Inconspicuous Ankle Foot Orthosis (AFO) for teen

PRODUCT DESIGN SPECIFICATIONS (PDS)

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Rise and Stride

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Function/Problem Statement:

Facioscapulohumeral Dystrophy (FSHD) is the most common type of muscular dystrophy, affecting approximately 4-10 in 100,000 individuals. This genetic disorder leads to progressive muscle weakness, and while there is currently no cure, physical therapy, orthotics, and surgery can help manage symptoms [1]. However, there is limited clinical research focusing on children with FSHD, leaving gaps in understanding and addressing their specific needs. This project aims to raise awareness of FSDH and explore the benefits of discrete ankle-foot orthoses (AFOs) for individuals with progressive muscle weakness. The team aims to design a brace for the patient to aid in natural gait 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, restricting medio-lateral ankle motion, 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 supports dorsiflexion and prevents foot inversion while remaining flexible enough for the patient to carry out their daily activities. Additionally, the client prefers the AFO to be discreet, fitting inside a shoe and minimizing visibility. Functionality, however, is starting to outweigh discreteness as the patient's disease progresses.

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].
        ii. The device should mimic normal gait without providing any resistive moment during dorsiflexion [2]. Additionally, it should allow a range of motion of more than 30° from the initial ankle angle to facilitate foot clearance [3].
        iii. The device should generate a resistive moment in the plantarflexion direction and should be adjustable in the range of 5-10 Nm per 10° of plantarflexion [3].

iv. Moment-angle characteristics should be 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 [4].

v. The design must withstand the maximum bodyweight forces exerted by a teen. The average weight of a 16-year-old teenager in the United States is 136.2 lbs [5] and during walking, forces exerted on the AFO are estimated to be three times the body weight [6].

vi. 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.

vii. 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.

viii. The rigid component of the brace must accommodate a force of at least 266 N [6].

ix. AFO design must prevent inversion angles greater than 25° [7].

b. Safety

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

ii. In a manufactured and marketed design, the chosen material must be non-toxic and hypoallergenic to minimize the risk of skin irritation or allergic reactions. All surfaces must be smooth and free of sharp or ridged edges to prevent risk of surface wounds or abrasions.

iii. The outer surface of the AFO material must offer sufficient traction to prevent slipping when worn without shoes.

iv. Adjustable components of the design must remain secure under strong impacts while avoiding restriction of blood flow.

v. Any fastening mechanisms should prevent loosening or dislodgement during regular physical activity.

vi. The AFO must feature mechanisms for quick and easy removal in case of emergency without the need for specialized tools.

vii. The design should allow breathability to prevent overheating and moisture buildup.

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 [8]. 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 tailored to the patient's specific measurements and support needs. They are designed for immediate and continuous use. If left unused for an extended period, the patient's measurement or support requirements could change, making the AFO 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 material composition, frequency or intensity of use, and changes to the patient's needs. Generally, it should last around 5 years [9].

ii. AFOs fabricated using semi-rigid materials like carbon fiber, fiberglass, or polyethylene may last longer than less-stiff materials [10].

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 [11].

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 around the house, during the school day, and

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 [12].

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. The design should allow for adjustments to accommodate the growth, such as adjustable straps to ensure a secure and personalized fit for the intended product life in service.
    iii. 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 [13].
    iv. Padding should be provided around sensitive areas, such as the Achilles tendon, ankle, and foot base, to prevent discomfort and skin irritation.
    v. The orthosis should maintain a low profile and be able to fit comfortably within a standard shoe, without requiring the user to wear specialized footwear [3].
    vi. Any moveable components of the design should function quietly.
    vii. AFOs can increase step length and step velocity of patients which results in more fluid body movement and less energy excursion. AFOs can provide more stability during gait which improves the patient's daily life [14].

h. Size:
    i. The size of the AFO must be tailored to the patient's dimensions. Measurements have been taken to closely match the leg. The orthotic should match these measurements, with minor adjustments for padding or other anti-chafing mechanisms in the design [15].
        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. Typically, an AFO's thickness will be 3.175 mm to adequately support the foot [16]. The device should deform only minimally during use while maintaining enough flexibility to avoid excessive stiffness that could cause instability [3].

iii. AFO must be small enough to fit comfortably inside of a shoe.

i. Weight

i. The orthosis 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 [17].

j. Materials

i. The foot sleeve of the brace as well as the bungee cord will be composed of a blend of nylon, polyester, and latex. These materials were chosen for their specific properties that enhance both functionality and comfort [18].

1. The sleeve's breathability will absorb sweat and keep the foot dry, providing comfort during extended use. The material will also be tight and

strong, ensuring that the sleeve stays securely in place without sliding [19].

2. The fabric is smooth and soft, adding comfort, while its graduated compression promotes circulation, providing support and pain relief to the user [19].
    a. Nylon is specifically selected for its low elongation, strength, high-temperature resistance, and ability to make the brace visually appealing and lightweight [19].
    b. Polyester, known for its durability and strength, is ideal as it retains its shape and resists wrinkles, shrinking, and environmental elements like water and wind, which is crucial since the device will frequently be exposed to outdoor conditions [20].
    c. Latex contributes flexibility, durability, and excellent resistance to liquids, making it an effective barrier against moisture while maintaining overall strength [21].

ii. The effectiveness of preventing ankle inversion depends highly on the rigid strength of the cast. 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 [22].

iii. The rigid supporting piece along the ankle will be constructed using fiberglass polymer tape. This material was selected for the following characteristics: lightweight, moldable, radiolucent, resistant to degradation by water, inexpensive, high strength-to-weight ratio, and thin profile [22].

iv. There is potential to include a 3D printed component within the fiberglass tape that is modeled after the patient's own anatomy and acts as a reinforcement against ankle inversion. This piece would be fabricated using PLA.

v. Fiberglass substrate'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,

fiberglass substrate's porous nature will allow the patient comfort and breathability. These combined properties maximize the aid needed for foot-dragging prevention, ankle stabilization, and overall gait improvement.

k. Aesthetics, Appearance, and Finish
    i. The AFO will have a black, sleek design to reduce its visibility. It will resemble an athletic brace, promoting a more natural appearance when worn in public. The brace is designed to fit comfortably in tennis shoes and Converse, giving the patient the freedom to maintain their personal style.
    ii. The brace will have a smooth finish and a slim appearance, making it as inconspicuous as possible while still providing the necessary support.

2. Production Characteristics
    a. Quantity
        i. This project consists of making one right-leg AFO. However, considering mass production, the quantity would meet market demands among teens needing right-leg and/or left-leg AFOs.
    b. Target Product Cost
        i. This project is funded by Biomedical Engineering (BME) Design at the University of Wisconsin-Madison. The monetary supplementation is $100 with room for expansion where needed.
        ii. The initial prototype accounted for $189.02 of last semester's budget of $300. $8.71 was covered by the BME department, so the total spent through BME Design funding was $180.30.
        iii. The remaining budget is to be spent on fabricating a rigid support to inhibit the patient's ankle inversion. Because fiberglass substrates are relatively inexpensive, this support should cost under $50 to implement in an initial prototype [23].

3. Miscellaneous
    a. Standards and Specifications
        i. Code of Federal Regulations Title 21, Section 890.3025
            1. This device is classified as a Class I Medical Device. The device will be considered a Class II Medical Device if an electronic component is incorporated [24].
        ii. 501(k) requirements, premarket submission

1. Most class I medical devices are exempt from 501(k) requirements. The device may be exempt if the FDA determines that a 501(k) is not required to provide reasonable assurance of the safety and effectiveness of the device [25].

iii. Code of Federal Regulations Title 21, Section 890.3475

1. This defines a limb orthosis as a medical device worn on upper or lower limbs to support, correct, prevent deformities, or 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 [26].

iv. Code of Federal Regulations, Title 21, Chapter 1 Part 803

1. Manufacturers and facilities that use the device must report deaths and serious injuries that the device has caused or contributed to through a Medical Device Report (MDR) [27].

v. ISO Standard 14971:2019

1. Risk analysis through Failure Modes and Effects Analysis (FMEA) should be completed to identify potential risks for the patient, operator, and property. This includes gathering data and reviewing literature about the risks of similar medical devices. This standard states the concept of risk involves the probability of occurrence of harm and the severity of its consequences [28].

vi. 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 [29].

vii. 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 [30].

viii. 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.
2. Testing should be completed on how the prosthetic device performs under repeated, cyclical loading conditions that simulate the forces and motions experienced during the complete stance phase of walking. This includes 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 [31].

b. Customer [32]

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 degrees 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. Economic Impact
   i. Given that approximately 53,000 AFOs are fabricated each year in the United States at an average Medicare reimbursement of $417, more than $2.2 million per year are spent on them [33]. These costs may make AFOs inaccessible to low-income families.
   ii. For patients with muscular dystrophies, expenses incur in the form of direct and indirect medical costs.
      1. Direct medical costs include hospital visits, therapy, pharmaceutical treatments, and insurance coverages. The sum of these factors amounts to about $22,533 per year in the United States [34].
      2. Indirect costs include home renovations, vehicle accommodations, home relocations, professional caregiving, dietary supplements, travel expenses, and more. In total, indirect costs in the United States cost approximately $12,939 per patient per year [34].
   iii. One of the largest contributors to the loss of income in families with a member who suffers from a muscular disorder is loss of productivity. While race, age, gender, duration of disease, level of education of the primary income member, and number of adults in the family are considered, the annual loss of income for a family with a patient requiring care is $21,600 less than those who do not need care [34].
   iv. Overall, the total cost of muscular dystrophy disorders in the United States ranges from $1.07 to $1.4 billion per year [34].

v. Providing a cost-effective AFO will alleviate the long-term economic burden of FSHD and increase the productivity of individuals who have the condition, raising their income levels and allocating more funds to treating the condition.

f. 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. This system is incorporated in the majority of existing AFO designs [35].

i. Passive-Dynamic AFO (PD-AFO)
    1. Sleek and flexible design, ideal for patients with less severe ankle weakness.
    2. Have a flexible calf shell, which can absorb energy to promote dorsiflexion by releasing additional energy during the push-off phase of walking.
    3. Shown to provide better comfort and improve spatio-temporal parameters.
    4. Able to customize dimensions for the user through 3D printing but unable to adjust stiffness and support to match the patient's level of ankle impairment [1].

ii. Supramalleolar Orthosis (SMO)
    1. Pediatric SMO's are made from thin and flexible thermoplastic that provides support just above the ankle bones (malleoli).
    2. Primarily used to control subtalar joint alignment to maintain a vertical or neutral heel to help improve mediolateral movement.
    3. Comfortable to wear in shoes due to their thin and minimally restrictive design [36].

iii. Variable Stiffness Orthosis (VSO)

1. This powered AFO features a customizable cam-based transmission able to specify any torque-angle and change the magnitude of its overall stiffness in real time.
2. Found to lead to reduced foot drop and increased total ankle moments.
3. In the research stages, not currently on the market [37].

iv. Jointed AFO

1. Features a hinge at the ankle joint, allowing for motion
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 [35].

Resources

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