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Distal Limb Pressure Device

Jenna Fortner

University of Portland
Shiley School of Engineering

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Senior Honors Project

Jenna Fortner

Students:
Olivia Beckham
Jenna Fortner
Kiley Gersch
Nicholas Nelson

Faculty Advisor:
Dr. Jennifer Symons

Industry Advisor:
Dr. Nathan Kemalyan

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Abstract

Lymphedema is a medical condition associated with venous insufficiency that causes swelling in the distal limbs, generally starting at the ankles. Lymphedema affects roughly 4 million Americans today and can be caused by a number of factors, including injury, aging, diabetes, and pregnancy. The severity of lymphedema is classified into four stages, and the more severe the stage, the higher risk of experiencing additional side effects including infections, skin ulcers, and reduced locomotion capabilities in the afflicted limb. Depending on the severity of lymphedema, various treatment options are available, including exercise, elevation, and compression for lower stages and surgery or diuretics for more severe stages. Current compression methods directed towards alleviating the symptoms of lymphedema include compression stockings and inflatable trousers. While compression stockings allow the user to be mobile, they are difficult to put on and take off, and the constant pressure application can cause skin ulcers and intertrigo, or rashes. On the other hand, inflatable trousers provide sequential or alternating pressure, which reduces the risk of developing ulcers; however, they require immobilization of the user. Therefore, the scope of this project was to design and develop a wearable and mobile device that could supply sufficient sequential pressure to the leg. The team opted to use airbags as the medium to apply the required pressure.

Acknowledgements

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Additionally, the team would like to thank Helen Christians for her expertise and guidance in the realm of current pressure application methods. Her guidance helped the team make informed decisions regarding what design elements from current solutions could best serve the purposes of the team.

Susan Bonde played a major role with helping the team achieve an aesthetically pleasing and comfortable design by providing the team with pattern-making materials and for sewing the inner sock and outer wrap of the design.

Christina Chrestatos, Jared Rees, and Jacob Amos ensured team members were properly trained to work in the different lab rooms of Shiley Hall. They also assisted with manufacturing key aspects of the design, including the rotating valve and the heat-welding presses.

Stephanie Fortner and Jenifer Hiatt assisted with and supervised the process of creating a fabric pattern to ensure the team would have a good fitting and comfortable wearable device.

Dr. Jordan Farina and Dr. V. Murty helped the team research different types of pumps that could serve the team's purposes and provided advice regarding fluid-based systems in biomedical applications.

Finally, the team would like to thank Spencer Scott for his work in designing a team logo.

Without the individuals named above, the team would not have made so much progress or found as much success throughout the course of the project.

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1. Introduction

1.1. Project Description

Failing venous systems due to ineffectual valves and over-dilated veins is a growing issue for the aging population and for overweight individuals, among many others. One of the major concerns associated with failing venous systems is lymphedema, which is described at the pooling of lymphatic fluid that generally manifests itself as swelling in the lower limbs of the body. Venous insufficiency may also cause changes in the skin that cause it to ulcerate, causing painful wounds and possible skin infections. Currently, there are no direct cures of failing venous and lymphatic return systems, as many of the structures of the venous system are incredibly delicate. There is currently no active substitute for the loss of the body's natural calf-muscle-pump in ambulatory patients. Therefore, there is a need for modern external compression devices that can mediate symptoms as a "patch" until viable cures are discovered. The opportunity presented was to design and build a low-profile wearable device featuring a pump system that could act as a substitute for the calf-muscle-pump by providing pressure inward toward the soft tissues of the calf and moving cephalad or up the leg, starting at the ankle.

1.2. Project Scope

The scope of the project was to develop a working prototype of an external, wearable device that could supply sufficient rolling pressure to the calf while allowing the user to maintain an active lifestyle. The goal of the team was to make this prototype as market-ready as possible, opening the door for future iterations to ensure FDA requirements are met. The scope of the project did not include patient testing due to the extended evaluation period required by the Institutional Review Board and the search for willing and able lymphedema patients; however, patient testing should be pursued down the road if future iterations of the design are intended to go to market.

1.3. Team Member Roles and Responsibilities

Olivia Beckham was designated as the team communicator. Her primary responsibilities to fulfill this role were to communicate weekly with the industry advisor Dr. Kemalyan and schedule ample meeting times with him. In terms of the science behind the project, Olivia was responsible for researching different media that could serve as internal structures for the airbags and providing prototypes of these structures. It was also her responsibility to handle and cut the airbags.

Jenna Fortner had the roles of team editor and secretary. Her responsibilities were to record meeting minutes at all nonmanufacturing-based meetings and provide the final edits on all major written deliverables, including reports and presentations. She was also responsible for providing hand-sketches of the overall design and configuration. She also developed the last used as a model for the human leg, as well as designed and prepared all fabric patterns and garment elements of the device.

Kiley Gersch served the role as team budgeter. She tracked and maintained the team's budget and oversaw all purchases requested by team members. She was also the primary communicator with external companies whose products could serve the needs of the team. Kiley also performed extensive research in the field of pumps and compressors and assisted with the design and manufacturing of the team's rotating valve and heat presses.

Nick Nelson had the role as team manager. His responsibilities were to develop agendas for the team, update action item logs, and provide faculty advisor updates at weekly team meetings. In terms of the development of the device, Nick was primary responsible for the design and development of the rotating valve. He also wrote the Arduino code and ensured that all mechanical and electrical elements of the device interfaced together.

2. Background

2.1. Physiology

Today, over 4 million Americans are afflicted with edema [1]. Edema is defined as the accumulation of excess lymphatic fluid in the interstitial spaces or cavities of soft tissues, and it generally manifests itself as swelling [2]. Specifically, high pressure in the veins of the leg causes blood cells, proteins, and fluid to seep through the walls of small reticular veins and into the interstitial spaces of soft tissues, resulting in swelling [3]. Often found in the distal or lower extremities of the body, edema is generally caused by a number of factors, including venous insufficiency, pregnancy, aging, diabetes, obesity, injury, or surgery.

When veins are healthy, fluid flow in the venous system is promoted by the calf-muscle-pump. When muscles contract, such as when doing daily activities like walking, pressure is applied to the veins, causing a small valve in the vein to open and allow blood to move upward and back to the heart, as seen in the schematic of Figure 1. Lymphatic fluid travels up and around the heart into the thoracic duct, while venous blood travels through the vena cava [4]. Likewise, when calf muscles like the soleus and gastrocnemius are relaxed, the valves of the veins close to prevent backflow of blood. However, venous insufficiency or injury can inhibit the proper functions of these valves. Specifically, venous insufficiency prevents these valves from closing fully, causing backflow of blood due to gravity when the calf muscles are relaxed, also pictured in Figure 1. This backflow of blood applies high pressure to superficial veins such as the great saphenous vein, obstructing venous systems and preventing blood from returning to the heart. When high pressures are applied to the reticular veins, fluid buildup can seep through the walls of the weakened veins and into the cavities of the surrounding soft tissues, causing swelling [5].

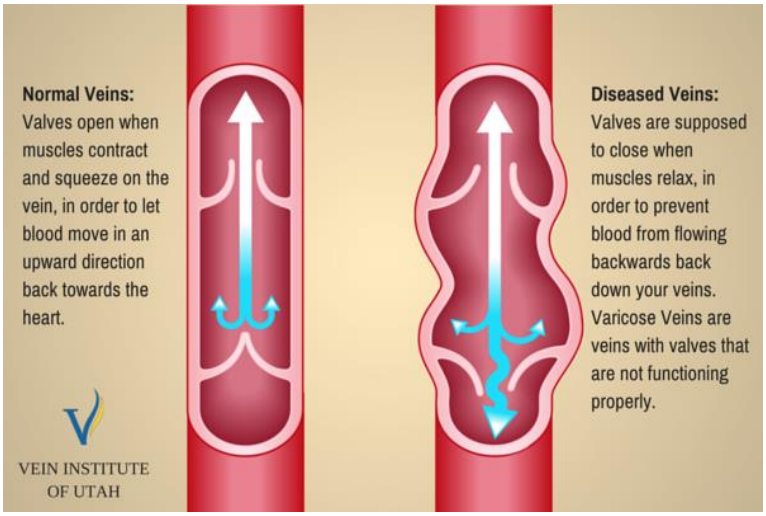


Figure 1: An image describing the blood flow when muscles contract around health veins (left) and incompetent veins (right) [6].

Accumulation of such lymphatic fluid in the soft tissues can then be diagnosed as edema, which can be further classified into four different stages of severity. Generally, stage 1 lymphedema is considered to be fairly asymptomatic; however, upon pressure application, it can produce signs of mild pitting or indentation that vanishes when the pressure is removed. Stages 2 and 3 produce deeper pitting upon pressure application that generally takes longer to disappear, with stage 3 being the more severe case of the two. During these middle stages of lymphedema, there is noticeable swelling about the circumference of the leg. Finally, during stage 4 lymphedema, pitting is extremely deep and the appearance of the leg is severely distorted, generally reflecting the appearance of elephantitis [7].

Edema can cause a wide range of side effects and complications. Swelling can occur either unilaterally or bilaterally in the distal limbs. Not only does the swelling cause a range of discomfort, but it also weakens the skin and can cause it to ulcerate. Venous skin ulcers take a long time to heal, generally several months to a year. This is because the blood circulation in an edema-ridden distal limb is poor, preventing oxygen and nutrients from the blood from promoting the necessary collagen proliferation for wound healing [8]. Long-term ulcers increase the risk of infection, which can lead to further dire health complications. Additionally, for those with lymphedema, skin can appear dry and stained from the leakage of blood to the interstitial sites underneath the skin. Over time or in higher stages of lymphedema, fluid accumulation in the distal limbs can act as an added weight around the ankles, causing deviations in walking gait that affect its natural symmetry and negatively altering one's posture [2].

2.2. Existing Solutions

2.2.1. Treatments

There are currently no cures for lymphedema that can reverse the effects of vein insufficiency or weakening. There are also no current medical or mechanical replacements for the failed aspects of the weakened venous system. Therefore, current methodologies for addressing lymphedema are more geared towards management techniques and symptom alleviation rather than treatments or cures. In general, for all stages of lymphedema, current symptom alleviation methods include elevation, compression, and exercise. For those with more severe cases of lymphedema, such as those diagnosed with stage 4 lymphedema, surgery or diuretic medications may be considered viable directions; however, there are many post-operational risks and potential side-effects that should also be discussed [7].

Generally, compression methods, exercise, and elevation are considered the best directives for alleviating the symptoms of lymphedema because each assists with redistributing lymphatic fluid throughout the body. Compression methods physically drive the fluid up the leg for redistribution. Physical exercise helps strengthen the calf-muscle-pump for fluid redistribution. Finally, elevation works against gravity to allow excess fluid to travel back to the heart and the lymphatic system.

2.2.2. Existing Solutions and Patents

One of the main methods used to address the symptoms of lymphedema is pressure application systems. The team researched a variety of US patents and FDA-approved clinical products to develop a comprehensive understanding of current application methods. Such research allowed the team to evaluate the advantages and disadvantages of the available devices. In doing so, the team could gain a better understanding of what aspects of current designs could be utilized in the team's design and what ideas could be modified to meet the team's needs. Two of the primary methods used for redistributing lymphatic fluid in the lower extremities are compression stockings and inflatable trousers, as seen in Figure 2.

Compression stockings are widely available by a number of companies, and they are generally graded at 15-40 mmHg of pressure application. Beneficial to the consumer, they are also generally inexpensive and can serve those with any stage of lymphedema. They also allow the user to remain mobile and wear any type of shoe. Unfortunately, in order to provide the necessary pressure application to redistribute lymphatic fluid, the socks must have a very snug fit around the circumference of the leg. This makes the sock very difficult to put on and take off, especially for those who have severe fluctuations in the amount of swelling they experience from day to day. The most concerning part, however, is that the constant pressure applied to the skin can cause weakened skin to experience ulcerations, which increases risk of infections.

On the other hand, inflatable trousers provide modulated, alternating, and sequential pressure. Because the trousers apply pressure to one region of the leg, and then release the pressure at that

region as the pressure application moves up the leg, there is lesser chance of developing ulcers or lesions on weakened skin because there is not a constant pressure that causes the skin to break. The cyclic inflation and deflation of the sleeves provide more active redistribution of lymphatic fluid by sequentially increasing and decreasing pressure through multiple chambers. The disadvantage of inflatable trousers, however, is that they need to attach to a large pump that must be powered through a wall outlet. This means that the user must be immobilized while the system is running. The trousers and pumping system are also more expensive than compression stockings, and generally require an additional person to operate, such as a medical professional. Due to the need for immobilization and potentially clinician visits, inflatable trousers require extensive time commitments that are not feasible for all patients [4]

Figure 2: Existing solutions for lymphedema management: (a) inflatable compression trousers and (b) compression stockings [9], [10].

Several patented devices aim to address pressure application using a variety of methods and designs. One of the patented devices that aims to incorporate a mobile design with pneumatic or sequential compression is an inflatable air boot that utilizes the compression of an air bag placed below the foot to drive sequential pressure up the leg [11], as seen in Figure 3a. For this reason, the device is very effective at providing sufficient pressure for fluid redistribution; however, this type of device can be bulky and impede the user's normal walking gait. Figure 3b demonstrates a patent that utilizes mechanical rollers as its main mode of pressure application [12]. The chambers along the leg apply pressure using a powered belt-like roller. While this is a good method for ensuring sufficient pressure application, there is the disadvantage that elevation and connection to a power source are required, which reduces mobility of the user. Finally, as show in Figure 3c, other patents customize devices for each patient. One such design injects air into multiple valves, creating static pressure points that consistently apply pressure to certain areas of the distal limb [13]. While these pressure points can be customized to target the regions where the patient needs the most pressure application, the static pressure may cause ulcers or skin lesions.

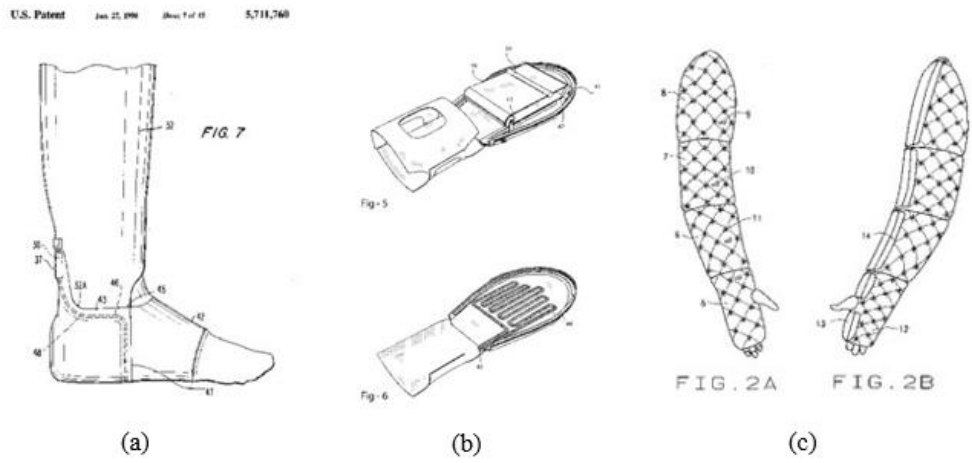


Figure 3: Existing patents for pressure application products [11], [12], [13].

2.3. Observations

Dr. Nathan Kemalyan, a general surgeon who specializes in burn and hernia treatment, was the industry sponsor and advisor for the Distal Limb Pressure Device team. At the start of the project in April 2018, Dr. Kemalyan provided the team with a general concept and set of criteria for the design. He asked the team to then expand upon his recommendations and ideas. In summer 2018, Dr. Kemalyan proposed that the team take advantage of the warm weather to make observations of calf shape and form of passersby. He emphasized that an understanding of the general population's lower extremities could benefit the team in that it would demonstrate the wide range of lymphatic stages that can appear. He also stressed that it is important to gain an understanding of how each person's walking gait is different, and that it is important to understand how feet and calves affect that gait. During these summer observations, the team recognized the different degrees of lymphedema, from mild to noticeable swelling, as well as how frequently lymphedema appears unilaterally or bilaterally.

When the project was first proposed by Dr. Kemalyan, he expressed that external devices that substitute failing venous systems and lymphatic return mechanisms serve as a patch, rather than a direct treatment to the problem at hand. Dr. Kemalyan also expressed that with such devices, including compression stockings, there are patient accountability issues, which makes it difficult for patients to attain the necessary relief. The reason for such accountability issues is that patients have a difficult time donning and doffing external compression devices. This can result in temporary or complete abandonment of the device, during which time swelling may increase severely and make it difficult to restart usage of the device. For this reason, Dr. Kemalyan stressed the importance of an adjustable device. An additional downfall of some external devices, such as compression trousers, is that they do not allow the user to be mobile for long periods of time, often due to bulkiness or a stationary element such as a pump that must connect to a wall outlet. Those who avoid external devices and choose to manage lymphedema with elevation are likewise subjected to long hours of immobilizing the affected limb. In short, many current treatment methods are not feasible for active individuals or those whose careers require maximal standing

and walking, such as teachers and nurses. Therefore, Dr. Kemalyan tasked the team with addressing such problems by creating a proof of concept for a wearable, easy to use, effective, and low-profile device to aid a person with a failing venous and lymphatic return system.

2.4. Experiences

In fall 2018, the team had its most informative experience with pressure application systems. Dr. Kemalyan invited colleague Helen Christians, a retired occupational therapist who specialized in compression systems, to visit with the team on campus one afternoon. Helen and the team discussed lymphedema as a whole and in terms of the specific biological features it affects. She gave the team insight regarding the functions of the calf-muscle-pump and the vascular pathways of lymphatic vessels. She also informed the team that patients with an insufficient ankle-brachial index (ABI), which is the ratio of leg systolic blood pressure to arm systolic blood pressure, of less than 1 should not be treated with compressive devices due to the presence of arterial disease [4].

Figure 4: A photo from the team's informative meeting with Helen Christians (back right) and Dr. Nathan Kemalyan (back left). Nick Nelson, Jenna Fortner, Olivia Beckham, and Kiley Gersch (front row from left to right) are pictured wearing pressure devices.

Helen also gave the team some perspective about different design considerations. She informed the team that a pressure range of 30-40 mmHg has been proven to promote venous fluid flow, and that this should be the maximal pressure range that the team pursues. Additionally, she offered that swelling from lymphedema appears all throughout the distal limb, so some mode of compression is necessary on the foot to prevent pressure application on the calf from sending the fluid downward. This informed the team’s decision to pursue modifications to compression stockings and inflation methods.

Finally, Helen allowed the team to test several current compression devices. Jenna and Olivia each wore Lympha-Press inflatable trousers, as pictured in Figure 4. The trousers with a range of 20-80 mmHg were set to 40 mmHg to give the team an idea of what their maximal pressure should feel like. Generally lymphedema patients could wear such trousers for about an hour to receive necessary relief, but elevation and immobilization are required.

Additionally in Figure 4, Nick is pictured wearing a short-stretch wrap. These wraps are generally worn until swelling or wounds can be better managed. They are typically worn for about 24 hours several times a week, and the frequency is reduced until the edema is well-managed or wounds have healed. Kiley is pictured wearing a generic compression stocking, which was far more difficult to put on than the short-stretch wrap.

3. Problem Statement

"Create a low-profile, wearable device to be used by active individuals (on their feet for several hours a day), which supplies sufficient sequential pressure cephalad from the user's ankle up their calf to manage or lessen symptoms of stage 1 to early stage 3 lymphedema."

The team was tasked with creating a low-profile, wearable maintenance device to address swelling in the distal limbs caused by lymphedema. The purpose of this device was to supply adequate peristaltic pressure cephalad, or upwards rolling pressure, to manage the levels of swelling in individuals with stage 1 to early stage 3 lymphedema at a minimum. The ultimate goal was that the device would be able to supply sufficient rolling pressure to reduce the swelling caused by pooling of lymphatic fluid in the lower limbs.

Currently, the main issue surrounding compressive devices for lymphedema is that none of the prominent existing solutions can successfully integrate all of the following properties in a single design: providing sufficient rolling pressure to the lower extremity, maintaining a discreet appearance particularly underneath articles of clothing, limiting the possibility of re-aggravating skin irritations and sores, and having a simple enough design that the user can easily put on and take off the device. Particularly, compression stockings and pneumatic compression trousers fall on opposite ends of the spectrum. Compression stockings have the benefit of being mobile and low-profile, but they sacrifice functionality. Pneumatic compression trousers require immobility and are generally bulky, but they have the benefit of high functionality. The team sought to develop a device that could both take the benefits from these existing solutions by being low-profile but having high functionality.

The intended user for this device is an active individual who is afflicted with stage 1 to early stage 3 lymphedema. For individuals' whose occupations require lengthy hours on their feet, immobilizing pressure trousers or elevation are not feasible methods of alleviating swelling of the distal limbs. Additionally, for those who have a busy lifestyle, remembering to put on compression stockings or socks may not always occur, and after several days, swelling may increase to a point where putting on a compression sock becomes too difficult. The user needs a wearable device that

can be worn throughout the day and provide sufficient rolling pressure to assist with the swelling, adjustable to fluctuating levels of swelling.

Today, there is a greater need for a comfortable and mobile pressure application method because one of the primary causes of lower leg edema is aging. Within the next decade or so, many more individuals will be afflicted with lymphedema, so there is a greater need for a standardized device that can be accessed by anyone needing to alleviate the symptoms of lower leg edema. Developing a mobile device that can apply sufficient pressure and be adjusted today means that down the road, further iterations of the device can better meet the needs of the population. Ideally, in the future, active individuals afflicted with lower leg edema will no longer need to sacrifice valuable time by using methods such as inflatable trousers or elevation or sacrifice comfort by wearing difficult compression stockings.

4. Design Criteria

4.1. Constraints

Design constraints guided the team during the process of design and development by providing a list of defined requirements that would best meet the needs of the project. Table 1 outlines the design criteria that the team defined in the early stages of the project in fall 2018. Each criterion was ranked based on the degree of importance that the final design should adhere to. Items with a higher ranking indicated that during the design process, that criterion should be catered to and not compromised. Such criteria held higher precedence during design decisions and conceptual brainstorming.

The first constraint concerns the profile of the device and its extension from the surface area of the skin. The team's industry advisor, Dr. Kemalyan, first stressed the importance of low profile devices due to the unfortunate stigma concerning those wearing medical devices. The team determined that a 1 inch extension from the surface of the leg would be satisfactory as the device could still go undetected under most pairs of pants. The second constraint focuses on the importance of developing a device that was as light as possible. Specifically, it considered the usability and the long-term effects of wearing the device. If the device were to be too heavy, users could be deterred from wearing the device. If the user were to choose to wear the device on a regular basis for long-term alleviation of symptoms, a heavier device could eventually alter one's walking gait and posture. After considering the weight of current medical walking boots, the team determined that a limit of 1.5 lbs would be satisfactory for long-term use of the product.

Thirdly, the team prioritized the overall cost of the device. With millions of people in the United States alone suffering from lymphedema, the need for an accessible device that can alleviate the symptoms of lymphedema is prevalent. The team sought to keep the overall cost of the device below $200 so that the device could be easily accessed, especially by those with health insurance that could partially cover the costs, should the product be marketed as a medical device. The fourth constraint focuses on the aesthetics of the device, judged by the client, the team's industry advisor.

Finally, the fifth constraint concerns the comfort of the user. After wearing a device all day, the user would likely sweat, which could cause some discomfort. Ideally, the device would have some "breathability" aspect that could wick away the sweat and make the user more comfortable. The breathability of the device's materials was determined using a test that measured the amount of water that could seep through the material after a given amount of time.

Table 1: Design constraints

#	Description of Constraint	Priority Rating
1	The profile should not exceed a thickness 1 inch from the surface of the leg	High
2	The weight should not exceed 1.5 pounds	High
3	The final device's cost of assembly should not exceed $200	Medium
4	The appearance of the device should meet the aesthetic criteria of the client	Medium
5	The device should pass a 'breathability test'	Low

4.2. Functional Requirements

Functional requirements established the team's overall goals for how the final device would function and perform by the spring deadline in 2019. Similar to the design criteria, the functional requirements listed in Table 2 were organized and ranked according to their importance and priority within the scope of the project.

The first requirement listed in Table 2 describes the overarching goal of the function of the device. The purpose of the device was to maintain or lessen the symptoms of lymphedema, so the team felt that fulfilling this purpose of the device would be the highest-ranked requirement. The next two criteria work conjointly to fulfill the overall function of the device. Supplying massaging pressure up the leg would help guide the excess fluid out of the interstitial sites and redistribute it to the lymphatic system. Additionally, supplying this pressure at 15-40 mmHg is sufficient for fluid recirculation, as many compression socks and full-leg trousers are classified at this pressure range.

The last four functional requirements describe the team's expectations for the device's usability. Specifically, the requirements address the interface of the device with its user both in terms of its daily use and its long-term effects. The fourth requirement specifies that it should not take the user more than approximately 60 seconds to don and doff the device. One of the concerns with current compression socks is that they are very difficult to put on, especially if swelling has increased since the last time putting one on, so one of the goals of this project was to ensure that the device is minimally cumbersome and can easily be put on or taken off. The fifth, sixth, and seventh requirements focus on maintaining the symmetry of the user's walking gait. If the user's walking speed is compromised by using the device, then the device creates an additional unwarranted hindrance. If the use of the device results in reduced ankle flexion or extension, then the user has an additional interference of limited mobility, which is problematic for particularly active individuals. More dire consequences could result if the device causes a skewed hip alignment or

pelvic tilt. Abnormalities in pelvic alignment signal nerves to fire pain signals generally in the lower back, causing discomfort and postural insufficiencies. These final three requirements were evaluated using a motion capture system.

Table 2: Functional requirements

#	Description of Requirement	Priority Rating
1	Maintains or reduces swelling in individuals with stage 1-3 lymphedema	High
2	Apply a massaging pressure up the leg	High
3	Apply pressures from 15-40 mmHg	High
4	Takes less than 60 seconds to don and doff	Medium
5	Slows walking speed by less than 10%	Medium
6	Reduces ability for ankle flexion/extension by less than 10%	Medium
7	Skews hip alignment no more than 10%	Medium

5. Selection Methods

5.1. Concepts

To meet the criteria and constraints outlined in section 4, the team developed three generalized concepts in fall 2018 that could deliver sufficient massaging pressure to the user's calf. Each brainstormed idea utilized a different mode of pressure application, and each of these were evaluated based on their expected performance in each of the design criteria categories. Whichever option the team best felt would meet the criteria would then be explored further and modified as seen fit. The three proposed modes of pressure application were fluid, tension, and mechanical.

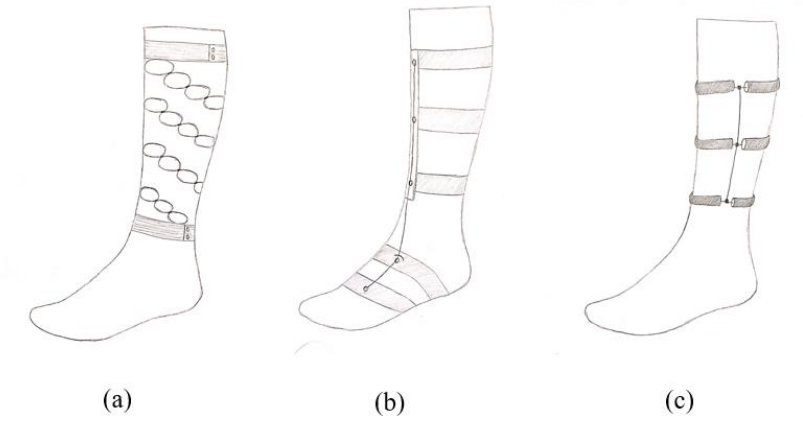


Figure 5: General sketches of the proposed pressure application concepts. From left to right are the (a) fluid, (b) tension, and (c) mechanical modes for pressure application.

The fluid method of pressure application, demonstrated in Figure 5a, was planned to have a series of airbags or air bladders wrapped around the circumference of the leg. The airbags would be

pressurized by an actuator such as a diaphragm pump that would deliver air to each bag sequentially up the leg. Many widely used pressure applications utilize fluid systems, so the team felt confident that an idea consisting of airbags would be relatively reliable.

The tension mode of pressure application, seen in Figure 5b, was designed to be a series of bands wrapped around the calf that would be connected via cable. When the cable is pulled in tension, either by an activated system or by passive actuation such as walking, the bands would tighten around the calf and force excess fluid cephalad, or upwards. The team was intrigued by this design because it is not an actively pursued method of pressure application, and therefore had potential as a strictly unique design.

The mechanical form of pressure application, as pictured in Figure 5c, was imagined to reflect the foam rollers used for massaging muscles in athletes. The design consisted of a series of small foam rollers that would cover the circumference of the leg. The rollers would be actuated such that they could be driven up the calf and then loosely roll back down to ensure fluid is distributed up the calf. The use of foam rollers that are mechanically actuated would ensure that a high enough pressure could be directed inward and up the leg to promote fluid redistribution and circulation.

5.2. Design Matrix

The team evaluated each of the brainstormed ideas using a decision matrix, as seen in Table 3. A decision matrix allowed the team to put a numerical "weight" to each of their design criteria originally presented in section 4, as well as give a numerical ranking as to how well the team anticipated each brainstormed idea would satisfy the criterion in question. Criteria were given a multiplier from 1 to 5, where 5 was considered highly important. Similarly, each brainstormed idea would be given a score from 1 to 5 depending on how well it was anticipated the method would satisfy the criterion, with 5 being the highest capability of satisfying the criterion. Once each brainstormed item was ranked for each category, the sum score was calculated for each brainstormed idea, which allowed for a quantitative comparison between each idea.

Table 3: Design decision matrix

Criteria	Multiplier	Fluid	Tension	Mechanical
Massaging	5	5	2.5	3.5
Pressure Range	5	4.5	3	5
Weight	4	3.5	5	2
Thickness	3	3.5	5	2.5
Cost	2	5	4	3.5
Comfort	3	4.5	5	3
Ease of Use	4	4	5	2.5
	Sum	111.5	105.5	84

There are some notable takeaways from the decision matrix. The first is that it was believed that the fluid mode of pressure application would best satisfy the need for a massaging or sequential pressure, and was second to the mechanical rollers in terms of being able to reach the desired pressure range of 15-40 mmHg. The fluid system was also considered the second-most lightweight of the options and the least expensive. Mechanical rollers, on the other hand, were expected to be the heaviest and the most costly. The tension straps were the most successful in the minimal weight and thickness categories as well as the ease of use and comfort categories. Although the tension straps scored very highly in these categories, the team was not certain of how well they could deliver massaging pressure at the desired range, which covered the two most important categories. For this reason, the fluid mode of pressure application edged out the other brainstormed ideas and was considered the most feasible method to produce a successful device.

6. Subsystems and Key Features

6.1. Subsystems

6.1.1. Wearable System

The purpose of the wearable system is to enhance the interface between the user's leg and the device. The user's comfort and ease when using the device were prioritized in the wearable system, or garment. For this reason, there were a lot of design considerations and fabrication choices that were implemented into the design, from large-scale functions to minute details.

The innermost layer of the device is a specialized compression sock, consisting of three different fabrics, as seen in Figure 6. The inner fabric of the sock is antimicrobial and moisture-wicking with a 4-way stretch. It was intended to help prevent bacterial growth that could develop after wearing the sock and sweating all day. Such bacterial growth could cause infection in sensitive regions of the skin, which may ulcerate or have lesions. Infections could be detrimental to patient health, especially if gone untreated, so the team sought to prevent as many of the risks as possible.

A compression garment was requisite for the purposes of this project because it would ensure that there was a compressive element that reached the foot, which also generally shows signs of swelling due to lymphedema. The garment would then extend up the calf to ensure the entirety of the distal limb would experience some degree of compression. A compressive nylon fabric was layered on the external side of the garment to provide the necessary compression. This fabric was added to give the garment additional structure and thickness that the antimicrobial fabric alone lacked.

One of the risks associated with many compression socks, however, is that the constant pressure on the skin can cause ulcers or sores to form where the skin has weakened or thinned due to the swelling. This most commonly occurs at the top of the foot, where the foot intersects with the leg.

Therefore, a non-compressive stretch mesh was placed on the *extensor retinaculum*, the intersection of the top of the foot and the leg.

User comfort was prioritized during the making of the compressive garment. Internal seams were cut down as much as possible to safeguard the user against discomfort due to bulges from excess material creating focal pressures on the skin. Seams were also placed strategically to maximize patient comfort.

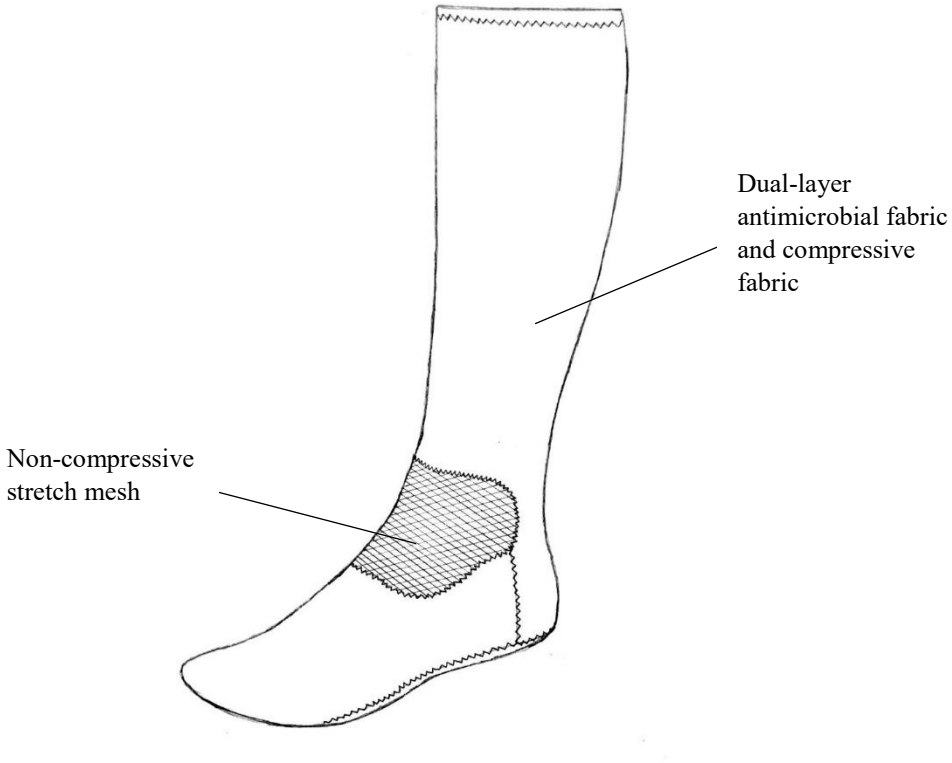


Figure 6: Sketch of the device's compression sock component.

The second component to the wearable system was the outer pocketed wrap that contained the airbag layer, pictured in Figure 7. The wrap consists of two layers of the compressive nylon that are stitched together strategically to create four pockets or channels for the airbags to slip into from the sides. The compressive nylon provides some external pressure to the airbags to ensure that they do not balloon excessively when inflated, keeping the device low-profile. The channels were curved in nature to better fit the geometry of the calf. On the posterior side of the leg, there is an opening for a tube fitting connected to each airbag and attached to the tubing that moves up the leg. Once the tube fittings are positioned at the back side of the leg, the user can pull the sides to the anterior side of the leg and fasten the wrap using Velcro along the tibia.

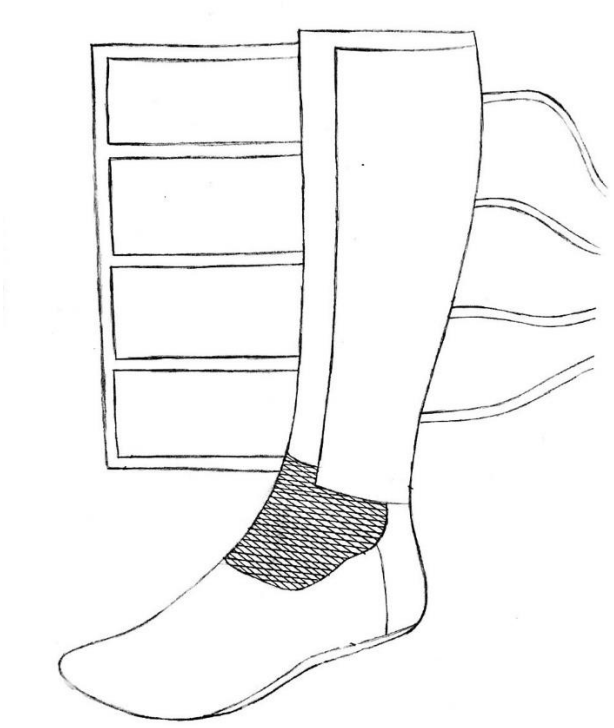


Figure 7: Schematic of the wearable system, including the outer pocketed wrap and compression sock.

The compressive garment and outer wrap were designed by Jenna Fortner. The process by which the patterns were made can be found in section 7. The garment and outer wrap were sewn by Sue Bonde, from the University of Portland's theater department.

6.1.2. Air Bladder System

The air bladder, or airbag, configuration and shape were chosen in order to best meet the criteria given and allow for the most efficient system. The shape of the airbags can best be seen in Figure 8. The curve of the airbags was modeled after the curvature of the compressive outer wrap discussed in the previous section. The airbags were constructed from PVC-coated nylon that was heat welded along the edges of the air bladders.

The air bladders experienced sequential inflation to apply peristaltic compression up the leg. To reduce the chances of backflow, two airbags always had to be inflated at any given point as the sequence moved up the leg. Numbering the airbags in Figure 8 from 1-4, with 1 starting at the bottom, we would see airbag 1 inflate, followed by airbag 2 once airbag 1 attained the correct pressure reading. Then, as airbag 3 inflates, airbag 1 deflates, while airbag 2 remains inflated. Then, as airbag 4 inflates, airbag 2 deflates, and airbag 3 remains inflated. This pattern continues

indefinitely until the system is turned off, and it takes approximately one minute to complete a single cycle of this motion.

Figure 8: Curved airbags with tube fittings.

6.1.3. Pump, Valve, and Control System

One of the primary goals of this project was to ensure that the device was low-profile. This ultimately meant that all components of the device had to be minimized in weight and size while still adhering to the functional requirements of the device. For the air delivery mechanism, the team decided to use a micro-diaphragm pump as pictured in Figure 9. This decision was made after conversing with Dr. Jordan Farina and Dr. V. Murty regarding existing pumps and compressors that could meet the team's needs. The micro-diaphragm pump drives ambient air into and out of the air bladders at a steady, continuous weight. The pump is conducive to the team's goal of a low-profile device because it weighs only 0.5 ounces and has a width of 13.5 mm. The pump can operate at low voltages while delivering a high flow rate of 800 mL/min of gas, so battery packs could be utilized in powering the system. The air bladders can be filled relatively quickly without the pump having to draw excess current. The pump emits 44 dB of noise, which is fairly quiet but can still be noticed without having some sort of insulating barrier that muffles the sound. The pump heats very little during operation, so it could be stored with the other electrical components of the device in the fanny pack, which served as the noise insulator for the device. The low cost of the pump drives down the overall cost of the device, making it more accessible to the general public.

Figure 9: Parker Hannifin T2-05 Micro Diaphragm Pump weighing 0.5 oz and driving a maximum of 800 mL/min of gas for inflating air bladders [14].

One of the most innovative aspects of this project was the rotating valve designed by Nick. The final iteration of the valve is pictured below in Figure 10, attached to the Servo motor that powers the rotation of the inner canister. The two holes pictured at the bottom of the inner canister correspond to inlet and outlet air tubes. There are eight additional ports located on the exterior curved edge of the outer canister, and the inner canister has two stacked ports that rotate to align with any of the four sets of two ports on the outer canister. One port triggers inflation of one airbag while the other triggers deflation of another airbag. A CAD rendering that demonstrates the details of this description can be found in section 7.2.

Figure 10: Final rotating valve iteration with attached Servo motor.

The inflation pattern actuated by the rotating valves consists of four stages, outlined in Table 4, where each airbag is either full, empty, being inflated, or being deflated.

Table 4: Inflation and deflation mechanism for each stage of rotation.

	Airbag Status			
	Airbag #1 (lower)	Airbag #2	Airbag #3	Airbag #4 (upper)
Stage 1	Inflate	Empty	Deflate	Full
Stage 2	Full	Inflate	Empty	Deflate
Stage 3	Deflate	Full	Inflate	Empty
Stage 4	Empty	Deflate	Full	Inflate

To modulate the inflation pattern described in Table 4, the team used an Arduino Mega pictured in Figure 11 as the control system or "brain" of the device. The Arduino consists of 54 ports, which allows for a wide range of potential controls that can be incorporated into the device's functionality and configurations. The flexibility for customizable controls in the coding system allowed the team to develop a pattern that could produce sequential and peristaltic inflation of the airbags, which is a critical criterion for this device's ability to redistribute fluid to the lymphatic system.

Figure 11: Arduino Mega 2560 with 54 digital I/O pins for wide range of control capabilities and combinations [15].

The Arduino was connected to a pressure sensor, pictured in Figure 12. The pressure sensor provides continuous feedback to the Arduino. If the airbag being inflated is not yet at 30 mmHg, then the pressure sensor tells the Arduino to tell the pump to continue with inflation of that airbag. Once the pressure sensor notices the airbag is at 30 mmHg, it sends a message to the Arduino that the pump needs to move on to the next airbag. Including a pressure sensor in the overall design allowed the team to validate that the targeted pressure of 30 mmHg was being delivered to the air bladders, and therefore to the surface of the leg.

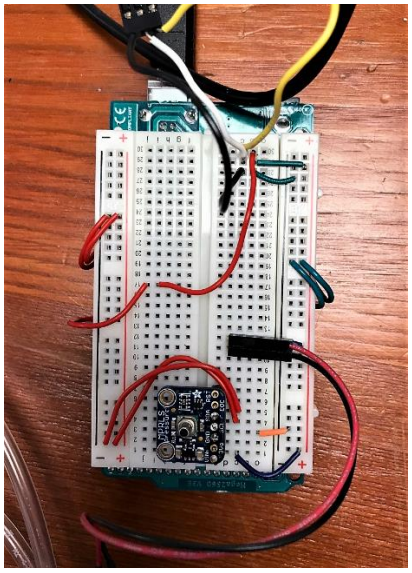


Figure 12: Pressure sensor attached to lower end of electrical breadboard.

6.2. Key Features of Overall Design

The team chose to name their final device LymphGo to emphasize the importance of a mobile device designed to address lymphedema. The functional schematic below in Figure 13 demonstrates how all of the subsystems described in section 6.1 function as a single unit. The Servo motor and micro-diaphragm pump are both directly controlled by the Arduino Mega, which receives continuous feedback from the pressure sensor regarding the air pressure in the airbags. When the airbag being inflated by the pump reaches its optimal pressure as indicated by the pressure sensor, the Servo motor turns the rotating valve so that the pump can send air to the next airbag in sequence.

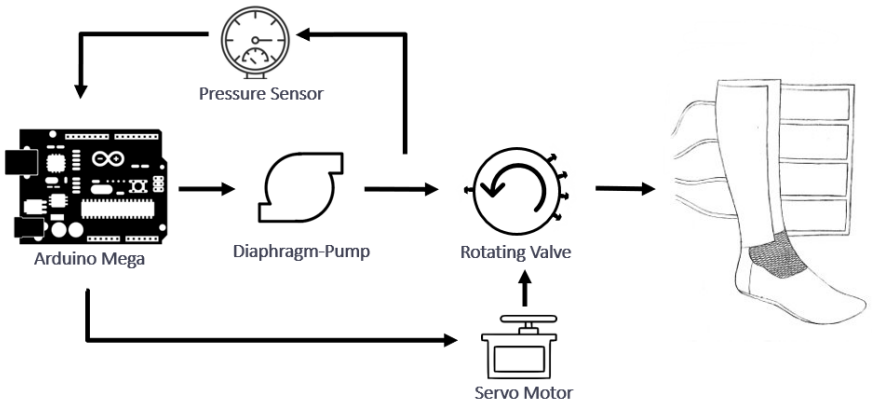


Figure 13: Overall interface and function of design components.

With so many electrical and mechanical components contributing to the overall function of the device, the team had to develop a way to house all of these components away from the distal limb to prevent excess weight inhibiting walking gait. The team therefore chose to house all of the

mechanical and electrical components in a fanny pack stationed at the hip, as pictured in Figure 14, with the inflatable airbag wrap and compressive sock worn on the left leg.

Figure 14: Jenna pictured wearing the fanny pack with the electrical and mechanical components as well as the pressurized airbag wrap.

For a closer view, the final iteration of the compressive garment is pictured in Figure 15 and the outer airbag wrap with the fanny pack are pictured in Figure 16.

Figure 15: Final iteration of compressive garment pictured on last.

Figure 16: Final iteration of outer airbag wrap with channeled pockets, alongside fanny pack containing electrical and mechanical components.

6.3. Intellectual Property

With many current modes of pressure application available to the general public and in clinical settings, the team had to use strong engineering design in order to create a device that was unique and addressed a wide variety of issues surrounding lymphedema. Iterative processes for innovative design were key to the functionality of the team's device, which will be outlined in further sections.

The most successful and innovative aspect of intellectual property incorporated into this project was the rotating valve designed by Nick Nelson, discussed in section 6.1.3. The valve was imperative to the functionality of the team's device because it allowed for the ordered and sequential inflating and back-flating of the individual airbags utilized in the team's design. The rotational aspect ensured that air from the micro-diaphragm pump was being directed to the correct airbag until the correction pressure reading was obtained, and allowed for the system to remove air from the air bladders that needed to be deflated and send that air to the airbags that needed to be inflated. Without Nick's innovative design, the team would have likely needed to use two smaller rotating valves, one of which would have addressed inflating and the other back-flating, but this would have required more synchronization in the Arduino code.

Another aspect of intellectual property embedded in this project was the non-compressive stretch mesh portion of the wearable garment that Jenna Fortner designed. Knowing that the team needed to implement a compressive element to the foot while honoring the need for something low-profile that could be worn in a shoe, the team decided to move forward with a custom compression stocking. However, the team also had to design around the fact that ulcers and sores can form in sensitive regions of the skin under constant pressure, so Jenna designed an innovative non-compressive stretch mesh element that could be placed at the top of the foot at the intersection of the leg to minimize the chances of ulceration in this sensitive region of the foot.

Another innovative element of the team's design was not actually implemented into the final product, but rather is something that the team hopes will be explored further in the future. Olivia was credited with researching and prototyping internal structures for the air bladders that would minimize the ballooning effect when inflated. As a first iteration, these internal structures consisted of straws that were duct taped together. This created a structure that could bend around the circumference of a leg while still maintaining its stiffness along the axis of each straw.

Finally, Kiley was responsible for finding and purchasing a small fanny pack that could contain all of the device's mechanical and electrical components that would be too heavy and bulky to be placed on the lower leg. This was inspired by diabetic patients who keep insulin pumps attached at the hip in a low-profile fashion. While the fanny pack utilized by the team is not the most low-profile, it does successfully hide all of the electrical and mechanical components and protect them from damage.

7. Development

7.1. Manufacturing and Construction of Prototypes

7.1.1. Development of the Last

One of the important developments in this project was the creation of a last, which modeled the human leg. Having access to a modeled leg gave the team some insight as to the physical geometry of the distal limb and how different materials behave when wrapped around the leg. This informed many of the team's decisions moving forward including airbag geometry and garment patterns. Jenna, with the assistance of her mother Stephanie Fortner, created a model of her right leg using a knee-high sock, some duct tape, and plastic bags. The first step to create the last was to tightly cover the sock while on the leg with duct tape, as pictured in Figure 17.

Figure 17: Stephanie Fortner covering the sock on Jenna's leg with duct tape.

Once the sock was completely covered in duct tape, a straight line had to be cut down the sock so the last could be removed from the leg. Then, the cut could be resealed with duct tape. The last was then filled with plastic bags to provide structure, stability, and shape to the last. The final structure, pictured in Figure 18, then reflected the geometry of Jenna's right leg. While not representative of a leg afflicted with lymphedema, the last gave the team geometry and curvature to work with for the purposes of creating a proof of concept with their design.

Figure 18: Finished version of right leg last.

7.1.2. Wearable System: Pattern-Making and Sewing

Having access to a relatively anatomically correct model of a leg made it easier to develop patterns for a form-fitting and compressive garment, as well as an outer channeled wrap for the airbags.

When creating a pattern for a garment, the first step was to outline the desired seams by taping string or pipe cleaner to the last. Then, once all desired seams were outlined, aluminum foil was layered onto the last, as seen in Figure 19. Using a pen, a line could be drawn along where the strings or pipe cleaners could be felt underneath the foil. The foil could then be cut along these drawn lines, flattened, and traced onto paper, as seen in Figure 20.

Figure 19: Aluminum foil layering onto last for patterns.

Figure 20: Foil with traced compressive sock patterns on paper.

Once paper patterns were produced, Jenna's aunt, Jenifer Hiatt, assisted with cutting out the fabric pieces that matched the patterns with 5/8 inch seam tolerances, as seen in Figure 21. The cut pieces were then brought to Sue Bonde from the University of Portland's theater department. As the garment was designed to stretch a significant amount, Sue used a serger as well as a standard zig-

zag stitch to allow for seams to stretch without breaking, pictured in Figure 22. The first iteration of the compressive garment is pictured in Figure 23.

Figure 21: Fabric pieces cut for compressive garment construction.

Figure 22: Sue Bonde attaching the non-compressive stretch mesh to the garment using a serger.

Figure 23: First iteration of the compressive garment.

The patterns used for the first iteration were reused in the development of the final iteration, which was pictured in section 6.2. The final iteration consisted of a cleaner seam attaching the stretch mesh to the other fabric components as well as trimmed internal seams for increased user comfort.

The same process was used when designing the outer pocketed wrap that would house the airbags. An image of the pattern development is seen in Figure 24, with the final product seen in section 6.2.

Figure 24: Outer wrap pattern.

Prior to having the finished outer wrap, the team's first prototype of a "wearable" airbag system consisted of fastening the airbags to the last with Velcro, as seen in Figure 25.

Figure 25: The team with their first "wearable" device, prior to the development of the outer wrap.

7.1.3. Air Bladders: Design Decisions

When the team first decided to pursue an inflatable system, the team acquired the blood pressure cuff pictured in Figure 26. The team evaluated material properties of blood pressure cuffs, aiming for their final design to have the same air-tightness as a blood pressure cuff.

Figure 26: Blood pressure cuff.

In the early stages of prototyping, the team wanted to have an idea of how airbags would inflate if they were constructed in different shapes. As seen below in Figure 27, when the team built airbags out of saran wrap and masking tape, the airbags behaved with a ballooning effect.

Figure 27: Early prototyping of inflated airbags.

The team obtained a sample of calendar vinyl to test as the material for the airbags, seen in Figure 28. Two methods were used to fuse two small sheets of calendar vinyl together: adhesives and heat

welding. Adhesives were messy and left inconsistent seamlines. Heat-welding caused the material to curl onto itself. When inflated, the vinyl would stretch slightly, causing thinning of the material and increased risk of bursting. The team also began 3D printing barbs or tube fittings for the airbags during early prototyping, which were attached to the inside of the airbag using adhesive.

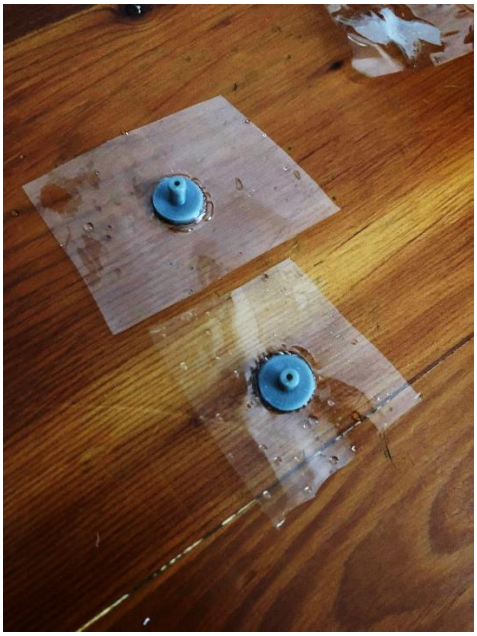


Figure 28: Calendar vinyl with 3D printed tube fittings.

Calendar vinyl was not the most biocompatible material available, so the team explored other alternatives that would be airtight. Neoprene and thermoplastic polyurethane were researched and considered to be viable options; however, due to accessibility, the team chose to use PVC-coated nylon, as pictured in Figure 29. The team attempted to use both methods of fusion again, but adhesives were still messy and inconsistent, so the team began creating heat-welded seams using a standard household iron. When inflated, the airbags still demonstrated a substantial ballooning effect.

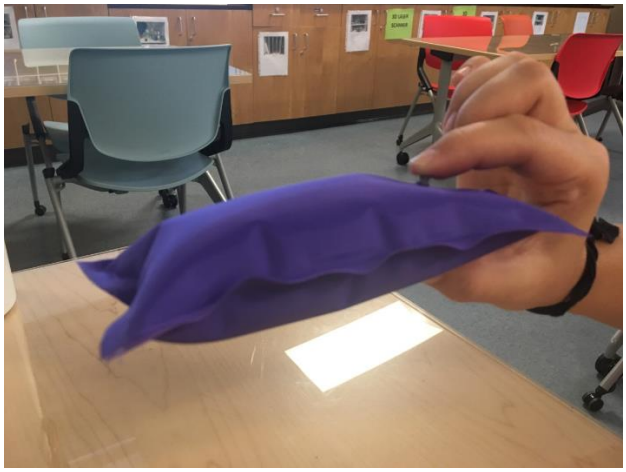


Figure 29: Rectangular inflated airbag from PVC-coated nylon.

In order to mitigate the ballooning effect, the team decided to research and prototype different possibilities that could restrict the expansion of the air bladders. The first internal structure considered was a series of straws taped together, as seen in Figure 30. When slipped inside the airbag, as in Figure 31, the straws could restrict the tendency for the long seams to move in towards each other as the height of the air bladder grows.

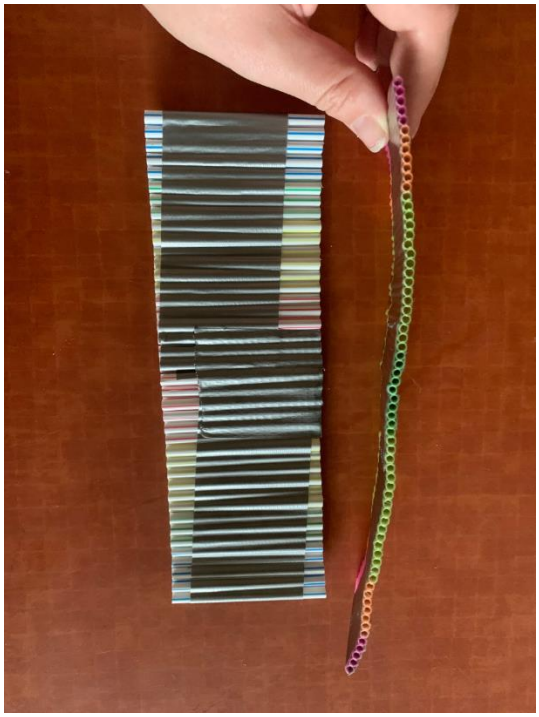


Figure 30: Straw internal structure.

Figure 31: Air bladders with straw internal structure.

The team also explored the possibility of heat-welded internal structures, which could be created using the heat press that the team developed in Figure 32. Like the straws, the intent behind the heat welds was to see if these could prevent the ballooning effect. However, as seen in Figure 33, when the air bladders were inflated with the heat-welded internal structure, they inflated in a contorted fashion that ultimately broke all of the internal structural seams.

Figure 32: Heat presses with welded internal structure.

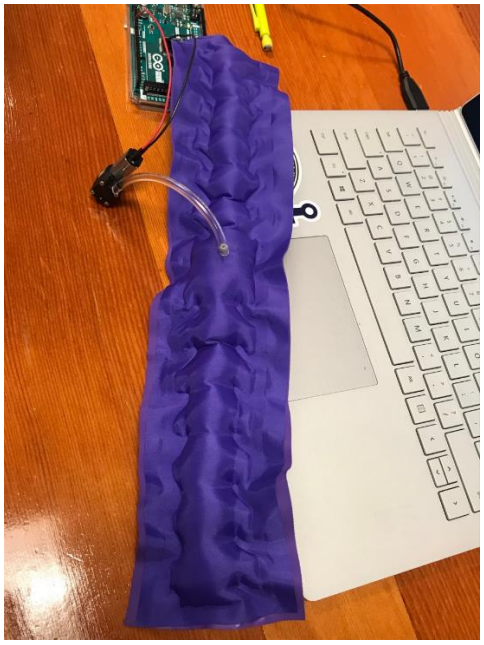


Figure 33: Inflated air bladder with heat-welded internal structures.

The team ultimately decided to nix the idea of internal structures once the outer wrap was developed. This was because the outer wrap was made out of a compressive fabric that would push against the air bladders as they inflated, preventing the ballooning effect, as seen in Figure 34. The team also decided to use curved or arched airbags because they matched the geometry of the leg better and could more effectively apply pressure. Rectangular airbags wrapped around a curved surface could not have supplied sufficient enough pressure to the entirety of the leg because the leg is not a perfect cylinder, but rather has a tapering effect that must be accounted for. At the time of these design decisions, the team also chose to invest in 90-degree tube fittings to connect to the airbags because the 3D printed barbs were too fragile for the functions of the project.

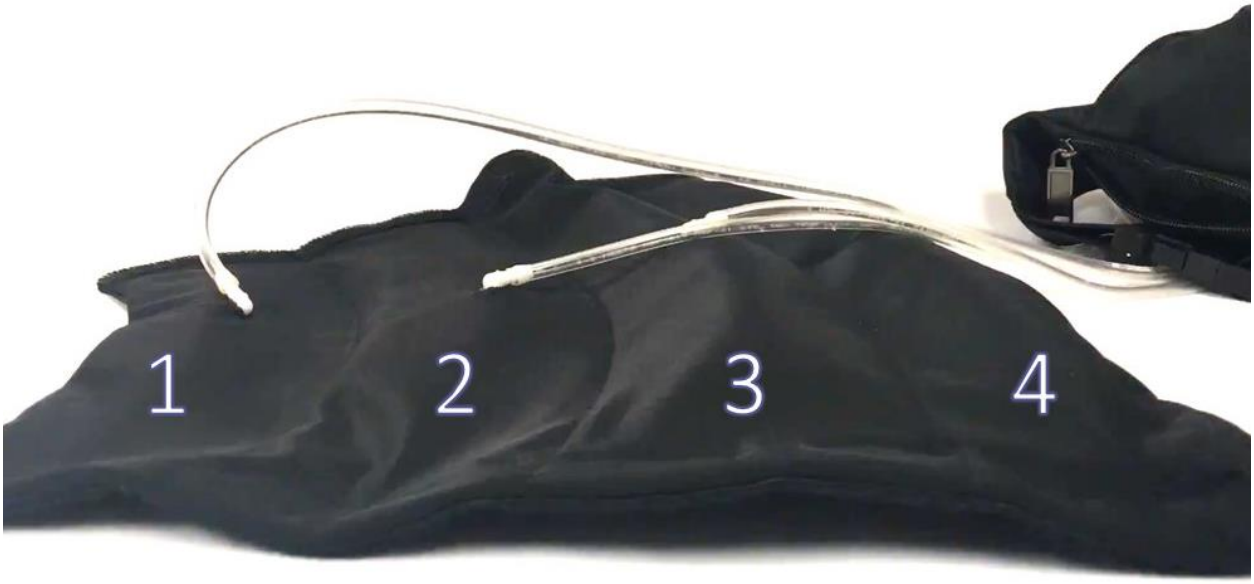


Figure 34: Final design of curved airbags in pockets of outer wrap.

7.1.4. Valve: Iterations

The design and development of the rotating valve was imperative to the team's understanding of the iterative process used in most engineering applications. Over the course of the spring semester, there were seven iterations of the rotating valve, six of which are pictured in Figure 35 in chronological order.

Figure 35: Rotating valve iterations.

The first couple rotating valves served more as a proof of concept. There was not a clear mechanism by which the valve could rotate using the attachment of an external actuator. However, these initial designs gave the team an idea of how further iterations could better augment the functional requirements of the design.

By the third iteration, the team established a way to attach the Servo motor to drive the rotations. Each subsequent iteration thereafter incorporated a similar mechanism to allow the motor and rotating valve to function as a single unit.

The fifth and sixth iterations were highly successful in their ability to rotate and fill certain airbags. However, the loose fitting of a 3D printed valve between the internal canister and the external casing caused a large amount of air losses throughout the system. While the air bladders could still be pressurized to the desired 30 mmHg, it took quite a while for the air bladders to actually fully inflate.

Due to the air losses in the 3D printed valves, the team decided to machine metal valves for the sixth (not pictured) and seventh iterations. Machining allowed for much tighter tolerances, which created a more air-tight function for the valve. The sixth iteration was highly successful in directing airflow sequentially to the air bladders; however, the issue of back-flating, or deflating some air bladders while others are being inflated, still could not be rectified using this single valve. The seventh iteration, as discussed earlier in section 6.2, found success in sequential and paired inflation and deflation between partnered airbladders, as previously outlined in Table 4. Tubing was split using T-splitters as seen in Figure 36 demonstrates the pairing of inflation and deflation between partnered air bladders.

Figure 36: Splitting tubes along rotating valve.

7.2. Modeling

The team used SolidWorks modeling when designing and prototyping different valves and tube fittings. The first several valves from section 7.1 were drawn in SolidWorks and then 3D printed from a plastic material. The final valve design was also modeled in CAD, but it was machined out of an aluminum alloy for tighter tolerances. An exploded view of the final valve model is in Figure 37. In the model, the leftmost side of the image consists of the internal rotating component, while the rightmost side demonstrates the external stationary component. Plastic tube fittings and a rubber slip are also present in the model. The internal rotating component is directly attached to the Servo motor, and the external stationary component attaches to tubing that connects to the individual air bladders.

Figure 37: An exploded view of the final valve model, credited to Nicholas Nelson.

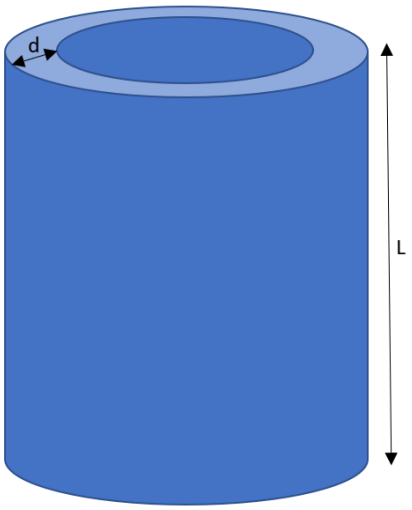
7.3. Analyses and Calculations

7.3.1. Time to Fill Air Bladders

One of the important aspects of this project was ensuring that the device can inflate the airbags in a reasonably-timed cycle. That is, the air bladders cannot inflate too quickly or too frequently as they would be disruptive to the user. Similarly, the air bladders cannot inflate too slowly, otherwise they will become ineffective in redistributing lymphatic fluid. The airbag layer was approximated as a hollow cylinder about the circumference of the leg. It was crucial to determine if the micro diaphragm pump could supply an adequate flow rate.

Assume:

- L=1/4 length of calf
- Leg and air bladder are perfect cylinders that fill uniformly
- Average circumference used for leg



Given: $Circumference = 38.1\ cm;\ d = 1cm;\ L_{calf} 30\ cm;$
$P = 700\ mL/min*$

$$C = 2\pi r = 38.1\ cm$$

$$r_i = 6.064\ cm$$

$$r_o = r_i + d = 7.064\ cm$$

$$l = 7.5\ cm = \frac{1}{4} L_{calf}$$

$$V = \pi h(r_o^2 - r_i^2) = \pi(7.5\ cm)(7.064^2 - 6.064^2) cm^2$$

$$V = 309.32\ mL$$

$$t = 309.32\ mL * \left(\frac{min}{700mL}\right)$$

$$t = 0.4419\ min = 26.5\ sec$$

**Parker T2-05 Micro Diaphragm Pump specifications* [16]

Using the above calculations, the airbag set was approximated as a single outer cylinder that wraps around the circumference of the leg that is taken to be 38.1cm, which is an average. Based on the calculations of this approximation, it will take 26.5 seconds to fill the airbag layer. This model was an idealized representative of how the airbags would behave, especially since the team opted to use four smaller sequential airbags, which were designed for a smaller circumference. By physical testing, the team observed the true cycle length is approximately one minute, which is still a reasonable length.

7.3.2. Air Bladder Material Under Stress

One of the concerns with proceeding with an airbag-based design was the burst resistance of the material chosen to construct the airbags. At the time, the team had been debating the effectiveness of heat welds as compared to adhesive. The team believed that thermoplastic polyurethane (TPU) would be the best fit based on considerations of noise when inflating, elasticity and expansion, and ability to weld under heat or using a compatible adhesive. However, the team ultimately chose to use a PVC-coated nylon for the airbags, so the calculation using TPU serves as an approximation for the PVC, which possesses some shared or similar traits to TPU. The calculations demonstrate

the relationship between the stress on the airbags and the strength of the TPU and the polymer adhesive.

Assume:

- Approximate edge as sphere R = 1cm
- TPU (thermoplastic polyurethane) as a linear elastic material

Given:

$Radius: R = 1\ cm = 0.01m;$
$Pressure\ Differential: \Delta P = 5333\ Pa;$
$Material\ Thickness: \delta = \frac{5}{1000} in = 0.127 * 10^{-3} m$

$$Material\ Stress: \sigma = \frac{1}{2}\frac{R\Delta P}{\delta}$$

$$= \frac{1}{2}\frac{(0.01m)(5333Pa)}{(0.127 * 10^{-3}m)}$$
$$= 210kPa$$

$$TPU\ Ultimate\ Tensile\ Strength:$$

$$S_{ut} = 3.5MPa$$

$$Polymer\ Adhesive\ Shear\ Strength:$$

$$\tau = 6.87MPa$$

If the stress that the material is under exceeds the ultimate tensile strength of that material it is expected that the airbag constructed of TPU will burst. However, due to the low pressure application inside the air bladders, the stress would be several orders of magnitude less than the tensile stress of the TPU or even the PVC that the team ultimately decided to use. Therefore, it could be expected that the airbags would not burst. Similarly, if the stress were to be greater than the shear strength of the adhesive, then it could be expected that the adhesive would not hold. However, in the design, the stress is several orders of magnitude less than the shear strength of the adhesive, so the use of adhesive would also be an equally viable option for constructing the airbags. It was found that airbags will likely retain their shape when using heat welding or adhesive. The team ultimately chose to pursue heat welding because it produced cleaner, more consistent seams. More consistent seams were beneficial to the team because they allowed for better identification what regions along the seam needed more heat attention or were nearing cyclic fatigue failure.

7.4. Testing

7.4.1. Walking Gait

7.4.1.1. Methods

On April 9, 2019, the team tested to see if wearing the device would affect walking gait. The team decided to observe ankle flexion, knee flexion, and vertical hip displacement. The team chose to observe ankle flexion to ensure the compression from the sock did not hinder motion. Similarly, knee flexion was observed due to the weight of the device. Finally, as external devices can cause a discrepancy in hip height due to weigh or bulkiness, the team wanted to ensure that no such loss of symmetry in walking gait was caused by the device. As the device was designed to fit the geometry of Jenna's leg, Jenna served as the test subject.

The test was conducted using six infrared cameras. The infrared cameras were set up on tripods and positioned so that they were orthogonal to the sagittal plane in the direction of motion. The field of view along the sagittal plane was set at 5 meters in length. The cameras were positioned so that when a marker was placed in the frame, at least two cameras could view each marker while ensuring the cameras were not capturing infrared light from other cameras. Ambient light in the testing environment was reduced to increase the likelihood of the cameras seeing the markers. Additionally, any reflective objects in the testing environment, with the exception of the retroreflective markers placed bilaterally on Jenna's toes, ankles, knees, and hips, were either removed from the field of view or covered.

During calibration of the cameras using the Motive software, a calibration square was placed in the center of the frame and oriented such that the z-direction was parallel to the direction of motion through the sagittal plane, the x-direction was perpendicular to the direction of motion to Jenna's left, and the y-direction was the vertical direction facing upward from the ground. To calibrate the cameras with respect to field of view, a wand with retroreflective markers was motioned throughout the entire view of the cameras.

Jenna was then asked to stand in the frame in a position where all eight markers were visible to at least two cameras, while data was recorded in Motive. This provided the standing calibration data. Jenna then walked along the frame a total of six times, three times while wearing the device and three times without the device.

The positions of each of the markers were recorded in Motive, and the data for maximum ankle flexion and hip flexion were calculated in MATLAB for each of the trials for the right and left sides. Walking speed was evaluated by finding the average amount of time it took to walk the 5 meter frame. Vertical hip displacement was evaluated graphically.

Figure 38 and Figure 39 both demonstrate approximately the same moment during Jenna's stride with the device, with the second image being Motive software's marker recording based on the

motion seen in the first image. Retroreflective markers can be seen on the hip, knee, ankle, and toe.

Figure 38: Image of Jenna during walking gait testing.

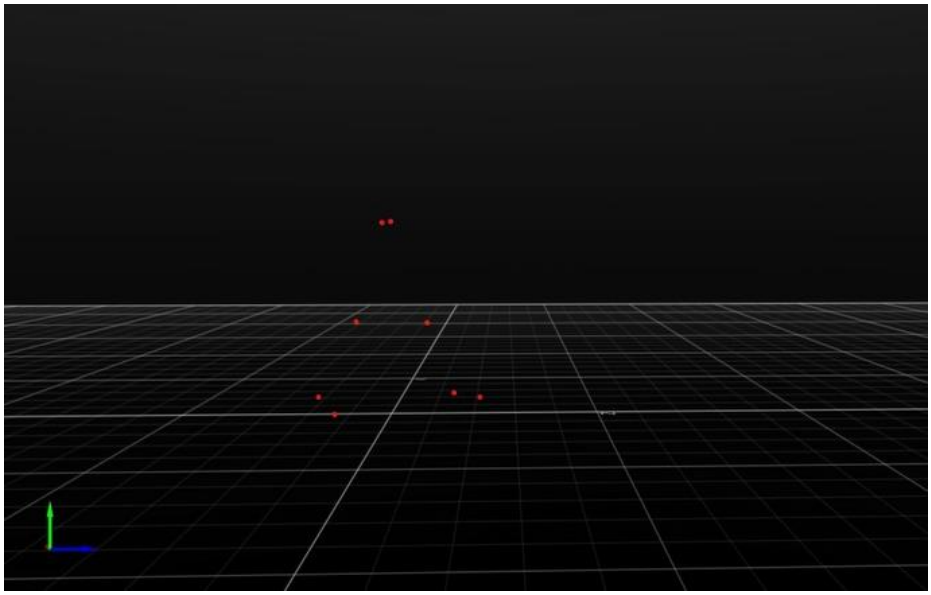


Figure 39: Motive software's recording of retroreflective markers during stride.

7.4.1.2. Results

The average speed when wearing the device was 1.17 m/s, and the average speed without the device was 1.15 m/s. The average speed with the device is within 10% of the average speed without the device, as desired, so the team believes that wearing the device does not hinder walking speed to a significant degree.

Vertical hip displacement was evaluated graphically, as seen in Figure 40. The mean hip displacement was calculated and is seen as the gray line at the center of the plot. The team wanted to ensure that when the device was worn, hip alignment or displacement did not exceed 10% of the mean displacement without the device. The range that satisfies 10% above and below the mean height is shaded in gray. As seen in the plot, at no point does the hip height exit this range when the device is on, indicating that the device did not have a noticeable effect on left hip displacement.

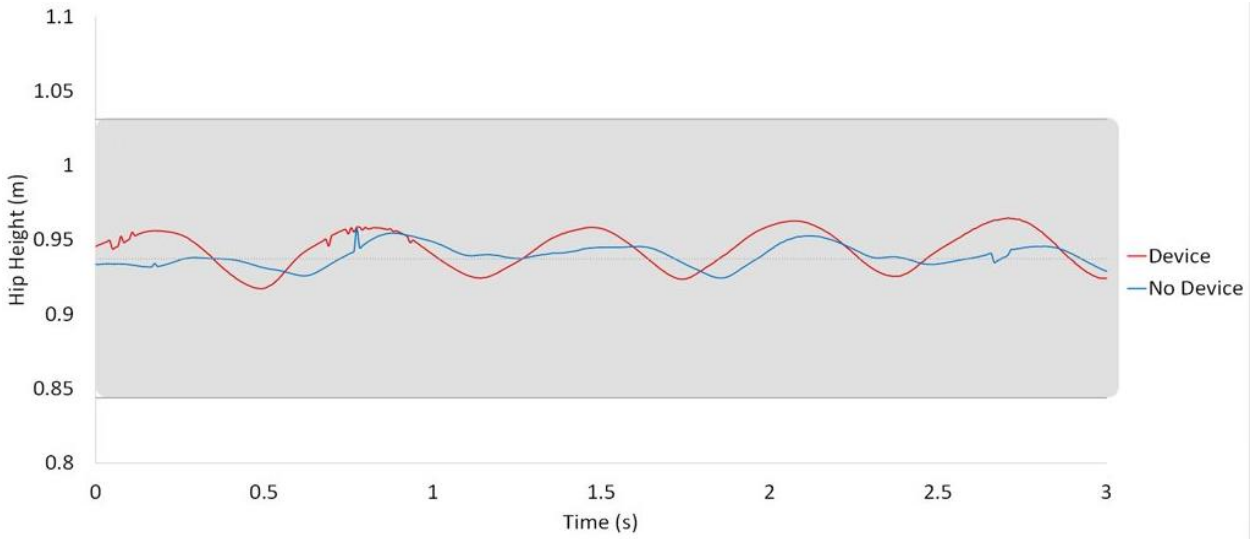


Figure 40: Plot of left hip height with and without device.

Left ankle mean flexion is plotted below in Figure 41. Gaps in the data occurred when the retroreflective markers were not picked up by the infrared cameras.

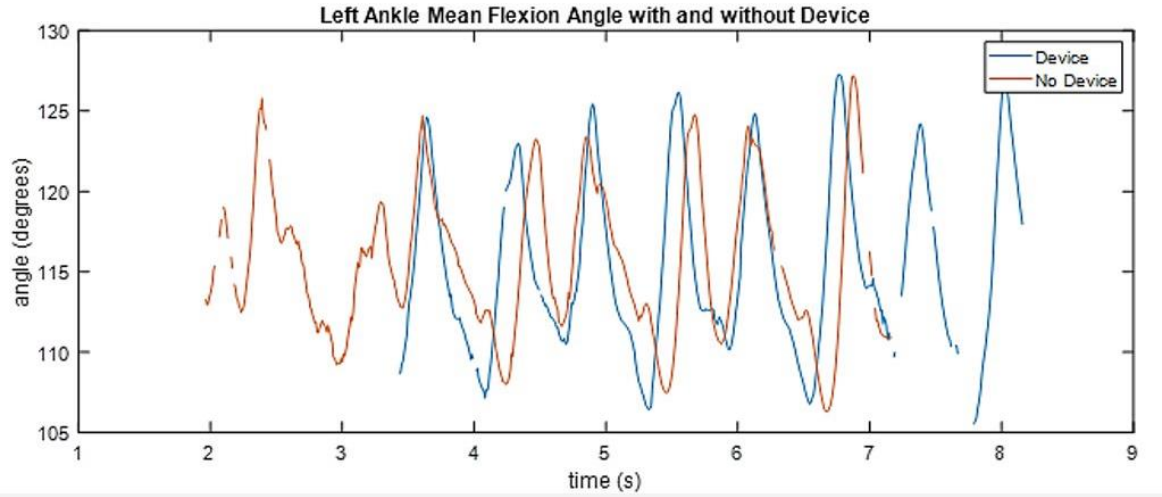


Figure 41: Plot of left ankle mean flexion with and without the device.

The average maximum ankle flexion angle was 165.9° with the device and 160.7° without the device. Additionally, the average maximum knee flexion angle was 172.5° with the device and without the device, with slight differences due to rounding.

7.4.1.3. Statistical Analyses

A statistical test was performed on the differences in average maximum ankle flexion between wearing the device and not wearing the device. The same test was performed for the average maximum hip flexion between the two conditions. For both tests, the null hypothesis was that the mean flexion angle with and without the device was the same. The alternative hypothesis was that the mean flexion angle differed with and without the device.

$$H_o: \mu_{device} = \mu_{no\ device}$$
$$H_a: \mu_{device} \neq \mu_{no\ device}$$

For ankle flexion, we found the sample means to be $\bar{x}_{device} = 165.9$ and $\bar{x}_{no\ device} = 160.7$. The sample standard deviations were $s_{device} = 14.15$ and $s_{no\ device} = 0.72$. Both had sample size $n = 3$. The test statistic was found using:

$$t = \frac{\bar{x}_{device} - \bar{x}_{no\ device}}{\sqrt{\frac{{s_{device}}^2 + {s_{no\ device}}^2}{n}}}$$

For ankle flexion, the test statistic was $t = 0.63$. This corresponds to $p\ value = 0.592$, the region shaded in red in Figure 42.

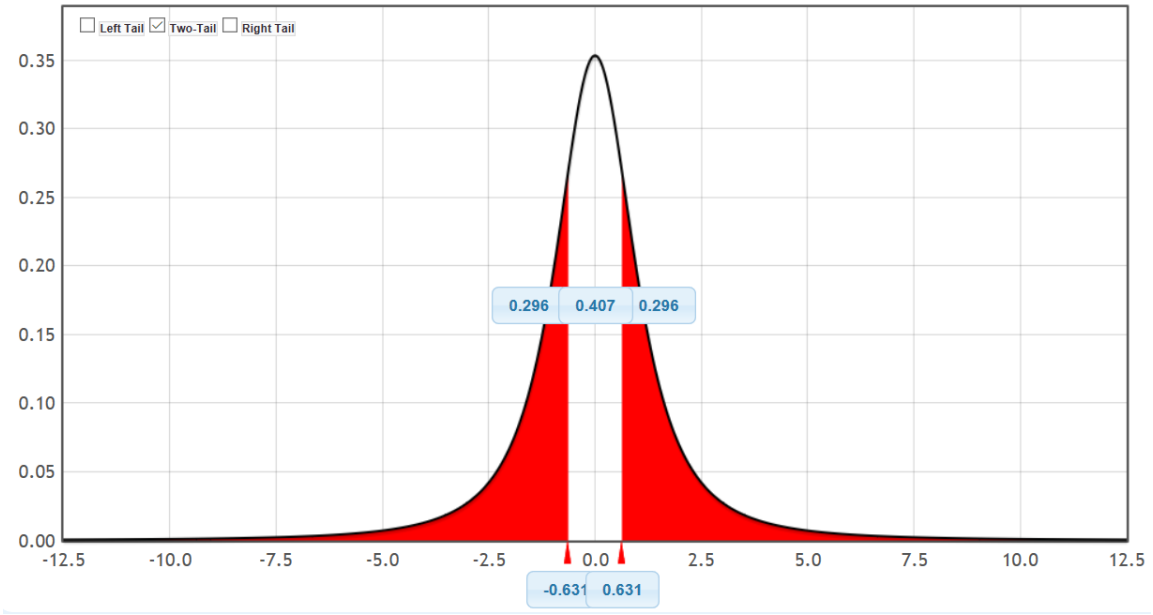


Figure 42: T-Test for difference in ankle flexion.

For knee flexion, we found the sample means to be $\bar{x}_{device} = 172.5$ and $\bar{x}_{no\ device} = 172.5$. During the following analysis the rounding error was removed. The sample standard deviations

were $s_{device} = 0.02$ and $s_{no\ device} = 0.04$. Both had sample size $n = 3$. Using the same equation as for ankle flexion test statistic, the knee flexion test statistic was found to be $t = 0.12$. This corresponds to $p\ value = 0.918$, the region shaded in red in Figure 43.

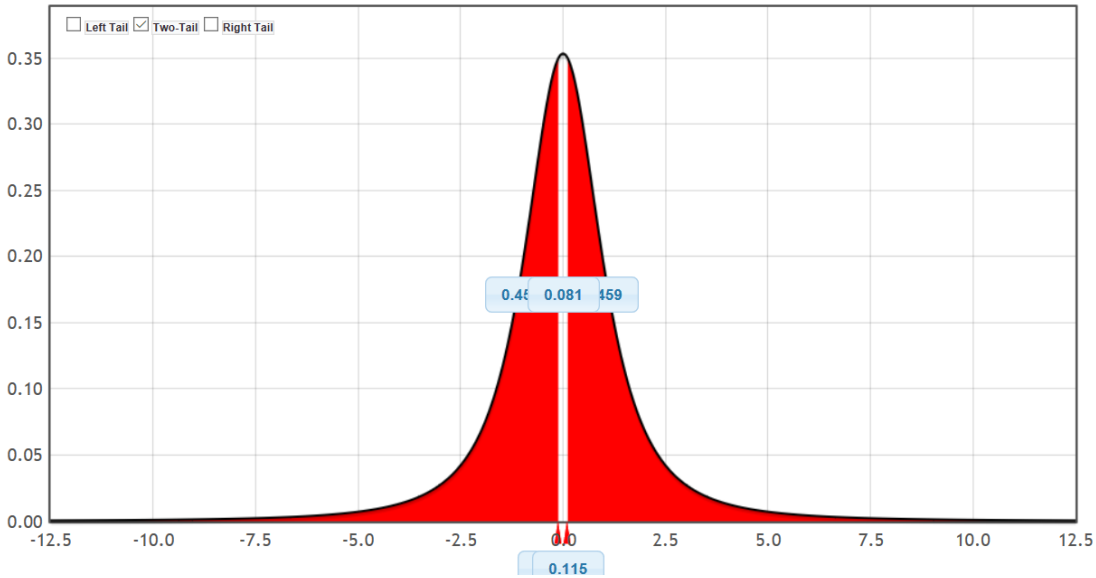


Figure 43: T-Test for difference in knee flexion.

The p-value indicates the probability that a statistic as extreme as or more extreme than the sample difference in means would occur by random chance alone. For both ankle flexion and knee flexion, extremely high p-values were obtained, so there was a high chance that any difference in mean flexion angles between wearing the device and not wearing the device were due to random chance. Therefore, there was not enough statistical evidence to say that the device caused a change in flexion angles. The team found this to be satisfactory for claiming that the device does not hinder walking gait. Future testing with a larger number of samples is recommended to validate these findings.

7.4.2. Breathability

7.4.2.1. Methods

From April 8, 2019 to April 9, 2019, the team conducted a breathability test to evaluate how much water could seep through the fabric during a 24-hour period. The purpose of this test was to determine if the materials used in the project could optimize user comfort. If the user wears the device all day, it would be uncomfortable if the material had a high water retention because the user's feet would likely feel sticky and wet from sweat. The team chose to evaluate the breathability of just the compressive stocking. The reasoning behind this was that the air bladder layer would likely be not breathable at all because the physical airbags had to be impermeable in order to be airtight.

In order to test the breathability of the compressive garment, the team elected to use the Inverted Cup Method [16]. During this test, a plastic cup was filled partially with water and the antimicrobial fabric followed by the compressive fabric were secured to the top of the cup with a rubber band, as pictured below in Figure 44. The mass of the cup with the water was first measured prior to securing fabrics.

Figure 44: Image of a single cup test set-up prior to inversion.

A second cup was then secured to the top of the water-filled cup using duct tape to minimize chances of leakage. This set-up was repeated for three separate trials, all of which are pictured in Figure 45. At first glance, the fabrics originally let a fair amount of water seep through within the first 30 minutes of testing. However, this amount plateaued very rapidly thereafter. After the 24-hour period was complete, the upper cup with the fabric attached was removed and the mass of the lower water-collection cup was recorded.

Figure 45: Three trials pictured approximately 30 minutes after inversion.

7.4.2.2. Results

The initial and final masses recorded are presented below in Table 5. The mass of the cup without water has already been subtracted from the raw data.

Table 5: Inverted Cup Method results

	Inverted cup initial mass [g]	Collection cup final mass [g]	Percent permeable [%]	Average percent permeable [%]
Trial 1	84	13	15.5	11.9
Trial 2	84	11	13.1	
Trial 3	84	6	7.1	

The average percent permeability of the three trials was 11.9%. This is lower than the team had originally hoped for and anticipated, but it gave the team some insight as to why the breathability was so low.

The first reasoning is because the fabrics were layered on top of the cup, creating a thicker barrier for the water to have to pass through. The second reasoning is because the fabrics were not stretched fully across the top of the cup. When stretched fully underneath a lightly running sink, more water passed through each layer individually. Of the two fabrics, the compressive nylon seemed to be the most breathable. It made sense that the antimicrobial fabric performed worse in terms of breathability since it is specifically a moisture-wicking fabric. As an example on the extreme end of the spectrum, raincoats are moisture-wicking as they repel water; however, they are not always very breathable. This is one of the compromises that was made by using the moisture-wicking antimicrobial fabric. The team felt that having an antimicrobial fabric was crucial to user comfort and health when wearing the device, so a compromise was made in the breathability sector. The compressive garment was designed as a separate entity from the airbag layer, so the compressive garment could be hand-washed on a daily basis.

There is also one major improvement that should be made to the test set-up. In order to minimize leaks, the inverted cup should be suspended over the collection cup (which should likely be more like a basin), rather than secured directly to it. This would not affect the results of the test, but it would make it easier to isolate the collected water for weighing.

8. Conclusions

8.1. Summary of Project

With a budget of only $500, the team was able to design, develop, and iterate upon an innovative pneumatic and peristaltic compression method that is both low-profile and highly functional. The device allows for active individuals who are on their feet all day to experience mobile pressure

application methods with a minimized risk of side effects such as ulcers. While the team had a lot of success with the design and development, there were still many areas for improvement. One area for improvement is the life of the air bladders. Unfortunately, the heat welds that hold the air bladders together are not extremely strong, so the seams tend to open upon after a few tests of cyclic loading. Once a successful and strong air bladder construction method has been determined, the device can move to its next phase of cyclic loading under patient trials.

8.2. Impact

8.2.1. Factors

There were many factors that came into play when the team was designing and developing the pressure device. One of the biggest considerations was its viability for mass production. The prototype that the team completed was custom-fit to a specific leg shape; however, the team felt that the design could be sized up or down to fit a wider variety of legs, and could be produced in sizes such as extra-small, small, medium, large, and extra-large. This would increase the manufacturability of the product. The team also had to consider manufacturability when designing the rotating valve, such that it would be feasible for mass-production. The fabrication of the design elements such as the airbags had to be considered, as well as power-sources utilized. Cost was a major factor, as the team wanted to be able to provide a device that could be easily accessible by the public. Finally, user comfort with the types of fabrics used and position of the seamlines also had to be considered.

8.2.2. Areas of Impact

8.2.2.1. Healthcare

The largest field that the team's device will benefit is the healthcare realm. Designed with clinical-grade effect, the device was developed to be used by a wide variety of audiences that could be easily accessed by anyone in need of an effective pressure application method. Multiple aspects of the device were carefully considered in order to optimize patient interface with the device. For example, the team knew that a compressive element had to be placed on the foot so that pooling would not occur; however, the team then had to make modifications to the designed compression sock in order to avoid focal pressures at the top of the foot that could result in ulcers. Therefore, the team placed a non-compressive stretch mesh at the top of the foot on the compression stocking. The team also took into account user comfort when wearing the device all day. Bacterial growth on fabric from sweat could cause infections on broken skin, so the team opted to use an anti-microbial and moisture-wicking fabric that would directly interface with the skin. After a day's use, this compressive sock would need to be washed, so the team ensured that it was a separate article from the airbag wrap. The airbag wrap was designed to be relatively adjustable, as it can be secured using Velcro. This would allow a wider variety of users to comfortably benefit from the device. Finally, the team wanted to make sure that the walking gait of the user was minimally affected by the device. Therefore, the team placed heavier elements such as the Arduino,

breadboard, pump, valve, and servo motor in a fanny pack located at the hip. This would reduce the likelihood of long-term pelvic displacement caused by having a unilateral excess weight on a distal extremity.

8.2.2.2. Economics

One of the primary concerns with the team's device was its accessibility. Cost was one of the major factors that had to be considered in order to satisfy this. Cost to manufacture the device was roughly $130, which is an order of magnitude less expensive than the leading pneumatic pressure applicator, the NormaTec Recovery System (inflatable trousers), which is priced at nearly $1300. The team's device is a more economically viable option for the general public, plus it adds the benefit of being a mobile device. One of the main long-term benefits of using the team's device is that it not only provides an alternative to more expensive compression methods, but it reduces annual spending on healthcare by making it so that lymphedema patients do not need to pay for clinical visits to use high-tech compression methods.

8.2.2.3. Social

One of the concerns the team had early on was the profile of the device. Unfortunately, there is a lot of stigma for those who wear medical devices. The team sought to reduce the chances of this stigma by making a device that could be as low-profile as possible and could therefore be hidden underneath the user's regular clothing and shoes. Such design implications could raise the user's morale and comfort-level with receiving on-the-go pressure application and symptom alleviation.

8.2.2.4. Environmental

As with any engineering design, environmental impact must be considered. The device was designed to have the Arduino, pumping system, and motor powered by a battery. Batteries contribute to air and water pollution when they are disposed into landfills and when mining occurs to obtain the necessary raw materials to manufacture the batteries. For this reason, the team chose to reduce such pollution by utilizing rechargeable battery packs, mitigating the amount of debris that would have been caused by single-use batteries. Unfortunately, one aspect of the manufacturing of the device was not the most environmentally sustainable. The team chose to heat-weld the airbags because that method provided the cleanest and most airtight seal. However, because the airbags were developed out of PVC-coated nylon, the PVC had to melt in order to produce the seal. When PVC is heated, it releases dioxins, which can cause immune system suppression and hormonal system disruption [17]. PVC also releases formaldehyde, which can cause watery eyes, nausea, rashes, and headaches [17]. Inhaling such fumes is unhealthy to the manufacturer and to the environment, so a proper ventilation system is requisite.

8.3. Future Work

One of the goals Dr. Kemalyan had for this project was that a first iteration from the team could eventually be developed into a marketable product down the road. During summer 2019, Jenna is set to work with Dr. Kemalyan at HK Ideation to continue the development of this device, and ideally produce a second iteration that could be more market-ready.

In order for such future work to be conducted, the team had to evaluate the project's shortfalls and things that could have been done better overall, given more time and finances. The four categories the team felt should be addressed in future work are integrated biological systems monitoring for continuous feedback, size adjustability, smaller micro-compressors and pumps, and minimizing the size of the upper fanny pack containing all of the electrical and mechanical components of the design. Future work could also explore the potential of internal structures for the airbags.

Integrated biological systems monitoring would mean that the device could automatically adjust based on the feedback readings it obtains from the body. For example, one monitor could observe if the circumference of the leg decreases while wearing the device, and send a notification to the Arduino to trigger the device to tighten around the leg. Another example could be a built-in blood pressure monitor, which could adjust the pressure of inside the airbags as necessary.

Size adjustability is a major path of exploration available for the future iterations of the device. One of the early design considerations for adjustability was using the BOA lacing system, sketched below in Figure 46, with a series of eye-hooks. When the BOA is turned, it pretensions the laces so that the entire device fits snugly around the leg, as seen in Figure 47. Additionally, multiple size options for the device could be considered.

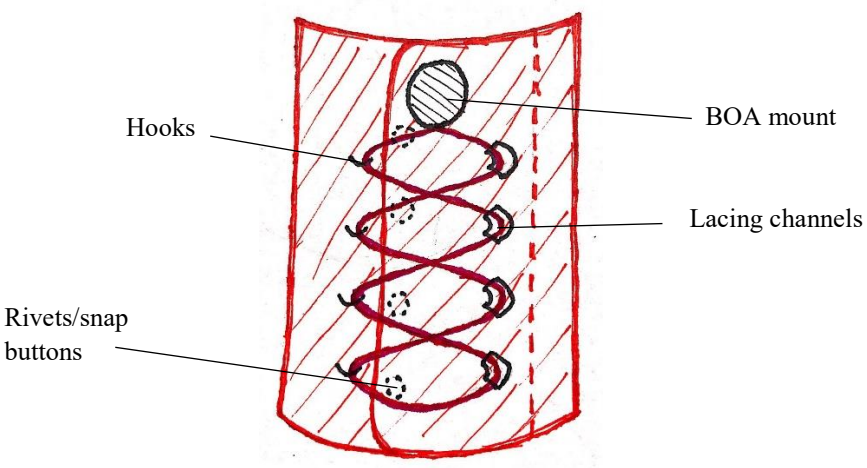


Figure 46: A sketch of the outer wrap and BOA lacing system.

Figure 47: Image of the BOA lacing system [18].

Other factors that could be considered in future iterations include smaller micro-compressors and pumps. While the team found success in purchasing very small components, there are still other products available that are smaller, but the team was not certain if the budget was flexible enough to allow for such purchases. Future iterations with a wider budget should consider finding smaller electrical and mechanical components. This would also be beneficial to the design because it would mean that a smaller and less bulky fanny pack could be utilized to hold each of the components.

Finally, exploring the idea of internal structures for the airbags should be considered. When the airbags inflate, they become more cylindrical, and the presence of a flexible structure placed inside the airbags could prevent such an extreme ballooning effect, yet still allow sufficient air to enter the inflatables and provide necessary pressure.

In the future, cyclic fatigue tests should be conducted to determine the life of each airbag incorporated into the design. If the cyclic life of the airbags is low, then future iterations of the device may need to explore alternative materials for airbag construction or greater temperature consistency when heat-welding the airbags.

Imperative to knowing actually how well this device meets its purpose would be to go through clinical trials. This is something the team would have loved to have pursued over the course of the year; however, the team would have needed approval from an Institutional Review Board, which would have taken at least a month to process. Aside from that, the team would have needed to find willing, able, and committed lymphedema patients to undergo the trial. Additionally, the team would have needed to create multiple copies of the device to ensure that each subject had a device readily available.

The design had a lot of successes, but there are still plenty of areas where the device can grow and become optimized for the consumer market. Exploration of such options in summer 2019 will

hopefully open many doors for providing an accessible, mobile, and sequential pressure device to anyone afflicted with early stage lymphedema.

8.4. Experiences as a Public Intellectual

Completion of this project required collaboration with medical professionals as well as engineers to ensure that what was being designed for the client and his patients employed the best engineering methods available to address the symptoms of lymphedema within a given budget. Multiple points of view, perspectives, and ideas had to be incorporated, both from the team members themselves and external sources, in order for the project to find the success that it did. The project also required frequent presentations to both lay audiences and fellow engineering students. In the fall of 2018, the team presented their proposed design to visitors at the Shiley Poster Showcase, which required explaining a technical design to an audience of varying degrees of pre-existing technical knowledge. In the spring of 2019, the team was required to give three separate project updates to fellow engineering peers. Frequent practice in presenting technical concepts helped the team prepare for their final presentation at Shiley Showcase on April 26th.

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From left to right: Jenna Fortner, Olivia Beckham, Kiley Gersch, Nicholas Nelson