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.

Client requirements:

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

Design requirements:

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

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

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

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

b. Safety

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

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

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

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

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

c. Accuracy and Reliability

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

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

d. Shelf Life

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

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

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

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

i. Weight

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

j. Materials

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

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

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

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

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

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

vi. To enhance resistance against ankle inversion, a custom 3D-printed PLA insert may be integrated within the fiberglass. This reinforcement would be modeled directly on the patient's anatomy to improve fit and structural stability.

vii. Fiberglass provides several advantages for long-term use. Its low weight minimizes fatigue and discomfort, making it easier for the user to move naturally. At the same time, its durability ensures resistance to daily wear and tear, extending the service life of the device. The material's porous structure improves airflow, reducing heat and moisture buildup for greater comfort. Together, these characteristics maximize the orthosis' effectiveness in preventing foot drag, stabilizing the ankle, and improving gait.

k. Aesthetics, Appearance, and Finish

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

ii. The surface will be smooth, slim, and inconspicuous, while still offering the necessary support.

2. Production Characteristics

a. Quantity

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

b. Target Product Cost

i. This project is funded by Biomedical Engineering (BME) Design at the University of Wisconsin-Madison. The expected cost of this semester's continuation will be $100 dollars.

ii. In fall 2024, the initial prototype accounted for $189.02 of the $300 budget, with $8.71 covered by the BME department and $180.30 from the BME Design fund. In spring 2025, project expenses were $37.95, of which $13.60 was covered by the department. In total, project costs came to $226.97, with $22.31 supported by the department and $204.65 through the BME Design fund.

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

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

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

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

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

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

f. Competition

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

i. Passive-Dynamic AFO (PD-AFO)

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

ii. Supramalleolar Orthosis (SMO)

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

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

iii. Variable Stiffness Orthosis (VSO)

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

iv. Jointed AFO

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

Resources

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