Department of Biomedical Engineering
UNIVERSITY OF WISCONSIN–MADISON

Amputee Advanced Donning Device

BME 200/300 - Preliminary Report

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Abstract

Amputation, the surgical removal of a limb or appendage, is an increasingly prevalent medical procedure in the United States, with more than 500 new cases each day. Following amputation, patients are typically required to wear a compressive garment known as a shrinker. A shrinker helps shape the residual limb for prosthetic fitting while also reducing inflammation, promoting healing, and minimizing fluid buildup. The current shrinker donning device, which consists of a rigid acrylic tube, requires patients to manually stretch the compressive sock, a task that can be physically demanding and difficult for individuals with limited hand strength or dexterity. To address this challenge, the team designed an **e**xpanding pulley mechanism that stretches the shrinker sock, eliminating the need for manual effort. The device consists of six panels connected to a rotating plate that expands the circumference of the device when actuated. Expansion is electronically controlled via a simple switch, requiring minimal user exertion. The shrinker sock is placed around the device in its smallest state, and when activated, the device expands to stretch the sock for easy application onto the residual limb. Comprehensive electronic and mechanical testing will be conducted to verify the functionality, safety, and reliability of the device, ensuring it meets clinical and user requirements while improving accessibility and ease of use for amputee patients.

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Introduction

Motivation and Societal Impact

Amputation can be a life altering procedure. In the United States, major limb loss is a growing problem. From 2016 to 2019, the number of amputations grew from 1.95 million to 2.3 million, and this number is expected to more than double by 2050, reaching 3.6 million [1]. In the United States, there are over 500 new amputee patients every day [2]. The majority of amputations occur due to Peripheral Artery Disease (PAD) and diabetes [3], both of which impact motor skills. PAD is directly linked to muscle weakness and physical disability, including decreased grip strength [4]. Diabetes can affect the function and dexterity in the hands [5]. Following amputation, patients typically require use of a shrinker sock, which helps to reshape the residual limb and reduce swelling, preparing the residual limb to be fit for a permanent prosthetic. Without use of a shrinker sock, inflammation remains uncontrolled, and fitting of the prosthetic can be compromised [6].

Existing Devices and Current Methods

Despite the exponential growth of amputation in the United States, patients currently rely on an outdated and physically demanding device to apply shrinker socks, known as a Donning Tube. The device consists of a rigid acrylic tube that requires patients to manually stretch the compressive shrinker sock over the tube. Due to the level of compression of the shrinker garment, this can be extremely difficult for patients to use, especially those with low dexterity, who make up the majority of the amputee population [7].

Aside from the Donning Tube, current competition on the market is minimal. 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 [8]. While this device uses similar technology it is specifically applicable to prosthetic liners [9].

Problem Statement

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.

Background

Physiology and Biology

Amputation is the surgical removal of an appendage, meaning a limb or extremity. The most common type of amputation is a transtibial, or below knee amputation, accounting for approximately 71% of all amputations [3]. The majority of amputations occur as a result of vascular diseases, such as Peripheral Artery Disease (PAD) and Peripheral Neuropathy, both of which can be complications from diabetes. Peripheral Neuropathy is characterized by long term high blood sugar levels, oxidative stress, and inflammation, which can lead to nerve damage in extremities. This decreased sensitivity may result in wounds and blisters that go unnoticed leading to infection and potentially amputation. Peripheral Artery Disease is a fat build up in the blood vessels causing constriction and reduced blood flow. These complications slow wound healing and weaken the immune system, making the need for amputation more likely [10]. After amputation, patients must wear a sock-like compression bandage known as a shrinker sock, which helps to shape the residual limb and prepare the limb to be fit for a permanent prosthesis. Shrinkers also aid in reducing phantom limb discomfort, skin protection, desensitization, and preventing fluid buildup [11].

Client Information

The client, Mr. Daniel Kutschera, P.T., is a physical therapist who works in neuro-rehabilitation. He works with many amputee patients, specifically those with below-knee amputations. His goal is for the team to create a modernized device that simplifies donning of shrinker socks, minimizing the physical effort required from patients. This simplified process will encourage patients to be more consistent and diligent in using the shrinker garment during their recovery.

Design Specifications

The client has tasked the team with developing an advanced donning device designed to simplify the application of amputation shrinker garments. The device functions by stretching the shrinker garment, thereby reducing the manual effort required by the user to apply it to the residual limb. The device must remain lightweight and portable, with a target weight of less than 10 pounds to ensure ease of handling and transport. It must also withstand frequent, daily use, remaining functional during the entire recovery period, which spans 3-12 months [12]. The device must be large enough to fit comfortably around an average male thigh, which has a circumference of 53.8 cm and a diameter of 17.1 cm [13]. The knitted material that makes up the majority of shrinker socks requires a force of 30 N to 40 N and to be stretched to the desired diameter of 20.3 cm [14]. All moving parts of the device must be carefully enclosed, thereby ensuring no risk of pinching or sharp contact. The device must obey the regulations of IEC 60601-1-11, which is to be applied for all medical electrical equipment used in a home healthcare

environment [15]. Additionally, the device must obey the regulations of ISO 10993-1, which requires a medical device that comes into contact with the human body to be evaluated with a risk management process [16]. The team is operating under a flexible budget of $500.

Preliminary Designs

Design Materials

The team considered three different materials to construct the main body of the device. These materials each contained a variety of merits that made them a reasonable choice.

Material 1: Nylon

Nylon is a type of synthetic plastic polymer. Nylons offer extremely good wear resistance, coupled with a tensile strength of 79.3 MPa, a compressive strength of 86.2 MPa, and a compressive modulus of 2900 MPa. They also have high impact resistance, a high heat distortion temperature, and resist wear, abrasion, and vibration. In addition, nylons can withstand sustained contact with a wide variety of chemicals, alkalis, dilute acids, or oxidizing agents. Nylon is currently used in medical settings as it is highly biocompatible. Nylon has a density of 1.15 g/cm^3 [17]. Nylon 12 Powder is available to be 3D printed by Selective Laser Sintering (SLS) at the Design Innovation Lab in Wendt at UW-Madison for a cost of $0.10 per gram [18].

Figure 1: Nylon Plastic Tubes [19]

Material 2: Acrylic

Acrylic is a transparent plastic material. It has a tensile strength of 69.0 MPa, a compressive strength of 117 MPa, a flexural modulus of elasticity of 3310 MPa, and a tensile modulus of elasticity of 2760 MPa. When considering types of acrylic, cast acrylic has better chemical resistance and machining characteristics than extruded acrylic. Additionally, acrylic offers the best aesthetics. Acrylic has a density of 1.18 g/cm^3 [20].

Figure 2: Acrylic [21]

Material 3: Polyvinyl Chloride (PVC)

Polyvinyl chloride is a synthetic plastic polymer. PVC features a tensile strength of 51.7 MPa, a flexural strength of 88.3 MPa, and a tensile modulus of 2830 MPa. It has a density of 1.41 g/cm^3. Its favorable qualities include light weight, durability, and low cost. Additionally, PVC is resistant to weathering, chemical rotting, and corrosion. For these reasons, it is commonly used in medical devices [22].

Figure 3: Polyvinyl Chloride [23]

Body and Expansion Mechanism Designs

The team considered three preliminary designs, each with a differing functional mechanism. These different designs allowed for evaluation of a wide variety of potential paths this project could take.

Design 1: Finger Trap

The Finger Trap design, shown in Figure 4 below, is a completely mechanical-centered design. This device features no electronic elements. The mechanism functions similar to a finger trap children's toy, where applying compressive force onto the open circular ends widens the diameter of the opening, shortening the length of the cylinder. Applying tensile force to the open circular ends narrows the

diameter of the opening, elongating the length of the cylinder. The end user is able to leverage these interactions to simplify donning their compressive shrinker sock. By stretching the sock around the narrow opening when the device is in its elongated position and then applying a downward compressive force to where the sock is applied, the end user stretches the sock to a desirable width and can then insert their residual limb and use this design as if it was a standard shrinker sock donning tube. This alleviates the difficulty of stretching the compressive sock around a large opening.

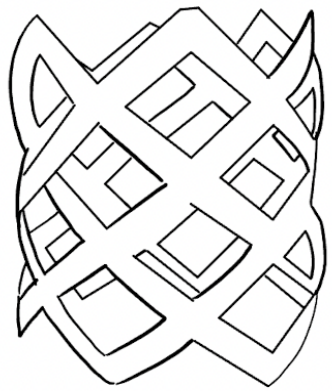

Figure 4: Finger Trap Design

Design 2: Expanding Pulley Mechanism

The Expanding Pulley Mechanism design is pictured in its entirety in Figure 5, and a closer view of the mechanism is depicted in Figure 6. The mechanism utilizes a rotating driving plate to drive springs and pistons to expand the diameter of the device. There are 6 separate outer walls that will hold the shrinker sock and be pushed apart from each other by the pistons. As these walls separate, the diameter of the device expands, stretching the shrinker sock open. This allows for simple application of the shrinker sock to the residual limb. The device is operable by a switch to run a motor which will expand the device for the user, eliminating almost all required force input. As the driving plate is rotated, the pistons move along the axis holes, expanding the overall diameter. At the largest extent of expansion, the device locks at that diameter. This expansion and locking is depicted in Figure 7. As the driving plate is rotated in the opposite direction, the pistons retract to the original position [24].

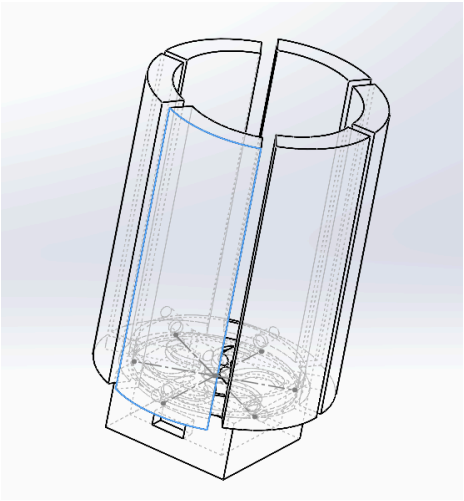

Figure 5: Expanding Pulley Mechanism Design

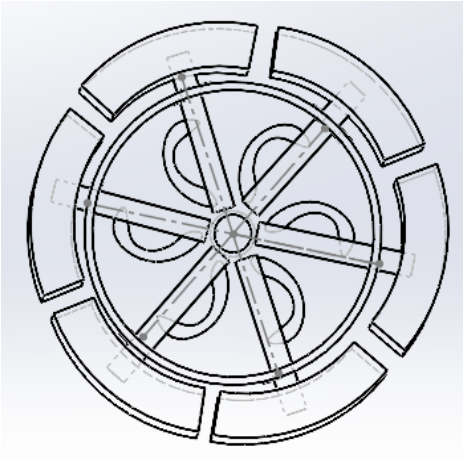

Figure 6: Expanding Pulley Mechanism

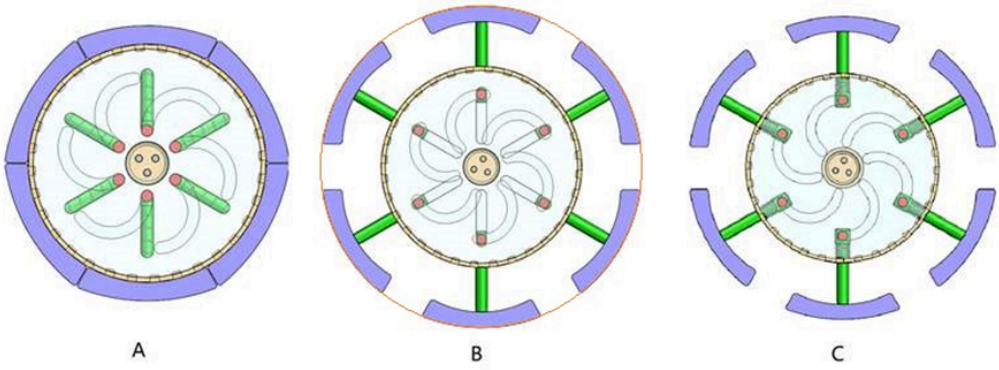

Figure 7: Expanding Pulley Mechanism in Expansion [24]

Design 3: Piston

The Piston design, shown in Figure 8, uses a piston to push open two separate interlocking semi-cylinders. As the piston extends, the semi-cylinders gradually un-interlock from each other, expanding the overall diameter of the device. The end user will apply the shrinker to the un-expanded cylinder and push a button to pump pressure to activate the piston. This pushes the interlocking cylinders apart. Then, the end user dons the stretched shrinker sock to their residual limb, as in the previous two design ideas.

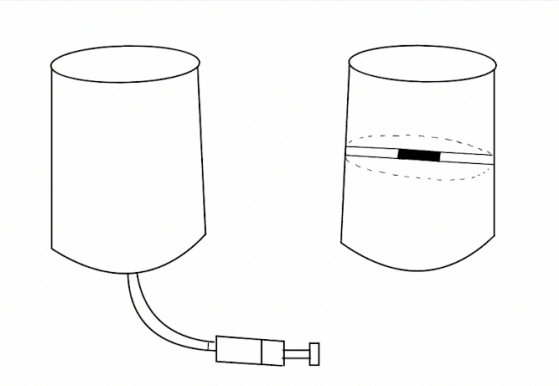

Figure 8: Piston Design

Preliminary Design Evaluation

Materials

Criteria (Weight)	**Option #1** Nylon		**Option #2** Acrylic		**Option #3** Polyvinyl Chloride (PVC)	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Biocompatibility (25)	5/5	25	5/5	25	5/5	25
Weight (25)	4.6/5	23	4.6/5	23	4/5	20
Ease of Fabrication (15)	4/5	12	1.67/5	5	4.67/5	14
Durability (15)	4.33/5	13	4.33/5	13	3.33/5	10
Cost (10)	4/5	8	3/5	6	5/5	10
Aesthetics (10)	4/5	8	4.5/5	9	3.5/5	7
Total (100)	89		81		86	

Table 1: Materials Matrix

Material selection was particularly important for this design, as in its use it would be coming into contact with skin. Research was done to determine top choices, with team members considering commonly used materials and availability. Plastic was quickly determined to be the best choice for this design. Team members then narrowed down the search to specific types of plastic. Strength and moldability were top considerations and nylon, acrylic, and polyvinyl chloride (PVC) won out as the top three choices for materials.

The team determined that top criteria would be biocompatibility, due to the device's foreseeable contact with skin, and weight, to accommodate necessities of portability and ease of use. These were followed by equally weighted ease of fabrication and durability, key considerations for the creation of the design and its ability to withstand repeated use. Cost and aesthetics rounded out the materials matrix with the lowest scores; important factors but not chief of concern.

Nylon received the highest score in the materials matrix. This was mainly due to its high biocompatibility, low weight, and durability over time. Additionally, it is low in cost, allowing the team to maintain that $500 budget goal. Acrylic was docked heavily under ease of fabrication, as it is prone to cracking during machining, and PVC was nixed due to its low durability and aesthetic appeal. Therefore, the team decided to move forward with nylon.

Structural and Expansion Mechanism Design Matrix

Criteria (Weight)	**Design #1** Finger Trap		**Design #2** Expanding Pulley Mechanism		**Design #3** Piston	
	Raw Score	Weighted Score	Raw Score	Weighted Score	Raw Score	Weighted Score
Ease of Use (25)	3.6/5	18	4.8/5	24	4/5	20
Mechanical Function (20)	3.75/5	14	4.5/5	18	4/5	16
Safety (20)	4/5	16	4.25/5	17	4.5/5	18
Ease of Fabrication (10)	4.5/5	9	3/5	6	3.5/5	7
Size (10)	3/5	6	4/5	8	4/5	8
Cost (10)	4.5/5	9	3.5/5	7	4/5	8
Aesthetics (5)	4.5/5	4.5	5/5	5	5/5	5
Total (100)	76.5		85		82	

Table 2: Structural and Expansion Mechanism Design Matrix

Three designs were selected in terms of the overall structure and mode of mechanical expansion of the device. Criteria was chosen to help compare the designs. Ease of use refers to the patient's ability to use the device without excess force. This criterion was rated the highest, as complaints surrounding the current donning device often reference how difficult it is to use. Mechanical function pertains to the effectiveness of the design. This was another key consideration, as the ability of the device to carry out its function is imperative. Safety was given a weight equal to mechanical function. Safety refers to the ability of the device to operate without injuring the patient in any way. Ideally, the device should be fashioned in a manner that avoids pinching or clamping, and its electronics should be safely enclosed.

Ease of fabrication, size, and cost were all given equal weight. Ease of fabrication refers to the ability of the designers to replicate the device. This is important when considering replicatability. Size relates to the physical dimensions of the design as well as its weight. Portability is a concern, and thus dimensions should be of reasonable size. Weight is a consideration due to patient demographics, which skew elderly. The intended budget of the project is $500, which makes cost a factor. Finally, aesthetics was given the lowest weight in the matrix. Aesthetic refers to the look and visual appeal of the design. This is of some concern, but is not very important to device functionality.

The expanding pulley mechanism design scored the highest overall, excelling in the most heavily weighted categories of ease of use and mechanical function. Although the piston design performed best in safety, it was weaker in other areas. The fingertrap design scored the lowest overall and did not lead in any key category. Based on the design matrix results, the team selected the Expanding Pulley Mechanism as the final design.

Proposed Final Design

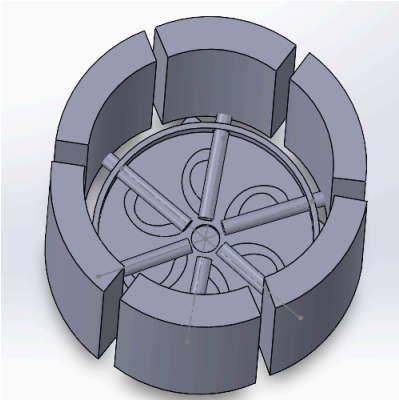

Figure 9: Final CAD Design Top View

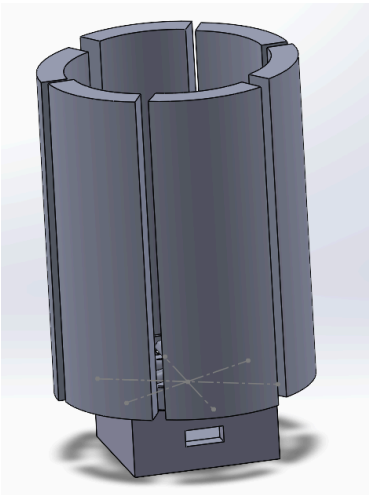

Figure 10: Final CAD Design Side View

After evaluating the design matrix and collaborating as a team, the group selected the Expanding Pulley Mechanism as the final design concept. This is pictured in Figures 9 and 10. This design utilizes a gear-driven expansion system to generate output forces. When the smaller gear rotates, it drives the larger gear, resulting in the controlled expansion or contraction of the device. The expanding pulley mechanism is designed to accommodate a range of diameters based on the user's individual anthropometric measurements. Current donning tubes have 2 diameter options, 20.32 cm and 25.4 cm [25]. To accommodate for a wide variety of thigh sizes the device will have a maximum expansion of 25.4 cm.

The expanding mechanism being utilized in this device is an expanding pulley mechanism. A cylindrical body freely holds a driving plate allowing it to spin. The nylon body pieces of the device will be connected to the cylindrical body via six pistons with springs. Each piston includes a circular hole through which a pin will be inserted. These pins will go through the piston and into a curved slot extruded from the driving plate. In the devices most constricted form the pins will be located at the tip of the slot closest to the interior of the cylinder body, with the springs of the pistons stretched. As the driving plate spins the spring compresses and the pin moves toward the exterior of the driving plate until it reaches its maximum expansion [24].

The smaller gear is powered by an electronic motor supplied by AA batteries. A double-pole, triple-throw switch allows users to toggle between three settings: expansion, contraction, and off. For user safety, a locking mechanism is integrated to prevent unintended motion, minimizing the risk of pinching or injury.

Attached to the expanding pulley mechanism are six machined nylon plastic pieces over which the shrinker garment is stretched. Each nylon piece will measure 27 cm in height, allowing the user to insert a substantial portion of their limb into the device for effective shrinker application. The thickness of the obtained nylon material will be determined through SolidWorks testing to be conducted in the near future. These simulations will allow the team to assess the strength of nylon components at varying thicknesses. Based on the results and the mechanical requirements of the device, an appropriate thickness will be selected to ensure optimal performance and durability. As the device expands, these nylon segments move outward, stretching the shrinker garment accordingly.

All electronic components, including the motor control circuitry and batteries, are enclosed within a 3D-printed circuit box that ensures protection, organization, and ease of maintenance. Within the box, electrical components will be soldered together and secured in position. This 3D-printed box will include 2 compartments, one that's easily accessible for any needed battery changes and one that houses the motor. The enclosed motor section will also have an extruded cut where the switch will be placed. The design and its dimensions can be found in Appendix C.

Fabrication

Materials

This product will come into frequent contact with human skin; therefore, all materials used must be nontoxic and biocompatible. The primary structural material selected for the device is nylon plastic, which is widely used in existing medical devices and meets biocompatibility standards. Additionally, nylon's lightweight nature makes it ideal for achieving the project's goal of creating a portable and user-friendly device. Nylon will be used to construct the pillars over which the shrinker garment will be stretched during expansion. The device's electronic components will include a double-pole double-throw (DPDT) switch, breadboard, wires, resistors, and AA batteries. Circuit components will be soldered together using 96.5% Tin, 3% Silver, 0.5% copper soldering wire. Electrical tape will be used if needed to secure electrical components in position within the circuit box. Finally, the circuit housing will be 3D-printed using polypropylene, chosen for its durability, flexibility, and chemical resistance, which together ensure reliable protection of the enclosed electrical components.

Methods

The CAD model of the circuit box will be 3D-printed using the Ultimaker printer with polypropylene (PP) filament. Inside the circuit box, circuit components will be soldered using 96.5% tin, 3% silver, and 0.5% copper soldering wire. Once the circuit is completed, all electrical components will be secured in place within the box using electrical tape to prevent movement and potential damage. The nylon plastic pieces will be machined using a band saw, as this tool is well-suited for cutting rods and tubes. Because nylon has a relatively low thermal conductivity, it can become excessively warm and expand during fabrication. To minimize deformation, the nylon will be machined at the highest cutting speed [26]. After cutting, the nylon pieces will be fastened to the metal pistons extending from the central section of the expanding mechanism using screws. Prior to screw insertion, the metal pistons will be modified using a milling machine to create grooves in each piece, allowing the screws to be properly inserted and secured. Additional components of the expanding pulley mechanism will be fabricated using metal-working equipment, including the mill and lathe.

Testing and Results

To evaluate the strength and functionality of the design, several tests will be performed. These tests include mechanical testing and overall functionality testing.

Mechanical Testing

The first tests that will be conducted will utilize the MTS machine for compression and tensile tests on the materials. As Nylon is a rigid plastic the testing of this material will follow the guidelines of ASTM D695. This is the standardized test method used for determining compressive properties of reinforced and unreinforced rigid plastics [25]. A singular nylon pillar will be placed between parallel

compressive plates and compressed along its major axis at a constant rate of displacement until fracture. This type of testing will provide the nylons modulus of elasticity, yield strength, deformation beyond yield point and compressive strength. The results of these tests will provide further insight into the total strength of our design and its ability to apply its necessary force [28].

An additional test will be conducted on the shrinker provided by the client. The exact composition of the shrinker is not known as different shrinkers are made of varying materials [6]. This test will provide a general understanding of the force required to stretch a shrinker, with slight deviations considered for different shrinkers. ASTM D4964 is the standard test method for tension and elongation of elastic fabrics [27]. This test requires a constant rate of extension, or CRE, machine which is satisfied by the MTS machine available. The shrinker will be placed around 2 band clamps, then extended to a specified elongation for 3 cycles. From these cycles a tension-recovery curve can be plotted to determine the tension needed for the desired elongation [30].

In addition to mechanical testing using the MTS machine, gear strength analysis will be conducted in SolidWorks. Before purchasing the gears and the motor that will drive them, the appropriate gear ratio must be determined. To accomplish this, SolidWorks Simulation will be used to apply forces to individual gear teeth. The applied moment on each tooth will generate shear stress at the tooth base, which can ultimately lead to shear failure.

Functionality Testing

In order to ensure the functionality of the final design, a number of tests will be conducted following fabrication. The shrinker will be placed over the device in its must constricted form and expanded to varying diameters. This test will evaluate the device's ability to hold the shrinker for the required expansion. Following this testing, modifications can be made to the exterior of the nylon pieces. Potential additions include hooks or adhesives to improve grip.

Discussion

Ethical Considerations

Affordability remains an important ethical consideration in the development of the Advanced Amputee Donning Device. While the current prototype can be produced within a budget of approximately $500, this cost still may be prohibitive for many patients. Future versions should therefore aim to reduce production costs through optimized material selection or simplified manufacturing. This will help ensure the device remains accessible to patients across diverse socioeconomic backgrounds and supports ideals of equitable healthcare. An additional ethical concern involves the sizing limitations of the device. The current prototype has a maximum expansion range, which may not accommodate all users with varying limb sizes. To ensure inclusivity, future iterations of the device should include multiple size options or adjustable components that can expand to fit a broader range of users.

Sources of Error

While moving through the design process, several potential sources of error were identified. The first involves the nylon plastic used for the structural components, which may not exhibit sufficient long-term durability and could deform under repeated compression forces from the shrinker sleeve. Should this issue arise during testing, additional reinforcement strategies, such as integrating support ribs or substituting a higher-strength plastic, may be required to enhance structural stability. Another potential issue lies within the motor system, which currently lacks a safety lock or automatic stop feature. Without such a safeguard, the motor may continue to rotate after the device reaches its maximum expansion, resulting in unnecessary strain on the gears and potential mechanical failure of the internal expansion mechanism. Incorporating a limit-switch would prevent overextension, reduce the risk of damage, and improve both the lifespan of the device.

Conclusions

To promote and simplify the use of shrinker garments among below-the-knee amputation patients, the team proposes a device that utilizes an expanding pulley mechanism to electronically stretch the garment, requiring minimal manual effort from the user. The final design incorporates an electronically powered motor that drives a gear system, enabling controlled expansion and contraction of the device.

The team will begin fabrication in the near future. The first step will involve ordering all necessary materials, including the electronic components—such as the DPDT switch and motor—as well as the nylon plastic pieces required for structural assembly. Once the materials arrive, the team will utilize the Design Innovation Lab to perform the previously outlined fabrication procedures on the nylon components. Simultaneously, the electronic circuit will be constructed and the circuit box will be 3D-printed. After each individual component has been completed and independently tested, the final assembly of the device will take place. Final testing will then be performed to verify proper functionality and safety.

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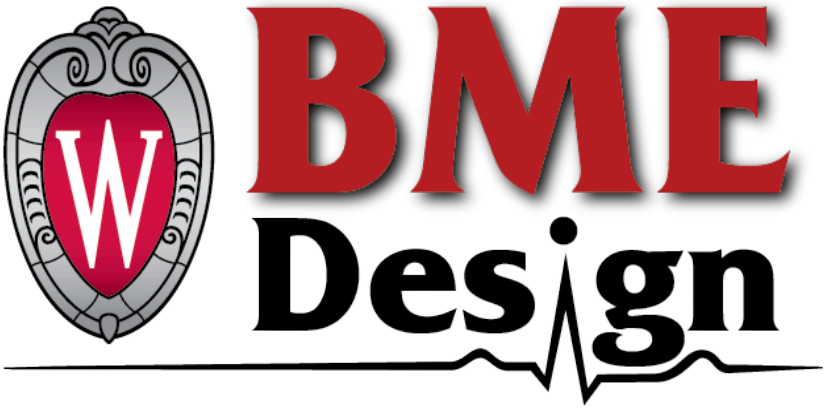
Appendix

Appendix A: Product Design Specification



Amputee Advanced Donning Device

Product Design Specification

BME 200/300, Lab 301

9/19/25

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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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Appendix B: Expenses and Purchases

No purchases have been made yet.

Appendix C: Circuit Box Design Drawings