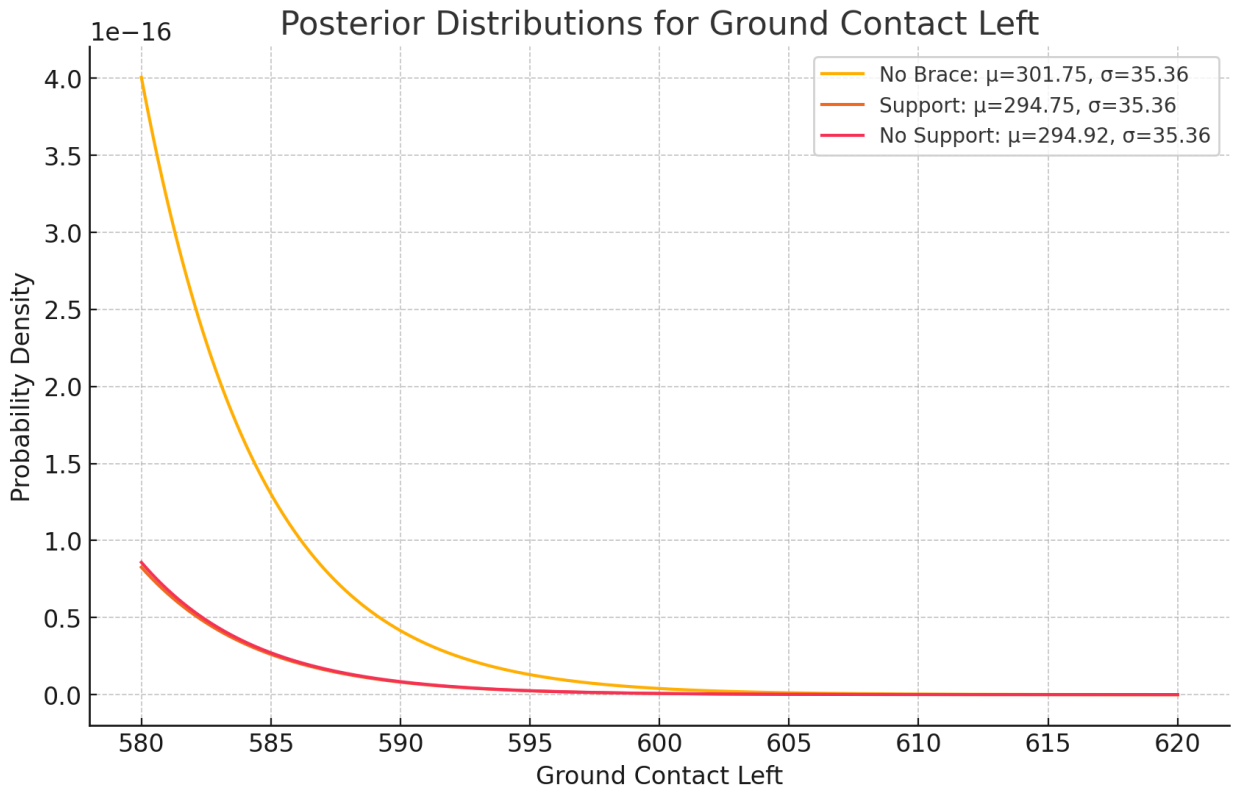

Posterior Distributions for Dynamic Stability Right
No Brace: μ=4.30, σ=0.71
Support: μ=4.37, σ=0.71
No Support: μ=4.47, σ=0.71
Probability Density
0.0
0.1
0.2
0.3
0.4
0.5
−5.0
−2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
Dynamic Stability Right

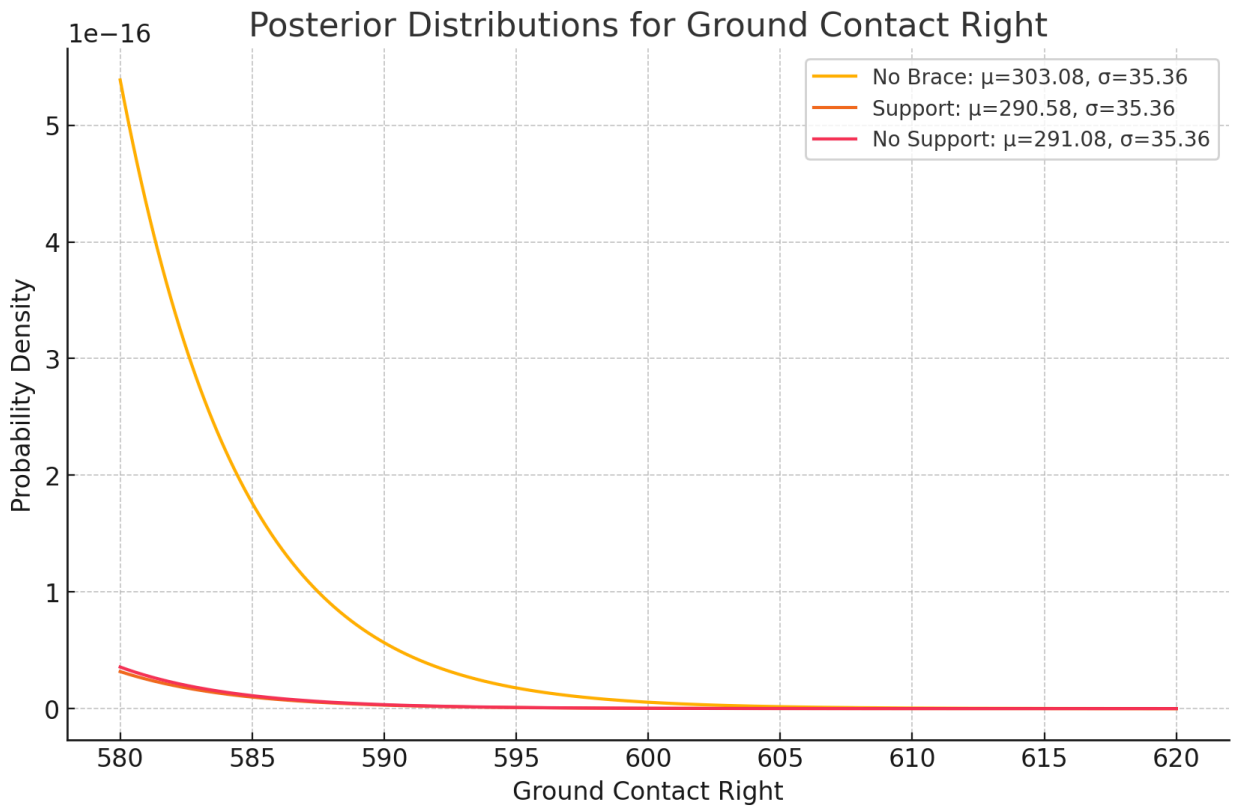

Posterior Distributions for Impact Magnitudes Left
No Brace: μ=0.93, σ=0.71
Support: μ=0.96, σ=0.71
No Support: μ=0.97, σ=0.71
Probability Density
0.0
0.1
0.2
0.3
0.4
0.5
−5.0
−2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
Impact Magnitudes Left

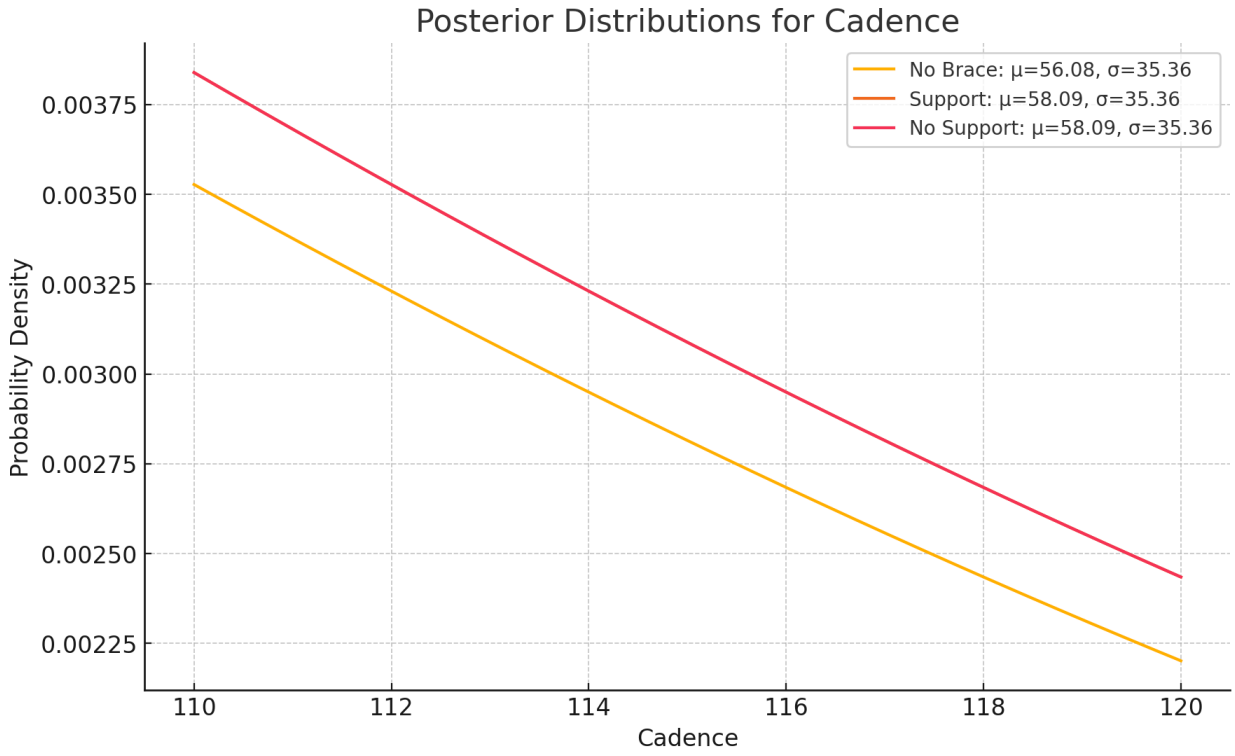

Posterior Distributions for Impact Magnitudes Right
No Brace: μ=0.92, σ=0.71
Support: μ=0.97, σ=0.71
No Support: μ=0.97, σ=0.71
Probability Density
0.0
0.1
0.2
0.3
0.4
0.5
−5.0
−2.5
0.0
2.5
5.0
7.5
10.0
12.5
15.0
Impact Magnitudes Right

Adjustments for ground contact and cadence:

*increased the prior and likelihood standard deviation to 50 to better reflect the scale of the observed values and account for variability in larger values.







Conclusions:

Dynamic Stability

- **Left and Right Foot**:
    - The posterior distributions for Dynamic Stability across all three conditions (No Brace, Support, No Support) have nearly identical means and significant overlap.
    - This indicates that the conditions provide comparable stability, with no condition clearly outperforming the others.

Conclusion: There is no significant difference in Dynamic Stability across the three conditions for both feet.

Impact Magnitudes

- **Left and Right Foot**:
    - All three conditions have very close posterior distributions with significant overlap.
    - Differences in means are minimal, suggesting little to no practical difference in impact magnitudes among the conditions.

Conclusion: None of the conditions clearly outperforms the others in reducing impact magnitudes.

Ground Contact

- **Left and Right Foot**:
    - No Brace consistently shows higher ground contact times, indicating longer foot-ground interaction.
    - Support and No Support have similar, shorter ground contact times, with overlapping distributions.

Conclusion: No Brace promotes longer ground contact, while support and no support favor quicker ground interaction.

Cadence

- No Brace has a slightly lower cadence compared to Support and No Support, which show almost identical posterior distributions.
- Higher cadence in Support and No Support may reflect a faster or more efficient gait pattern.

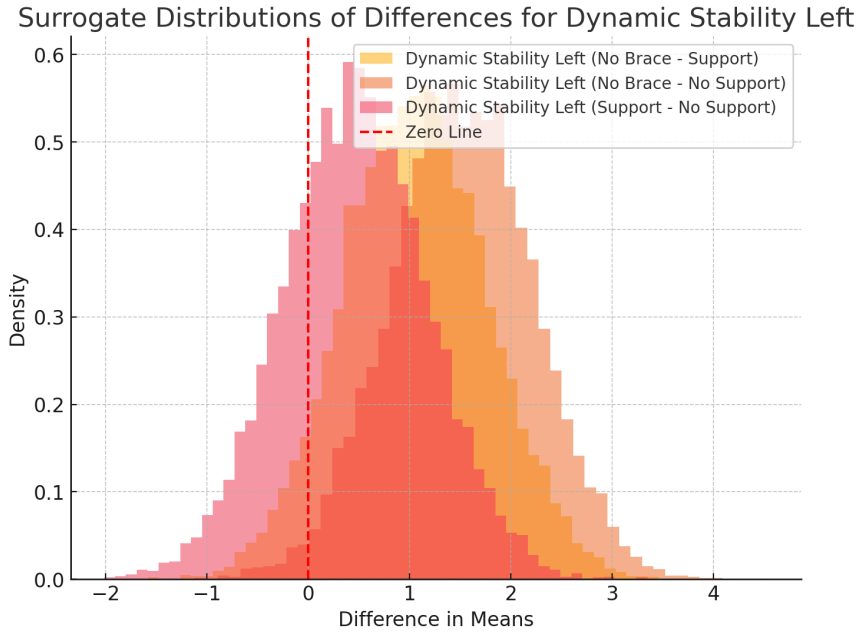
Conclusion: Support and No Support promote higher cadence, while No Brace results in slightly slower steps.

Updated Overall Conclusion

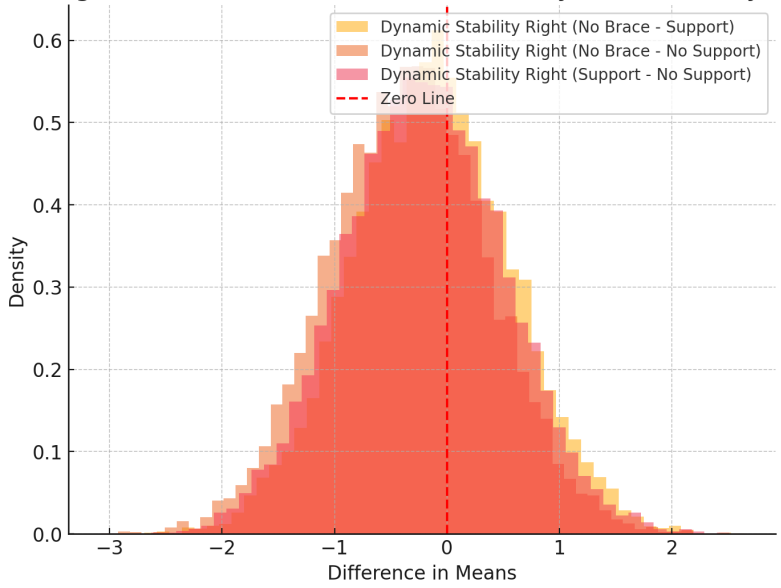
1. **No Brace**:
    - Promotes longer Ground Contact but results in slightly lower Cadence.
    - Comparable to other conditions in Dynamic Stability and Impact Magnitudes.
2. **Support**:
    - Promotes higher Cadence and shorter Ground Contact.
    - Comparable to others in Dynamic Stability and Impact Magnitudes.
3. **No Support**:
    - Performs similarly to Support in all metrics, with no significant differences.

Since Grace does not have foot drop, these results align with our hypothesis, as the brace did not negatively affect her dynamic stability or impact magnitude. When considering ground contact and cadence, the results demonstrate significant improvement with the brace compared to without it, as the brace facilitates shorter ground contact times and promotes a faster, more efficient gait pattern. Additionally, no significant differences in performance were observed between the support and no support conditions.

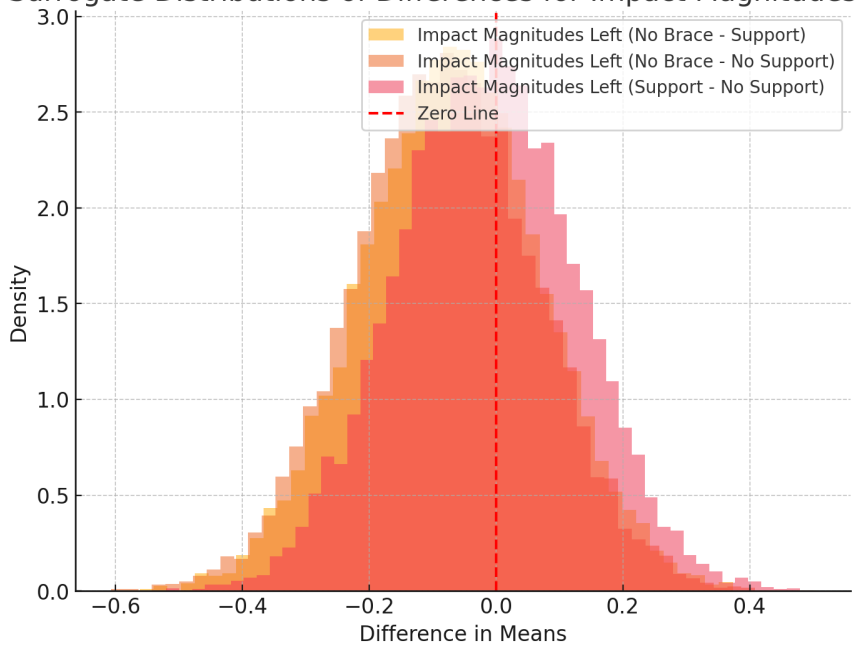
Testing significance:

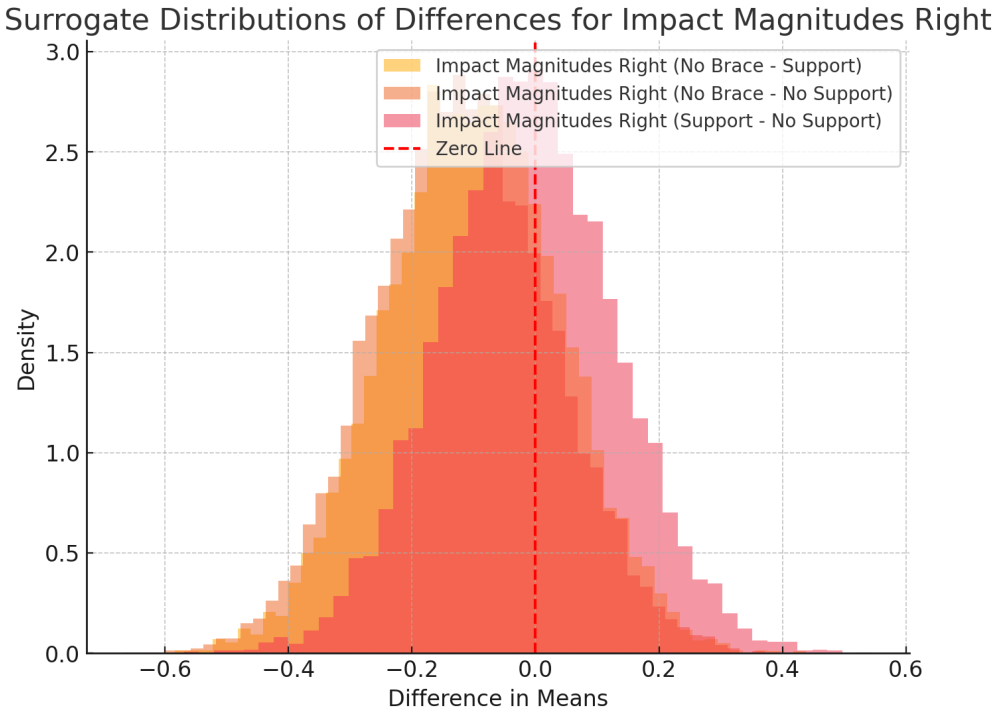


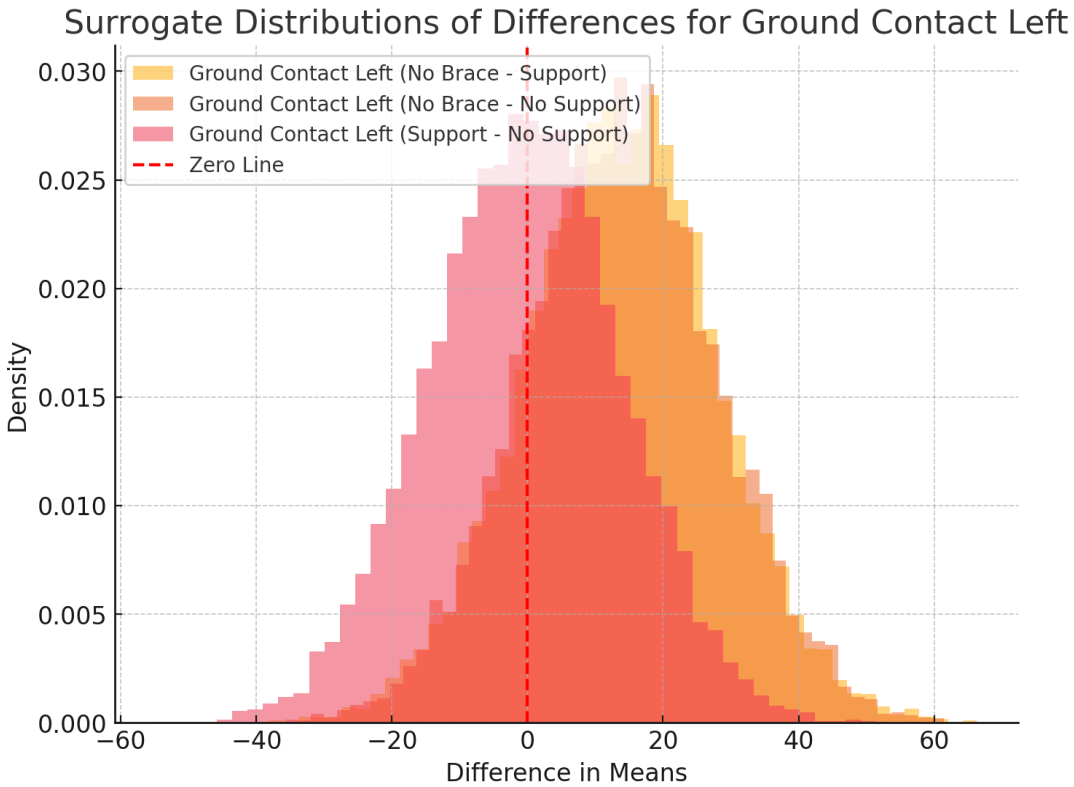
Surrogate Distributions of Differences for Dynamic Stability Right

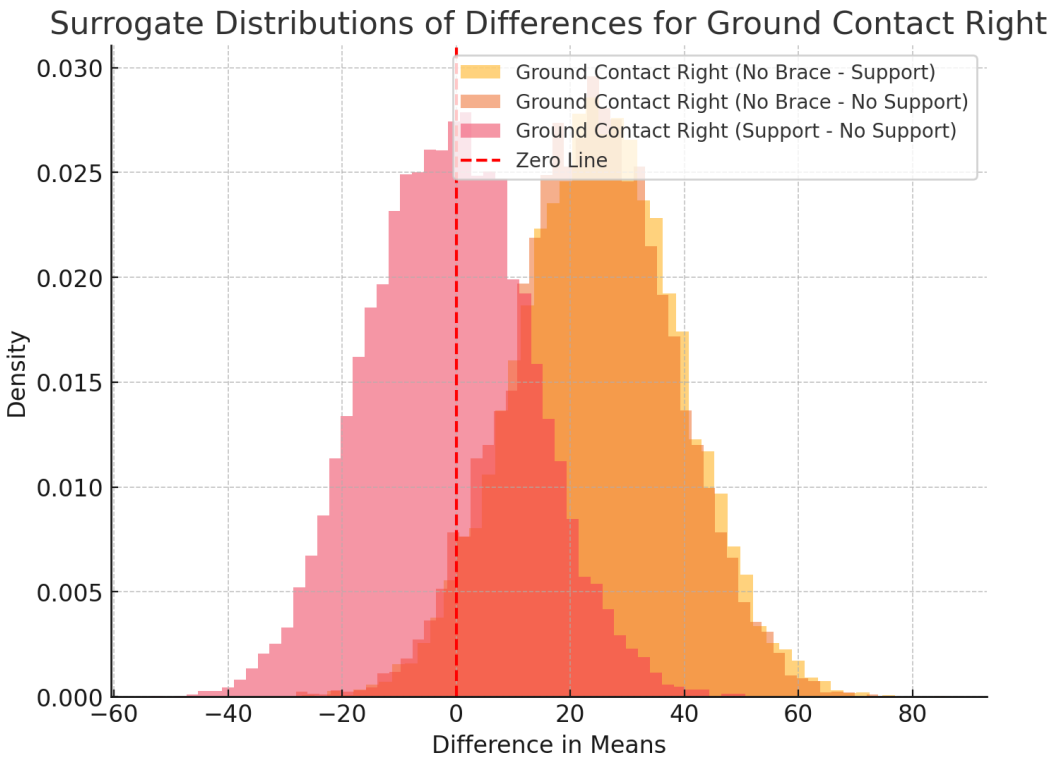


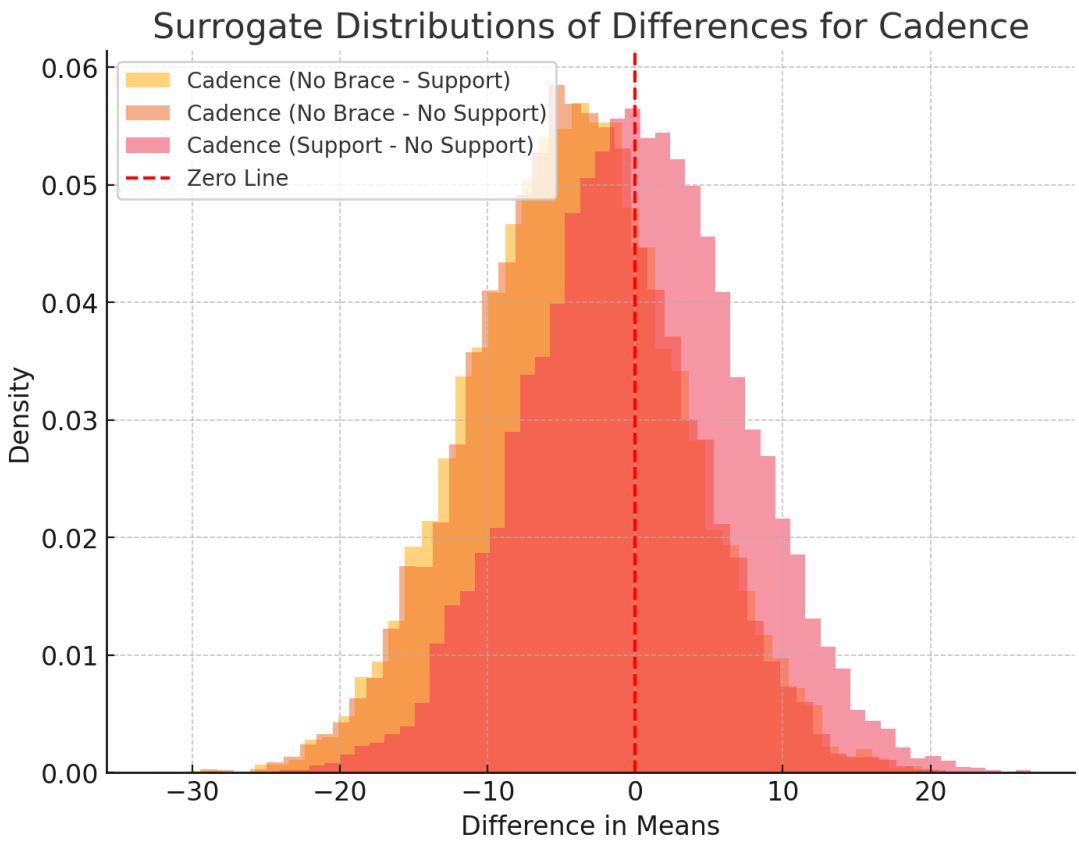
Surrogate Distributions of Differences for Impact Magnitudes Left




Surrogate Distributions of Differences for Impact Magnitudes Right
Impact Magnitudes Right (No Brace - Support)
Impact Magnitudes Right (No Brace - No Support)
Impact Magnitudes Right (Support - No Support)
Zero Line
Density
Difference in Means
3.0
2.5
2.0
1.5
1.0
0.5
0.0
−0.6
−0.4
−0.2
0.0
0.2
0.4
0.6


Surrogate Distributions of Differences for Ground Contact Left
Ground Contact Left (No Brace - Support)
Ground Contact Left (No Brace - No Support)
Ground Contact Left (Support - No Support)
Zero Line
Density
Difference in Means
0.030
0.025
0.020
0.015
0.010
0.005
0.000
−60
−40
−20
0
20
40
60


Surrogate Distributions of Differences for Ground Contact Right
Ground Contact Right (No Brace - Support)
Ground Contact Right (No Brace - No Support)
Ground Contact Right (Support - No Support)
Zero Line
Density
0.030
0.025
0.020
0.015
0.010
0.005
0.000
−60
−40
−20
0
20
40
60
80
Difference in Means



Updated conclusions:

Dynamic Stability Left:

- No Brace - Support: Not significant (credible interval includes zero)
- No Brace - No Support: Significant (credible interval does not include zero)
- Support - No Support: Not significant (credible interval includes zero)

Dynamic Stability Right: All comparisons are **not significant** (credible interval includes zero).
Impact Magnitudes (Left & Right): All comparisons are **not significant** (credible interval includes zero).
Ground Contact (Left & Right): All comparisons are **not significant** (credible interval includes zero).
Cadence: All comparisons are **not significant** (credible interval includes zero).

Although most of the results are not significant, this aligns with our hypothesis, as Grace does not have foot drop. The brace was not expected to significantly alter her gait, and the results confirm that it did not negatively impact her dynamic stability, impact magnitudes, or overall gait patterns. Specifically, the lack of significant differences across most metrics suggests that the

brace neither hindered nor substantially improved her gait mechanics compared to the support and no support conditions. This is consistent with the expectation that the brace would not dramatically influence gait parameters in individuals without specific impairments like foot drop.

BPAG Cost Spreadsheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link	
Ankle Brace - Component 1											
Ankle Brace	Cloth brace	**Abiram**		Amazon		10/10/2024	1	$14.88	$14.88	Link	
Gel padding	medical grade padding	**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 attatch various fabrics	**Basic Home**		Amazon		12/03/2024	**1**	$8.43	$8.43	Link	
Carbon Fiber piece - Component 2											

3D printing prototype	3D printing of back support	**Bambu printer**		Makerspace		11/8/2024	1	1.4	$1.40	***covered by our given $50 per team**	
3D printing prototype - 3 variants	3D printing of back support	**Bambu printer**		Makerspace		11/12/2024	1	3.8	$3.80	***covered by our given $50 per team**	
3D printing prototype	3D printing of back support	**Bambu printer**		Makerspace		11/13/2024	1	1.71	$1.71	***covered by our given $50 per team**	
Lock lace piece	3D printing the lock lace piece	**Bambu printer**		Makerspace		11/18/2024	1	0.23	$0.23	***covered by our given $50 per team**	**$8.71**
3D Printing Final Prototype	3D printing of back support	**Shen Printer**		Makerspace		12/3/2024	1	1.57	$1.57	***covered by our given $50 per team**	
Epoxy Mold - Component 3											
Epoxy	Take cast of the leg	**Easy Pour Epoxy**		Amazon		11/14/2024	1	$39.97	$39.97	Link	
Mold release Agent	PVA release agent - Prevent bonding to the cast	**Mrealeazy**		Amazon		11/14/2024	1	0	$0.00	***Used the provided materials in ECB**	
								TOTAL:	**$189.02**		