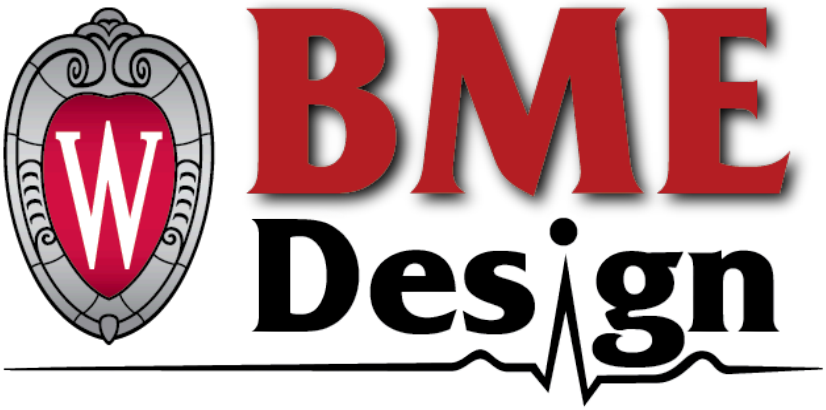

Amputee Advanced Donning Device

Product Design Specification

BME 200/300, Lab 301

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Group members

Co-Leader/Co-BWIG: Eleanor Hollander, erhollander@wisc.edu

Co-Leader/Co-BWIG: Carly Villa, cpvilla@wisc.edu

Communicator: Anna van Riessen, avanriessen@wisc.edu

BSAC: Sam Kamin, sjkamin@wisc.edu

BPAG: Ava Hopper, aghopper@wisc.edu

Client: Mr. Daniel Kutschera

Advisor: Dr. John Puccinelli

Function

During rehabilitation, it is critical for amputee patients to wear a specialized compression garment known as a shrinker. A shrinker aims to shape the residual limb in preparation for prosthetic fitting and prevent post-operative complications like swelling and excessive fluid retention. For application of the shrinker, patients currently rely on basic donning tubes, in which the shrinker is stretched over a plastic tube and pulled over the residual limb. Because shrinkers are designed to apply strong, consistent compression they can be very difficult to stretch over donning tubes. This challenge is especially significant for elderly patients, who may have limited strength, dexterity, or mobility. This project aims to create an advanced donning device that stretches the garment to the desired diameter using electronics, simplifying shrinker application and eliminating the need for the user to manually stretch the garment.

Client requirements

- The device must effectively simplify the application of the shrinker by minimizing the manual effort required from the user
- The device should be lightweight and portable to support ease of use in various settings.
- Production of the device must be approximately $500, with slight flexibility if higher cost significantly improves product quality

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**

        The Advanced Amputee Donning Device must be designed to withstand frequent use, likely multiple times per day over the course of several months. Patients recovering from below-the-knee amputations are instructed to wear shrinkers throughout the entire post-operative healing period, beginning 1–2 days after stitch removal and continuing until they are fitted with a permanent prosthetic [1]. This stage of recovery is essential for proper limb shaping, minimizing fluid retention, and reducing phantom limb pain. Because shrinker garments are extremely tight and difficult to apply, the device must significantly reduce the manual effort required for donning. The device must not require excessive strength, fine motor skills, or bending to operate, ensuring it is accessible for elderly patients or those with limited mobility due to conditions such as arthritis or diabetes. To maintain accessibility and ease of use, the device should also be lightweight and portable, allowing for convenient use at home, in physical therapy settings, or during travel.

b. **Safety**

i. The device will include expanding and contracting mechanisms. All moving parts must be carefully enclosed or shielded to ensure that they do not present any risk of pinching or sharp contact, thereby protecting the user from injury. The design must also incorporate mechanical or electronic safeguards to prevent overexpansion of the shrinker garment, which could damage its structural integrity and compromise its therapeutic function.

ii. All surfaces that may come into contact with the patient's skin must be non-abrasive, hypoallergenic, and easy to clean or disinfect, to minimize the risk of skin irritation or infection, particularly important given the recent surgical context in which this device is used.

iii. Additionally, because the device is intended to be electrically powered via a rechargeable battery, all electronic subsystems must comply with IEC 60601-1, the internationally recognized standard for the safety and essential performance of medical electrical equipment [2]. It ensures the safety of both the patient and healthcare provider.

c. **Accuracy and Reliability:**

According to anthropometric data, the average circumference of the male leg is 53.8 centimeters and the average circumference of the female leg is 52.9 centimeters [3]. The average diameter of the male leg 17.1 centimeters and the average circumference of the female leg is 16.8 centimeters Therefore, to perform its function of applying the shrinker to the patient’s limb, the product must consistently expand to at least the diameter 18 centimeters in order to ensure it is effective in putting the shrinker onto both male and female patient’s legs. If this value is not reached then the device is ineffective.

d. **Life in Service:**

This product is intended for use during the recovery period following a below-the-knee amputation. Accordingly, the device must remain functional throughout the entire rehabilitation timeline, from the removal of surgical stitches to the patient’s final fitting for a permanent prosthetic limb. While this recovery period may vary based on individual healing rates and response to rehabilitation protocols, it generally spans several months. Therefore, the device must be designed to perform reliably across that full duration [4]. Because the shrinker is

intended to be worn daily, the device must be capable of withstanding consistent, everyday use over the course of several months [1].

e. **Shelf Life:**

The device does not have any foreseeable components that will require crucial consideration in regards to shelf life. 10 years of uninterrupted shelf aging leaves lithium-ion cells retaining 96%-98% of their original capacity [5].

f. **Operating Environmen**t:

The device must be operational in a home environment and a healthcare environment such as a physical therapy facility or hospital. It is not expected to be used outdoors but if need be the device should maintain functionality in the presence of humidity, dust, and dirt. Due to the client's presence in Wisconsin the device must be able to withstand temperatures ranging from -10℃ to 30℃ [6].

g. **Ergonomics:**

The device must not have any sharp edges to cut the end user during its use. The device must be lightweight and portable for simple daily use to promote habits of consistently donning the shrinker sock to improve medical outcomes post-surgery. The device must not require excessive force to use in order to accommodate users with arthritis, peripheral neuropathy, or other chronic conditions causing pain and discomfort.

h. **Size:**

The device must be large enough to fit comfortably around the circumference of an average male thigh. On average, a male thigh has a circumference of 53.8 centimeters and a diameter of 17.1 centimeters [3]. Existing donning tubes are 20.3 centimeters in diameter and 30.5 centimeters tall [7]. The advanced donning device should thus align with these dimensions. The device will be roughly 30.5 centimeters tall and expand to a diameter of 20.3 centimeters.

i. **Weight:**

The weight should be small enough to be comfortably lifted by the patient. This device specifically is targeting patients with arthritis, which is a top consideration. A study done on the grip strength of adults with arthritis found their average grip strength to be 37 pounds [8]. Thus, the device should not exceed that metric.

j. **Materials:**

The knitted fabric that makes up the majority of shrinkers on the market requires 30 N to 40 N of force to expand to the desired diameter of 20.3 cm [9]. The material that the device is constructed from must be able to withstand forces greater than the quantities listed above. The material cannot be too dense, as it must be accessible to patients with low dexterity. Electronic components must be safe and easy for all patients to use. Any component that comes in contact with the skin must be nontoxic and safe for the patient.

k. **Aesthetics, Appearance, and Finish:**

The device must be accessible for patients with low dexterity to use, so it must be easy to hold and carry. It cannot be too heavy or bulky. It should be as lightweight and small as possible, while still being fully functional.

2. **Production Characteristics**
    a. **Quantity:**

    The client only requires us to produce one single device to aid in the application of shrinkers.

    b. **Target Product Cost:**

    The target cost ceiling for the product is $500. However, the client has indicated flexibility in this limit if the inclusion of certain features leads to a significant improvement in product quality. In such cases, a modest increase above the $500 ceiling may be acceptable, provided that the added value is clearly justified.

3. **Miscellaneous**
    a. **Standards and Specifications:**
        i. The device is to be used by patients in a home healthcare environment, so it must obey the regulations of IEC 60601-1-11.
            1. This standard is to be applied for all medical electrical equipment and medical electrical systems used in a home healthcare environment, to ensure basic safety and essential performance. These requirements hold true whether the main operator is the patient or a trained healthcare professional. Supply mains should have no voltage in excess of 110% or less than 85% of the nominal voltage between any of the conductors of the system or between any of these conductors and earth. The device also should be operational when stored from 25 °C to + 5 °C, or + 5 °C to + 35 °C at a relative humidity up to 90 %, or > 35 °C to 70 °C at a water vapour pressure up to 50 hPa [2].

ii. The donning device will directly or indirectly come into contact with the human body, so ISO 10993-1 must be considered.
    1. ISO 10993-1 requires a medical device that comes in contact with the human body to be evaluated with a risk management process. An evaluation of the sort would require assessment of the devices materials, the manufacturing process, the intended use of the device, and the duration and frequency of use. Potential risk identification should consider chemical toxicity as well as physical characteristics that could elicit unintended tissue response. ISO 10993-1:2018, Clause 4.1 states that "Evaluation can include both a review of relevant existing preclinical and clinical data and actual testing. Such an evaluation might result in the conclusion that no testing is needed if the material has a demonstrable safe history of use in a specified role and physical form that is equivalent to that of the medical device under design" [10].

b. **Customer:**

The primary users of this product are below-knee amputation patients. This demographic largely consists of individuals affected by diabetes, leading to a need for amputations. Peripheral neuropathy, a complication of diabetes that can lead to amputation, can make extremities weak and further complicate shrinker application [11]. Certain end user groups that could benefit the most from this device are elderly patients, those with peripheral neuropathy, and those with arthritis.

c. **Patient-related concerns:**

The device must not harm the patient. The device must be used with careful consideration as to not overstretch and damage the shrinker. Additionally, the device will be easy to use and simplify the current shrinker application process.

d. **Competition:**

The current competition on the market is minimal. The client primarily utilizes a donning tube composed of acrylic material which requires the patient to manually stretch their shrinker over the exterior lip of the device [7]. These devices come in different diameters to account for different sizes of the residual limb.

Alternative devices for prosthesis donning have been patented such as U.S. Pat. 0004717. This is a liner donning device for prosthetic liners. A vacuum is created between the device and the liner to expand the liner, making application easier. Similar to a shrinker these liners have a smaller diameter than the residual limb, but they differ in composition. Liners are composed of silicone or other polymeric

material whereas shrinkers are made from elasticized fabric [12]. While this device uses similar technology it is specifically applicable to prosthetic liners [13].

Patent WO2023205312A1, a prosthetic liner assist device, claims:

1. “A device to assist donning of a prosthetic liner, said device comprising: a holder device configured to removeably receive the prosthetic liner, comprising: a base; a plurality of elongate fingers arranged concentrically about a central space, each said finger comprising: a lower end pivotably attached to said base; and an upper end; wherein each said upper end of each said finger is elastically connected to two adjacent said fingers thereby permitting said fingers to move radially outwardly and inwardly away from and toward said central space.”

This device is another example of a liner donning aid, this time utilizing mechanical force in the form of elastic cords to assist liner application [14].

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