Designing a Dynamic Prosthetic Socket for Transtibial Amputees

A Major Qualifying Project Report

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In partial fulfillment of the requirements for the

Degree of Bachelor of Science in Biomedical Engineering, Robotics Engineering and

Mechanical Engineering, Design concentration

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Abstract

When an amputee wears a prosthesis for an extended period of time, the various pressures within the prosthetic socket due to cyclic loading often results in physical discomfort, swelling, and other potential issues within the residual limb. The goal of this project was to design and test a novel prosthetic socket for transtibial (below-knee) amputees that reduces stress on the skin and soft tissues of the limb by automatically redistributing the pressures between the limb and the socket. The final design consisted of a system of soft bladders and servo-actuated valves controlled using input from force sensors. All design specifications were met and pressures were successfully redistributed across the limb.
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I. Introduction

Statement of Need

Prosthetics serve as a means of replacing limbs lost from traumatic incidents in patients. The cause of trauma can stem from injuries like crushed limbs, infection or other complications from diseases such as diabetes. Generally, using a prosthesis can allow the amputee to carry on with their daily tasks while mitigating the difficulties of losing parts of a limb.

![Range of Lower Limb Prosthetics](image.png)

*Figure 1 Range of Lower Limb Prosthetics (G3 Sky, 2014)*

Yet, issues can persist for the amputee in cases for improper care and maintenance of the prosthetic socket; the prosthesis, as a whole, does not function exactly the same way as the limb replaced would have prior to amputation. Professionals in the medical industry have long been researching and implementing prosthetic limbs with a variety of controls, materials, and fittings. Although there are many active systems, the focus has been on motor control instead of adaptive grip and fit. Grip quality is the biggest source of complaint by amputee patients.

The design should be tailored to transtibial amputees who experience the impact of grip quality which correlates to comfort based on time and amount of activity. The leg will undergo several changes that will cause small but significant increases in size (normally in diabetics) or...
decreases based on muscular dystrophy experienced in other amputees. If the fitting is too tight, this can lead to issues in circulation, nerve damage, pain and skin abrasions, which can worsen the condition of the residual limb. If too small, the socket will not properly support the amputee and inhibit blood circulation. Thus, a dynamic socket that will adjust to the conditions for the patient is necessary for the highest quality possible.

Current solutions for amputees are normally static, and consist of polyurethane socket liners that can be used to augment the suspension so the sensitive end of the residual limb does not have any direct force against from the bottom of the hard socket (Carroll, 2009). Unfortunately, there are still issues experienced with the use of this type of liner, because the limb size changes frequently, thus requiring a design that can pose as a solution to the dynamic nature of the amputee’s limb. One design that is used to address these problems is the bladder socket design from Sandia Labs. The design uses sensors and water pockets embedded in the soft socket liner to adjust the amount of fluid to increase and decrease the spacing between the limb and the socket, providing optimal pressure and support to the user (Sandia National Labs, 2015). One problem that can potentially raise concern is the ability for the liner to withstand damage to possible leaks and tears that could destroy the circuitry in the system of sensors.

This gives us an opportunity to explore the design of sockets to improve the quality of life in amputees. The goal of our project was to create a dynamic socket fitting that will allow elderly transtibial (below-the-knee) amputees to experience comfort and support. This novel design will adapt to the activities of a transtibial amputee patient and will change grip pressure and profile as load varies during daily use and exercise. To meet our goal, we established the following objectives: map the needs of the stakeholders through research and inquiry to prosthetic experts,
develop suitable design and actuation concepts, acquire necessary materials for prototype construction, and test pressure measurements for results.

Economic and Societal Impact

This new type of socket is aimed at amputees who are older and less active; however, the technology, if executed correctly, could be used to help younger, more active amputees such as those who have lost limbs overseas in foreign conflict. A socket that increases comfort and allows for longer wear with less tissue damage could help veteran amputees and active service members who are overseas by allowing them to continue to serve their country with more comfort.
Current Solutions for Transtibial Amputee Patients

*Transtibial Amputation*

Transtibial amputation is where the person has the leg amputated below the knee. Annually, 40,000 people in the U.S. become transtibial amputees; in fact, it is the most common major limb amputation in the U.S, U.K, and Australia (Brown University, 2003). The amount of infection or damage in the lower limb determines to what extent the lower limb must be amputated. The goal of the procedure is to have a cylindrical residual limb that will have padding to compensate for unnatural forces on the residual leg when walking with a prosthesis (Brown University, 2003). To get to this point, the surgeon removes the infected region of the leg, leaving behind a muscular flap comprised of both the gastrocnemius and soleus muscles (Brown University, 2003). This can be illustrated in Figure 2, showing the basic procedure of transtibial amputation.

![Figure 2 Below the Knee Amputation (Doctor Stock, 2016)](image_url)

As a result, the knee is still intact allowing the person to still have enough power to lift or lower themselves and maintain balance in daily activities. This makes creating a prosthesis easier because recreating a knee joint can be difficult since the mechanics will not be entirely the same
after amputation (Smith, 2003). Thus, the only part to focus in the prosthesis is an artificial ankle/foot mechanism. Yet, problems can still arise within amputees with this shift in the anatomy of their lower limb. As the surgery requires the muscles to be folded over at the bottom of the knee, this does not protect the residual bone covered as seen below in Figure 3. The tibia and fibula are covered with the muscular flap to create the desired shape for the residual limb but the pressures from the weight can damage the muscles causing deep tissue damage and increase fragility in the bone since there is a higher concentration of stress (LTI, 2015).

![Figure 3 Bone within the Residual Limb (Werner, 2015)](image)

The residual limb is more susceptible to pain when walking because the shape of the limb is not suitable for walking; the limb is not flat like the foot, where it would be more comfortable and there would cause fewer complications in walking. There are new sensations that are experienced within the residual limb that must be addressed when the amputee is using a prosthesis. According to Cockrell, generally, there are pressure sensitive and tolerant areas in the residual limb which can dictate how the prosthesis must be tailored to provide comfort for the person (Cockrell, 1971). Below is a diagram of the pressure sensitive and tolerant areas within the residual limb of a transtibial amputee.
On the right side of the Figure 4, the names of the bones inside of the residual limb are labeled. These regions are significant because they are also the sensitive areas in the limb. Thus, this diagram reinstates the fact that the bonier areas of the limb that are more inclined to experience discomfort must be carefully considered in creating the prosthetic fitting for the person.

Overall, the transformation of the lower limb does not stop at amputation. Amputation greatly affects the very nature of the lower limb and can create challenges for a person. Therefore, accommodations must be met in prosthetics for the user to safely transition from walking before and after amputating the lower region of the leg.
**Prosthetic Sockets**

A prosthesis is comprised of two parts: the exterior hard socket and the interior liner. A hard socket is used to protect the residual limb and acts as an interface for the fake limb, whether it is an artificial arm, hand, leg, or foot. The hard socket is normally made from polypropylene or woven carbon fiber composite materials (Brown University, 2003). It is designed to fit the contours of the leg, thus making the shape of the socket unique for each user. The interior liner acts as a barrier between the residual limb and the hard socket. Comprised of softer silicone materials, such as urethane, the main purpose of the soft shell is to prevent chafing between the skin of a patient and the hard socket (Brown University, 2003). The interior socket liner is integral to the comfort of the wearer, because of its importance to the connection and support from the prosthetic leg. The reaction forces from the person’s weight, the shock absorption from the person’s gait and the change of fit throughout the course of the day are all integral factors that affect the comfort for the user. Below, Figure 5 is an illustration of how a liner is put into the hard socket.
For diabetic users, there is a greater chance that these forces can cause damage to the limb because of a loss of feeling within it. The fit of the socket can create sweat, making the user more susceptible to skin abrasions (LTI, 2015). Also, in the case of excessive wear, the residual limb can swell, increasing the chances of discomfort with the risk of damage to the skin and the tissue. As a result, without the appropriate fit, the socket can cause further amputation, the worse possible outcome for an amputee.

Different methods to fit the limb inside the socket include vacuum suspension, suction through donning, and shuttle lock. These suspension methods are very effective for securing the limb in place inside of the socket so that as the amputee is walking, slippage and pistoning can be prevented (Ottobock, 2013). If the liner is not properly secured inside of the socket, it can create instability, friction and pain at pressure sensitive areas for the user and therefore make walking more difficult (LTI, 2015).
The donning method is where a person uses a plastic covering to allow the user to slide their limb within the socket with ease. This allows the liner and the interior layer of the socket to lie perfectly adjacent to one another with a vacuuming effect, creating stability and a reducing friction and shear forces inside the socket as well (LTI, 2015). Once the limb is secure in the socket, the plastic covering can be removed via the hole at the bottom of the socket. A depiction of this can be seen in Figure 6 below.

*Figure 6 Donning Technique to Put on Socket (Amputee Supplies, 2016)*
Another method is using a shuttle lock to hold the liner and socket together. This method requires a padded liner with a pin at the end that is inserted into a shuttle lock built into the bottom of the socket, the only point of connection (Ottoblock, 2013). This can be illustrated in Figure 7 below.

![Shuttle Lock for holding the liner and socket together](image)

*Figure 7 Shuttle Lock for holding the liner and socket together (Coleman, 2004)*

This method is useful for most patients, but if an amputee's residual limb is especially sensitive to pressure or if their residual bone is particularly sharp, it is not the best method to use. The residual bone is particularly vulnerable to damaging the tissue below it, as stated before. Although the bone is filed during surgery, its size and shape inside the residual limb may result in discomfort under excessive force. It could also fracture as a result of excessive force being applied.
Lastly, the most effective type of suspension is the vacuum technique, which consists of a sleeve that seals the top edge of a socket and a pump and exhaust system is used to remove air (Ottobock, 2013). It requires more equipment to do this method however it is worth the effort because the user will find more comfort from this type of fit (Fairley, 2008). An illustration of this can be seen in Figure 8.

![Figure 8 Vacuum suspension system for lower-limb prostheses (Oregon Orthotic Services, 2016)](image)

The vacuum suspension system performs much better than a suction suspension system because of its refined performance in reducing pistoning, creating better load distribution, stable residual limb volume, and potentially improved circulation (Ottobock, 2013). Overall, the vacuum suspension system would be an optimal approach to creating a better fit for the user.

Overall, these solutions are pivotal to the daily use and wear of a prosthesis for an amputee. Ensuring a secure method of wear aids in a more normal gait, and a longer wear time, but it does
not address the comfort experienced as the fit changes. A diabetic amputee's limb can undergo shrinkage and expansion, which would make tight fitting a hindrance to their limb health. It is therefore essential to address the different stages that a person can experience throughout the day based on the amount of activity and time passed. Therefore, this gives us more of a reason to explore a dynamic socket fitting that can address these issues and improve the quality of using a transtibial socket.

**Pre-existing Designs**

Currently, there are solutions for fit and comfort available for amputees that we found including the Sandia Labs liner and Revolimb dynamic socket. Both designs have different approaches to adjusting the fit inside the socket to cater to the changes experienced in the limb. Hence, they pose as good examples for our project to explore the advantages and disadvantages that assisted us in creating an optimal design.

The Sandia Labs dynamic liner was produced through government funding to create a better fitting using a liner embedded with sensors that will detect volume change in the residual limb (Sandia National Labs, 2015). The reaction to the forces from the residual limb will shift the fluid provided in the liner’s bladders to make adjustments (Sandia National Labs, 2015). The liner is made from a gel-like material that will have all of the sensors on the inside. The sensors are three-axis pressure sensors that detect the normal and shear forces of the residual limb (Holmes, 2014). This information is then transferred to the computer, which gives commands to change the fluid around (Holmes, 2014). The fluid comes from a reservoir and the bladders are activated with sensors that can detect volume loss or gain, depending on the changes in the residual limb (Holmes, 2014). Additionally, the same sensors provide information in real time to a computer to monitor the blood pressure in the residual limb (Holmes, 2014). Below in Figure 9 is a picture of the liner.
One issue with the design is that it has fluid which can damage the electrical components in the liner. This can be a problem and thus, the method of adjusting pressure must consider the medium that is used to provide comfort for the user.

Another design that we found upon our research was the Revolimb dynamic socket which is a commercial product. The Revolimb is a dynamic socket that has various plates located in the pressure tolerant areas in the residual limb (Click Medical, 2015). As seen in Figure 10 below, the plates are adjusted with wiring that can be pulled tighter or loosened to adjust the fit in those areas using a dial in the back of the socket.
This allows the user to have specific points of pressure adjusted rather than the entire socket changing. Although this socket does target different points in the limb, the design does not allow the plates to have different ranges of tightness to accommodate the difference in comfort levels in each region of the leg. This is the case because it has only one dial to make these adjustments. Additionally, the socket requires the user to have manual adjustments rather than automatic changes like the Sandia Labs socket, which means that the user must be fully aware of the discomfort in their limb. This can be an issue for users because this would require them to stop and make adjustments themselves in their daily activities.

Overall, from analyzing these designs, the need for a socket that is both automatic and manual should be implemented. The socket should be able to do both so that in case the user does not sense the pressure in their limb, the system in the socket will change accordingly; if the system does not change or malfunction, the user should also have a choice to make different changes in their limb. This way, the design can adjust to different conditions based on the user and can provide
safety in case the system fails or the user fails to provide the necessary conditions to keep the residual limb in good shape while under loading within the socket.
II. Design Methodology

The goal of our project is to create a dynamic socket fitting that will provide comfort and proper fitting for transtibial amputees. In order to accomplish this goal, we identified four main objectives: 1) map the needs of the stakeholders through research and inquiry to prosthetic experts, 2) develop suitable design and actuation concepts, 3) acquire necessary materials for prototype construction, and 4) test pressure measurements to analyze the effectiveness of our design. Below is a flow chart of our methods.

![Design Methodology Flow Chart]

Figure 11 Design Methodology

In order to fulfill the first objective, we conducted research and inquired about prosthetic users with Liberated Technologies Inc. to identified the stakeholders for the project and rank the priorities. This way, we could properly address who would be impacted greatly from the deliverables of our project. We identified four stakeholders: the patient, advisors, and
LTI/Prosthetic Industry and ourselves. Each stakeholder was given a number for their level of importance, with the highest priority as 1 and the lowest as 3. The first stakeholder, which is the patient, has a priority of 1 who will depend greatly on the deliverable of the project the most.

<table>
<thead>
<tr>
<th>ID</th>
<th>Title</th>
<th>Description</th>
<th>Role</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>SH.1</td>
<td>Patient</td>
<td>Non-Compliant, Diabetic, 50+years old, with necropathy and transtibial amputation.</td>
<td>No direct role or influence, represented by Students</td>
<td>1</td>
</tr>
<tr>
<td>SH.2</td>
<td>Advisors</td>
<td>“Managing Body”, Ultimately Approve Project</td>
<td>Advise, approve and oversee Project</td>
<td>1</td>
</tr>
<tr>
<td>SH.3</td>
<td>LTI/Industry</td>
<td>Experienced in Industry &amp; knowledgeable about patients</td>
<td>Insight about market, patient, and integration</td>
<td>3</td>
</tr>
<tr>
<td>SH.4</td>
<td>Students</td>
<td>Want a viable and working product that can be marketed to amputees.</td>
<td>Building the product, Identifying needs and requirements. representing SH.1 patient</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 1 List of Stakeholders

To narrow down the type of user and the general lifestyle that our design to address, we chose to cater to diabetic transtibial amputees over the age of 50. These users would have a high chance of necropathy due to their disease which makes a comfortable, non-abrasive socket all the more important for them to use. Our other stakeholders including ourselves that are in gray, were considered secondary priorities because the patient is the only stakeholder that would be directly impacted by the fit and comfort of the socket. Thus, the secondary stakeholders contribute to how the socket will be produced via insight. Our second sets of stakeholders are our advisors, listed
with a priority of 1, who had to approve the design of our prototype to deem whether the design will be successful. Our third stakeholder would be LTI and the prosthetics industry with a priority of 3 because we sought to create a new design which must be innovative enough to market without recreating pre-existing designs. Lastly, the design would impact us because we aimed to have a working product that would satisfy the first stakeholder.

After identifying our stakeholders, we gathered the information about the needs for the amputee and how we can correlate our design to comfort. Additionally, our research from various journal articles, websites, and papers in relation to prosthetics provided us with a large range of information to help us understand what kinds of issues amputees endure and the current solutions provided to solve them. Once we gathered the information from our research, we were able to map our requirements to address and rank the priorities of the project. Below is the list of our requirements in Table 2. Each need describes what the socket must address and which stakeholder it affects. Our needs are there to map what factors are addressed in designing the socket and to link them to stakeholders.

<table>
<thead>
<tr>
<th>ID</th>
<th>Title</th>
<th>Description</th>
<th>Compliance</th>
<th>Traceability</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>N.1</td>
<td>Degree Requirements</td>
<td>Design, Production, Testing, Medical Integration, Sensing, Intelligence, Actuation</td>
<td>Accomplishes all degree requirements for students involved</td>
<td>SH.4 Students</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SH.2 Advisors</td>
<td></td>
</tr>
<tr>
<td>N.2</td>
<td>Sensory Error &amp; User Neglect</td>
<td>“Set and forget” Patient does not want to be constantly notified or adjusted.</td>
<td>Prosthetic can still operate as a static socket while keeping patient safe.</td>
<td>SH.1 Patient</td>
<td>3</td>
</tr>
<tr>
<td>N.3</td>
<td>Adjusting Fit (Pressure, Form, Slip)</td>
<td>No pain inflicted from excessive pressure, slippage, or poor fitment.</td>
<td>Adjusts automatically or manually for changes in residual limb.</td>
<td>SH.1 Patient</td>
<td>1</td>
</tr>
<tr>
<td>N.4</td>
<td>Skin Health</td>
<td>Patient needs to experience none or minimal skin abrasion as a result of daily use</td>
<td>Dragon Skin silicone could show stresses on skin</td>
<td>SH.1 Patient</td>
<td>2</td>
</tr>
<tr>
<td>N.5</td>
<td>Deep Tissue Health</td>
<td>Patient’s necropathy is not worsened, and fitting does not occlude blood flow causing damage (Sanders et. al)</td>
<td>Notifies Patient of dangerous levels and then relieves pressure if at dangerous levels according to (Sanders et. al)</td>
<td>SH.1 Patient</td>
<td>1</td>
</tr>
<tr>
<td>N.6</td>
<td>Limb Model</td>
<td>Allows Students to test fitting to prove requirements successfully achieved on a model of a residual limb of the patient</td>
<td>Made to emulate patients residual limb for N.2,4,5 (recipe from LTI)</td>
<td>SH.2 Advisors SH.4 Students</td>
<td>1</td>
</tr>
<tr>
<td>N.7</td>
<td>The Innovation</td>
<td>A viable, marketable, dynamic socket that adjusts both automatically, and by user input</td>
<td>User can adjust fit (pressure) manually in addition to automatic pressure adjustments</td>
<td>SH.1 Patient SH.2 Advisors SH.3 LTI/Industry SH.4 Students</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2 List of Needs According to Stakeholders

To address more specifically the important factors, we create task specifications and requirements that would help us decide what the socket must have in order to successfully meet the needs of our stakeholder. Below are the requirements for the socket. The needs are listed within the validation column to justify the requirements while the verification column describes the
method and concept that must be used to satisfy the requirement. The priority is ranked as the same as the previous tables, 1 being the highest and 3 being the lowest.

<table>
<thead>
<tr>
<th>ID</th>
<th>Title</th>
<th>Description</th>
<th>Verification</th>
<th>Validation</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>FR.1</td>
<td>Blood Flow</td>
<td>Pressure Time Relationship maintained within x% of pressure for y% of time according to Sanders et. Al</td>
<td>Develop model of average daily use for audience, test against Limb Model Does pressures applied fall below threshold while maintaining functionality</td>
<td>N.3 Adjusting Fit N.5 Deep Tissue Health N.6 Limb Model N.7 The Innovation</td>
<td>1</td>
</tr>
<tr>
<td>FR.2</td>
<td>Limb Model Durometer</td>
<td>Durometer rating will be between x and y (LTI measurements)</td>
<td>Measure with durometer for verification</td>
<td>N.6 Limb Model N.1 Degree Requirements</td>
<td>2</td>
</tr>
<tr>
<td>FR.3a</td>
<td>“Backwards Compatible”</td>
<td>System shall be able to act as a conventional static prosthetic and maintain preset shape with no user involvement or power</td>
<td>Define a preset. Remove power and user input, Does the socket stay static and imitate existing prosthesis?</td>
<td>N.2 Sensor Error &amp; User Neglect</td>
<td>2.5</td>
</tr>
<tr>
<td>FR.3b</td>
<td>Failsafe</td>
<td>Mechanically limits maximum pressure of X psi in case primary pressure regulation fails</td>
<td>Run actuators full power, then make sure pressure does not exceed max threshold</td>
<td>N.2 Sensory Error &amp; User Neglect N.3 Adjusting Fit N.4 Skin Health N.5 Deep Tissue Health</td>
<td>3</td>
</tr>
</tbody>
</table>
Furthermore, we came up with a list of basic task specifications to set benchmarks for the design that we created. Our original design goals are as follows:

**Initial Project Goals**

1. The socket will be able to function under a vertical ground reaction force of 1.2 times the patient’s body weight. We aim account for a patient weight of 200 lbs.

2. We must determine the Young’s, shear, and bulk moduli of the residual limb on an older patient. If a literature review does not yield these values, we will determine them experimentally.

3. Install 4-6 force/pressure sensors monitoring the effect of 4-6 actuators inside the socket for closed loop control of pressure against the residual limb.

4. The fit of the socket must change through a self-actuated closed loop control with a duration of under 1.5 seconds of command to relieve discomfort and provide basic functionality from the patient. Functionality includes adjusting in response to the wearer’s gait cycle.

---

**Table 3 Requirements Based on Needs**

| FR.4 Automation | a) System changes shape via self actuation  
b) System senses effect of actuation | Specify set pressure to system; does it automatically achieve that goal? | N.1 Degree Requirements  
N.3 Adjusting Fit  
N.7 The Innovation | 1 |
|-----------------|-----------------------------------------------|-------------------------------------------------|-------------------|
| FR.5 Notification | System shall notify user before adjusting pressure of fit. | Can system make notification before adjusting? | N.2 Sensory Error & User Neglect  
N.7 The Innovation | 3 |
5. The socket must withstand repetitive loading in order to ensure that it can function under cyclic loading coming from an amputee’s gait cycle.

6. Wiring within the socket must be protected to prevent damage and ensure safety for the user. The final prototype must be able to withstand environmental conditions such as precipitation and a wide temperature range.

7. The socket must allow adequate tissue perfusion through the course of 8 hours. Therefore, the socket must allow enough blood circulation for the user over this period of time based on the average amount of time we propose the person would be walking on a daily basis.

**Analysis of Initial Project Goals**

The original design goals as stated above guided us through our project, with some exceptions. The first goal we listed was a basic weight requirement for the function of our final prototype. As we continued to learn about the function of sockets under the functional weight of amputees, we discovered that if we modified a static hard socket, we could easily achieve this goal. The second goal listed above required us to perform an extensive literature review with little result. Because we could not find values to match the yield, shear, and bulk moduli for an amputee’s residual limb, we attempted to perform experiments to determine these values; however, the values we found were dubious. With much deliberation with our advisors, it was determined that these values were irrelevant to the project goal, because these values could vary significantly from patient to patient.

We accomplished the third, fourth, and fifth goal, but with minor adjustments to the specifications. We implemented 8 force-resistive sensors with three actuators inside the socket. We were able to implement closed-loop control that responded in real-time to the wearer’s movements. The socket was also able to function under cyclic loading. We were unable to
meet goals 6 and 7, because the final actuation design took longer to implement than that was expected, and we ran out of time to make our actuation more efficient and weatherproof, but it was not a major issue because it was not necessary to do so in order to accurately experiment with our final design. When attempting to follow the goals we set for ourselves, we found that goal 7 was erroneous, because the dynamicity of our ideal final prototype meant that the pressures within the system would never stay in one place on the residual limb for excessive periods of time. This static pressure is the cause of blood occlusion and irreparable tissue damage, therefore we determined that this goal was not necessary. Our system was designed to maintain pressures within the safe range for patients.

As the project progressed, we realized that the significance of creating a working model of the concept we chose carried more weight than we had realized initially. It was determined that many of our initial goals were out of the scope of this project, and that if this project were to continue at Popovic Labs, a future team could address goals that we were unable to reach. From our initial project goals, we devised realistic design criteria that we adhered to for the latter half of our project. The final design criteria can be seen below.

**Final Design Criteria**

1. Withstand a patient weight of 200 pounds

2. Change fit through automated control

3. Withstand repetitive loading from walking/standing

4. Monitor 4-6 force/pressure sensors to control the effect of the socket on the limb

5. Apply pressure against tolerant regions to relieve from painful regions
6. Durable and flexible material to allow volume change

7. Compensate for loss in volume of residual limb

8. Lightweight so the patient expends less energy using it.

To fulfill the second, third and fourth objectives, we decided to do an iterative design approach because of the complexity of our project. The four steps in the iterative design process are ideate, prototype, build and analyze. This process can be illustrated in Figure 12 below.

![Iterative Design Process](image)

**Figure 12: Iterative Design Process**

From the ideation phase, we were able to come up with three designs: bladder, moving plate and corset socket concepts. Below is a weighting chart that we used to determine which idea we perceived to be the most suitable. For basic design purposes, we focused on cost, production, operation, maintenance, resolution, dependability, and weight based on the specifications stated earlier.
<table>
<thead>
<tr>
<th></th>
<th>Cost (7)</th>
<th>Production (10)</th>
<th>Operation (9)</th>
<th>Maintenance (8)</th>
<th>Resolution (5)</th>
<th>Dependability (7)</th>
<th>Weight (3)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder</td>
<td>4</td>
<td>6</td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>226</td>
</tr>
<tr>
<td>Moving Plate</td>
<td>7</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>8</td>
<td>9</td>
<td>5</td>
<td>241</td>
</tr>
<tr>
<td>Corset</td>
<td>7</td>
<td>10</td>
<td>9</td>
<td>7</td>
<td>1</td>
<td>8</td>
<td>9</td>
<td>374</td>
</tr>
</tbody>
</table>

Table 4: Weighted Decision Matrix for three potential designs

At first glance, one can see that the highest scoring was for the corset mechanism. However, we realized that the design was too similar to a pre-existing concept that we found upon research so we decided to create the turn-key socket concept following the iterative design process to adjust the socket concept.

Lastly, to test pressure measurements, we created a test apparatus comprised of a fake residual limb placed under loading that would accurately simulate the pressure experienced if the user wore the socket. This was necessary because we could see whether our design would be feasible and accomplish our overall goal of providing comfort for the user.

**Client Statement**

The goal of our project is to build a dynamic prosthetic socket for transtibial amputees that is able to redistribute the forces within the socket in response to the wearer’s movements in addition to compensate for the volumetric increases and decreases in a patient’s residual limb over time. This socket must be able to function under at least 200 pounds with an automatic actuation system. The overall system must be light enough such that an amputee could wear it without feeling weighed down (under 15 pounds).
The success of the final design will be determined by constructing a model residual limb with embedded sensors that can read and output the pressures felt inside the model limb in real-time. A bone-like structure will be embedded within the model limb to act as the weight-bearing mechanism for the system. This will give an accurate value of pressures a real patient could experience. The weight of a patient will be simulated by loading the system with weights.
III. Preliminary Designs

As part of the design process, we came up with preliminary designs that we thought would accomplish the goal that we set for a dynamic socket. With each concept, we evaluated the characteristic differences in the designs to fully map out their strengths and weaknesses based on resolution, dependability, type of actuation, and degradability. Below in Table 5, are the differences between each socket concept. In this section, we will also discuss the realization phase of each design.

<table>
<thead>
<tr>
<th>Design Components</th>
<th>Bladder</th>
<th>Moving Plate</th>
<th>Corset</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Compressed air/hydraulic</td>
<td>• Mechanical actuation</td>
<td>• Mechanical actuation</td>
</tr>
<tr>
<td></td>
<td>• Partially/fully automated</td>
<td>• User-operated/automatable</td>
<td>• Automatable</td>
</tr>
<tr>
<td></td>
<td>• Medium resolution</td>
<td>• High resolution</td>
<td>• Low resolution</td>
</tr>
<tr>
<td></td>
<td>• Easy to use</td>
<td>• Hardest to use</td>
<td>• Easy to use</td>
</tr>
<tr>
<td></td>
<td>• Has more maintenance</td>
<td>• Least maintenance</td>
<td>• Medium maintenance</td>
</tr>
<tr>
<td></td>
<td>• Hard to construct</td>
<td>• Easy to construct</td>
<td>• Easy to construct</td>
</tr>
<tr>
<td></td>
<td>• Worst degradability</td>
<td>• Best degradability</td>
<td>• Medium degradability</td>
</tr>
<tr>
<td></td>
<td>• Heaviest</td>
<td>• Medium weight</td>
<td>• Lightweight</td>
</tr>
</tbody>
</table>

*Table 5 Decision components for each design*
Moving Plate Design

The first design that we decided to pursue was the Moving Plate Design. The concept of this design included a series of moving plates that could be adjusted individually to provide or release pressure at several designated locations. At first, we felt that screws were the best way to move the plates within the socket; so we designed several models in SolidWorks using screws that moved in and out of the socket and connected to the plates via a spherical or ball joint.

We designed the first CAD model with the intent to emphasize the design concept itself. Therefore, we distributed several plates across the residual limb evenly, and we exaggerated the size of the screws that moved each plate. As is customary for some amputees to wear a silicon liner with their prosthetic, we decided to incorporate a liner directly into our moving plate design. This would prevent any direct contact between the plates and the amputee’s skin, and would also distribute some of the applied pressure from the plates. Our first CAD model is shown below in Figure 13.

Figure 13 First CAD model of Moving Plate design
We designed the second CAD model with the intent to incorporate consideration of the pressure tolerant areas along with more realistic screw sizes. Since the tibia is typically one of the more sensitive areas on a transtibial residual limb, we made sure to put plates around it instead of directly on the tibia. Likewise, since the pressure tolerant areas consist of the more muscular parts of the leg, most of the plates targeted parts of the calf muscles. The plate orientation can be more clearly understood by looking at Figure 14. In the top view of our model, the front end faces the top of this paper, meaning that the tibia, lying between the two front plates, would face the top of the paper within the socket as well.

![Figure 14 Second CAD model of Moving Plate design](image)

When we started to construct our actual prototype of this design, we decided to use hydraulics to push the plates instead of screws. Since we eventually needed to apply actuation to the system, hydraulics was a better option; a hydraulic system provided us with more control while having to actually actuate less, and therefore, our socket would weigh less, and be less bulky. Our hydraulic system contained water as its fluid, and included several valves, and syringes, which
served as the reservoir, the pump, and the plate moving mechanism within the hydraulic system. We felt that water would serve best to move the plates because it is incompressible.

As a whole, the functionality of our hydraulic system was to build up pressure in the syringe serving as a pump to later distribute throughout the system. In what would be our final design, we intended to have pressure build as the amputee walked, by incorporating the pump directly into the prosthetic leg itself. Each step would store pressure in the pump, represented by the syringe in our prototype, which would then be released into the system by opening the pump’s valve.

Based on the orientation of the valves, the pressure within the system would either build up, move to be stored in the reservoir, move water from the reservoir to one of the plate moving mechanisms, or move the water in one of the plate moving mechanisms back to the reservoir. In Figure 15, the hydraulic system is displayed.

![Hydraulic System for Second Iteration](image)

The rest of our hydraulic moving plate design consisted of an actual prosthetic socket and a 3D printed part. A section of the socket was cut to create a plate that would be adjusted with the plunger within the syringe. This was designed to have the plate follow the contour of the leg while
compensating for the volume changes experienced on the residual limb. Figures 16 and 17 below illustrate the final iteration of this design.

*Figure 16 Plate Cut Out*

*Figure 17 Complete Design with 3-D Part*
Bladder Design

One of the preliminary designs that we decided to pursue was the bladder design. The basic concept of this design was a socket fitted with pouches (or bladders) that inflated and deflated to redistribute the pressure against the amputee's residual limb. As seen in the table above, in comparison to the other preliminary designs, this concept was rated to have the heaviest construct and the worst degradability; however, this design was rated as the easiest to use, with a medium to high resolution. This prototype can be seen in Figure 18 below.

Figure 18 First iteration of Bladder design
The first working model for this concept was constructed by lining a femoral (above-knee) socket with three PDR Air Wedges. These bladders were off-the-shelf products, and their marketed purpose was to act as an inflatable wedge for leveling, and to open locked car doors. These bladders were adhered to the inner walls of the femoral socket with industrial-strength Velcro. These bags were inflated and deflated by a preliminary actuation system comprised of a micro servo attached to a three-way valve that rotated and allowed air into the individual bags based on controls provided form a Pololu Micro Maestro 6-channel USB Servo controller (Pololu, Las Vegas, Nevada). The type of micro servo that was used for this prototype was the BK Micro Servo 3001 HV. This model was chosen for its small size and weight (20g), and its high torque output (5.8kg/cm at 7.4V), which was necessary to compensate for the friction within the valves.

![Figure 19 Schematic of Air Bladder Socket](image-url)
Figure 19 above shows the basic actuation schematic of the first prototype for the bladder concept. As the foot check valve sends air to the valve, the valve rotates in time, allowing for air in the separate bladders to be filled and released in sequence.

The second prototype for the bladder concept was comprised of six smaller bladders within a socket shaped into a bypass prosthesis. A bypass prosthesis is a type of socket that allows for the testing of a new design. It allows for a person who is not an amputee to try on the design and put weight on it, in order to gauge comfort for a patient. The hard outer shell was manufactured from Kydex V, a type of thermoform plastic manufactured by Sekisui-Spi Inc. (Sekisui-Spi Inc., Holland, Michigan). The Kydex was heated with the use of a heat gun, and shaped around one of our team member's knee in order to get an accurate shape for the bypass. Then, the plastic was fitted with six small neonatal blood pressure bags with the use of industrial Velcro for modularity. The bags were 'daisy-chained' together such that only one input was necessary for the system. A blood pressure cuff check valve was used for the input and output, while a secondary output valve was fitted on to the bypass for safety. The completed prototype can be seen in Figure 20.
Although this prototype consisted of a manual actuation scheme, it provided an accurate means of assessing the function of a potential final design concept, because it allowed for us to see what the potential socket could feel like.

**Corset Design**

The third design we explored for our dynamic prosthetic socket was partially inspired by the Revolimb design. The concept behind this design was to redistribute pressures in the system by physically tightening and loosening the socket as a whole against the residual limb of the amputee. This motion could be controlled by pressures sensed within the system, and performed by a simple lead screw attached to a motor. The screw is fastened to both crimping ends of the socket. The non-back-drivable motor is also housed on the exterior of the socket.
In order to explore this design, we created a proof of concept by molding a piece of Kydex thermoform plastic around the exterior of an existing transtibial socket, and attaching the motor and lead screw to its exterior. This proof of concept can be seen below in Figure 21. We found that although this design was the easiest to actuate, its low resolution and poor fit for the patient led us to decide to not pursue this for our final design.

![Figure 21 Proof of concept for corset design](image)

**Analysis**

Once all prototypes were made and fully tested, they were re-evaluated for viability for our final prototype. Each working model for the turn-key, bladder, and corset design was compared against each other, and against the characteristics we anticipated in Table 4. It was decided that the bladder design was actually the easiest to actuate, the lightest design if pneumatically actuated, and also the least mechanically complex with the greatest functionality.
IV. Final Design

The final design we chose to pursue after testing our various concepts was the bladder design. We chose this design because although it was not the simplest of the designs, it gave the highest amount of resolution, with the lightest overall frame. Our final dynamic bladder-fitted socket was constructed by using fiberglass to take a mold of an existing transtibial socket. This mold was taken with three bladders between the socket and the fiberglass in order to capture the profile of them, and allot space for them within the final design. Fiberglass was used in the final construction, because prosthetic socket manufacturers often use this material to make hard sockets for patients. Many layers of fiberglass were used to ensure that the final socket was structurally sound, and did not bend under loading forces during testing.

Once the fiberglass cured, it was shaped and sanded to eliminate any excess resin, while also maintaining the shape of the original socket that it was molded out of. Three holes were strategically cut to allow for tubes to thread to each bladder, once embedded in the system. The bladders used for this system were medical-grade neonatal blood pressure bags. These bags, manufactured by MDF, were latex-free and rated for use within blood pressure cuffs. We ensured that the bags used within the system met medical standards, because they were to interface with the patient's residual limb, and as a result, could not be made of any material that could cause an allergic or toxic reaction (MDF, Los Angeles, California). These bags met the standards of the American Heart Association, as well as the European Standard 1060-1:1995, 1060-2:1995, and ANSI/AAMI SP10: 2002.

The bags were adhered to the inside of the fiberglass socket using industrial Velcro. Once bags were fitted inside, tubes were attached to each one to the actuation mechanism. The actuation mechanism was comprised of three valves, each one controlled by a micro servo. The micro servos
we used were BK Micro Servo 3001V. These servos weighed 20g each, and were capable of up to 4.7kg/cm of torque (BK Servo, Alberta, Canada). These servos were controlled using signals from an Arduino Mega. In tandem, line pressures within the tubes leading to the bags were read by small Honeywell Pressure Sensors. The read pressures controlled the action of the bag valves. Depending on the line pressures, each bag would inflate or deflate. Finally, the exterior of the manufactured hard socket was wrapped in a carbon fiber vinyl laminate to increase the aesthetic appeal. The final prototype can be seen in Figure 22 below.
V. Bill of Materials

Final Prototype

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>BK Micro Servos</td>
<td>Used to turn the valves to control the air in the bladders</td>
<td>$64.00 (x3)</td>
</tr>
<tr>
<td>Neonatal Blood Pressure Cuffs</td>
<td>Used as bladders to redistribute pressures</td>
<td>$7.99 (x3)</td>
</tr>
<tr>
<td>Fiberglass Resin</td>
<td>Used to manufacture a hard socket with reliefs for the bladders</td>
<td>$14.97</td>
</tr>
<tr>
<td>Fiberglass Cloth</td>
<td>Used for hard socket manufacturing</td>
<td>$6.97</td>
</tr>
<tr>
<td>Carbon Fiber Vinyl Laminate</td>
<td>Used to cover the exterior of the final prototype</td>
<td>Provided by LTI</td>
</tr>
<tr>
<td>Honeywell Vented Gauge Pressure Sensor</td>
<td>Used to measure the pressure in air bladders</td>
<td>$17.30 (x4)</td>
</tr>
<tr>
<td>Arduino Mega</td>
<td>Used to read pressure from Honeywell pressure sensors and control servos</td>
<td>Provided by student</td>
</tr>
<tr>
<td>Luer Lock Valves</td>
<td>Used to control charge and discharge air into bladders</td>
<td>Provided by WPI</td>
</tr>
<tr>
<td>Air Compressor</td>
<td>Serves as compressed air source</td>
<td>Provided by student</td>
</tr>
<tr>
<td>Syringe Tubing</td>
<td>Connects pneumatic components</td>
<td>Provided by WPI</td>
</tr>
</tbody>
</table>

Experimental Apparatus

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>OOMOO 30 Silicone</td>
<td>Used to construct the silicone residual limb</td>
<td>$26.49</td>
</tr>
<tr>
<td>Dragon Skin Silicone</td>
<td>Simulated skin on residual limb</td>
<td>$35.61</td>
</tr>
<tr>
<td>Force-resistive Sensors</td>
<td>Embedded under simulated skin to read pressures</td>
<td>$5.60 (x 10)</td>
</tr>
<tr>
<td>Aluminum</td>
<td>Simulated bone and weight bearing part</td>
<td>$110</td>
</tr>
</tbody>
</table>

Please see the “Part References” section in the References Chapter for more information on each part.
VI. Experimentation and Results

To test our final design, we conducted two tests based on the socket’s ability to withstand an actual person’s weight. In order to conduct these two tests, we decided to create a testing apparatus for us to see how much pressure would be applied with a person’s weight. The test procedures can be seen in the appendix.

The key components in testing included a fake residual limb made from OOMOO 30 Silicone and dragon skin, force-resistive sensors and an aluminum shaft and platform to stack weights onto the socket. To read the information and provide air flow to bladders, we had two systems: a National Instruments Data Acquisition (DAQ) box connected to all FSRs and a Luer Lock valve system with servo motors to pump air to any of the bladders according a sequence from an Arduino board. The overall socket system and testing apparatus is seen in Figure 23 below.

Figure 23 Socket under Weights for Testing
Testing Apparatus

*Aluminum Shaft and Platform*

In order to test the socket’s ability to withstand weight, we designed a platform to stack weights. The shaft is threaded to attach the plate that would uphold the weights. We obtained weights from the school’s gym because we thought they were suitable. Below are images of the shaft and platform used.

![Figure 24 CAD model of Shaft and Platform for Weights](image)

The weights would slide onto the shaft and land on the plate as seen previously in Figure 23. In total, we had 270 pounds to simulate the weight of the person.
Mock Residual Limb

In order to test this final prototype, we manufactured a model residual limb by mixing silicone and using a soft liner of a transtibial socket as a mold. We used Smooth-On silicone OOMOO 30 rubber, as it was the most cost-effective option for its purpose (Smooth-On Inc., Macungie, PA). OOMOO 30 has a shore hardness of 30A, and a cure time of about 6 hours, which allowed us to quickly and accurately model the residual limb of an older amputee. The mold was taken with an aluminum structure embedded within it, to act as a model bone, and also to hold weights we would be loading the system with during testing. Once the silicone mold had fully cured, we coated it with Smooth-On Dragon Skin Silicone Rubber, which simulated skin for the model residual limb (Smooth-On, Macungie, PA).

Below the surface of the Dragon Skin, we embedded Force Resistive Sensors to gauge the pressures a real amputee would potentially experience within this system, if he or she were to wear it. Eight FSRs were embedded within the model residual limb; two were placed under where each bladder would go, and two were placed on the bottom-most part of the limb.

Force Sensitive Resistors

With respect to the pressure tolerant areas of the residual limb, we decided to embed eight sensors within the “skin” in the mock limb. The force sensors are SEN-09375 Force Sensitive Resistors. These were used to produce an analog output for the Arduino. This allowed us to record the pressure changes experienced in the limb. The sensors were calibrated using two term exponential equations generated from data input to MATLAB (see appendix). The graph, shown in Figure 25 below, shows the exponential curve for one of the FSRs, and the table, shown in Table 6 below, shows the equations generated from MATLAB based on each sensor’s behavior:
The data from these FSRs was also sent to a National Instruments Data Acquisition (DAQ) box, which was hooked up to a LabVIEW Virtual Instrument that showed the forces shifting inside the mock limb in real time. The locations of the sensors and a screenshot of the VI can be seen below.
In Figure 26 above, the placements of the FSRs can be seen on the left. The forces on the limb correspond to the colored bars within the VI on the right, based on the color of the sensor. The VI also shows two bi-linearly interpolated heat maps for the anterior and posterior sides of the limb. During experimentation, the VI displayed forces as they changed and redistributed across the mock limb when each bag inflated and deflated.

**Bladder Control**

Luer Lock 3-way petcock valves were used for ease of adjustment. There are servo motors at three of the valves to control air flow. The method used was the Bang-Bang control for an appropriate response of pressure changes in the bladders when the weight is applied or released.

**Results**

The test we ran on our system compared readings from the Honeywell Pressure sensors, and FSRs. We set the Arduino code to run a sequence that charged and discharged one of the bladders, while a MATLAB program took in serial readings from both types of sensors. The MATLAB program then generated plots from this data, highlighting the pressure readings from the charging bladder, and one of the selected sensors on the residual limb. We performed this
sequence with different loads applied to the residual limb, ranging from 0 to 270 extra pounds, and made sure to isolate each bladder and sensor output in the data within the MATLAB program. This allowed us to analyze the affect that charging a particular bladder had on a particular sensor. The most significant results are shown in the graphs below:

Figure 27 Bladder 1 pressure vs. Anterior 1 Sensor force with no weight
Figure 28 Bladder 1 pressure vs. Anterior 1 Sensor force with 90 lbs

Figure 29 Bladder 3 pressure vs. Posterior 6 Sensor force with no weight
In the graphs shown above, the thick blue line represents the pressure in the bladder that is being charged and discharged, the thick red line is the emphasized force reading in the chosen sensor, and the purple lines are the force readings on the sensors that are not emphasizes in the given case. The first two graphs (Figures 27 and 28) display readings from the Anterior 1 sensor as Bladder 1 charges and discharges. From these graphs, it is clear that as the pressure in the bladder increases, the force in most of the sensors increases as well, except for the force on the Anterior 1 sensor, which decreases with the increase in bladder pressure. This phenomenon occurs with and without extra weight on the residual limb model.

A similar event occurs on the Posterior 6 sensor when Bladder 3 is pressurized, as seen by the third and fourth graphs shown above (Figures 29 and 30). With and without extra loading on the residual limb, as the pressure in Bladder 3 increases, most of the forces on the sensors increase with it, except for the Posterior 6 sensor, which experiences a decrease in force. The decrease in
force on these sensors in response to an increase in one of the bladder’s applied pressures proves that our final design successfully redistributes force throughout the residual limb. More from this test are highlighted in the Appendix.

The reason we were able to successfully redistribute forces within the limb, that is, decrease forces in some areas while increasing forces in other areas, is because we are addressing the change in volume in the residual limb with our design. An amputee may experience pain or discomfort from concentrated loads on their residual limb due to an improper fit; if the socket does not perfectly fit the limb, the interface between limb and socket is compromised. Therefore, the surface area which bears the amputee’s weight, that is the side walls of the socket, is less than a socket that provides a proper fit. Since our design is able to correct the improper fit by increasing the volume of our bladders, we are effectively changing the shape of the surface area, as well as increasing the surface area that would bear the amputee’s weight. This in turn decreases the overall pressure experienced on the limb and also alleviates highly concentrated forces on the limb.

VII. Conclusion

Upon the completion of the project, we learned the difficulties faced in understanding how to gauge comfort and how to create a suitable design to meet our goal. The project was challenging due to the many iterations of designs, and the necessity of such iterations in the world of science and medicine. Despite the challenge, the iterative design process helped us discover alternative methods for solving the problems of poor fit and lack of comfort presented by current prosthetic sockets; the air bladder design was the final result of this process. After experimenting with our final design, we confirmed that the air bladder design successfully redistributed forces within the
residual limb, and that the iterative process we used to design a dynamic fitting for a prosthetic socket was fruitful.

**VIII. Future Improvements**

**Manufacturability and Sustainability**

Although we performed extensive testing using our experimental apparatus, the full potential of this design for patients must be tested through human clinical trials. We were able to somewhat simulate what an amputee would feel, when wearing our socket, but true comfort cannot be measured unless a patient were to wear our socket while sitting, standing, and walking.

One of the biggest advantages to the design we chose is the marketability. If a prosthetist were to implement this design for an amputee's socket, it would take very little effort for him or her to simply configure the bags to fit under the pressure tolerant areas of the system. If this became a product available to amputees, it would most likely be manufactured at companies such as Next Step Bionics and Prosthetics Inc. that specializes in prostheses manufacturing. Or, the bladders could be embedded into a secondary sleeve for the patient to wear underneath his or her hard socket. It is also a possibility that majority of the hardware, such as the valves and the servos, would be scaled down and made such that it could be embedded or sit right on the surface of the hard socket.

A possibility for mass manufacturing could be 3D printing all components within the hard socket, such that after a prosthetist takes the mold of a patient's residual limb, he or she could simply upload the contours and some minor specifications into a Computer-aided design model and print a hard socket for a patient. This could significantly reduce the cost of sockets for the patient.
Our product would be successful on market, because it cost significantly less than a current state-of-the-art dynamic sockets on the market. According to our bill of materials (seen in the section above), the total cost of manufacturing or final prototype was $247.89. If this product was to be manufactured on a large scale, the cost could be reduced significantly.

**Ethical Concerns and Safety Issues**

When designing a new type of socket, it was important for us to remember that although this product could ultimately improve a person's life, it could also do the opposite if executed poorly. That is why we did not consider testing on a real patient until we knew the forces sensed on our model residual limb were of reasonable range for human use. It would be highly unethical to perform human subject tests without first verifying that the socket is safe for human use. In order for this testing to occur, our circuitry would have to be printed on to a circuit board and shielded from the user to prevent any electric shock. Also, the valves and air tubes would have to be secured in place to prevent any breakages, which could lead to sudden drops of pressure in the system. If this happened, a patient could lose their balance and fall.
IX. Appendix

Arduino Code

```c
#define ATM 100
#define MAXP 211
#define INC 80
#define BP1 80
#define BP2 BP1
#define BP3 BP1
#define THRESH 10

#include <Servo.h>
#define HOLD 100
#define VENT 160-40 // 40 normal
#define CHARGE 60+26 //+28 is really slow

#define BLAD1 A1
#define BLAD2 A2
#define BLAD3 A3
#define TANK A0

#define S1 2
#define S2 3
#define S3 4

#define a1pin 15
#define a2pin 14
#define a3pin 13
#define a4pin 12
#define a5pin 11
#define p6pin 10
#define p7pin 19
#define p8pin 18

#define SERVOPOWER 5
#define SEQLEN 12

int sequence[12][3]= {
    {BP1, BP2, BP3},
    {BP1+INC, BP2, BP3},
    {BP1+INC, BP2+INC, BP3},
    {BP1+INC, BP2+INC, BP3+INC},
    {BP1+INC, BP2+INC, BP3},
    {BP1+INC, BP2, BP3},
    {BP1, BP2, BP3},
    {BP1+INC, BP2, BP3},
    {BP1+INC, BP2+INC, BP3},
    {BP1+INC, BP2+INC, BP3+INC},
    {BP1+INC, BP2+INC, BP3},
    {BP1+INC, BP2, BP3},
```

57
long unsigned int start=0;
Servo s1; int s1pos=0;
Servo s2; int s2pos=0;
Servo s3; int s3pos=0;
tank=0;
int blad1=0; int blad2=0; int blad3=0;
int bp1=BP1; int bp2=BP2; int bp3=BP3;
int a1=0; int a2=0; int a3=0; int a4=0; int a5=0;
int p6=0; int p7=0; int p8=0;
int blad1kpa=0;
int blad2kpa=0;
int blad3kpa=0;

void setup() {
  pinMode(BLAD1,INPUT); pinMode(BLAD2,INPUT); pinMode(BLAD3,INPUT);
  pinMode(S1,OUTPUT); pinMode(S2,OUTPUT); pinMode(S3,OUTPUT);
  pinMode(a1pin,INPUT); pinMode(a2pin,INPUT); pinMode(a3pin,INPUT);
  pinMode(a4pin,INPUT); pinMode(a5pin,INPUT);
  pinMode(p6pin,INPUT); pinMode(p7pin,INPUT); pinMode(p8pin,INPUT);
  pinMode(SERVOPOWER,OUTPUT); digitalWrite(SERVOPOWER,LOW);
  s1.attach(S1); s2.attach(S2); s3.attach(S3);
  Serial.begin(9600);
  start=millis();
}

void loop() {
  //seq();
  control();
}

void control(){
  readPressure();
  bladder1(bp1);
  bladder2(bp2);
  bladder3(bp3);
  readLimb();
  printLimb();
}

void seq(){
  for(int i=0; i<SEQLEN; i++){
    int st = millis();
    while(millis() < st+1250){
      bp1=sequence[i][0];
      bp2=sequence[i][1];
      bp3=sequence[i][2];
      control();
    }
  }
}

void servoSleep(){
  if(millis() > start+1000){
    start = millis();
    digitalWrite(SERVOPOWER,LOW);
  }
void readLimb()
{
    a1=analogRead(a1pin);
    a2=analogRead(a2pin);
    a3=analogRead(a3pin);
    a4=analogRead(a4pin);
    a5=analogRead(a5pin);
    p6=analogRead(p6pin);
    p7=analogRead(p7pin);
    p8=analogRead(p8pin);
}

int bladder1(int pressure){
    if(blad1 > pressure - THRESH && blad1 < pressure + THRESH) {
        digitalWrite(SERVOPOWER, HIGH); s1.write(HOLD);
    } else if (blad1 > pressure - THRESH) {digitalWrite(SERVOPOWER, HIGH);
        s1.write(VENT);
    } else if (blad1 < pressure - THRESH && blad1) {
        digitalWrite(SERVOPOWER, HIGH); s1.write(CHARGE);
    } else if (blad1 < pressure - THRESH && !(tank > pressure + THRESH)) {
        digitalWrite(SERVOPOWER, HIGH); s1.write(HOLD);
    }
    return blad1;
}

int bladder2(int pressure){
    digitalWrite(SERVOPOWER, HIGH);
    if(blad2 > pressure - THRESH && blad2 < pressure + THRESH) s2.write(HOLD);
    else if (blad2 > pressure - THRESH) s2.write(VENT);
    else if (blad2 < pressure - THRESH && blad2) s2.write(CHARGE);
    else if (blad2 < pressure - THRESH && !(tank > pressure + THRESH)) s2.write(HOLD);
    return blad2;
}

int bladder3(int pressure){
    digitalWrite(SERVOPOWER, HIGH);
    if(blad3 > pressure - THRESH && blad3 < pressure + THRESH) s3.write(HOLD);
    else if (blad3 > pressure - THRESH) s3.write(VENT);
    else if (blad3 < pressure - THRESH && blad3) s3.write(CHARGE);
    else if (blad3 < pressure - THRESH && !(tank > pressure + THRESH)) s3.write(HOLD);
    return blad3;
}

void off(){
    s1.detach(); digitalWrite(S1, LOW); s1.attach(S1);
    s2.detach(); digitalWrite(S2, LOW); s2.attach(S2);
    s3.detach(); digitalWrite(S3, LOW); s3.attach(S3);
}

void printData(){
    int in = 0;
    in = Serial.read();

    int minlen=1;
int maxlen=4;
char buffer [4];
String str = itoa(tank, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(blad1kpa, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(blad2kpa, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(blad3kpa, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
Serial.println();

void printLimb(){
    int in = 0;
in = Serial.read();

    int minlen=1;
    int maxlen=4;
char buffer [5];
String str = itoa(tank, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(blad1kpa, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(blad2kpa, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(blad3kpa, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
Serial.print(|");
maxlen=5;
str = itoa(a1, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(a2, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(a3, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(a4, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(a5, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(p6, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(p7, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);
str = itoa(p8, buffer, 10); for(int i=0; i<maxlen; i++)
if(str.length()<maxlen) str.concat(" ");
Serial.print(str);Serial.print(digitalRead(SERVOPOWER));
Serial.println(" ");

// digitalWrite(SERVOPOWER,HIGH);
if(in==48){ s1.write(HOLD); s2.write(HOLD); s3.write(HOLD); delay(1000);
} else if(in==49){ s1.write(VENT); s2.write(VENT); s3.write(VENT);
    int cont=0; Serial.println("VENTED SEND 2 to resume operation");delay(500);digitalWrite(SERVOPOWER,LOW);
    while(!cont){ in=Serial.read(); if(in==50){cont=1;}}}
else if(in==50){ s1.write(CHARGE); s2.write(CHARGE); s3.write(CHARGE);
    delay(1000); }
}

void readPressure()
{
    tank = analogRead(TANK); tank = max(tank-ATM,0);
    blad1 = analogRead(BLAD1); blad1kpa = (0.488*blad1)-49.97 ; blad1 = max(blad1-ATM,0);
    blad2 = analogRead(BLAD2); blad2kpa = (0.488*blad2)-49.97 ; blad2 = max(blad2-ATM,0);
    blad3 = analogRead(BLAD3); blad3kpa = (0.488*blad3)-49.97 ; blad3 = max(blad3-ATM,0);
}

float mapdouble(double x, double in_min, double in_max, double out_min,
double out_max)
{
    return (double)(x - in_min) * (out_max - out_min) / (double)(in_max - in_min) + out_min;
}

Matlab Code Template used for calibration

sensorCalibrationTemplate.m

clc; clear;

%Volts in V <insert average readings between semicolons>
Volts = [ ; ; ; ;
        ; ; ; ;
        ; ; ; ;
        ; ; ; ];

%Weight in grams <these were the different weights I used>
Weight = [50; 70; 90; 110;
         130; 150; 170; 190;
         210; 220; 1002.4383; 1628.3953;
         2177.2416; 2431.2531; 4658.3898; 9071.84];
%Generate and plot trendline
trend = fit(Volts, Weight, 'exp2');
plot(trend, Volts, Weight);
display(trend);

Matlab Code for plotting bladder pressure and sensor forces

Posterior6unload.m

close all;
fig1=figure(1); set(fig1,'Position', [480, 540, 480, 540]);
[ax,hLine1,hLine2] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,11),5)); hold on;
[ax,hLine1,a2response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,7),5));
set(a2response,'Color', [0.5,0,0.5]); hold on;
[ax,hLine1,a3response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,8),5));
set(a3response,'Color', [0.5,0,0.5]); hold on;
[ax,hLine1,a4response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,9),5));
set(a4response,'Color', [0.5,0,0.5]); hold on;
[ax,hLine1,a5response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,10),5));
set(a5response,'Color', [0.5,0,0.5]); hold on;
[ax,hLine1,a6response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,11),5));
set(a6response,'Color', [0.5,0,0.5]); hold on;
[ax,hLine1,p7response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,12),5));
set(p7response,'Color', [0.5,0,0.5]); hold on;
[ax,hLine1,p8response] = plotyy(dat(:,1),dat(:,3),dat(:,1),smooth(dat(:,13),5));
set(p8response,'Color', [0.5,0,0.5]); hold on;

set(hLine1,'LineWidth',3, 'Color', 'blue');
set(hLine2,'LineWidth',3, 'Color', 'red');
title('Posterior 6', 'FontSize', 50);
xlabel('Samples', 'FontSize', 32);
ylabel(ax(1), sprintf('Pressure in Bladder 1 [kPa]\n'), 'FontSize', 32);
set(gca, 'FontSize', 20);
ylabel(ax(2), sprintf('\nForce on Sensor P6 [N]\'), 'FontSize', 32);
set(gca, 'FontSize', 20);
postLeg = legend([hLine1,hLine2], 'Pressure in Bladder 1 [kPa]', 'Force on Sensor P6 [N]', 'Location', 'northeast');
set(postLeg, 'FontSize', 24);
close all; clear all; clc;

s = instrfind('Status', 'open');
if (length(s))
    fclose(s);
end
s = serial('COM4');
fopen(s);
dat = zeros(13);
for i = 1:500
    line = strsplit(fgets(s), ' ');
    tank = str2double(line{1});
    blad1 = str2double(line{2});
    blad2 = str2double(line{3});
    blad3 = str2double(line{4});
    a1 = map(str2double(line{6}), 0, 1023, 0, 5);
    a1 = 0.00980665002864*((0.008977*exp(3.26*a1))+(66.38*exp(1.227*a1)));
    a2 = map(str2double(line{7}), 0, 1023, 0, 5);
    a2 = 0.00980665002864*((91.56*exp(0.3116*a2))+(3.131*exp(2.193*a2)));
    a3 = map(str2double(line{8}), 0, 1023, 0, 5);
    a3 = 0.00980665002864*((81.1*exp(0.5779*a3))+(1.614*exp(2.393*a3)));
    a4 = map(str2double(line{9}), 0, 1023, 0, 5);
    a4 = 0.00980665002864*((44.97*exp(-0.9329*a4))+(22.91*exp(1.782*a4)));
    a5 = map(str2double(line{10}), 0, 1023, 0, 5);
    a5 = 0.00980665002864*((65.03*exp(1.051*a5))+(0.9344*exp(2.46*a5)));
    p6 = map(str2double(line{11}), 0, 1023, 0, 5);
    p6 = 0.00980665002864*((0.003204*exp(3.7*p6))+(72.18*exp(1.164*p6)));
    p7 = map(str2double(line{12}), 0, 1023, 0, 5);
    p7 = 0.00980665002864*((80.07*exp(0.9728*p7))+(0.5645*exp(2.551*p7)));
    p8 = map(str2double(line{13}), 0, 1023, 0, 5);
    p8 = 0.00980665002864*((77.38*exp(1.067*p8))+(0.02001*exp(3.382*p8)));
    dat(:, :) = [i, tank, blad1, blad2, blad3, a1, a2, a3, a4, a5, p6, p7, p8];
end
plotyy(dat(:, 1), dat(:, 3), dat(:, 1), smooth(dat(:, 6), 5)); drawnow;
fclose(s);
Map.m

function [out] = map(in,inmin,inmax,outmin,outmax)
%UNTITLED2 Summary of this function goes here
% Detailed explanation goes here
    out= (in-inmin)*(outmax-outmin)/(inmax-inmin)+outmin;
end

Sensor Calibration Data

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<th>Volts (V)</th>
<th>Weight (g)</th>
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**Testing Results**

![Graph](image-url)
Anterior 1 vs. Bladder 1 (45 lb)

Anterior 1 vs. Bladder 1 (90 lb)
Anterior 3 vs. Bladder 2 (270 lb)

Anterior 3 vs. Bladder 3 (no weight)
Anterior 3 vs. Bladder 3 (270 lb)

Anterior 4 vs. Bladder 1 (no weight)
Posterior 7 vs. Bladder 1 (180 lb)

Posterior 7 vs. Bladder 1 (270 lb)
Posterior 7 vs. Bladder 2 (no weight)

Posterior 7 vs. Bladder 2 (45 lb)
Posterior 7 vs. Bladder 3 (270 lb)

Posterior 8 vs. Bladder 1 (no weight)
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Figure Citations


- **Figure 2**: "Below the Knee Amputation of the Left Foot | Doctor Stock." Below the Knee Amputation of the Left Foot | Doctor Stock. Doctor Stock, n.d. Web. 27 Apr. 2016. <http://doctorstock.photoshelter.com/image/I0000NvLNaPsTqZo>.


- **Figure 10**: RevoFit Solutions - Click Medical. (2015). Retrieved April 19, 2016, from <https://www.clickmedical.co/store/revofit/revo/>.
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