Inconspicuous Ankle Foot Orthosis (AFO) for teen

PRELIMINARY REPORT

Fall 2024 BME 200/300 Lab 304

Team Name:

AFO Group

Team Members:

Anya Hadim (Team Leader)
Lucy Hockerman (BSAC)
Presley Hansen (Communicator)
Alex Conover (BPAG)
Grace Neuville (BWIG)

Client:

Debbie Eggleston

Advisor:

Dr. Brandon Coventry

13 October 2024

Abstract

Facioscapulohumeral Dystrophy (FSHD) is the most common type of muscular dystrophy and affects around 4-10 in 100,000 people. FSHD is a genetic disorder that causes progressive muscle weakness. There is currently no cure for FSHD, but common treatments are physical therapy, orthotics, and surgery [1].

A discreet ankle foot orthosis for the right foot was designed for a teen with FSHD. The AFO should support dorsiflexion to prevent foot drop while remaining flexible enough for daily activities, and it should be discreet to easily fit inside the user's shoe. The proposed AFO uses a compression sleeve with neoprene straps to support the ankle and to hold the carbon fiber medial ankle support in place. A bungee cord will be attached to the straps above the metatarsals of the foot, and connected to a drawstring mechanism just above the ankle. This drawstring mechanism will be used for adjusting the tautness of the bungee cord, which brings the foot into dorsiflexion. The AFO will be tested to make sure it is safe for constant use and effectively improves gait cycle patterns.

Table of Contents

Table of Contents

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 what their peers think.

Additionally, there are currently no 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 also can be noisy due to the hinge mechanism and may break more easily. The patient is looking for an orthosis that allows for some range of motion; however, due to the bulkiness of this device, it does not meet the criterion the patient is looking for. [5].

Figure 2. 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; so, 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].

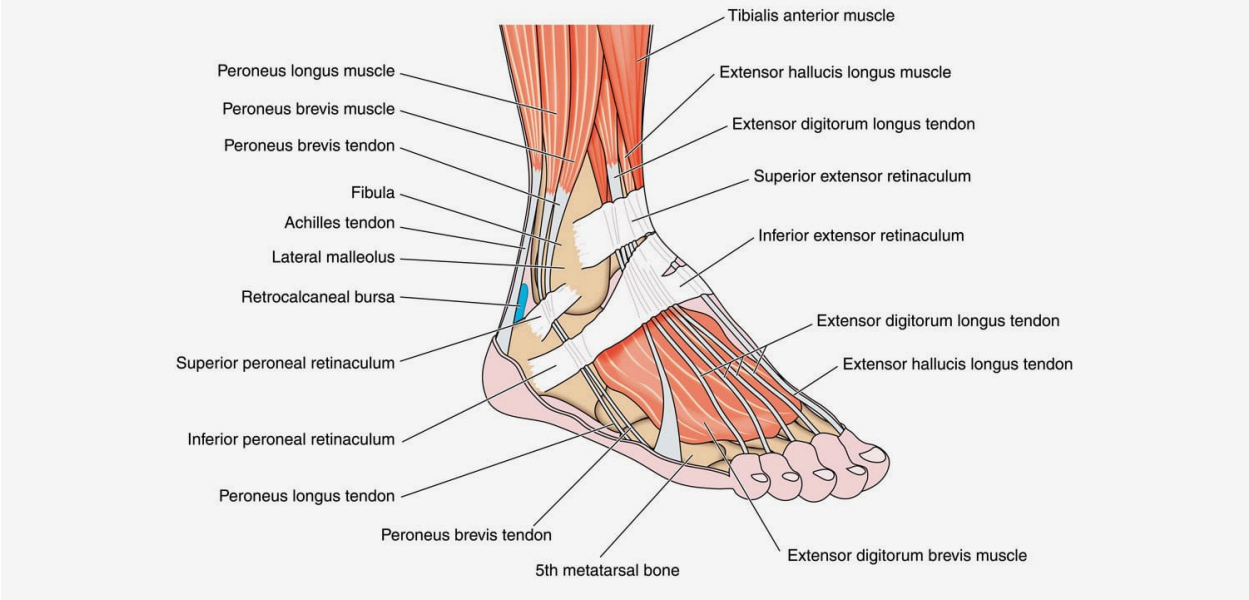


Figure 4: Ankle Muscle Anatomy [9]

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 5 years now, and she continues to be a driving force in advocating for FSHD patients.

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

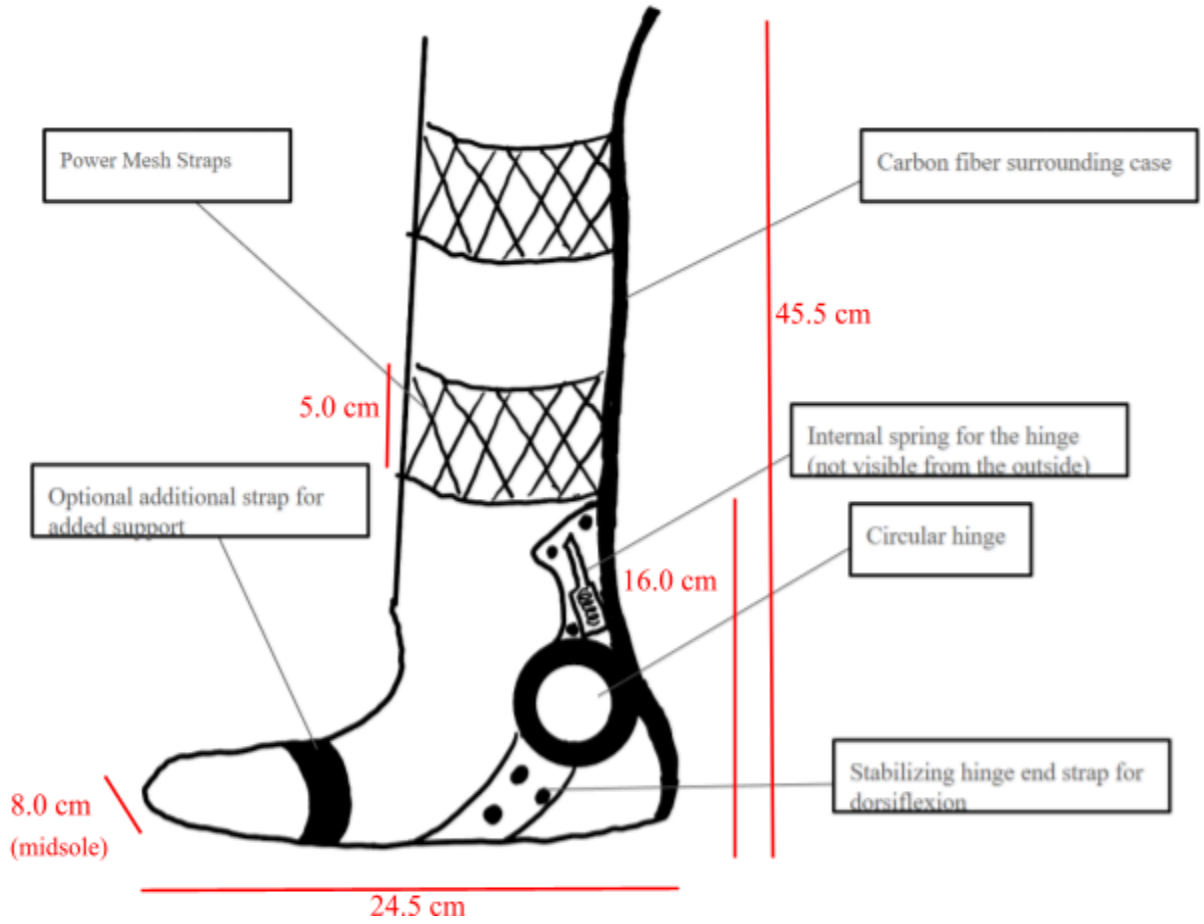


Figure 5: Hinge Design Sketch, Medial View

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 7: 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

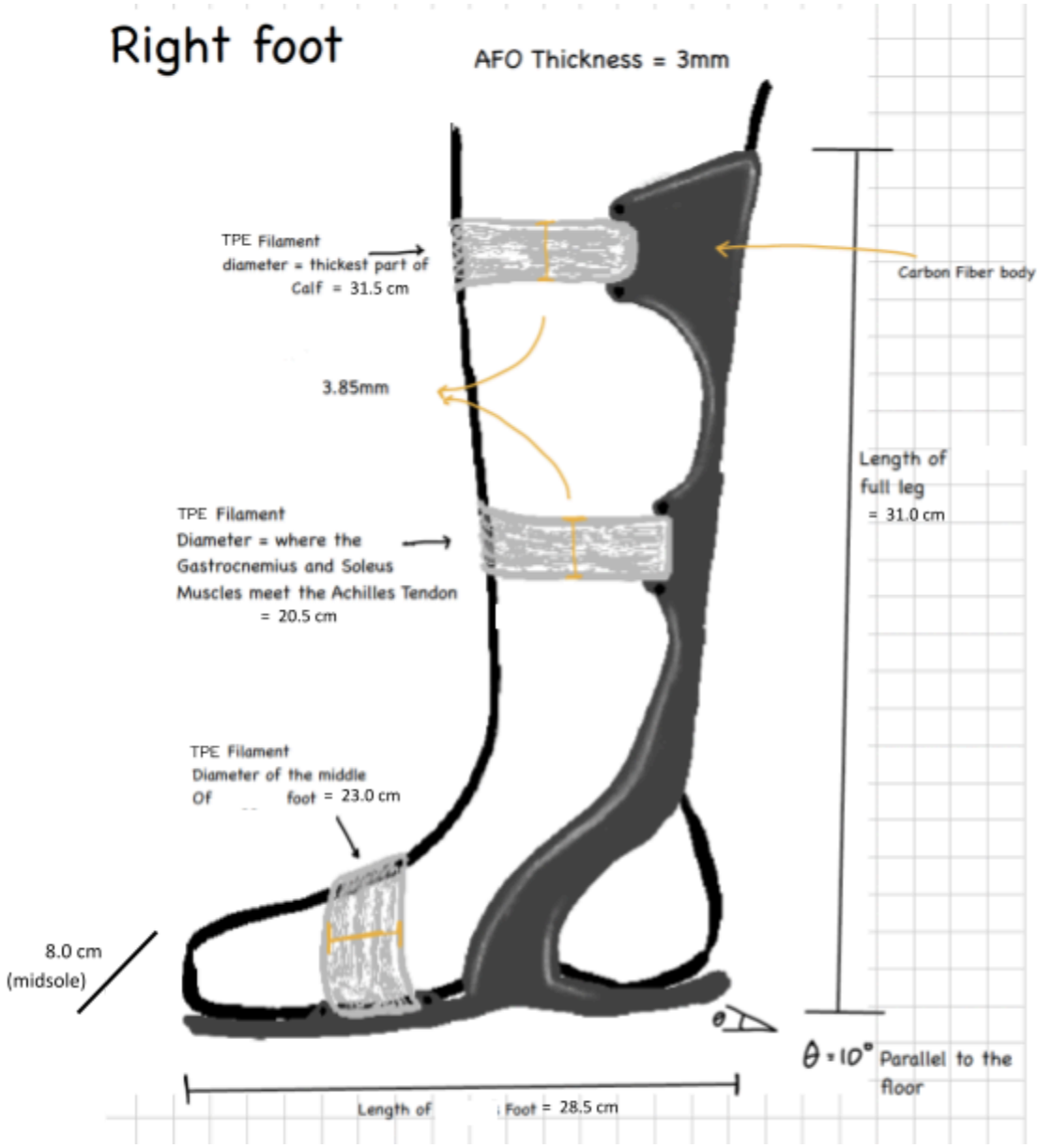


Figure 8: Strap Brace Design Sketch, Medial View

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

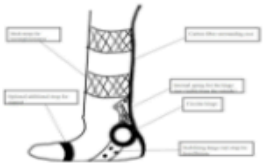
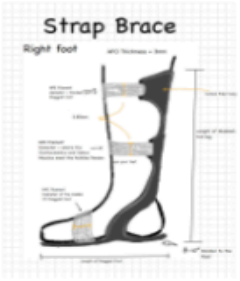
Criteria	Weight	Design 1 Hinge Design		Design 2 Bungee Brace Design		Design 3 Strap Design	
							
		Score |	Weighted Score	Score |	Weighted Score	Score |	Weighted Score
Support	20	3/5	12	3/5	12	5/5	20
Discreetness	20	3/5	12	5/5	20	4/5	16
Safety	15	3/5	9	4/5	12	4/5	12
Flexibility	15	4/5	12	5/5	15	3/5	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

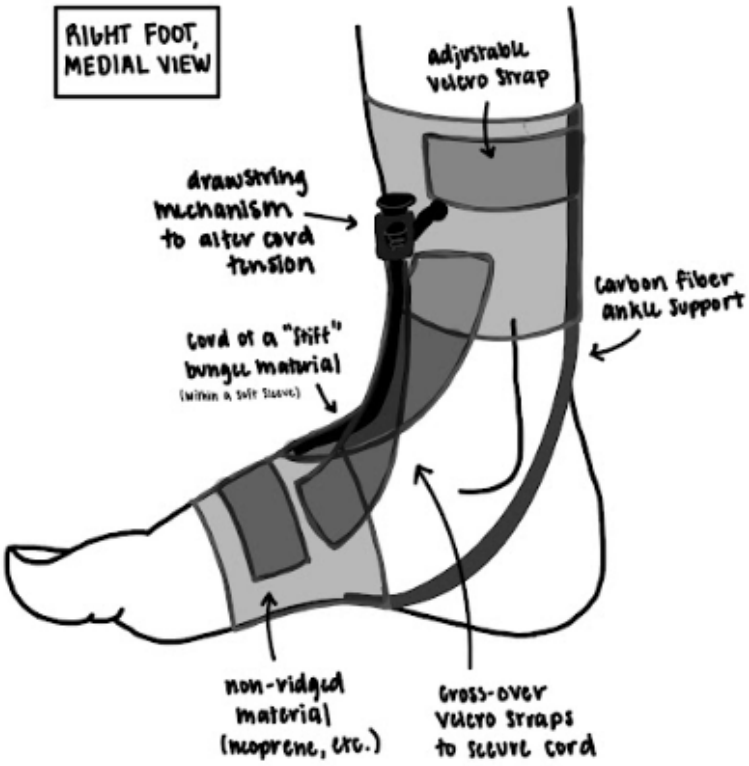


Figure 9: Proposed Final Design Sketch

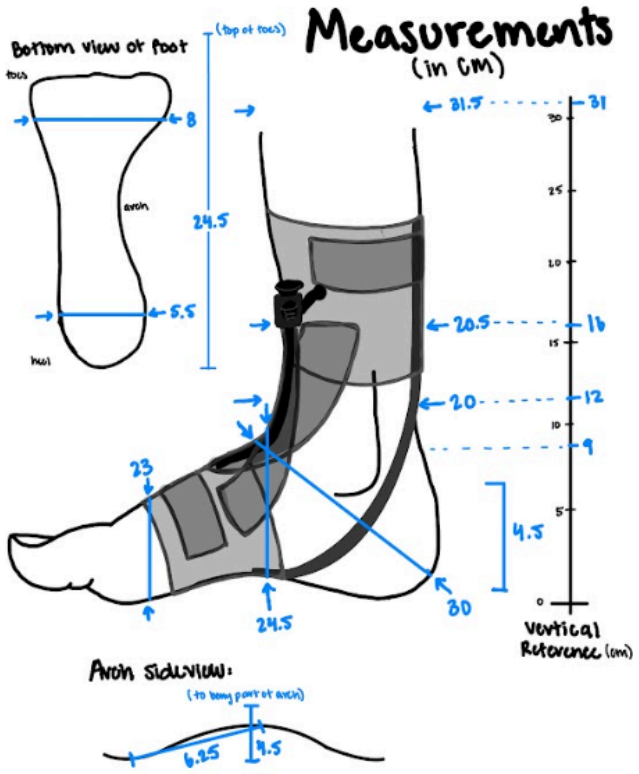


Figure 10: Proposed Final Design Sketch with Dimensions

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 9 and 10. 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.

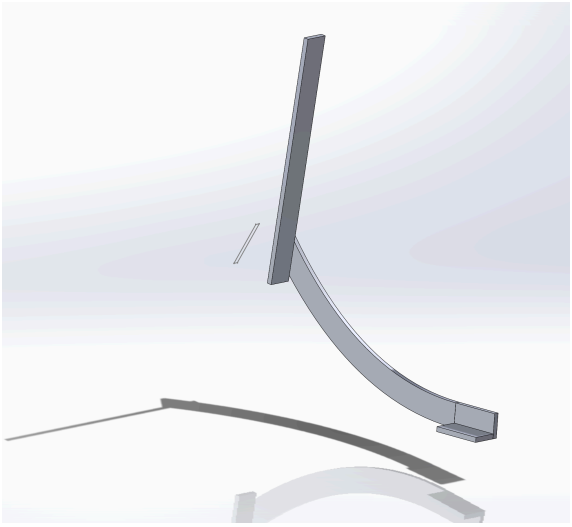


Figure 11: Lateral View of Carbon Fiber Support in Solidworks

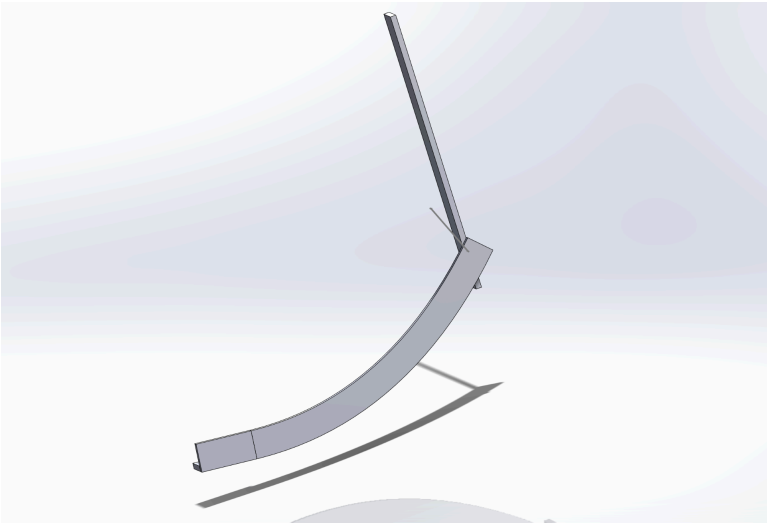


Figure 12: Medial View of Carbon Fiber Support in Solidworks

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 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. 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.

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 will be made using a cheaper material to save costs prior to the final design (see the final prototype section for more details).

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 will be designed in SolidWorks and subsequently 3D printed at the UW-Makerspace using the Markforged Onyx Pro 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 plastic cord lock, which will also be purchased and integrated into the design.

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 sewn on the sock based on the patient's pressure points 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 using the sewing machines available at the UW-Makerspace. The plastic cord lock 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 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

The team has not yet fabricated a final prototype. The final SolidWorks design for the carbon fiber attachment will be 3D printed using a less expensive material available at the UW-Makerspace, chosen for its ability to mimic the properties of carbon fiber. The material selected is PAHT-CF from the Bambu Lab printer, which offers high tensile strength, 57.5 kJ/m² toughness, 125 MPa strength, and 4230 MPa stiffness [17]. This material provides sufficient strength and durability for prototyping while keeping costs lower.

The compressive sock, gel pads, and foot brace have been ordered. For the final prototype, the gel pads will not be sewn in until the patient comes in for testing. This ensures resource efficiency, staying economically savvy and environmentally friendly. The bungee cord and plastic locks have also been purchased and will be sewn onto the foot sleeve, as described in the final design (see Methods section for clarification). These components will be assembled to replicate the final design and ensure proper functionality before patient testing.

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.

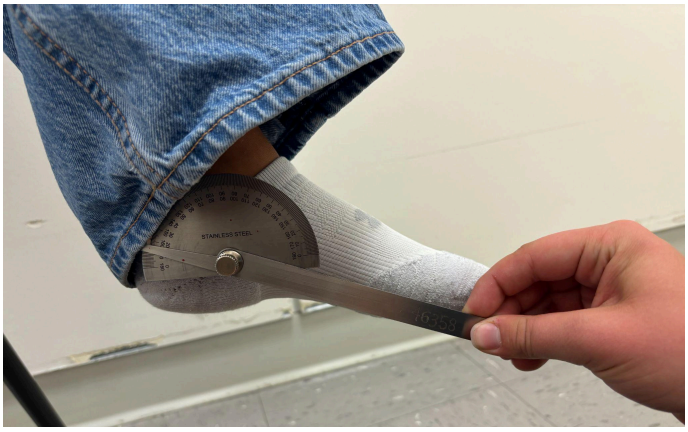


Figure 13: Resting Foot Angle Measurement with Protractor

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

Future Testing: Simulations and MTS testing

The group plans to run simulations on the finalized SolidWorks design to evaluate key mechanical properties such as compressive and tensile strength. These simulations will help identify potential failure points and guide the selection of the most suitable materials for future

fabrication via 3D printing. This process ensures that the rigid support design is optimized for durability and performance before physical prototyping.

Future Testing: In-person with Client

After fabricating the initial prototype, both functionality and comfort will be assessed. To evaluate functionality, the team will conduct an active assessment of gait using a Six-Minute Walk Test (6MWT). In the 6MWT, cones are placed at either end of a 30-meter stretch, and the patient is instructed to walk as far as possible within six minutes. An increase in distance walking suggests an improvement in basic mobility. This test will be conducted both with and without the designed AFO, allowing for significant rest periods between trials to observe any differences in distance covered. According to an amputee rehabilitation study, a "real" improvement in patient mobility is marked by an increase of 45 meters in distance walked [18]. Additionally, tracking the distance walked each minute will provide insights into fatigue patterns [19].

Comfort is another critical factor in evaluating the prototype. To assess this, the patient will provide feedback on pain levels using a scale from 1 to 10, and report any specific points of discomfort in the lower leg during the 6MWT. Pain levels will be recorded before the test, every minute during the walk, and after the test. If discomfort reaches a level that causes moderate pain, testing will be stopped immediately. The patient will also rate pain and discomfort after performing typical daily activities, such as walking, squatting, ascending and descending stairs, and vertical jumping. These activities simulate a range of movements that place different stresses on the lower leg. The feedback will help identify areas of pressure or irritation, guiding further design refinements.

The 6MWT will provide valuable initial insights into the patient's mobility and comfort while using the designed ankle-foot orthosis, helping us improve the prototype based on short-term outcomes. However, this test does not capture the full scope of musculoskeletal effects. To thoroughly understand the effectiveness of the AFO, the team plans to utilize OpenSim 3D motion capture technology through the Badger Athletic Performance Lab. OpenSim will allow for a detailed analysis of the AFO's impact on biomechanical structures, including joint kinematics, muscle activation, and skeletal alignment.

An inverse kinematics simulation will be the most appropriate method for assessing changes in gait dynamics. This approach will involve 3D marker coordinates placed around affected anatomical regions, including the foot, ankle, and mid-calf [20]. By comparing gait patterns with and without the AFO, the simulation will help identify specific muscular and skeletal changes influenced by the prototype. These simulations will provide insights into how the AFO alters gait mechanics, providing a deeper understanding of its long-term effects.

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 as well as 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. There is discussion about possible dates for physical testing in Madison, WI, but nothing is confirmed. The group will have to prepare alternate testing plans in case travel is not possible for the client and patient.

Additionally, the group is awaiting approval from the Badger Athletic Performance Lab to use the OpenSim 3D motion capture simulation. If approval is not granted, the group will need to develop alternative testing plans.

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 current final design, consisting of a carbon fiber support, straps, and bungee drawstring mechanism, will support ankle dorsiflexion, and ankle inversion, and look similar to an athletic brace, therefore limiting questions regarding the device's function. Once this prototype is made, testing with the patient can be done and improvements can be made where necessary.

Future Work

Future work for the team will include running simulations in Solidworks to evaluate the mechanical properties of the rigid backing and in-person testing with the patient after fabrication, as described in the Testing and Results section. Fabrication of the initial prototype including 3D printing the first iteration of the carbon fiber support is the next step. Weighing functionality and discreteness is a key point that will be considered throughout the design process. Also, the rotator dial was changed to a drawstring mechanism for simplicity of fabrication; this is an aspect that could be changed in the future for a more polished and discreet look. 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.

References

[1] “FSHD (Facioscapulohumeral Muscular Dystrophy),” Cleveland Clinic. Available: https://my.clevelandclinic.org/health/diseases/facioscapulohumeral-muscular-dystrophy-fshd

[2] “Biomechanics for Cerebral Palsy Orthotics,” Physiopedia, Nov. 2023. Available: https://www.physio-pedia.com/Biomechanics_for_Cerebral_Palsy_Orthotics. [Accessed: Oct. 07, 2024]

[3] “Foundations for Ankle Foot Orthoses,” Physiopedia. https://www.physio-pedia.com/Foundations_for_Ankle_Foot_Orthoses

[4] “Ankle-Foot Orthoses, AFOs, Boundless Bracing,” Boundless Biomechanical Bracing. Available: https://www.boundlessbracing.com/ankle-body-part

[5] “Foundations for Ankle Foot Orthoses,” Physiopedia. https://www.physio-pedia.com/Foundations_for_Ankle_Foot_Orthoses

[6] natomicalconceptsinc.com, 2024. https://www.anatomicalconceptsinc.com/hs-fs/hubfs/AFO_APU.png?width=975&name=AFO_APU.png (accessed Oct. 04, 2024).

[7] G. Rogati, P. Caravaggi, and A. Leardini, “Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: a review study,” Journal of Foot and Ankle Research, vol. 15, no. 1, May 2022, doi: https://doi.org/10.1186/s13047-022-00547-2

[8] P. Caravaggi et al., “Development of a Novel Passive-Dynamic Custom AFO for Drop-Foot Patients: Design Principles, Manufacturing Technique, Mechanical Properties Characterization and Functional Evaluation,” Applied Sciences, vol. 12, no. 9, p. 4721, May 2022, doi: https://doi.org/10.3390/app1209472.

[9] “Anatomy of the Ankle Joint & Common Conditions - Orthosports,” *Best Orthopedic Hospital in Dubai*, Aug. 08, 2023. Available: https://orthosp.com/ankle-joint/. [Accessed: Oct. 14, 2024]

[10] “Amazon.com: ABIRAM Foot Sleeve (Pair) with Compression Wrap, Ankle Brace For Arch, Ankle Support, Football, Basketball, Volleyball, Running, For Sprained Foot, Tendonitis, Plantar Fasciitis : Health & Household,” Amazon.com, 2024. https://www.amazon.com/dp/B074PWC89V?ref=cm_sw_r_cso_sms_apin_dp_4A7FNN5T1YBVSZNCNVPH&ref_=cm_sw_r_cso_sms_apin_dp_4A7FNN5T1YBVSZNCNVPH&social_share=cm_sw_r_cso_sms_apin_dp_4A7FNN5T1YBVSZNCNVPH&starsLeft=1&skipTwisterOG=1&th=1 (accessed Oct. 13, 2024).

[11] “Textile Industry,” Textile Industry. https://www.textileindustry.net/

[12] “Polyester | What Is It, Characteristic, Properties, Types, and Uses,” Ruitai Mould. https://www.rtprototype.com/what-is-polyester/

[13] P. Process, “Latex Polymer: Benefits, Uses, and Environmental Impact,” Polymer Process, Apr. 20, 2024. https://polymer-process.com/latex-polymer/ (accessed Oct. 13, 2024).

[14] “What is a Carbon Fiber AFO?,” Elevatemovement.com, 2024. https://www.elevatemovement.com/blog/what-is-a-carbon-fiber-afo (accessed Oct. 13, 2024).

[15] D. Zou et al., “Experimental and computational analysis of composite ankle-foot orthosis,” Journal of Rehabilitation Research and Development, vol. 51, no. 10, pp. 1525–1536, 2014, doi: https://doi.org/10.1682/jrrd.2014-02-0046. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5976490/

[16] 3D Printers, “3D Printers,” Design Innovation Lab, 2024. https://making.engr.wisc.edu/equipment/3d-printers/

[17] “Choose the right filament - 3D Filaments Guide for Bambu Lab Printers,” bambulab.com. https://bambulab.com/en/filament-guide

[18] Resnik, L. and Borgia, M., (2011). Reliability of outcome measures for people with lower-limbfckLRamputations: distinguishing true change from statistical error. Physical Therapy, 91(4), pp. 555-565.

[19] Foundations for Ankle Foot Orthoses. (2022, November 1). Physiopedia, . Retrieved 22:51, October 12, 2024 from https://www.physio-pedia.com/index.php?title=Foundations_for_Ankle_Foot_Orthoses&oldid=319489.

[20] Planning an opensim simulation—Opensim documentation—Opensim. (n.d.). Retrieved October 13, 2024, from https://opensimconfluence.atlassian.net/wiki/spaces/OpenSim/pages/53090652/Planning+an+OpenSim+Simulation

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. The selected material must be non-toxic and hypoallergenic to prevent skin irritation or allergic reactions. Additionally, the material must have insulating properties to avoid skin damage from frostbite or burns. 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. Various materials are used to create AFOs. Standard-grade polypropylene is typically used in children's AFOs and is the most common plastic in any AFO.

iii. Carbon fiber is increasingly popular due to its superior weight and flexibility compared to plastic and steel. The only downside is its higher cost, as it is more expensive than most other materials.

iv. Metal is commonly used for adult or heavier patients. 3D-printed materials are also on the rise and can be printed to precise specifications.

v. Wood and leather have been used in the past but are less common today due to the superiority of modern materials.

vi. The plastics used are generally thermoformable, allowing them to be molded directly to the patient's lower legs [16].

vii. Use the lightest material possible, carbon fiber, to create the most effective orthoses.

viii. Other plastics or fabrics can be used as padding between the skin and the body of the orthoses.

k. Aesthetics, Appearance, and Finish

i. The AFO will fit underneath the shoe and will likely be black or white to minimize clashing with the patient's choice of clothing.

ii. It 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.

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].

References

[1] Rogati, G., Caravaggi, P., & Leardini, A. (2022). Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: A review study. Journal of Foot and Ankle Research,15, 38. https://doi.org/10.1186/s13047-022-00547-2

[2] M. Reinold, "Ankle Mobility Exercises to Improve Dorsiflexion," Mike Reinold, Apr. 22, 2020. https://mikereinold.com/ankle-mobility-exercises-to-improve-dorsiflexion/#:~:text=The%20generally%20accepted%20normal%20range (accessed Sep. 18, 2024).

[3] T. Kobayashi et al., "The effects of an articulated ankle-foot orthosis with resistance-adjustable joints on lower limb joint kinematics and kinetics during gait in individuals post-stroke," Clinical Biomechanics, vol. 59, pp. 47–55, Nov. 2018, doi: https://doi.org/10.1016/j.clinbiomech.2018.08.003.

[4] Quotes, J. L. B. J. L. B. J. *Average height and weight for teenagers by age*. LoveToKnow. Retrieved September 19, 2024, from https://www.lovetoknow.com/parenting/teens/average-height-weight-teenager

[5] *Watch your step: Understanding the importance of your feet in the kinetic chain – foundation for chiropractic progress*. (n.d.). Foundation for Chiropractic Progress - Educating the Public to the Benefits of Chiropractic Care. Retrieved September 19, 2024, from https://www.f4cp.org/watch-your-step-understanding-the-importance-of-your-feet-in-the-kinetic-chain/

[6] Zou, D., He, T., Dailey, M., Smith, K. E., Silva, M. J., Sinacore, D. R., Mueller, M. J., & Hastings, M. K. (2014). Experimental and computational analysis of composite ankle-foot orthosis. *Journal of Rehabilitation Research and Development*, *51*(10), 1525–1536. https://doi.org/10.1682/JRRD.2014-02-0046

[6] T. Kobayashi et al., “The effects of an articulated ankle-foot orthosis with resistance-adjustable joints on lower limb joint kinematics and kinetics during gait in individuals post-stroke,” Clinical Biomechanics, vol. 59, pp. 47–55, Nov. 2018, doi: https://doi.org/10.1016/j.clinbiomech.2018.08.003.

[7] “Ankle Foot Braces (AFOs) for ALS| Your ALS Guide,” Your ALS Guide, 2024. https://www.youralsguide.com/ankle-foot-braces-for-als.html (accessed Sep. 18, 2024).

[8] “Texas Foot & Ankle Center,” Texas Foot and Ankle Center, Feb. 08, 2023. https://txfac.com/blog/how-often-do-i-need-to-replace-my-custom-orthotics/ (accessed Sep. 18, 2024).

[9] “Ankle Foot Orthosis (AFO) Information for patients.” Accessed: Sep. 18, 2024. [Online]. Available: https://apps.nhslothian.scot/files/sites/2/Ankle-Foot-Orthosis-AFO-1.pdf

[10] “How to Properly Wear and Maintain Your AFO - Align Clinic,” Align Clinic, May 17, 2020. https://align-clinic.com/how-to-properly-wear-and-maintain-your-afo/#:~:text=Clean%20Once%20a%20Week. (accessed Sep. 18, 2024).

[11] E. Russell Esposito, K. A. Schmidtbauer, and J. M. Wilken, “Experimental comparisons of passive and powered ankle-foot orthoses in individuals with limb reconstruction,” Journal of NeuroEngineering and Rehabilitation, vol. 15, no. 1, Nov. 2018, doi: https://doi.org/10.1186/s12984-018-0455-y.

[12] EDGE, The O&P. “Study Establishes AFO Thickness Threshold.” *The O&P EDGE Magazine*, 30 June 2023.

[13] *Orthomerica AFO*. https://www.spsco.com/orthomerica-afo.html. Accessed 17 Sept. 2024.

[14] S. L. Barnett, A. M. Bagley, and H. B. Skinner, “ANKLE WEIGHT EFFECT ON GAIT: ORTHOTIC IMPLICATIONS,” *Orthopedics*, vol. 16, no. 10, pp. 1127–1131, Oct. 1993, doi: https://doi.org/10.3928/0147-7447-19931001-08.

[15] D. Zou et al., “Experimental and computational analysis of composite ankle-foot orthosis,” Journal of Rehabilitation Research and Development, vol. 51, no. 10, pp. 1525–1536, 2014, doi: https://doi.org/10.1682/jrrd.2014-02-0046. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5976490/

[16] “Introduction to Ankle Foot Orthoses,” *Physiopedia*. https://www.physio-pedia.com/Introduction_to_Ankle_Foot_Orthoses#:~:text=They%20made%20from%20thermoformed%20plastic

[17] “Product Classification,” Fda.gov, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=IQO (accessed Sep. 18, 2024).

[18] *Limb Orthosis*, 21 CFR 890.3475, 2001 (accessed Sep. 13, 2024).

[19] Iso.org, 2024. https://www.iso.org/obp/ui/en/#iso:std:iso:8549:-3:ed-2:v1:en (accessed Sep. 18, 2024).

[20] Iso.org, 2024. https://www.iso.org/obp/ui/en/#iso:std:iso:8551:ed-2:v1:en (accessed Sep. 18, 2024).

[21] O. for, “ISO 22675:2016,” ISO, 2016. https://www.iso.org/standard/70203.html#:~:text=ISO%2022675%3A2016%20primarily%20specifies%20a%20cyclic%20test%20procedure (accessed Sep. 18, 2024).

[22] Madison, “University of Wisconsin-Madison Login,” Wisc.edu, 2024. https://bmedesign.engr.wisc.edu/selection/projects/1c7272db-b7dd-4646-9597-6c54967c1b99 (accessed Sep. 18, 2024).

[23] “Foundations for Ankle Foot Orthoses,” Physiopedia. https://www.physio-pedia.com/Foundations_for_Ankle_Foot_Orthoses