Inconspicuous Ankle Foot Orthosis (AFO) for teen

Preliminary Product Design Specifications

Fall 2024 BME 200/300 Lab 304

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AFO Group

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19 September 2024

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 dystrophies and for this project in particular, we are focusing on young individuals diagnosed with Facioscapulohumeral Dystrophy (FSHD), the most common kind of muscular dystrophy. The team aims to design a brace for client Maggie Eggleston 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 Maggie to carry out her 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 Maggie.

Recommended additional requirements:

The AFO will be designed to accommodate individuals in Maggie's age group, 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 plantarflexion and dorsiflexion 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 girl. The average weight of a 15 year old teenage girl 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 these daily activities effectively.

iv. The AFO dimensions must be tailored to the client's leg geometry and customizable to ensure a secure fit.

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. Self life is not applicable to AFOs, as they are designed for immediate and continuous use.

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.
    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 should be provided around sensitive areas, such as the Achilles tendon, ankle, and base of the foot, 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. Typically, an AFO's thickness will be 3.175 mm to adequately support the foot [13]. The device should deform only slightly during use.
    iii. 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. We aim to 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. For this project we will be 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. Our client is willing to increase the budget if our design is functional and will be used by our 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. Our 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 named Maggie, who has been diagnosed with Facioscapulohumeral Dystrophy. While the orthosis will be custom-fitted to Maggie'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 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 slap.
    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. *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 antero-posteriorly, with counter forces applied above and below the primary force, all summing to zero. The longer the lever of the orthosis, the farther apart the points of force are, resulting in greater correction. This technique can also help reduce pressure and discomfort when wearing the orthosis [23].

    i. Flexible AFO
        1. Provides flexibility around the ankle area.

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

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

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

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

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