The Prosthetic People

Project Proposal

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Problem Statement

Problem:

Our problem statement is how might we design, and make available to United States amputees, a prosthetic socket that adapts instantaneously to the residual limb. We want to focus on U.S. patients, because of proximity. In addition, we feel that we can make a significant impact on improving their quality of life, whether that be allowing them to continue working or contributing to a more comfortable retirement. Our goal is to find an adaptable, affordable prosthetic socket. Sockets are expensive and everyone should have an opportunity to obtain a socket that is usable. We believe that finding a way to make an affordable and adaptable prosthetic not only positively affects the lives of the amputated, but also makes a big impact on their family and friends. Finding a feasible solution within our problem space has the potential to change so many lives in a positive manner.

Significance:

Inability to access well-fitting and affordable prosthesis has a lasting impact not only on the patient but also on society as a whole. Without a prosthesis that fits the patient's body and needs, the patient will lose the ability to participate fully in his or her daily life. The California Health and Benefits Review Program found that if an amputee does not receive an adequate prosthesis within two years of amputation, there is a greater risk of psychological problems, chronic illness, and social dysfunction (Turner). Amputees who do not have access to properly fitting prosthetics will likely be unable to continue their working lives and will end up on social welfare. Being unable to reintegrate into society and adapt after amputation due to lack of prosthesis takes a toll on the patient, those close to the patient, and those funding the social welfare the patient receives. Because of this, patients after amputation are 32% more likely to experience depression. Without a prosthesis that allows them to regain normal function, they are 31% more likely to experience body image distortion and 13% more likely to commit suicide. Since not having access to an adequate prosthesis increases the risk of heart disease, obesity, chronic pain, and immunological deficiencies the future cost of the patient's medical bills amounts quickly and falls on the shoulders of the individuals or agencies, affecting society as a whole (Desmond, Coffey).

Currently, the costs of prostheses are one of the main reasons why patients are hindered in the process of obtaining their own prostheses. The high cost of prostheses is a result of supply and demand trends, as well as lack of public knowledge and advocacy for change. Insurance companies can get away with putting low limits on prosthesis coverage that does not cover the needs of the patients because there is no push for them to change. More technologically advanced prostheses tend to use more expensive materials that are hard to access and since there is not a large enough demand for prostheses and no significant campaign and publicity around the cost of prostheses these costs do not change (Aston, Lee).

Even before dealing with the cost and maintenance of using a prostheses, patients must undergo many tests and fittings to ensure the accuracy of the socket fit. Typically patients begin the long and arduous process of prosthetic socket fitting two to six months after their surgery. The delay occurs because of the need for the residual limb to be completely healed and settled before the prosthetist can begin to design a socket for their patient. After several appointments, the prosthetist is able to design the socket and prosthetic and manufacture it for the patient. However, even after this tedious process is over, the patient still must attend several more appointments so that the doctor is able to monitor the socket and make small changes to the fit (Amputee Coalition). If we were able to create a prosthetic that could easily and instantaneously adapt to the needs of any wearer, this long, drawn out procedure can be shortened and even eliminated.

Although prosthetic users make up a relatively small population, helping improve fit could still impact the lives of hundreds of thousands of people, especially those who can't afford expensive custom made prostheses. Of a survey of 134 prosthetic users by the Veteran's Association, 22% of prosthetic users admitted to adding their own modifications to their prosthesis so that it would fit more comfortable. These at home augmentations included sanding down the prosthesis to reduce pressure on a sensitive area, adding materials such as carpet, paper wedges, and foam to the socket to improve the fit, and drilling holes in the socket liner to allow more ventilation. When asked why they chose to make the modifications themselves rather than go to a prosthetist, some patients stated that the customizations would be too expensive. These situations could be easily avoided if prosthesis users were able to easily adjust their sockets on their own, avoiding both a trip to the doctors and an expensive medical bill.

Stakeholders:

Government:

The government funds many providers of and research programs for prosthetics. Health insurance programs like Medicaid, which are funded by both federal and state governments, provide financial aid to those who need it. Medicare Part B covers some of the cost for prosthetic devices. (Medicare.gov) However, there are issues concerning using government sponsored programs. Many times the government will not pay the full cost of the care and maintenance of a prosthetic, and rules, like with the Medicare program, will limit access to obtaining some limbs. (Kounang, 2015)

Families/Friends:

Family and friends of those who have been through limb loss play significant roles in their lives. Even with emotional and physical support, it is still hard for people to manage the change. The financial burden of buying and managing a prosthetic is also a big factor in the relationship of the family or friends with the prosthetic user. There are cases where they might abandon an amputee if they feel that they are incapable of providing or dealing with giving support (Healio, 2002). These problems can be helped with reducing the cost of a prosthetic. By creating a prosthetic socket that can be adjusted over time, the financial burden is relieved, as the prosthetic doesn't need to be replaced as often. Creating a prosthetic socket that is also more comfortable will also help alleviate many burdens put on family and friends. Users can more easily adjust and adapt to having a prosthetic that fits them well, making dependence on others less.

Patients:

Nearly two million people living in the United States alone are living with limb loss (Ziegler, 2008) and about 185,000 amputations occur each year (Owings, 1996). Prosthesis patients lose their limbs for a variety of different reasons, ranging from birth defects, accidents, or disease.

Common residual limb problems encountered by amputees include ongoing pain due to skin breakdown, weight bearing pressure, difficulties putting on/removing the socket, and sweating (LPC, 2015). All of these problems are due to socket issues. According to the Medical Center of Orthotics and Prosthetics, a patient should be able to answer yes to these three questions about their prosthetic:

1) Is it easy to put on and remove?

2) Is it wearable all day without irritation or discomfort?

3) Do you have full and complete control of the prosthesis?

If the patient answers no to any of these questions, there is a clear and critical socket problem (MPOC, 2016). Clearly, a patient would be eternally grateful for a prosthetic socket that is reliably comfortable throughout the day and doesn't have to be replaced constantly.

Prosthetic Manufactures:

Prosthetic manufacturers have to adapt to an ever-changing industry, as new materials, structures, and assembly processes are continuously being developed. Every prosthesis manufacturing company tends to focus on a specific type of prosthesis, whether that be upper extremities, lower extremities, or more specific parts such as hands, legs, toes, and so on. The main stakeholder our group is focusing on is the socket manufacturers. Even this subdivision of the industry is incredibly diverse, with companies focusing on vacuum socket systems (POA, 2015), liners (OrthoEurope, 2016), and 3D-printing (Molitch, 2014). The creation of a socket that is instantaneously adaptable to the residual limb, leading to a better fit, would result in a mixed opinion within the industry. The idea that the socket is fitted better for long term use leads to the unlikelihood that patients would have to constantly replace the socket, leading to lower income in the long run. However, companies may be able to charge a higher initial price for the socket, due to the longer lasting use.

Context & Existing Solutions:

Other groups have had similar ideas of making prostheses that can be changed to fit the needs of the patient over the course of a few months, but not instantaneously adaptable. An example of this type of adaptability is Limbitless Solutions and their 3D printed prostheses. Limbitless Solution is successful in creating prostheses that are extremely affordable (under $1,000), and moderately adaptable. The 3D printed files can be easily scaled, and a new arm can be printed for as little as $100, allowing the same design and electronic components to be used again as the user grows (Manero). This adaptability has made Limbitless Solutions a leader in prosthetics for children. However, their solution has major drawbacks; structurally, their 3D printed frame is quite brittle, and cannot deform to fit the residual limb well. (Pring)

While the prostheses created by Limbitless Solutions are adaptable to large growth, they cannot adapt to small day-to-day, or even hourly, changes that continuously occur with the residual limb. The size and shape of the residual limb can fluctuate depending on a number of factors, such as hydration and temperature. These fluctuations in the residual limb can make the prosthetic socket fit poorly and cause discomfort. Our group looks to increase the comfort and utility of existing prosthetics by making a socket that will continuously adapt to these minute changes in the residual limb.

Why is it still a problem?

Prosthetic systems for patients are generally composed of several components, such as the body/main structure, liner, sock, and the interface between the prosthesis and the patient's residual limb, or the socket. Although the socket itself only consists of a small portion of the prosthesis, it is one of the most crucial parts because, without it, there is no way to effectively apply the prosthesis the patient needs (Sabolich para. 1). Therefore, there is a large demand for the development of prosthetic sockets. However, there are two major obstacles to the success of prosthetic sockets: a daily fluctuations in size of the residual limb and inherent issues associated with supporting the weight of the body primarily with the muscular system rather than the skeletal system. As a result, researchers are constantly working to develop solutions that reduce the effects of these inherent issues with prosthetic sockets.

For example, the current method of fabricating sockets involves the iteration of a multi-step molding process. The first step involves creating a negative mold of the residual limb by wrapping it with strips of bandages covered in materials such as Plaster of Paris. Next, the negative mold is used to make a positive mold by filling it with water and more Plaster of Paris. Once the positive mold is made, it is tested and modified so that it evenly distributes pressure; the resulting positive mold is used to make a clear plastic socket. The socket is tested on the patient's residual limb, and if there are any imperfections in the socket, the whole process is reiterated until the final product fits perfectly to the residual limb and evenly distributes pressure on the limb (Muilenburg para. 7). Although this process is very effective in creating a perfectly fitting socket for the patient, there are two majors issues with this method: this process can take more than a month to complete and it is a static model of the residual limb, which means that, despite how accurate the mold is, the socket will not properly fit the residual limb for most of the day. No matter how perfect the original sizing is, a static socket cannot adjust to the daily cycle of size changes within the patient's residual limb, which means that the socket will only fit the patient for a small portion of the day (the time of day that aligns with the time at which the mold was taken). Although the difference in fit is very slight, it is enough to cause pistoning within the socket, which creates a lot of issues such as irritation of the skin and uneven application of pressure, which creates symptoms that range from discomfort to injury (Ali para. 9).

However, some groups have attempted to solve these issues created by pistoning through revolutionizing the ways that the fit of the socket is developed. A team at MIT is working on a project called the FitSocket Project, and one of the researchers spearheading the project is a double amputee named Hugh Herr. The FitSocket Project uses "laser surface scans, Magnetic Resonance Imaging, mechanical tissue indentation, and ultrasound imaging techniques" (Herr para. 4) to create a prosthetic socket that perfectly fits the residual limb. However, their ideal fit is very different from the perspectives of other teams'; rather than trying to create an impression of the shape residual limb, this project focuses on treating socket and limb like two puzzle pieces, creating a system in which the components perfectly mirror each other. However, they do not mirror each other in shape alone. The material they use to design the prostheses also changes in stiffness to mirror where the limb changes in stiffness, to apply even pressure to the residual limb. Through these methods, the FitSocket Project has developed a process in which they can develop a socket that perfectly fits the patient.Despite the pinpoint accuracy of the fit of the MIT team's socket, it does not accommodate the continuous changes of the residual limb and encounters the same problems as other teams attempting to address the issue of socket fit.

These issues represent a common trend between most of the solutions to design imperfections associated with prosthetic sockets that will not be adequately solved until the research teams refocus their objectives to developing a dynamic model, rather than a static model. A static prosthetic socket will never accomplish a comfortable, effective fit to a dynamic system such as the growing, changing residual limb of a patient's body. Therefore, as our group tackles the improper fit of modern prosthesis, we are prioritizing a dynamic nature for our solution whenever we brainstorm, and we are constantly searching for ways to effectively create a dynamic model to fit our problem space.

Proposed Work

Goal

The goal of our project is to design a prosthetic socket that adapts to the frequent, daily changes in the shape of the residual limb. We would like to identify current technologies that we can adapt to affordably build a better socket. By utilizing currently available technology, we will be able to make our project more feasible by cutting down on the amount of time and money needed for development. Our project is focusing on addressing the shortcomings of current prosthetic sockets, in terms of their ability to adapt to the every day fluctuations in size of the residual limb. By addressing this issues we will be able to make prosthetic sockets more comfortable and affordable, therefore better allowing patients to return to their pre-amputation lifestyle.

Objectives

1. Our first objective is to find an existing material to use in our prosthetic socket design that can adapt to the changing sizes of the residual limb throughout the day. This material will ultimately be the biggest factor of our design. It should be a material that can easily contract and expand when exposed to some stimulus such as pressure, heat, or an electric current. It could also be a material that can easily form and mold around changing shapes, almost like a memory form. This component is critical in the success of the design. Ultimately, utilizing this material will allow us to solve part of our problem statement. We don't expect to be able to invent a new material or innovate a brand new technology given our resources and knowledge. However, we hope to find a material used for other purposes that could be incorporated into our socket design. One such material we've looked at is a hydrogel that contracts when an electric current is passed through it. This hydrogel as of now is being used for soft robotics in aqueous environments. (Shipman) We have also looked at a process called micropacking. This is where particles compress and mold to shapes when they are in a vacuum. When the vacuum pressure is removed, the material becomes moldable. This could be applied to our sockets as it allows for instantaneous reshaping and shifting. We learned more about this technology from in our expert interview with Dr. Young-Hui Chang. As of now, this technology is being applied in robotics. It allows mechanic arms to pick up small objects of any shape without applying an unnecessary amount of pressure. This technology could be perfect for our

sockets. It would allow the socket to adapt to any shape while applying the correct amount of pressure.

Ultimately, we must sit down and decide on what material we want to experiment with. This would involve us obtaining a sample of the material and trying to configure it to suit our needs. We could conduct experiments for a few different materials. Factors that we are taking into consideration are accessibility, cost, adaptability, moisture and temperature control, and antibacterial. Once we decide what material we want to use, we have to find a way to create a socket liner containing the material. Multiple methods could be used depending on what material we decide to use.

The biggest obstacle associated with this objective is our ability to work with a newly innovated technology. Although we aren't inventing completely new materials, most of the materials we are looking at are still quite experimental. Trying to work with these materials will take a lot of research and experimentation on our parts. We must be willing to learn a lot about these materials on our own time so that we will be able to know how to utilize them in our socket liner.

2. Our second objective is to find different ways to improve and/or change existing outer sockets. The prosthetic socket is vital to the success of the overall prosthetic. It must fit well to the residual limb so that it may be used comfortably and safely by the patient, but it must also provide support to the limb. We hope to find a way to make the socket skeleton be able to be adjusted to the limb, as well as be durable and comfortable. The socket must also be breathable.

We want to incorporate existing technology to the outer socket. We are looking at the technology of a snowboarding boot, which has an adjustable tightening mechanism that can easily accommodate to the patient's needs. The tightening mechanism is quick and easy to use. As well as looking at the snowboarding boot technology, we are also trying to find other similar technologies that we can use and modify. Our current design for the socket exoskeleton includes segmented parts hinged to a structural spine that will allow users to easily adjust the tightness of different areas of their residual limb. There will be an external lacing system that will bind the socket as a whole and give users the opportunity to adjust it to meet their needs. Finding users to help test our socket design, will be one of our challenges we face.

3. Our third objective is to incorporate 3D printing to our socket. 3D printing will allow the socket to be more affordable, adaptable, and accessible to patients. It will also improve production by making it cheaper and quicker to produce. 3D printed designs of the prosthetic are also more easily accessible. If this objective is not accomplished, the prosthesis will cost much more and it will be less accessible to patients.

Before knowing if 3D printing can be incorporated to this project, an initial design of the prosthetic socket skeleton must be made and what material to 3D print needs to be decided. It might be hard to find a good design that can be 3D printed and fit to the residual limb.

Project Team

Potential Experts:

- Dr. Young-Hui Chang
- Geza F. Kogler
- Boris I. Prolutsky

Team Overview

Our current solution requires that we research and develop two parts of a prosthetic socket to be combined into a cohesive product. However, this means we must apportion the respective research and product development to different team members. As of right now, we must develop the gel inserts to be contained within the skeleton of the socket, and the skeleton of the socket itself; including the tightening mechanism we plan to develop and implement. As of right now, we are planning to divide the work as follows:

Liner insert

Team members:
-Tessa
-Sydney
-Elena
-Haley

The above team members will research the available options for the type of material to be used in our solution, and once they have found the ideal material, will work on finding a way to integrate the material so that it can be customizable to fit the patient's individual needs and preferences. In addition, they will test the material to ensure that it properly forms to the residual limb when pressure is applied to the insert.

Socket Skeleton

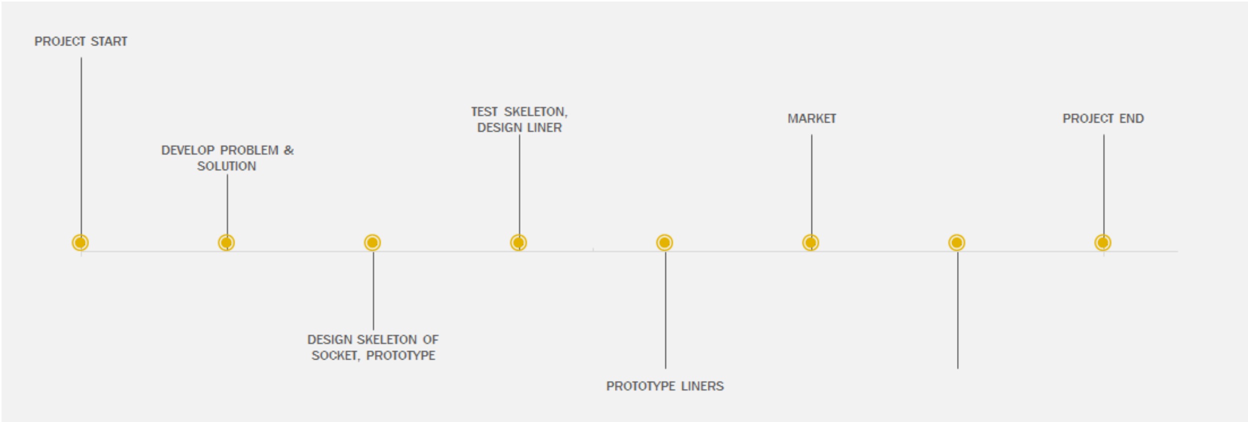
Team Members:
-Ken
-Caleb
-Beau

The listed team members will research the available options for materials that are compatible with 3D printers and fit the specifications for use as the main structural material within a prosthetic socket. Once they have found the ideal material, they will use 3D modeling programs such as SolidWorks to develop prototype models of a socket structure that integrates the tightening mechanism that we have developed in order to create a dynamic model of a socket, which can be adjusted to accommodate the changes of the residual limb. For each developed prototype, they will print and test the models to ensure that they can properly support the prosthesis and weight of a patient while applying even pressure to the gel insert that will be developed as the inner lining of the socket.

Although the work is mainly divided between two different groups within the team, each group will keep the entire team updated on advancements toward our goal and issues they encounter with their research and development. This way, there will be constant communication within the group regarding the development of the solution, and we can optimize our skill sets and time to improve our progress within our problem space. In addition, should we run into trouble with this current plan, we can consult our facilitator, Muaz, and the other experts helping us with the project in order to keep things running smoothly and efficiently.

Budget

Item	**Vendor**	**Price**	**Quantity**	**Total Price**
PLA Filament	Makerbot	$48	1 KG	$48
Flexible Filament	Makerbot	$130	1 KG	$130
Ratcheting Buckle Set	Burton Snowboards	$19.95	1 Set	$19.95
Ratcheting Tongue Set	Burton Snowboards	$7.95	1 Set	$7.95
Prototyping Gel Inserts	Various — Dr. Scholls, Superfeet, Powerstep, Dr. Fredricks	$14.18 - $44.95	3 Sets	$72.12
Professional 3D Printing	Shapeways or GaTech Invention Studio	$2.99 per cubic centimeter or $27 per cubic inch	-	-
FDA Compliance Consulting	IHL Consulting Group	-	-	<$2000



Project Start: November, 2015
Develop Problem & Solution: January-April, 2016
Design Prototype: September-November, 2016
Test & Redesign Prototype: November-April,2017

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