

Product Design Specification (PDS)

Project: Active ankle/foot orthotic (AFO) to enhance walking and balance

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Function: Create a device that actively enhances forefoot step-off and increases proprioception to improve balance for people experiencing ankle weakness, foot-drop and the inability to walk and balance safely as a result of various neurological diseases such as Charcot-Marie-Tooth disease, multiple sclerosis and stroke. The device should be non-obtrusive, fit in a shoe, comfortably attach to the leg, and be economical.

Client requirements:

- Ability to push off the ball of the foot
- Prevents foot drop
- Ankle stability

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements: The patient would like to use the device on a daily basis with activities ranging from walking around the house to hiking. The load that will be exerted on the device will be based on the patient's weight and load distribution throughout their foot and ankle.

b. Safety: The device cannot exert any pressures on the skin that could cause irritation. It must be breathable and very durable.

c. Accuracy and Reliability: The basic structure will be designed as a standard that can be used on a variety of patients. Parts of the structure will be custom fit and will have to be adapted to each individual patient.

d. Life in Service: The device will be worn on a daily basis while the person is mobile. Ideally it will be able to be worn at night so that in the event that a person needs to get out of bed they will be able to walk around with ease.

e. Shelf Life: The shelf life for this product is unlimited due to the use of plastics and other materials that do not have a limited shelf life.

f. Operating Environment: The operating environment for this device is somewhat unlimited and is only restricted to what the person wearing the device can withstand. The device will most likely be exposed to water, heat, sand, dirt, cold, etc.

g. Ergonomics: The device will be designed to withstand the forces exerted on it by the person wearing the device during their normal day to day activities. Height restrictions and shoe size can be adapted so that the device will be able to fit a variety of people. Forces that are out of the norm of forces exerted by a patient on the device will not necessarily be able to be withstood by the AFO.

h. Size: The size of the AFO will depend on the weight and height of the person wearing the device.

i. Weight: The weight of the device should be as light as possible so as not to impede the ability of the patient to lift their foot while walking.

j. Materials: Plastics, biopolymers, and carbon nano fibers.

k. Aesthetics, Appearance, and Finish: It will have a molded plastic or carbon nano fiber exterior. The majority of the device will be hidden within the shoe so aesthetics will not be that large of a concern. The part that will be visible will have two support bars on either side of the leg and a velcro strap around the top.

2. Production Characteristics

a. Quantity: For our client we will need one AFO for each ankle.

b. Target Product Cost: Our target cost is \$300.00.

3. Miscellaneous

a. Standards and Specifications: Currently there are no set specifications for this product.

b. Customer: The customer would like to see “new” materials being used. Currently a lot of plastics are being used on the product, so he would like to see a new material that is lightweight and that has more spring.

c. Patient-related concerns: The patient’s main concern is that she wants to be able to push off the toe/ball of her foot.

d. Competition: There are currently a variety of products on the market. The majority are made from plastic.