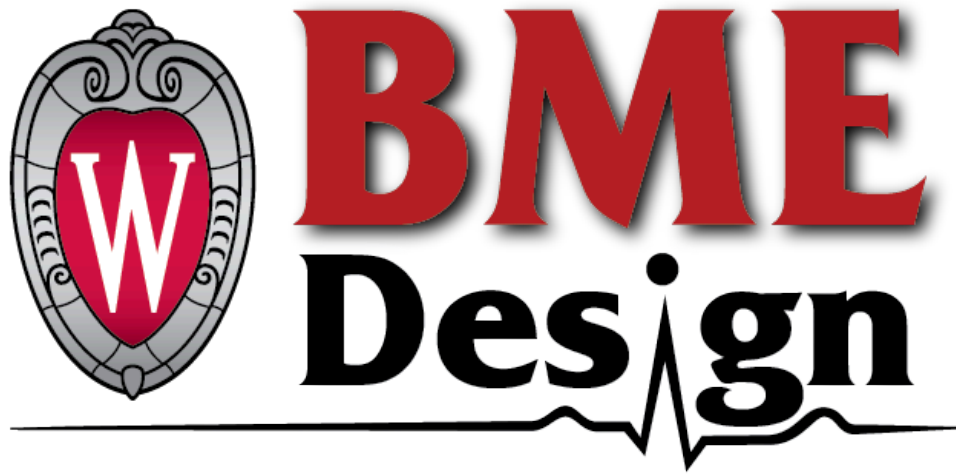




Amputee Advanced Donning Device

Preliminary Report

BME 400, Lab 306

October 7th, 2026

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Abstract

Amputation is a prevalent medical procedure in the United States, with approximately 300 to 500 amputations performed each day. During rehabilitation, patients are advised to wear a compressive shrinker sock to reduce swelling and shape the residual limb before being fitted for a prosthetic device. Currently, patients don shrinker socks using a rigid cylindrical donning tube, which requires users to manually stretch the sock over the tube. This process is physically demanding and can be especially challenging for individuals with limited dexterity, strength, or mobility. To address this problem, the team developed the Expanding Pulley Mechanism. The design consists of six panels connected to a gear-driven expansion system, in which a smaller gear drives a larger gear, resulting in the outward expansion of the panels. An electronic actuation system powers the mechanism, eliminating the need for manual user effort. The device will be fabricated using aluminum alloy and nylon to provide both durability and lightweight functionality. Comprehensive testing, including material testing using a Mechanical Testing System (MTS) and functional performance evaluations, will be conducted to verify safety, reliability, and effectiveness. The results will be analyzed to determine the device's ability to improve accessibility, reduce physical demands during shrinker sock application, and enhance the overall rehabilitation experience for amputee patients.

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Introduction

A. Motivation

In the United States, more than 2 million people are living with limb loss, with transtibial (below-the-knee) amputations accounting for approximately 82% of all cases [1, 2]. The prevalence of limb loss is expected to increase due to rising rates of peripheral artery disease, diabetes, and other chronic conditions associated with amputation [1]. Following an amputation, rehabilitation plays an important role in recovery and preparation for prosthetic fitting. One key part of this process is the use of a compression garment known as a shrinker sock, which helps shape the residual limb, reduce swelling, and prevent excess fluid retention [3, 4]. Consistent use of shrinker socks is critical for achieving successful prosthetic-fitting outcomes; however, applying these garments can be difficult because they are designed to provide strong, uniform compression [5]. These challenges can be especially significant for elderly individuals and patients with limited strength, mobility, or hand dexterity. The need for a more accessible solution is further emphasized by the fact that approximately 80% of patients undergoing lower-limb amputations have diabetes [6]. Diabetes-related complications, such as peripheral neuropathy and reduced fine motor control, can make handling compression garments more difficult and can reduce patient independence during rehabilitation [7]. As the number of individuals requiring rehabilitation continues to grow, there is a need for assistive technologies that make shrinker sock application easier and more accessible. A device that mechanically assists with stretching and applying shrinker socks could reduce the physical demands of donning, improve independence for patients with functional limitations, and support better adherence to post-operative rehabilitation plans.

B. Existing Devices

Few devices currently exist that are specifically designed to assist with the application of shrinker socks for individuals with lower-limb amputations. The most common method used is a donning tube, in which the shrinker sock is stretched over a rigid cylindrical tube and then pulled onto the residual limb (Figure 1). While this method is simple and inexpensive, it can be challenging for patients to use because shrinker socks are designed to provide high levels of compression and can require significant force to stretch. These difficulties are amplified for individuals with limited hand strength or reduced dexterity.



Figure 1. Donning tube used for current shrinker sock application [8].

Several products designed for compression sock application are available on the market for non-amputee patients. One example is the Doff N' Donner and Rolly system, which uses a rolling mechanism to assist with donning compression socks (Figure 2). Although this system reduces the effort required to apply a compression sock, users must still manually stretch and position the garment onto the device. As a result, many of the challenges associated with donning compressive garments remain.



Figure 2. Doff N' Donner and Rolly Combo by sigvaris, typically used for compression sock application [9].

Overall, the current market offers few solutions specifically for the application of shrinker socks for amputee patients. This gap highlights the need for a device that can more effectively assist individuals with limited physical function during the shrinker sock application process.

C. Problem Statement

During post-amputation rehabilitation, patients must wear shrinker socks daily to control edema and shape the residual limb for prosthetic fitting. Current donning methods require significant physical effort, making application difficult for patients with limited strength, dexterity, or mobility. Therefore, a lightweight (< 5 kg) device is needed to automatically expand shrinker socks to diameters of 20-25.4 cm (8-10 in) while overcoming compressive forces of 30-40 N, minimizing the manual effort required from patients.

Background

A. Background Research

Lower-limb amputation is often necessary as a result of trauma, vascular disease, infection, or complications arising from diabetes. Following amputation, successful rehabilitation depends on proper management of the residual limb, including controlling swelling, maintaining skin health, and preparing for prosthetic fitting. Shrinker socks are commonly used to manage residual-limb volume during the rehabilitation process. Controlled compression provided by shrinker socks reduces postoperative swelling and promotes

gradual shaping of the limb. The use of shrinker socks is especially important because excessive swelling can lead to complications such as delayed wound healing, discomfort, and poor prosthetic fit. Compression therapy helps prevent edema, or the accumulation of fluid beneath the skin, by promoting fluid return from the residual limb [10, 11]. If not managed properly, edema can stretch healing skin, increase tissue tension, delay recovery, and increase the risk of infection [12].

Approximately 80% of patients who undergo lower-leg amputations have complications related to diabetes [6]. Many diabetic patients also experience peripheral neuropathy, a condition in which nerve damage results in reduced sensation, impaired hand function, muscle weakness, and decreased fine motor dexterity [13]. In addition, elderly patients and individuals with arthritis may experience similar limitations in hand coordination and strength. The process of donning a shrinker sock can be particularly challenging for these populations because the process requires grip strength, hand coordination, and dexterity.

B. Design Research

To create a device that can effectively assist lower-limb amputation patients, the device must be capable of expanding shrinker socks reliably and consistently. Shrinker socks generate significant compressive forces when stretched, so the device must distribute force evenly around the circumference of the sock to prevent uneven expansion or overstressing of the material. To accomplish this, the device requires a structurally rigid design with components capable of withstanding repeated loading without deformation [14]. Maintaining uniform force distribution throughout the expansion will help ensure consistent performance and allow the device to accommodate a wide range of patients.

C. Client Information

The client, Dr. Daniel Kutschera, is a physical therapist practicing in the greater Madison, Wisconsin area. He works with lower-limb amputee patients during physical rehabilitation. The client identified that many individuals struggle to apply shrinker socks independently, which became the motivation for this project.

D. Design Specifications

The client provided design specifications to ensure the device is practical for both clinical and home use. The device must be capable of expanding a shrinker sock after it has been placed onto the mechanism and allow the sock to be applied to the patient once the mechanism is fully expanded. The device must provide sufficient and evenly distributed force to expand the shrinker sock consistently while remaining simple for the user to operate. The device must also be durable enough to withstand repeated daily use throughout a patient's rehabilitation period. Additionally, the device must be compatible with common sanitization methods, including disinfectant wipes and dilute bleach-water solutions used in clinical settings. The device should be portable, as it may need to be transported between patient rooms, and must have a total weight of less than 5 kg. Finally, the production cost of the device should remain below \$500. A complete Product Design Specification (PDS) can be found in Appendix A.

Preliminary Designs

A. Expanding Pulley Mechanism

The Expanding Pulley Mechanism in its current state was originally developed by a previous team working on this project (Figure 3). The design features a cylindrical base housing an internal gear-driven expansion mechanism. The small drive gear is rotated, which in turn rotates the larger gear contained within the base. The larger gear has slots that guide interconnected pins attached to the radial arms. As the gears rotate, the pins are driven outward, causing the arms to expand and increase the diameter of the device. This expansion stretches the shrinker sock to the desired diameter for application. Once fully expanded, the mechanism can be locked in place to prevent unintended movement during use. The device can be reversed, causing the arms to retract back to their original position. By incorporating a motorized drive system, the design eliminates the need for manual force.

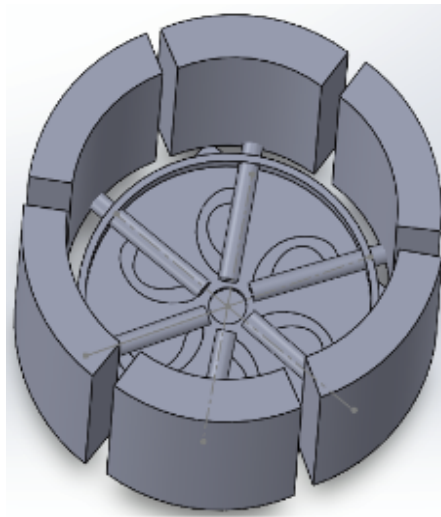


Figure 3. Expanding Pulley Mechanism model.

B. Expanding Rail System

The Expanding Rail System consists of a cylindrical base with at least four vertical pieces extending upward from it (Figure 4). These vertical pieces are attached to the base through an electrically powered rail system. During operation, the rail system moves the vertical pieces toward the center of the base to facilitate placement of the shrinker sock onto the device and then expands them outward to stretch the shrinker sock to the appropriate diameter. Each vertical piece consists of a structural backbone and an inner cover. The cover is made from a soft, hypoallergenic material that is non-irritating to the skin, ensuring user comfort should the device come into contact with the patient. The vertical pieces also each feature a force sensor to prevent excessive compression against the patient. If a force greater than a predetermined threshold is detected by any sensor, the device will automatically stop operating and alert the user. Most electronic components and all mechanical systems are housed within the cylindrical base.

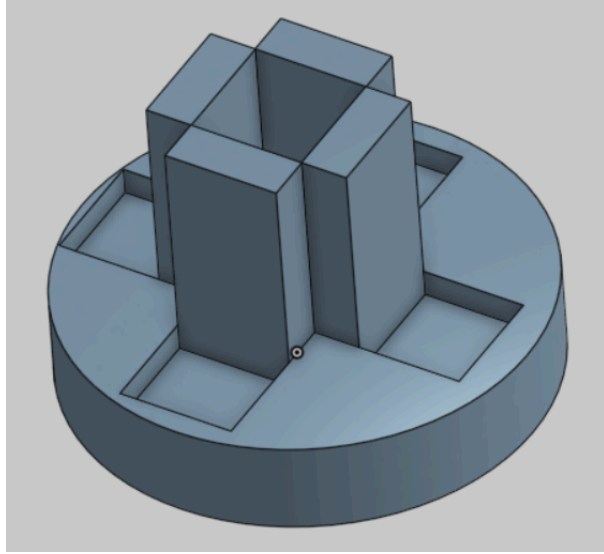


Figure 4. Simplified version of the Expanding Rail System.

C. Hoberman Design

The Hoberman Design is based on the Hoberman Mechanism shown in figure 5. The Hoberman Mechanism enables radial expansion and contraction through a series of interconnected linkages that move in a coordinated manner. This design incorporates the Hoberman Mechanism at its base and includes thin cylindrical vertical components attached around its circumference (Figure 6). These vertical components are evenly spaced to provide uniform support for the shrinker sock during expansion. As the mechanism expands and contracts, the vertical components move radially outward and inward, allowing the shrinker sock to be stretched to the desired diameter.

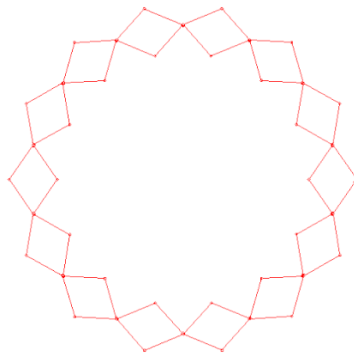


Figure 5. The Hoberman Mechanism [15].

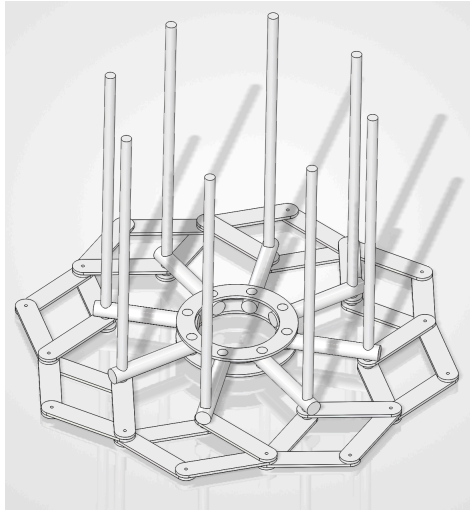


Figure 6. The Hoberman Design model.

Preliminary Materials

A. Aluminum Alloy

Aluminum alloy was considered due to its history of recorded use in medical devices and favorable mechanical properties. These properties include a high elastic modulus, shear modulus, tensile strength, and yield strength. The elastic modulus ranges from 10-10.8 GPa, the shear modulus ranges from 3.75-4 GPa, the tensile strength ranges from 11-78 MPa, and the yield strength ranges from 3.7-70 MPa [16]. These properties indicate that aluminum alloy can provide sufficient structural support to withstand the compressive force generated by the shrinker sock. Additionally, aluminum alloy is relatively inexpensive, with an estimated cost of approximately \$0.0065 per gram [16].

B. Polylactic Acid (PLA) (3D Print Filament)

PLA was considered because it was the material chosen by the previous design team and because it is inexpensive and easily manufactured using 3D printing. The previous team demonstrated in testing that PLA components were unable to consistently withstand the compressive forces exerted by the shrinker sock, particularly at the tops of the vertical components. The cost of PLA at the Grainger Engineering Design Innovation Lab is \$0.02 per gram.

C. Nylon (3D Print Filament)

Nylon was considered due to its documented use in medical applications, including sutures and prosthetic components [17]. This is an important consideration because the device may occasionally come into contact with a patient's skin or surgical site during use. Nylon 6,6 has an elastic modulus of 2.93 GPa, a tensile strength of 79.3 MPa, and a compressive strength of 86.2 MPa [18]. Nylon 12 has an elastic modulus of 1.6-1.7 GPa and a shear modulus of 0.5 GPa [19].

Design Evaluation

The most critical design specifications were considered when creating the design matrix (Table 1). Criteria are weighted and ordered based on importance. The winning design was the Expanding Pulley Mechanism.

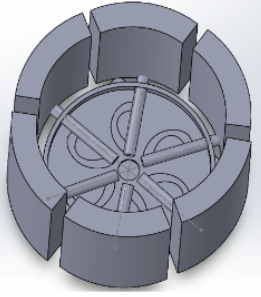
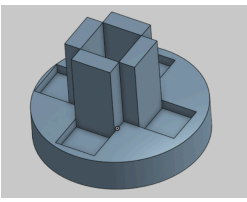
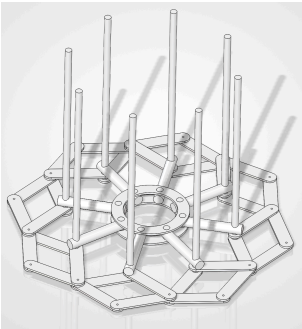
<i>Designs</i>		 Design 1: Expanding Pulley Mechanism		 Design 2: Expanding Rail System		 Design 3: Hoberman Design	
Rank	Criteria (Weight)	Score (/5)	Weighted Score	Score (/5)	Weighted Score	Score (/5)	Weighted Score
1	Ease of Donning (25)	3	15	4	20	3	15
2	User Comfort (20)	5	20	2	8	3	12
3	Safety (20)	4	16	5	20	4	16
4	Ease of Fabrication (15)	3	9	2	6	1	3
5	Durability (15)	4	12	3	9	3	9
6	Cost (5)	4	4	2	2	3	3
Total:	100	76	/100	65	/100	58	/100

Table 1. Design matrix evaluating three designs.

The design matrix was used to compare the three proposed designs based on ease of donning, user comfort, safety, ease of fabrication, durability, and cost. The Expanding Pulley mechanism received the highest overall score of 76/100 because it provided the best balance of user comfort, durability, safety, and cost while maintaining a relatively simple design. The Expanding Rail System earned a score of 65/100 and performed well in safety and ease of donning but was limited by its fabrication complexity and higher projected cost. The

Hoberman Design received the lowest score of 58/100 due primarily to its fabrication complexity, large number of components, and potential durability concerns. Based on the results of the design matrix, the Expanding Pulley Mechanism was selected as the most suitable design for further development because it best met design requirements while remaining practical to manufacture and use.

Material Evaluation

The most critical specifications were considered when creating the material matrix (Table 2). Criteria are weighted and ordered based on importance. The winning material was aluminum alloy.

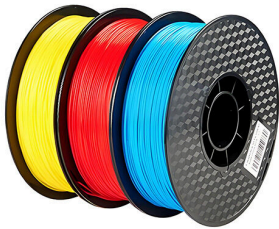
<i>Materials</i>		 Material 1: Aluminum Alloy [20]		 Material 2: PLA [21]		 Material 3: Nylon [22]	
Rank	Criteria (Weight)	Score (/5)	Weighted Score	Score (/5)	Weighted Score	Score (/5)	Weighted Score
1	Biocompatibility (30)	5	30	5	30	4	24
2	Durability (25)	4	20	1	5	5	25
3	Weight (20)	3	12	4	16	5	20
4	Ease of Fabrication (15)	4	12	5	15	2	6
5	Cost (10)	5	10	5	10	2	4
Total:	100	84	/100	76	/100	79	/100

Table 2. Material matrix evaluating three materials.

The material matrix was used to evaluate aluminum alloy, PLA, and nylon based on biocompatibility, durability, weight, ease of fabrication, and cost. Aluminum alloy received the highest overall score of 84/100 because of its excellent mechanical properties, strong biocompatibility, durability, and relatively low cost. PLA received a score of 76/100 and performed well in biocompatibility, manufacturability, and cost; however, its poor durability made it less suitable for use in the final device. Nylon received a score of 79/100 due to its high

durability, low weight, and suitability for medical applications, although its higher cost and fabrication difficulty reduced its overall ranking. Based on the results of the material matrix, a hybrid aluminum-nylon construction was selected for the final design to maximize structural strength and durability while maintaining a lightweight and manufacturable device.

Proposed Final Design

The final design chosen was the Expanding Pulley Mechanism (Figure 7). This mechanism uses a gear-driven system to move pistons outward through their interconnected pins. A motor rotates a small drive gear, which in turn rotates a larger gear located within the base of the device. The larger gear contains machined slots that guide pins connected to radial arms. As the gears rotate, the pins are pushed outward, causing the arms to expand and increase the diameter of the cylindrical structure. The device will be made from a hybrid aluminum-nylon design, allowing complex geometries to be manufactured using nylon while reinforcing with stronger aluminum components. This will allow the design to withstand 30-40 N of force from a shrinker sock while maintaining adequate structural rigidity. The cylinder will expand to a diameter of 25.4 cm (10 inches) and will have a length of 30 cm to ensure the shrinker sock can be positioned and applied correctly. The motor and electronic components will be housed in a compartment beneath the expansion mechanism, and a switch will allow for expansion and contraction of the arms.



Figure 7. Expanding Pulley Mechanism CAD model side view.

Fabrication

A. Materials

As discussed in the material matrix section, aluminum alloy, PLA, and nylon were selected as the primary materials for the device. Aluminum alloy will be used for structural support and reinforcement due to

its strength, durability, and favorable mechanical properties. PLA 3D-printing filament will be used during the prototyping phase because of its low cost and ease of manufacturing. Nylon 3D-printing filament will be used for the final prototype due to its improved durability and lower weight profile compared to PLA. Appendix B shows the proposed expense sheet with each material. This expense sheet will be updated periodically whenever materials are ordered or filament is used for prototyping.

B. Methods

The bulk of the device structure will be manufactured using 3D printing, with aluminum alloy reinforcements incorporated into high-stress regions to improve structural integrity and resist the forces generated during expansion of the shrinker sock. Initial prototypes will be fabricated using PLA to allow for rapid design iteration and evaluation. Following design refinement, final prototype components will be manufactured using nylon and reinforced with aluminum alloy where necessary.

Testing and Results

A. Shrinker Sock Application Testing

Shrinker sock application testing will evaluate whether the device can successfully expand a shrinker sock and maintain the required diameter for patient use. During testing, a shrinker sock will be placed on the device and the expansion mechanism will be activated. Measures of success will include successful device activation, successful expansion of the mechanism, and successful expansion of the shrinker sock to the target diameter. Multiple expansion cycles will be performed to evaluate the reliability and repeatability of the design over time. Consistent successful operation will demonstrate that the device is mechanically functional and capable of meeting the intended application requirements. The device will be designed to meet applicable patient-contact standards, including ISO 10993-1 requirements [23].

B. Battery Life Testing

Battery life testing will evaluate how long the device can operate before battery replacement or recharging is required. The device will be operated continuously under normal loading conditions while the operating time is recorded until battery depletion occurs. The results will be used to determine whether the device can meet the portability and usability requirements established in the Product Design Specification. This testing will also provide users with an estimate of expected battery life during routine operation.

C. MTS Testing

Mechanical Testing System (MTS) testing will be performed to evaluate the strength and durability of the materials used in the device. Testing will determine properties such as elastic modulus, compressive strength, and the ability of critical components to withstand the estimated 30-40 N loading produced by the shrinker sock. Because the majority of the load is transferred through the arms and pins of the mechanism, these components will be tested in compression. Multiple samples of each component will be tested and compared using statistical methods, including t-tests, to identify significant differences between samples. Components that maintain their geometry without permanent deformation will be considered capable of withstanding short-term

loading. In addition, creep calculations will be performed to estimate the potential for long-term deformation over the device's expected 5-10 year service life. Statistical analysis will include calculation of mean values, standard deviations, and p-values, with significance defined as $p < 0.05$.

Discussion

No testing results are currently available because prototype fabrication and validation testing have not yet been completed. Several potential sources of error have been identified, including uneven positioning of the shrinker sock during expansion, which may result in nonuniform force distribution throughout the device. Variations in 3D printing parameters, such as infill density, print orientation, and dimensional tolerances, may also affect the strength, stability, and durability of the final prototype. The proposed device is intended to improve patient independence by reducing the manual effort required to apply a shrinker sock; however, it may not fully address the needs of all users depending on their individual physical limitations. Following testing, the device design will be evaluated using both quantitative and qualitative results, and any necessary modifications will be incorporated into future design iterations.

Conclusion

The purpose of this device is to simplify the application of shrinker socks for lower-limb amputees in a home or clinical setting. Currently, the standard method requires users to manually stretch the shrinker sock over a hollow cylindrical donning tube before applying it to the residual limb. This process can be physically demanding for patients with reduced dexterity, grip strength, or mobility and must be performed multiple times each day throughout rehabilitation. The proposed device consists of a cylindrical structure with vertical arms that contract to allow placement of the shrinker sock and then expand using a motor-driven gear mechanism. A small drive gear rotates larger gears containing slots that guide interconnected pins attached to radial arms. As the mechanism expands, the shrinker sock is stretched to an appropriate diameter for donning and can be locked in place until application is complete.

Future work will focus on fabrication and testing of the proposed final design. Initial prototypes will be manufactured primarily through 3D printing using PLA to allow for rapid design iteration and refinement. The final prototype will be constructed from nylon and reinforced with aluminum alloy in high-stress regions to improve strength and durability. Validation testing will be performed using the final prototype, as PLA is not expected to withstand the compressive forces exerted by the shrinker sock during normal operation. Testing will include shrinker sock application testing, battery life testing, and mechanical testing using a Mechanical Testing System (MTS). These evaluations will determine whether the device can reliably perform its intended function throughout its expected service life. Results from these tests will be used to identify design improvements and guide future iterations of the device.

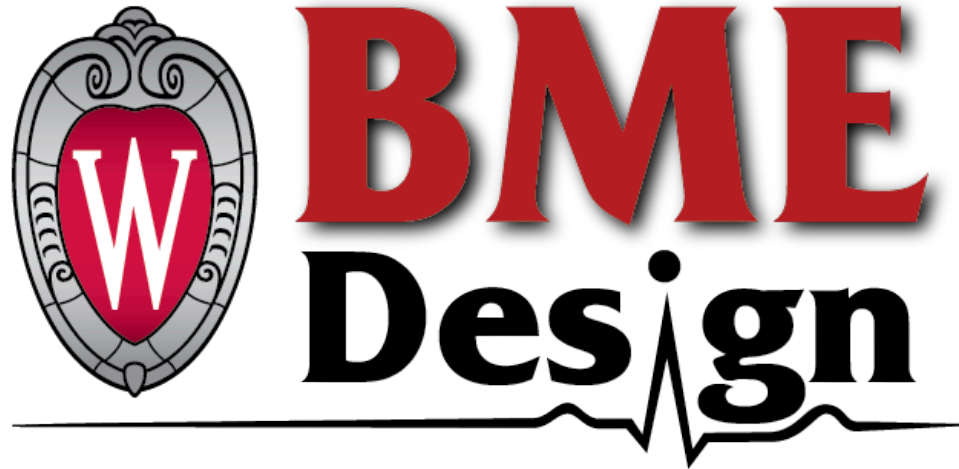
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Appendix

Appendix A: Product Design Statement (PDS)



Amputee Advanced Donning Device *Product Design Specification*

BME 400, Lab 306

September 17th, 2026

Client: Dr. Daniel Kutschera

Advisor: Dr. Justin Williams

Team:

Freyja Heggeland (Team Leader)

Adam Bauer (Communicator)

Megan Pearson (BSAC)

Carl Assmus (BWIG and BPAG)

Function:

During physical rehabilitation, it is critical for amputee patients to wear a specialized compression garment known as a shrinker sock. A shrinker sock aims to shape the residual limb in preparation for prosthetic fitting and prevent post-operative complications like swelling and excess fluid retention. To apply the shrinker, patients currently rely on basic donning tubes, where 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 device aims to create an advanced donning device that stretches the garment to the desired diameter using electronics and mechanical means, simplifying shrinker application and eliminating the need for manual user input to stretch the garment.

Client Requirements:

- The device must be able to withstand the compressive forces of a shrinker sock, effectively simplifying the application of the shrinker sock.
- The device must be durable as it will be used multiple times per day.
- The device must be able to withstand basic sterilization with a disinfectant wipe or bleach solution.
- The device should be portable and weigh no more than 5 kg.
- The production cost of the device must be less than \$500.

Design Requirements:**1. Physical and Operational Characteristics****a. Performance Requirements:**

- i. The device will be used to apply shrinker socks for patients with transtibial amputations, also known as below the knee amputations, requiring the device to expand the shrinker sock to a diameter of 25.4 cm [1].
- ii. The device must be able to withstand the 30-40 N force applied to it by the shrinker sock when stretching to the required diameter [2].
- iii. The device must not require excessive strength, bending, or fine motor skills to operate to ensure accessibility for patients.
- iv. The device should be lightweight and portable to ease use outside of a clinical setting.
- v. The device should be 50 cm long to prevent any potential bottom of the device from contacting the patient [3].

b. Safety:

- i. All mechanical and electrical driving mechanisms must be isolated from points of contact between the device and patient. Mechanical and electrical fail-safes should be implemented to prevent over and under expansion.
- ii. Any surface of the device that may come into contact with the patient should be rounded or smooth. The device should be lightweight and ergonomically designed to minimize pressure points.

- iii. The materials used in contact with the skin must comply with ISO 10993-1:2018, which specifies the biological evaluation of medical devices to prevent irritation and guarantee biocompatibility [4].
 - iv. The electrical components must comply with IEC 60601-1, which standardizes safety and performance of medical electrical equipment [5]. All electrical components must be securely enclosed in a shock-resistant housing to prevent accidental contact and electrical injuries.
- c. **Accuracy and Reliability:**
 - i. The target stretch diameter of 25.4 cm aligns with anthropometric data recorded by the CDC from 1999-2002. The average calf circumference for males aged 20 years and older is 39.1 cm, which translates to an average approximated diameter of 12.4 cm [6]. The stretch diameter of 25.4 cm will provide adequate space to manipulate the shrinker sock before application.
 - ii. The device must be able to resist the compressive forces of the shrinker sock by consistently generating the required force to stretch the shrinker.
- d. **Life in Service:**
 - i. The device must remain functional throughout the rehabilitation period, spanning from the removal of surgical stitches to the fitting for a prosthetic limb. This rehabilitation period varies per patient, typically spanning several months [7].
 - ii. A patient would generally use the device about two times per day to apply a shrinker sock following activities such as bathing or skin checks. In a clinical setting, the frequency of use would vary depending on patient volume and demand.
- e. **Shelf Life:**
 - i. The shelf life of the device will be finalized after material and component selection. Factors such as material degradation, battery stability, and long-term reliability of electronic components will need to be considered. The current design goal is to achieve a shelf life of approximately 5-10 years.
- f. **Operating Environment:**
 - i. The device is intended for use in both home and clinical settings. It is not expected to be used outdoors and should be operated in temperatures ranging from 15°C to 27°C [8].
- g. **Ergonomics:**
 - i. The device should not have sharp edges that could cause cuts or injuries to the patient.
 - ii. The force required to operate the device will be minimized to accommodate older patients and users with reduced hand strength or dexterity.
- h. **Size:**
 - i. The device will have a diameter of 25.4 cm when fully expanded, which is comparable to existing donning tubes and sufficient to accommodate the average male thigh circumference [1].
 - ii. The device will have a length of approximately 50 cm to allow the shrinker sock to be positioned and applied properly to the patient without causing discomfort [3].
- i. **Weight:**

- i. The device will weigh under 5 kg, allowing it to be portable as needed for patient use. It must be able to be moved between clinical rooms for use with multiple patients.
- j. **Materials:**
 - i. The material that will be used for construction of the device needs to be lightweight to be accommodating for patients with low dexterity.
 - ii. All finalized device components that come into contact with the user's skin must be biocompatible and non-irritating. Additionally, these components will withstand routine cleaning and disinfection in clinical settings without deterioration or degradation of device performance, appearance, or quality.
 - iii. The materials must be sufficiently durable to withstand the 30-40 N compressive forces exerted by the shrinker socks when stretched to a diameter of 25.4cm [2].
- k. **Aesthetics, Appearance, and Finish:**
 - i. The device will have a professional, high-quality appearance.
 - ii. The design will allow for simple cleaning and disinfection using disinfectant wipes or a bleach solution.
 - iii. The device will be accessible and easy to use for patients with limited dexterity.

2. Production Characteristics

- a. **Quantity:**
 - i. There will be a total of one unit constructed for this project. More prototypes and development may be made in the future, but are outside the scope of this project.
- b. **Target Product Cost:**
 - i. The target product cost will be within \$500 for a single unit.

3. Miscellaneous

- a. **Standards and Specifications:**
 - i. The final prototype must abide by the regulations for Class I medical devices under FDA 21 C.F.R. Part 890 [9].
 - ii. The final prototype will contain electronic components and may be subject to IEC code 62353:2014, ensuring that the electronic medical device does not cause harm to the user [10].
 - iii. Due to the donning device having the possibility to come into contact with the patients' body, it must also follow standard ISO 10993-1, ensuring additional safety precautions to be taken in device construction [4]. These standards set a precedent for the testing that needs to be performed after the device's production.
- b. **Customer:**
 - i. The primary users of this product are below-knee amputation patients, which largely consists of individuals affected by diabetes, leading to a need for amputations due to peripheral neuropathy [11]. Certain end user groups that could benefit the most from this device are patients that are elderly, have peripheral neuropathy, and those with arthritis or joint pain.
- c. **Client-related concerns:**

- i. As this device will be used with multiple patients in a clinical setting, it will need to be sterilized between uses. This device should be able to withstand basic sanitation with a disinfectant wipe or a bleach solution.
 - ii. The device must be made so it stretches the shrinker sock to a fit diameter, ensuring that overstretching and damage to the sock are avoided.
- d. **Competition:**
- i. Existing shrinker sock applicators within the clients' vision do not yet exist on the medical device market.
 - ii. Patent US4541554A functions as an applicator for post surgical dressings and may be used as design inspiration, but lacks electronic components, making this design inaccessible for patients with low dexterity [12].
 - iii. Similar patents have also been developed that discuss and model shrinker sock applications, but do not allow for low-dexterity use due to a physical hand crank [13]. This device will exceed these designs by allowing for electronic components to handle all mechanical work, rather than the patient or physician.

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Appendix B: Proposed Expense Spreadsheet

Materials have not yet been purchased, however, the materials in the table below will be purchased when the project moves forward in its present state. More items will be added to this list over time, due to acquiring more materials from the University of Wisconsin-Madison's TEAMLab and other online vendors when needed.

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Structural Materials										
Aluminum Alloy										
Nylon										
PLA										
Electronic Components										
TOTAL:									\$0	
Remaining Budget:									\$500	

Table 1. Expense spreadsheet, showing existing expenses, materials, total amount spent, and the remaining budget.

Appendix C: Computer Code

Code for the electronic components of this device and project have not yet been formulated, but will be added here in the future when it is developed. Code will be developed using the Arduino IDE software, the development of which has been heavily suggested and supported by the Biomedical Engineering curriculum at the University of Wisconsin-Madison.