Team Team Zebra (Group 4)
Aditya Balamuralikrishna, Caleb Beaver, Sameer Mishra, Skye Sheffield

One Fit and Done Prosthetic Socket

How Might We Statement

How might we bridge the gap in developing nations between the lack of clinicians and the difficulty of refitting prostheses for above-knee amputations?

The Problem

There is a lack of prosthetic clinicians in developing nations. According to the World Health Organization, there are approximately 30 million people that require prostheses in these countries. There is a lack of approximately 40,000 clinicians, with a prediction of only 18,000 new clinicians over the next fifty years (1). Also, as time goes on, the shape of a residual limb changes making multiple trips to clinicians very necessary. Within the first few months of wearing the prosthesis, the residual limb will shrink drastically (2). As time goes on, most patients need to refit the limb 15-20 times over the course of their adult lifetime (3). Since there is a lack of clinicians, many these people do not have easy access to get the necessary attention to refit their prosthetic socket.

This is a major issue in developing nations, as it greatly reduces the effectiveness of the prosthetic limb. If the socket is not refitted, then the patient may experience serious discomfort, and may even choose to not use the prosthetic limb. If this problem is not solved, there will be many patients who will end up wasting time and money on prosthetic limbs they will not even be able to use, and in developing nations, many of these people do not have the luxury of having a great deal of disposable income or the resources to survive without working.

This problem has multiple factors that contribute to it, with most stemming from the sheer number of patients and lack of clinicians. The large population of amputees of the developing nations can be attributed to the war-torn state of their countries. These nations, plagued by landmines, industrial accidents, and terrorist attacks are home to over 300,000 amputees (4). With the increasing amount of patients and slow growth of new clinicians, the problem of getting patients to see trained professionals to refit prostheses.

Why isn't this problem solved yet? Prosthetic limbs are almost always fitted and refitted by a professional prosthetist (clinician) (5). If someone was to make a socket that all untrained people can refit their own prosthesis, there would have to be some uniformity. Also, since no two people are alike, thus there is a need for customizability. With these two problems in mind, it is difficult to find a balance between uniformity and customizability without the help of clinicians.

The Solution

Goal

The solution we are focusing on is a self-adjustable socket for an above-the-knee prosthetic leg.

Quality:

We are focusing on solving the need in developing countries to make repeated visits to a clinician to refit the prosthetic socket for above-the-knee prostheses.

Rationale:

There is one primary reason we wanted to focus on creating a socket the patient could adjust. By allowing the patient to make the socket as tight or loose as they want, we theoretically eliminate the need for the patient to visit the clinic over and over again for refittings. The patient should only have to see the clinician once to actually receive the prosthetic limb and for an initial fitting, but never for a refitting of the limb.

Impact:

If successful, this socket could have a huge impact for this target population. Patients will no longer have to spend money and time they don't have to go see clinicians, and the patients that were not able to have their limbs refit would be able to properly use their prostheses. The clinics may see less activity if the project is successful, which may dissuade future clinicians from working in the area.

Solution Description

Our solution will replace the need for clinicians in developing countries by getting rid of the need to constantly change prosthetic sockets to adjust to the changing residual limbs of above-the-knee amputees. Currently, sockets are very hard to fit and must be changed regularly by a professional (5). By being easily adjustable by the amputee, the socket can be formed to the residual limb without the need of any special equipment or training.

The method of accomplishing this is by using a mildly inflatable liner for the socket, which adheres to the skin of the amputee by using skin friction between the skin of the amputee and a dotted silicone liner. The amputee can then inflate this by using a small specially made pump, which would create a fit as is needed for their limb.

If this is used, it would eliminate the need for amputees to go to a clinician/doctor just to be mildly refitted, which could be expensive, inconvenient and in some cases, impossible.

Objective 1: To prepare design tools and assess requirements of the device

Tasks for Objective 1:

- Talk to the patients and determine their needs *IN PROGRESS*
    - We have not yet been able to reach out to any patients; however, clinicians in the field have explained the patients' general needs However, we will still make sure to talk to patients in order to have a more comprehensive list of patient needs, as well as learn from their experiences with prosthetic limbs.
- Create "Objective Tree" based on what patients ideally want from the device COMPLETE
    - We based this off of clinician input
- Create a list of Engineering Requirements based on Patient Needs. COMPLETE
    - Put what the customer wants in quantifiable terms
- Create "Specification Sheet" based on engineering requirements, safety standards and patient's needs. IN PROGRESS
- Create "House of Quality" to determine the relationship between consumer needs and engineering specifications. COMPLETE
- Create "Function Tree" as part of functional decomposition of what the device must do. COMPLETE

For this objective, we set out to essentially complete the first stage of the design process. This objective will be completed when all of the aforementioned design tools will be finished and ready to use for conceptualizing and designing the solution. It is very important because it will allow us to have the foundation for future designs. The objective itself is very close to being finished, as can be seen by the number of completed tasks. The remaining task of reaching out to patients can be done by attending volunteering events and finding mentors that have contact with these patients, while creating a specification sheet will be completed once these patient needs are detailed. We have already moved on to the next objective because we do not want to spend more time on this objective, but we will make sure to complete it as soon as possible.

Objective 2: Conceptual and Detail Design: To decide on a design for the prosthetic limb

Tasks for Objective 2:

- Create "morphological chart" in which each function is assessed and different ways of accomplishing each function are created. COMPLETE
- Create 3-5 concepts with different ways of accomplishing each function. COMPLETE
    - Had each member of the group complete several concepts based off of the function tree
- Evaluate concepts and select best concept from the 3-5 to be prototyped and tested. COMPLETE
- Make detailed part and assembly drawings on SolidWorks. NOT THERE YET
    - (Use current software expertise to design and combine the parts into a complete concept)
- Work with the school of Applied Physiology to conduct part-specific testing and experimentation to further improve the prototype. NOT THERE YET

In this objective, we wanted to come up with several concepts, pick the best one,

and begin CAD drawing of this concept. This objective will be completed when all group members have agreed on a design for prototyping and we have a CAD model of the prosthetic that will be prototyped. At this point in time, we have managed to select a concept that we all approve of, and over the summer, we will hopefully finish part and assembly drawing in SolidWorks so we will have a prototype to begin building in the fall. The objective is extremely important as it allows us to narrow down potential designs for our solution, and allows us to progress towards the prototype stage. Once we have created a prototype, we will hopefully be able to work with the School of Applied Physiology and conduct detailed experimentation and testing in order to refine the prototype even further.

How Has the Project Changed

When we decided to focus on problems with prosthetic limbs, we were initially concerned with people being unable to learn how to actually use their new limbs. However, when we raised this issue with Dr. Robert Kistenberg and Wick Armstrong, he explained that most people do not have lasting issues when figuring out how to use their new limbs, and that socket refitting was a much more pressing concern. This was the primary factor behind our new focus on creating a self adjusting prosthetic socket. So far, we have been able to adapt to this new problem, mostly because our objectives of going through a design process, and prototyping have primarily stayed the same.

Future

There is still a great deal of work to complete. This project is going towards at least the completion of a prototype, and we will hopefully have a CAD design by the end of the summer. Over the next year, we hope to actually manufacture a working prototype, and continue to refine the design through experimental data and opinions from experts in the field. If we continue to work on this project after developing a prototype, we could look into applying for a patent, or trying to get more attention though conferences and other meetings. We have Denise Larkins who has already given us a great deal of help, and we are trying to find more collaborators at Procare Atlanta and in the School of Prosthetic and Orthotic Research here at Georgia Tech.

Works Cited

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