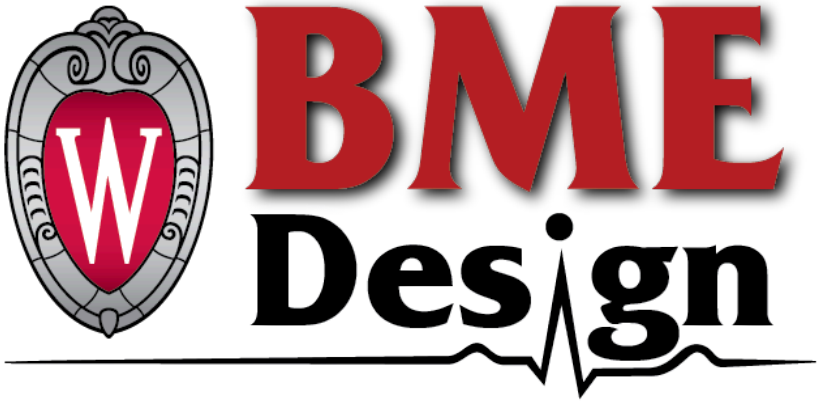

Inconspicuous Ankle Foot Orthosis (AFO) for teen

PRODUCT DESIGN SPECIFICATIONS (PDS)

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Team AFO

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Function/Problem Statement:

Ankle-foot orthoses (AFOs) are designed to support dorsiflexion during the swing phase of walking. They are commonly used in managing muscular dystrophies, and for this project, our focus is specifically on adolescents with Facioscapulohumeral Dystrophy (FSHD), the most prevalent form of muscular dystrophy [1]. Our goal is to create a brace that helps teens achieve safer walking by assisting ankle dorsiflexion, while remaining discreet, lightweight, and flexible enough to allow natural ankle motion. The main design priorities are to position the ankle in proper dorsiflexion, keep the brace slim and unobtrusive, and provide enough flexibility to reduce movement restrictions. This project has been ongoing throughout three semesters, and this semester, spring 2026, will be the final semester of the project; the team is hoping to create a device that fulfills all requests, as well as displays significant data.

Client requirements:

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

Design requirements:

1. Physical and Operational Characteristics
    a. Performance requirements
        i. The AFO is designed to remain discreet and lightweight, using minimal material while still providing strong support for ankle dorsiflexion and resisting ankle inversion to prevent gait irregularities [1]. It allows a natural walking pattern without generating resistive moments during dorsiflexion [2].
        ii. The device permits more than 30° of motion from the initial ankle angle to ensure proper foot clearance [3].
        iii. In plantarflexion, the orthosis generates an adjustable resistive moment ranging from 5–10 Nm per 10° of motion [3]. Overall, moment-angle performance should stay within ±30 Nm of torque. The brace also resists torsional forces that could cause misalignment of the ankle or foot during regular activity [4].
        iv. The AFO withstands forces equal to at least three times the user's bodyweight, reflecting the peak loads experienced during walking [5]. For a 16-year-old weighing approximately 118 lbs (53.4 kg), this translates into supporting a

maximum force of 1570 N [5]. The normal force exerted by the patient is 524 N. At the same time, the device must allow active concentric ankle movement so the user can perform daily activities such as squatting or climbing stairs.

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

vi. The rigid components must also limit inversion to less than 25° [6].

b. Safety

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

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

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

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

v. The device must withstand the forces put on it by the user as outlined in the performance requirements. Carbon fiber AFOs, for example, typically fail at the mid-shank calf support under forces of 1970 N [7].

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

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

c. Accuracy and Reliability

i. The AFO must maintain structural integrity through repeated use while continuing to provide consistent dorsiflexion support. The device will be used over long periods of time, and must provide consistent results throughout the entire duration of use.

ii. The device should be made with durable materials. Ideally, the materials should not degrade over time, or can be easily replaced to provide consistent results.
iii. The device should also provide consistent mediolateral support, but this is not currently the client's highest priority currently.

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

e. Life in Service
    i. The expected lifespan of a custom AFO is typically 2-5 years, though actual service life depends on the material, usage patterns, and patient needs [8]. Individuals who are experiencing rapid periods of growth, such as children, may need the AFO replaced as often as every 9-18 months [9].
    ii. Regular cleaning and upkeep of the device could help to increase the life in service.
    iii. Semi-rigid materials such as carbon fiber, fiberglass, and polyethylene generally last longer than softer materials as they are more resistant to damage [10]. Softer materials often need to be replaced more frequently than rigid materials.
    iv. Annual reviews by an orthotist are recommended to assess wear and ensure the device continues to meet the user's needs [11].

f. Operating Environment

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

    ii. The AFO must withstand exposure to varying environmental factors including temperatures, humidity, dirt, water, and sweat. To prevent infections due to

bacterial buildup, the device needs to be cleaned weekly with mild soap and water [12].

g. Ergonomics
    i. The device must distribute the user's weight evenly to avoid discomfort. Adjustable features such as straps and bands should allow for modularity of the AFO. This will help the device fit the user through growth and activity needs.
    ii. As most AFOs weigh between 0.3–3.4 kg [13], the inconspicuous design should weigh under 1kg. This will allow for a low profile brace that improves dorsiflexion gait without altering step due to extraneous weight.
    iii. Extra padding must be introduced around sensitive areas such as the base of the foot, ankle, and achilles tendon. The design must be low profile enough to fit into shoes so that there is no need for shoes tailored to the device. [3].
    iv. Moving parts must function quietly so it does not draw attention to the AFO.
    v. By supporting dorsiflexion, the AFO can improve step length, walking speed, and overall gait stability, helping the user move more efficiently in daily life [14].
h. Size:
    i. The AFO must match the patient's specific measurements, with slight adjustments to allow for padding and anti-chafing features [15]. Key measurements are as follows:
        1. The length of the leg (measured bottom of foot to directly below the kneecap) is 45.5 centimeters.
        2. The diameter directly below the kneecap (measured at top of the lower leg) is 31.5 centimeters.
        3. The diameter of the thickest part of the calf (measured mid-leg) is 31.5 centimeters.
        4. The diameter where the Achilles meets the calf (measured bottom of leg) is 20.5 centimeters.
        5. The diameter of the thinnest part of the ankle (measured where Achilles is felt) is 20 centimeters.
        6. The diameter across the middle of the ankle, through the joint is 30 centimeters.

7. The diameter just in front of the ankle joint (measured low ankle) is 24.5 centimeters.
8. Arch Measurements: bony prominence to floor is 4.5 centimeters and 6.25 centimeters in length.
9. The length of the foot is 24-24.5 centimeters.
10. The width of the foot (measured where the metatarsals meet the phalanges) is 8.25 centimeters.
11. The width of the foot (measured in midsole area) is 8 centimeters.
12. The width of the foot (measured at the heel) is 5.5 centimeters.
13. The patient weighs 53.4 kilograms.
14. The patient's height is 1.724 meters.
15. The patient's shoe size is 8.5-9 on a U.S. scale.

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

i. Weight

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

j. Materials

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

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

1. PLA-CF material properties include high ultimate tensile strength, high Young's modulus, high flexure stress, and low ductility [18].
2. Pure carbon fiber properties include high tensile and compressive strengths, high Young's modulus, low density, and high temperature tolerance [19].

iii. The dorsiflexion component of the brace will be made of either TPU filament or polyester fabric. Either of these materials will need to withstand forces from the patient walking, so around 1000 N of force to be within safety margins.

1. The notable properties of polyester include ductility, durability, mechanical strength, and moisture resistance [20].
2. 3D-printed thermoplastic polyurethane (TPU) exhibits lower elasticity when compared to the material in bulk. To mitigate premature failure, the orientation of the printed layers is critical, as strength in the Z-direction is significantly weaker; tensile loads should therefore be aligned in-plane with the filament paths [21]. Fatigue testing for TPU is vital due to its tendency to fail under continuous cyclic loads. Despite these limitations, TPU provides excellent abrasion resistance and environmental resistance, which enhances durability in applications like straps for both upper and lower body use [22].

iv. The padding should be made of two layers of mesh that are sewn together. These are then attached to the inside of the AFO via superglue [23].

k. Aesthetics, Appearance, and Finish

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

ii. The surface will be smooth, slim, and inconspicuous, while still offering the necessary support. The brace is similar to the look offered by an athletic brace.

2. Product Characteristics

a. Quantity

i. The project consists of designing and fabricating one right-leg AFO. However, with considerations of bringing the product to market, the design has to be easily fabricated in order to mass produce the inconspicuous AFO.

b. Target Product Cost

i. This project is funded by Biomedical Engineering Design at the University of Wisconsin-Madison. The expected cost of this semester's continuation is $50 with a possible increase with materials like carbon fiber for strong and light weight material options.

ii. As of fall 2025, the prototypes have accounted for $272.39. The semesterly breakdown of the budget is $189.02 for fall 2024, $37.95 for spring 2025, and

$45.42 for fall 2025. If the team stays under $77.61 then the project will be within $350 for all semesters.

iii. The goal for spring 2026 is creating a final working prototype; reworking the fall 2025 design based on data produced by the client, improving material selection for dorsiflexion gait and medial lateral support, and solidifying significant data to prove effectiveness. As the previous prototype does not have fully significant results a new design will be made within the constraints of the budget.

3. Miscellaneous

a. Standards and Specifications

i. CFR Title 21, Section 890.3025: This regulation classifies the device as a Class I medical device. If electronics are added, it would fall under Class II [24].

ii. 501(k) requirements: Most Class I devices are exempt from 501(k) submission. This AFO may be exempt if the FDA determines that additional review is not needed to ensure safety and effectiveness [25].

iii. CFR Title 21, Section 890.3475: Defines a limb orthosis as a medical device worn on the upper or lower limbs to support, correct, or prevent deformities. Examples include braces, splints, elastic stockings, and corrective shoes [26].

iv. CFR Title 21, Part 803: Manufacturers and facilities must report any deaths or serious injuries linked to the device through a Medical Device Report (MDR) [27].

v. ISO 14971:2019: Outlines risk management requirements. A Failure Modes and Effects Analysis (FMEA) should be done to identify possible risks for patients, users, and property. The standard defines risk as the combination of the chance of harm and the severity of the outcome [28].

vi. ISO 8549-3:2020: Defines an orthosis as an external device used to compensate for problems in the neuromuscular or skeletal system. An ankle-foot orthosis specifically covers the ankle joint and all or part of the foot [29].

vii. ISO 8551:2020: Provides guidelines for evaluating functional deficiencies in patients and setting clinical objectives when prescribing orthoses [30].

viii. ISO 2267:2016: Specifies testing methods for ankle-foot devices under repeated loading. Testing simulates the stance phase of walking, from heel strike to toe-off, to evaluate strength, durability, and service life [31].

b. Customer [32]
    i. This device is designed for daily use by a 16-year-old with Facioscapulohumeral Dystrophy (FSHD) that requests the device be as unnoticeable as possible. It should be able to be worn both with and without shoes. Although it is custom-fitted, the target group also includes other young patients with FSHD or related muscular dystrophies who require ankle inversion, eversion, and dorsiflexion support.
c. Patient-related concerns
    i. The orthosis must hold the ankle in dorsiflexion (approximately 10° above the neutral foot plane) when unweighted, ensuring proper foot clearance and reducing gait deviations. At the same time, it must allow enough flexibility for functional tasks such as squatting or descending stairs.
    ii. The device should minimize the need for eccentric muscle contractions while preventing foot slap, thereby supporting patients with weakened ankle muscles.
    iii. The AFO must balance flexibility and stability: flexible enough to allow natural gait, but strong enough to prevent foot drop and inversion. It should not interfere with daily activities and should remain discreet to avoid drawing attention.
        1. There has been minimal recovery of the ankle movement in the inversion and eversion aspect, leading the brace to focus more on dorsiflection support and less on eversion and eversion prevention.
    iv. A slim profile that can be hidden under clothing is essential to reduce the risk of stigma or bullying in social settings such as school.
d. Additional optional patient requests
    i. The device should be designed to fit comfortably within the patient's horse riding boot, if possible.
    ii. The device should resemble a standard athletic brace to avoid drawing attention in public settings.
e. Economic Impact

i. Each year, approximately 53,000 AFOs are fabricated in the United States, with an average Medicare reimbursement of $417, totaling more than $2.2 million annually [33]. AFOs can cost over $1000 and, for many families, these costs present a barrier to access [34][35].

ii. The global AFO market is expected to grow to over $330 million by 2034 as demand for mobility aids increases due to rises in neurological and musculoskeletal conditions [36]. This emphasizes the need for a cost-friendly, yet effective AFO.

iii. For patients with muscular dystrophies, additional expenses accumulate through both direct and indirect medical costs. Direct costs include hospital visits, therapy, pharmaceuticals, and insurance coverage, averaging $22,533 annually in the U.S. [37]. Indirect costs such as home modifications, vehicle accommodations, caregiving, dietary needs, and travel add approximately $12,939 per patient each year [37].

iv. Loss of income is another significant burden in situations where the condition worsens to the point of the patient not being able to work. Families with a member requiring care for a muscular disorder experience an annual income reduction of about $21,600 compared with unaffected households, even after accounting for demographic and socioeconomic variables [37].

v. Overall, the economic burden of muscular dystrophy disorders in the U.S. is estimated at $1.07–1.4 billion annually [37]. Developing a cost-effective AFO can help ease this financial strain by improving mobility, enabling greater independence, and supporting long-term productivity for individuals living with FSHD.

f. Competition

Most ankle–foot orthoses (AFOs) are based on the three-point force system, a common biomechanical approach used to control joint motion and limit unwanted movement. In this system, one main corrective force is applied in either the mediolateral or anteroposterior direction, while two opposing forces act above and below it to provide balance. Together, these forces stabilize the joint. Increasing the length of the orthosis spreads these force points farther apart, which improves how effectively the brace

controls motion. This wider spacing also helps spread pressure over a larger area, making the device more comfortable for the user [38].

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

ii. Supramalleolar Orthosis (SMO)
    1. Pediatric SMOs are constructed from thin, flexible thermoplastic and extend just above the ankle bones (malleoli).
    2. They primarily provide control of subtalar joint alignment, maintaining a neutral heel to improve mediolateral stability.
    3. Their lightweight, low-profile design makes them comfortable for daily wear and compatible with most shoes [39].

iii. Variable Stiffness Orthosis (VSO)
    1. The VSO is a powered AFO currently in the research phase. It uses a customizable cam-based transmission system that can define specific torque-angle relationships and adjust stiffness in real time.
    2. Early results suggest it reduces foot drop and increases overall ankle moments. However, VSOs are not yet commercially available [40].

iv. Jointed AFO
    1. Jointed AFOs include a hinge at the ankle joint, allowing controlled motion and enabling a more natural gait with a full range of movement.
    2. While they optimize gait patterns, drawbacks include greater bulk, potential noise during use, and a higher likelihood of mechanical component failure [38].

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