Prosthetic End-User Usability Survey

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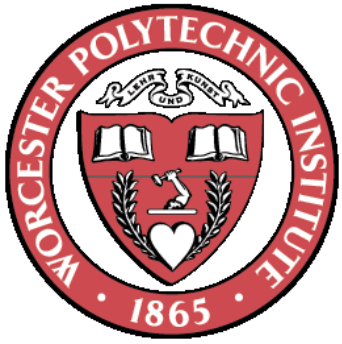

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Abstract

Understanding that loss of a limb results in a significant change in lifestyle, it becomes important to study the needs of amputees and to focus on ways to improve their usability. There has been very little research done thus far on understanding the main concerns that prosthesis users face in their daily lives. This study aimed to identify the aspect of wearing a prosthetic device that is the most limiting and hard to deal with for patients by conducting a survey. The survey was targeted to amputees who frequent online support groups and social forums for amputees. Analysis of the data showed that the most concerning aspect of wearing a prosthesis is the development of skin conditions, ranging from redness, swelling, blisters and bad smell, to fungal infections, open sores and tumor cysts.

The survey showed a direct relationship between the development of skin conditions and frequency of washing the prosthetic liner, where amputees who cleaned their prosthesis every day were found to have the most difficulty with these skin conditions. An engineering solution to eliminate this problem was proposed. The solution focused on improving the material of the liner using chemical modifications to increase the atomic bond strength. This would result in less debonding of the liner with frequent washes and thus prevent the development of skin conditions.

Introduction

It is estimated that one out of every 200 people in the United States has had an amputation and approximately 135,000 amputation surgeries happen annually1. For the majority of patients, preexisting health conditions are the cause for surgery, a common example of which is problems of the vascular system due to diabetes. In fact, 82 percent of all lower limb amputations occur due to vascular system conditions such as diabetes1. Cancer-related amputations make up ten percent of the total annual amputations2, congenital anomalies cover one percent and the rest are trauma-related surgeries1.

Looking into the future, the total number of people wearing prosthesis is expected to reach 2.4 million by 20203. Advances of modern medicine have made it possible for amputees to have a replacement for a lost limb. Prosthetic devices can be classified into three categories: cosmetic, body powered and myoelectric. Myeoelectric devices are the most technically advanced prosthesis currently available since they are driven by an outer power source. Even though the field has advanced tremendously, amputees still experience many problems with their prosthetic devices. Previous surveys have been conducted to rate general satisfaction of prosthesis users and have found common concerns of amputees, including limitations on the functionality of the device, comfort, durability, and cost [4], [5], [6], [7], [8], [9], [10].

Different from previous research, this study aims to identify particular aspects of wearing a prosthetic device that are the most limiting and hard to deal with for patients by conducting a survey. The ultimate goal is to develop an engineering solution that would increase the ability of prosthetic users to live a normal life.

Methodology

The survey was composed of multiple-choice and open-ended questions, designed to select the aspect of prosthesis use that requires the most improvement. The survey first inquired about general information on prosthetic use as well as functionality and comfort level of the patient. Furthermore, daily life experience of the participants was explored as it relates to their prosthesis, along with the impact that the artificial limb has on their social life and entertainment. In the last category of questions respondents were asked to rank different aspects of their prosthesis in order of importance for improvement. This category served as a direct guide to identify the most important problem that they face in order to achieve the desired engineering solution.

The survey was distributed to five online amputee communities (Lessthanfour.org, Dailystrength.org, Empoweringamputees.org, Unitedamputees.com, Limbdifferences.org). as well as to several amputee support groups in the Northeast. Participants were given a choice between filling out the survey online on the Survey Tool platform or mailing in a hard copy, both routes ensuring confidentiality and anonymity of answers. The surveys were collected between December 15, 2011 and March 25, 2012.

The analysis information provided by Survey Tool were used to draw conclusions from the data. The percentage of the responders that answered each option was presented in a bar graph form in the survey, which was used to determine the average answer. The values for each option of a question will be compared using a t-test. In order to determine statistical significance and a p value of less than 0.05 is required.

This analysis resulted in a list of the most prominent concerns for the amputee population which was then utilized as a resource to locate the main problem for which an engineering solution would be provided. Once the main concern has been located, further research was conducted on the specific issue, in order to learn more about the subject and to better define the problem statement.

Results

A total of 49 amputees were surveyed for this study, to obtain data with 95% statistical confidence and an interval of 14. Responses were received from people ranging in age from 22 to 85 years old, with an average age of 48.5 years old. Exact age distributions can be seen in Table 1. The average time that the respondents had been wearing a prosthetic was 8.2 years. 57.5% of respondents were male, and 42.5% were female. Most respondents (46%) were married. 50% of respondents were employed, 20% were unemployed whereas 25% were retired. As seen in Figure 1, the majority of the respondents are leg amputees, and 51% wear below the knee prosthetics. The most common cause of amputation was a vehicle accident, as seen for 33% of the population that was surveyed. The second most common cause of amputation was trauma, which affected 21% of respondents. Diabetes and heart problems were the cause of amputation only for 10% and 7% respectively for this survey. This breakdown is portrayed in Figure 2.

Table 1: Age distribution of survey participants.

	22-30	31-35	36-40	41-45	46-50	51-55	56-60	61-65	66-70	71+
Number of respondents	16%	7%	12%	16%	5%	7%	5%	16%	7%	9%

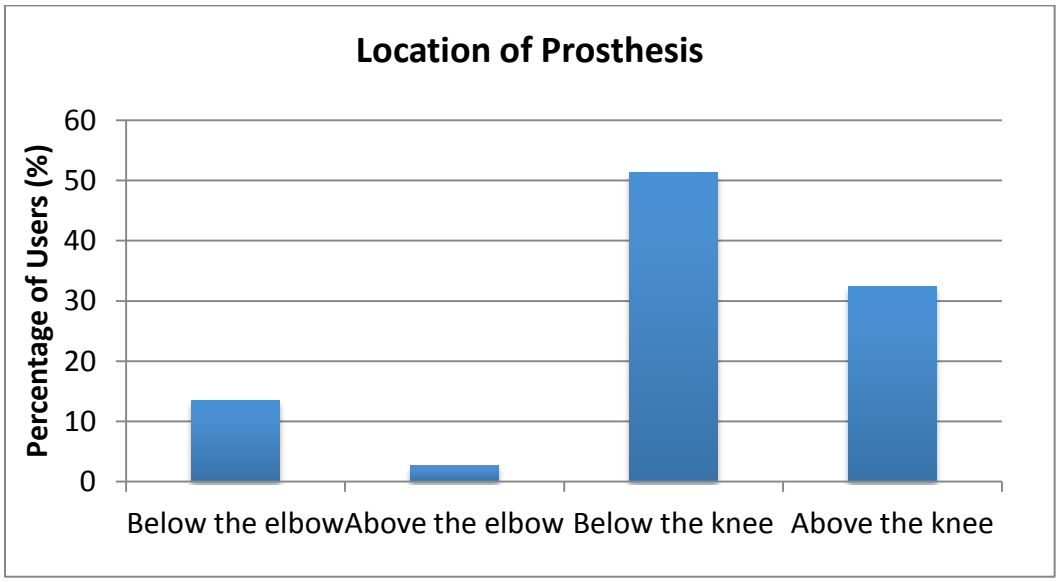

Figure 1: Summary of the location of amputation data from the survey participants

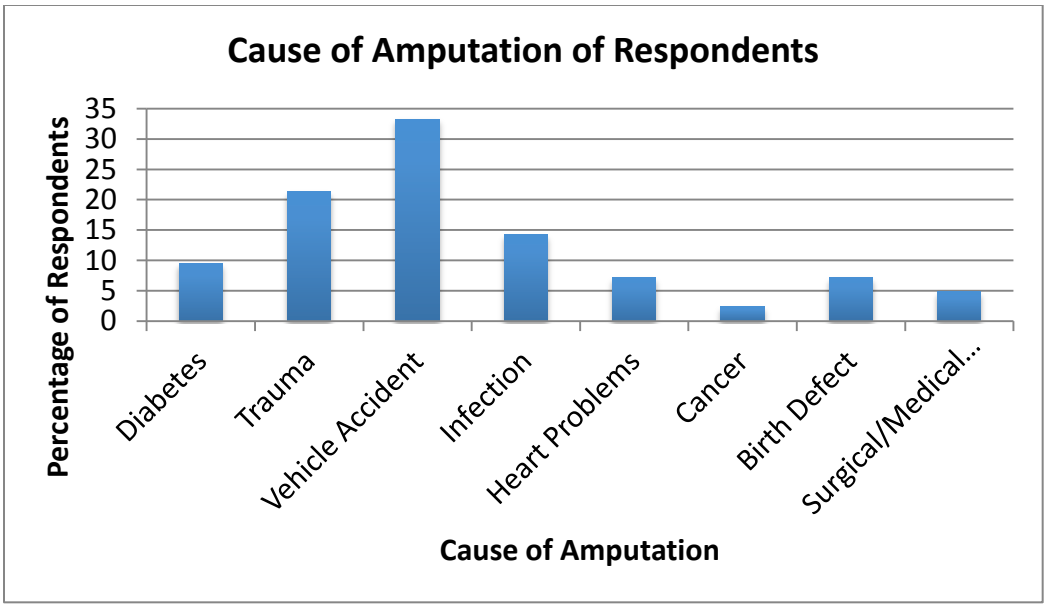

Figure 2: Summary of the cause of amputation of the survey respondents.

The first aspect that was analyzed in the survey was the cost of wearing of a prosthetic device. Figure 3 shows that many individuals do not pay anything at all for their prosthesis. However, 50% of individuals combined paid more than $1000 of which 30% pay over $5000 dollars. As seen in Figure 4, the annual cost for maintenance of the prosthesis for most respondents is $0, and over 60% of respondents pay less than $1000 per year.

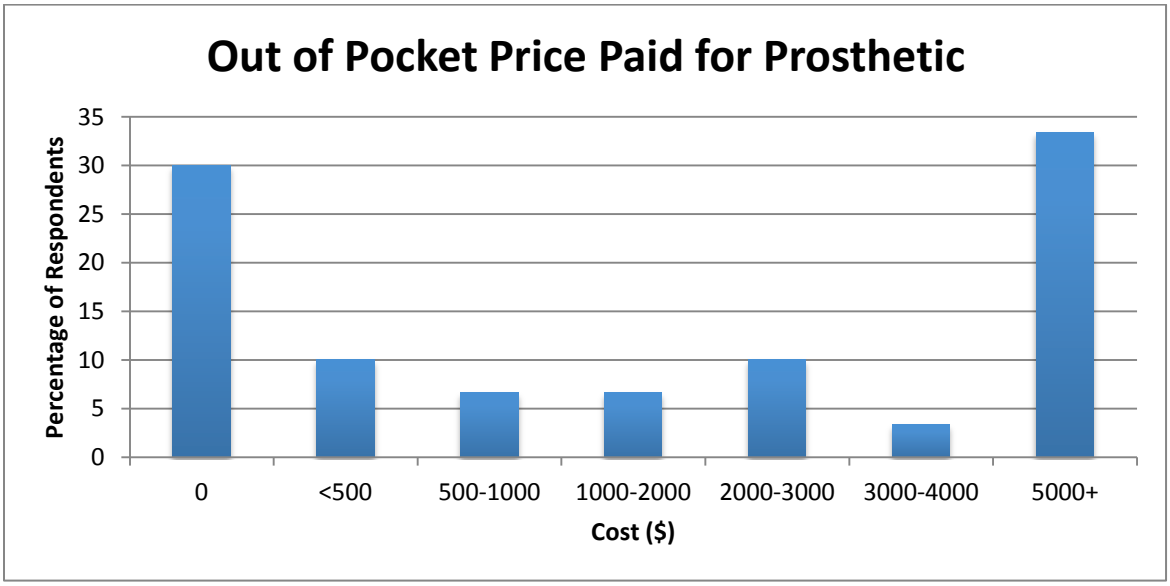

Figure 3: Distribution of out of pocket cost paid to obtain a prosthetic device.

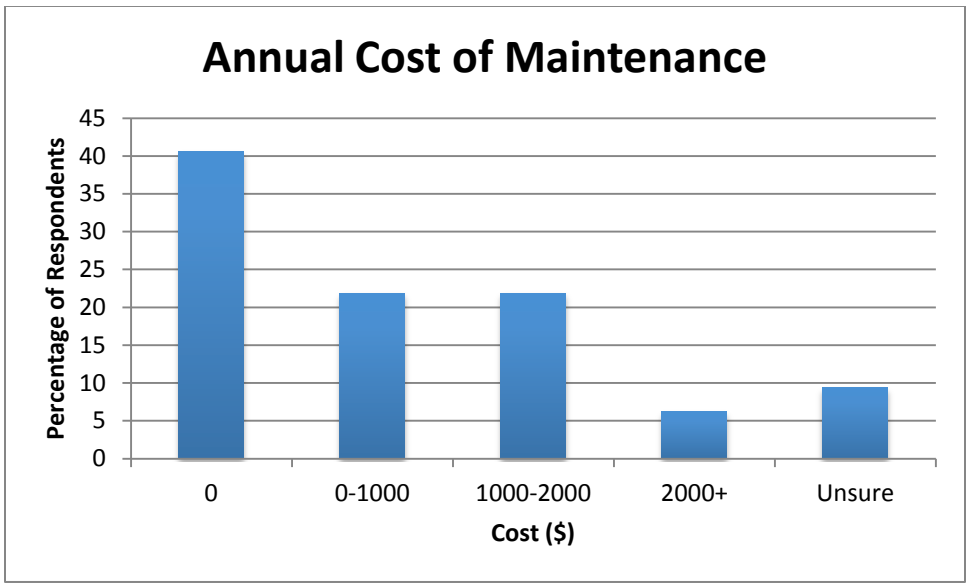

Figure 4: Distribution of the annual cost of maintenance for prosthetic users.

Table 2: Rating of different aspects of a prosthesis design, along with P-value distribution from a paired, type-one t-test.

Aspect	Average Score	Rating	P value				
Comfort	1.65	1	0.814				
Fitting	1.70	2		0.589			
Range of Motion	1.81	3			0.001		
Construction	2.79	4				0.017	
Texture	3.51	5					0.057
Color	3.93	6					

Participants were asked to rate several aspects of a prosthesis design according to their importance. Comfort ranked the highest, followed closely by fitting and range of motion. In order to determine the level of significance of the differences in rating, a paired, type one t-test was performed, as seen in Table 2. Because the p values between comfort, fitting and range of motion are greater than 0.05, it can be concluded with 95% confidence that the ratings of these three aspects are not statistically different. On the other hand, construction, texture and color

of the prosthesis are rated lower. With 95% confidence there is no statistical difference in the ratings between texture and color, but there is statistical difference in the ratings of range of motion and construction of device, as well as between construction and texture of device.

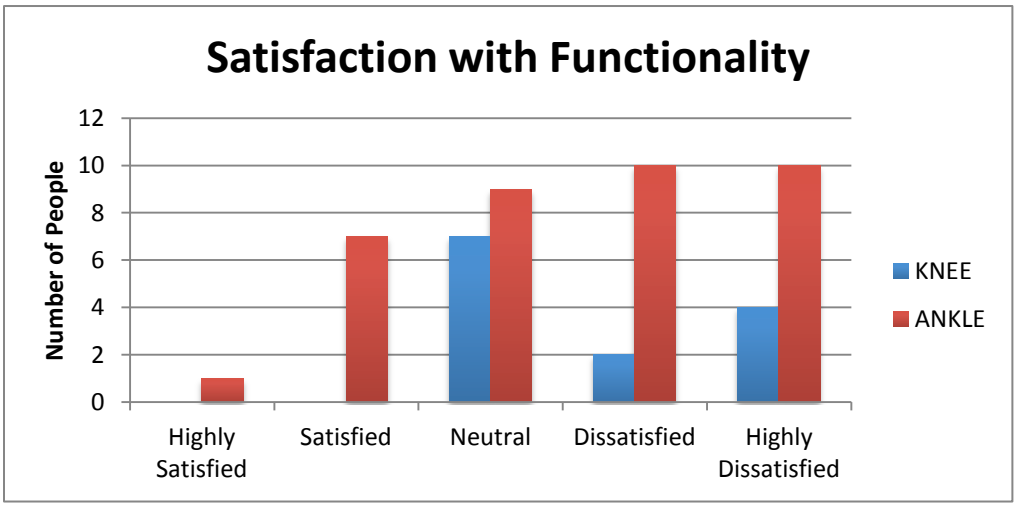

Figure 5: Participant rating of their satisfaction with the functionality of their current prosthetic device.

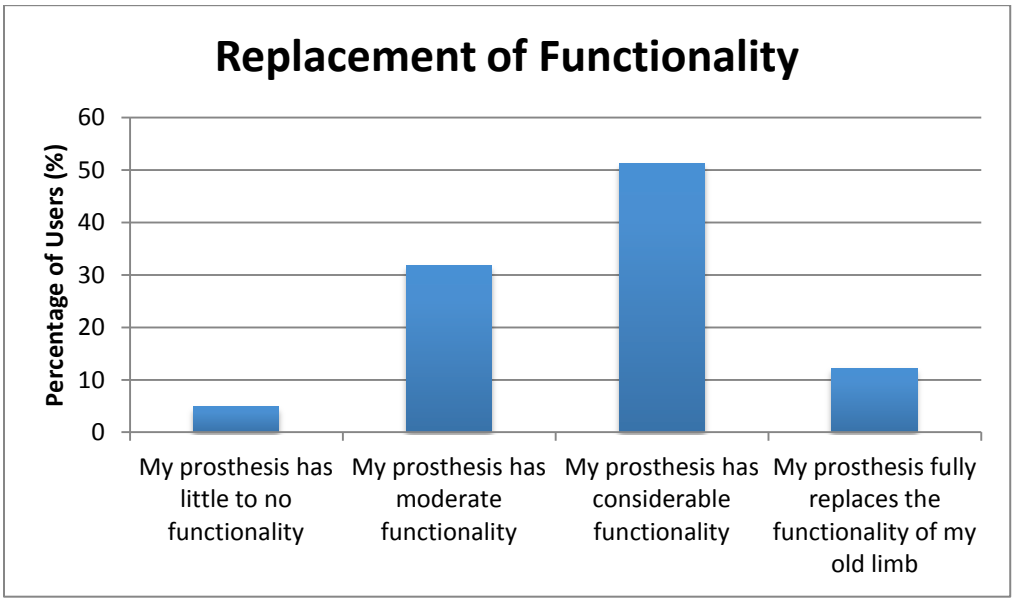

Figure 6: Participant rating on the functionality of the prosthetic device, compared to that of the old limb.

Several questions were asked to understand the functionality of the device, a sample of which is shown in Figures 5 and 6. The majority of respondents were dissatisfied with the mobility of both their knee and ankle joints, but the ankle joint was more problematic.

Furthermore, most respondents said that their prosthesis replaces the functionality of the limb by a considerable amount. 91% of respondents reported having trouble kneeling. 76% reported having trouble walking up stairs, and 67% had trouble walking down stairs. Additionally, 49% or respondents expressed a desire to run, but the amputation had impaired the ability to do. 28% expressed a desire to be able to swim, however that could not do so with their prosthesis.

A series of questions were asked to detail the level of comfort with the prosthesis. For lower limb amputees, 56% of respondents reported that they have pain in the leg opposite their prosthesis. The level of pain was studied in relationship to the how long the respondents had had their survey as shown in Figure 3. Although the data is not uniform, the trend that can be seen is that under one year most respondents had no pain, for 1-15 years pain in the opposite limb develops and after 15 years it seems to go away again. Furthermore, 56% of above the knee amputees experienced discomfort from their prosthetic pushing into the groin. Overall, 60% of the respondents predicted that they would choose to wear their prosthesis more if the socket was more flexible. Furthermore, 73% of respondents stated that the texture of the liner did not create discomfort.

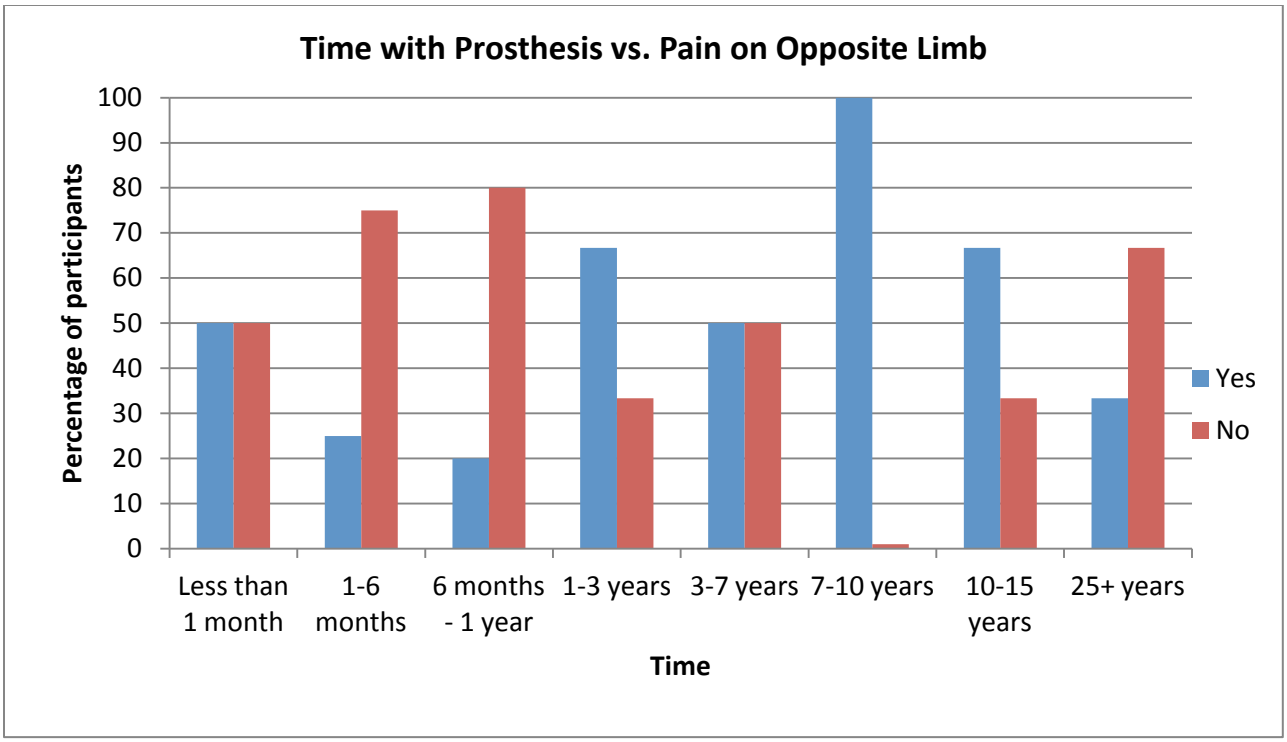

Figure 7: Relationship between the time period that participants had been wearing the prosthesis to the amount of pain they felt on the opposite limb.

Skin conditions were highly prevalent among all the responses received, as seen in Figure 7. 74% of participants had developed at least one skin condition at one point, with the average number of skin conditions per person was 5.

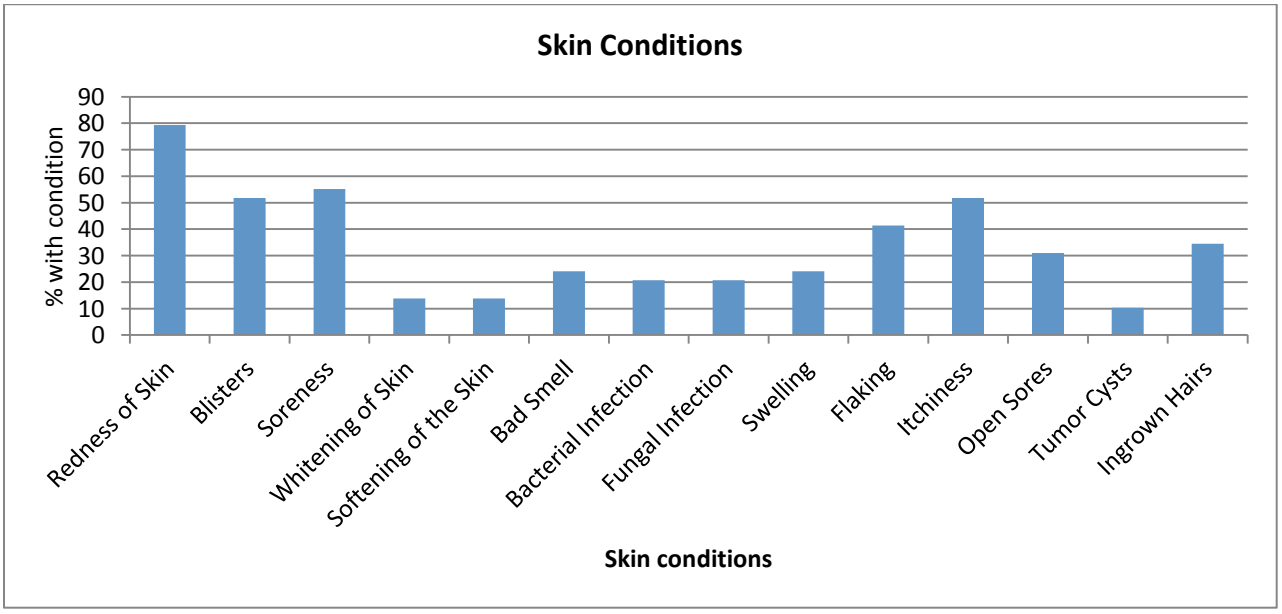

Figure 8: Presence of skin conditions on the surveyed amputees.

Along the same lines, the respondents were asked about their liner cleaning habits, in particular, about the frequency. 79% reported that they clean their liner every day. 18% of the respondents stated that they clean their liner less frequently than once a day, whereas 3% clean it more than once a day. The frequency of cleaning the liner was analyzed with regards to the presence of skin conditions and depicted in Table 3. The percentage of respondents who reported that they had experienced skin conditions was lower for those who cleaned their liner less frequently.

Table 3: Relationship between the frequency of cleaning the liner and the presence of skin conditions.

	Skin condition %	
Frequency of cleaning liner	**Yes**	**No**
More than once a day	3	97
Everyday	79	21
Every 2 days	12	88
Less than every 2 days	6	94

While the majority of respondents reported that they were participating in a form of exercise of moderate intensity, they reported several aspects about the prosthesis that affected their ability or satisfaction with exercising. 50% of the respondents suggested that the sweating during exercise creates large discomfort.

Another aspect of the prosthesis that was studied was the fitting. 38% reported that their residual limb did not change size during the day; for 17% it became larger whereas for 43% it became smaller throughout the course of the day, as seen in Figure 3. Therefore the majority of the respondents reported that they experienced a change in size of their residual limb over time. In order to understand if this is a concerning aspect, in other words, whether or it affects the daily life of amputees, the respondents were asked two more questions. First, they were asked if they were satisfied with the fit of their prosthetic device, to which 67% responded

with “yes”. Secondly they were asked if fluid retention impacted the fit of the prosthesis, for which 43% responded with “yes”.

Aspects of physical appearance of the prosthetic device, such as color, rated low on the importance rating (6). Furthermore, when asked if it was important that the prosthesis resembles a natural limb, 82% of the participants felt either neutral, disagreed or strongly disagreed with the statement, as seen in Figure 8. Along with appearance, the weight of the prosthetic proved not to be a concerning aspect.

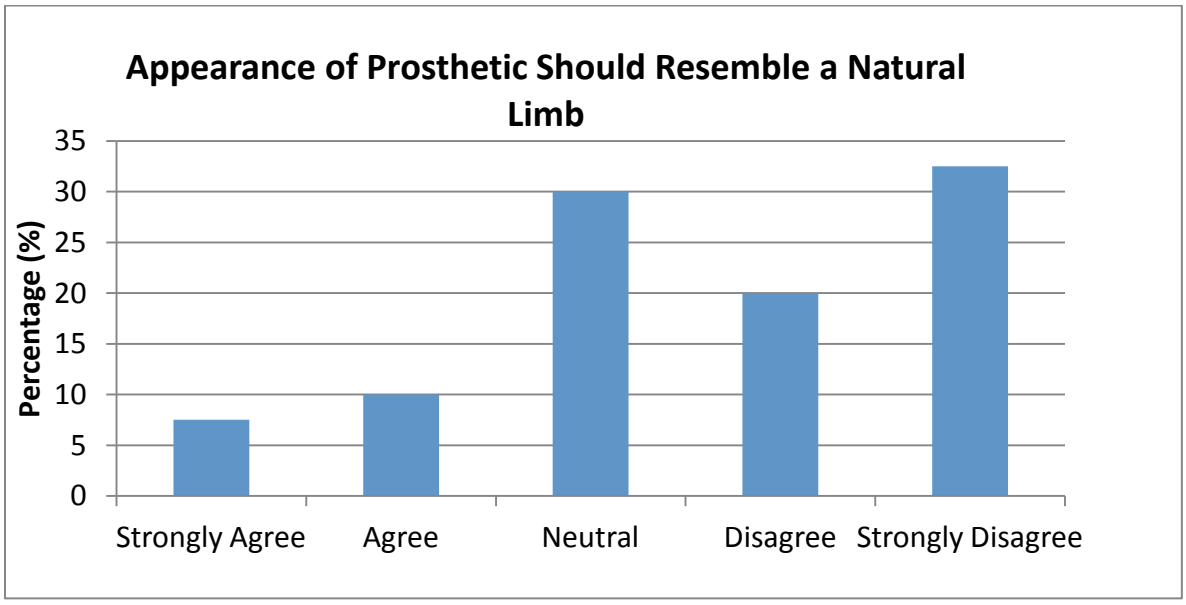

Figure 9: Participants attitude toward the natural appearance of the prosthetic device.

Discussion

As previously mentioned, surveys were distributed primarily via social networking websites for amputees. The average age of respondents in this study was 48, whereas the national average ranges from 66 to 711. Over half of amputations in the US are caused by diabetes1. On the other hand, for this study the most prevalent causes were vehicle accidents and trauma and only 10% of the respondents listed diabetes as the cause of amputation.

The reasons for this deviance from the national norms are most likely related to the choice of distribution medium. The survey was sent to amputees on online social networking sites. People who use relatively new technology such as social forums are considered younger and are therefore more likely to have suffered an accident than to have severe diabetes, which has age as a major risk factor [12].

It can also be argued that the population that was targeted in this study tends to have more proactive tendencies. After their amputation they are surfing the net to get answers and help to overcome issues they may be having with their prosthesis, and are therefore more likely to solve their issues, as compared to the amputees who may not have a support network readily available at all times. Considering this, the level of satisfaction that this study reports may not be representative of the entire population, but it is representative of the younger, more active part.

The most common amputation level of the respondents was below the knee, which is expected considering that most amputees worldwide are below knee amputees1. This shows that in this particular aspect, the survey sample resembles the characteristics of the entire population of amputees.

The cost of prosthesis did not follow a uniform trend: many individuals were not paying anything at all for their prosthesis, however many others paid over $5000 out of pocket to obtain a device. A possible explanation for this could be that the individuals who paid more may have a more advanced prosthesis that may not be fully covered by their insurance, in which case they needed to supply the rest of the cost out of pocket.

According to the results of the study, comfort, fitting and range of motion are the most important aspects to prosthetic device users. The physical assembly of the prosthesis, referred to in the survey as the construction of the prosthetic was less important. Furthermore, the outside appearance such as texture or color is a less important factor. While appearance may be a concerning issue in the first stages of wearing a prosthetic device, over time its importance is overrun by the need for a well-performing and comfortable device. These results determine which aspect of a prosthesis this project will focus on improving.

Several questions were asked regarding the fitting of the prosthetic device. Overall, the data suggested that even though there may be fitting issues with the prosthetic over the course of the day, they are not playing a big role in the satisfaction with the prosthesis for the majority of amputees.

The next aspect studied in depth was functionality. Many respondents expressed that their prosthesis had considerable functionality in comparison to the original limb which means that their prosthetic device can handle most daily functions. Although this seems slightly surprising, one should account for the factor of adjustment. The longer amputees wear a prosthetic the more comfortable they will be operating it and therefore the more satisfied they will be with its performance. On the other hand, slight dissatisfaction was seen regarding the range of motion of their device. This is an aspect that still requires a solution.

The study showed prosthesis users require more energy to walk than prior to their amputation. This is explained by the mechanics of the limb: in the natural leg or arm tendons and ligaments work together with the bone to contract a muscle and cause motion. On the other hand, with prosthesis the only point of support is the socket area and there are no available tendons or ligaments to support the motion. This may also be attributed to the thinking and planning lag period that is required to move the prosthetic with every motion. Therefore it comes with no surprise that 95% of responded reported that it did take more energy to walk with their prosthesis.

Comparing different activities showed that the most difficult motion to perform was kneeling down, which is explained by the biomechanics of the activity. This motion engages

both the ankle and the knee and for above knee amputees who are lacking both joints it is understandable that it will pose a serious challenge. On the other hand, walking up the stairs does not require as much motion on both joints, but is still harder than walking on flat surfaces because of the need to bend the knee up. Walking down the stairs was less problematic because bending the knee and ankle is not essential for progress, but without it the process becomes tedious and time consuming. Therefore, it was concluded that trouble walking up and down stairs and trouble kneeling are caused by the lack of mobility in the knee and ankle joints of modern prosthetics, which has a lot of room for improvement. One possible solution would be to make the prosthesis joints more close resemble the natural joints. In particular, allowing a joint to move in two axes to mimic pronation and supanation would be the ideal design.

The majority of lower limb respondents reported pain in the leg opposite their prosthesis. This is most likely due to patients being less comfortable and trusting of their prosthetic than of their natural limb. Therefore they tend to overcompensate for their prosthetic by using their natural limb more than usual, thus causing stress and strain on the muscles, tendons and ligaments of that limb. Over time, as the patient becomes used to their prosthetic and is able to control it more efficiently, they will learn to rely on the prosthesis more. As this happens, motion stress will be better distributed between both limbs, which means that the pain would be expected to decrease. This was the exact trend that was seen in this study. The first year the pain due to overcompensation had not developed yet. Between 1-15 years the overcompensation is a high level as the body started to learn to adjust to the missing limb. Then after 15 years the pain in the opposite limb was not as prominent. Therefore, in general the longer the participants had had their prosthesis the less likely they were to experience pain in the opposite limb.

Most above knee amputees also experienced discomfort from their prosthetic pushing into their groin. This is due to the socket being non-flexible and causing irritation of the soft tissue. If the material was more flexible, then patients would not experience discomfort, and as most respondents said that they would use their prosthetic more. A solution to this problem seems easy at first glance: design the socket out of a material that has a lower Young's

modulus. However, when doing so the effectiveness of the prosthesis would decrease because a flexible socket is not able to withhold the stresses that go into the prosthesis during motion. Therefore, flexibility of socket and functionality of the prosthesis go hand in hand and finding the correct balance between the two is necessary for a prosthetic device that is all around satisfactory.

The survey results provided significant concern about the development of skin conditions. Therefore, further investigation was performed to pin point the root cause of the skin conditions. Because the liner is the part that comes into direct contact with the skin, it was hypothesized that it plays an important role for the development of these conditions. Interesting data resulted from the analysis of the frequency of cleaning the liner against the development of skin conditions. A strong correlation seems to exist between cleaning the liner daily and developing skin conditions. This correlation cannot be accurately extended to a smaller frequency (less than once a day) because the number of respondents who reported to follow that frequency was very small (2 participants).

It may at first seem logical that cleaning the liner everyday would help to prevent development of skin conditions, however deeper analysis proves that that is not always the case. Cleaning liner frequently certainly removes excessive sweat, which may trap bacteria and viruses and cause an infection. However, cleaning of liner has been shown to also shown to cause debonding from the rest of the device, particularly in the case of silicone to polyurethane [11]. Deng et. al. found that aggressive cleaning may cause detrimental effects to the physical and chemical structure of the liner because it changes the bond strength of the material. The degrading structure then makes it prone to more rubbing against the skin in the residual limb and creating wounds. This becomes a problem especially when the same liner has been worn for extended periods of time.

Upon consideration of the participants cleaning habits, one suggestion to prevent debonding in the liner would be to only use water, without chemicals when cleaning it, however that is not a good alternative because water does not remove lipid buildup from sweating. For the same reason, reducing cleaning frequency may not be the best solution

either, even though the survey data suggests that in the long run it may prove advantageous. Another alternative is to develop an antibacterial coating inside the liner that helps against infections; however this solution would still not provide remedy for redness, swelling, sores, cysts etc.

The most promising approach would be to combine the antibacterial coating design with the design of material that does not suffer from debonding overtime when cleaned with water and soap. To chemically engineer this material in depth studying of the chemical bonds of the liner materials that are currently in the market would be the starting point. The next step would be to conduct an experiment to test the bond strengths that result from different chemical modifications. The modification that gives the highest bond strength should be employed in the liner formation in order to prevent the debonding effects that come with cleaning.

Several aspects that were asked about in the survey proved not to be a problem for prosthetic users and suggest that these categories may have already been addressed as issue prior to this study. Most respondents did not have trouble with the weight of the prosthesis, sleeping, using the bathroom, and balancing. Furthermore, pain in the residual limb was not an issue, nor was posture. Most surprisingly, the prosthetic did not prevent most respondents from exercising regularly at a moderate intensity.

Conclusion

The purpose of this study was to identify the major limitations of prosthesis that are most concerning to amputees and to provide engineering solutions. A possible solution would be to simply make the knee and ankle joints more maneuverable. This would allow for a more natural gate for the user and could also alleviate some pain that they might be experiencing. A solution that could be researched is an ankle that would allow two axis of motion both forward and backward and an angular motion that would allow for motion that would mimic pronation and supination of the ankle.

Since a significant number of respondents reported that they would like to be able to run and swim, future prosthetics could focus on improving the technology behind the prosthesis are already exist for these purposes, such as the cheetah leg or prosthesis fin. The ultimate goal would be to make these devices less expensive so they can be available to everyone. Today, amputees are forced to choose between price and functionality. By using different materials or better mass-production techniques future technology will be promising a more satisfactory experience with prosthetics to all amputees.

Analyzing the responses of the participants showed that the development of skin conditions was the most concerning issue for several reasons: because it was the most common problem reported, because the majority of participants reported on having experienced a series of skin conditions, and lastly, because it is an issue that may result in not being able to wear a prosthesis completely. Skin conditions were highly correlated with the frequency of cleaning of the liner. As reported in the literature, cleaning leads to debonding between polyurethane and silicone, which in turn results in the development of skin irritation. Several approaches were suggested to assimilate this problem: less frequent cleaning, development of antibacterial coating, cleaning without chemicals, and renewing the liner frequently. The most promising approach is to modify the chemical structure of the material to avoid debonding from cleaning in the first place. With the implementation of this change it is expected that the skin conditions will be less common and that the satisfaction of users with their prosthetic device will increase.

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