USER NEEDS AND REQUIRMENTS FOR THE DEVELOPMENT OF A MOISTURE PERMEABLE PROSTHETIC INTERFACE

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ABSTRACT

Previous research has shown that there is a need for improvement in the area of moisture management in prosthetic interfaces and that excess moisture accumulation within the prosthetic limb is a major source of reduction in quality of life for people who use prosthetics. In keeping with a systems engineering approach, the first step in the development of a new product is collecting requirements from all stakeholders. A qualitative study has been conducted using focus groups and interviews of prosthetic limb users. Two sites were selected and 4 participants were interviewed. The questions asked were specifically designed to answer the questions of interest to rehabilitation engineers which could not be obtained through other means. A directed analysis of the data was conducted and major results summarized. Results were used to compile a list of preliminary design metrics. All end users reported that mechanical instability was the primary negative outcome resulting from the accumulation of excess moisture. Topics covered also included coping with excess moisture, triggers for excessive sweating, amount of sweating, expected cost, and desired durability. A measure of effectiveness for future product testing was also inferred

BACKGROUND INFORMATION

An estimated 1.6 million individuals have been estimated to live with limb loss in the United States. By 2050 that number may be as high as 3.63 million due to growth in the aging population and an increase in the number of people with dysvascular diseases such as diabetes (Ziegler-Graham, 2008). Complaints about the inadequacies of the interface between the residual limb and prosthetic device are common. A 2006 survey asked respondents to rank the most pressing issues facing the field of prosthetics. The respondents (a majority were certified orthotists and/or prosthetists) selected sockets and interface issues and outcome measures to be most important and in need of future work (Northwestern University, 2006). A survey of 78 amputees found respondents less satisfied with the comfort of their prosthesis (43% satisfied) than with appearance (58% satisfied), weight (58% satisfied), or ease of use (60% satisfied). In the same study, 23% of the respondents reported being “extremely” or “very” bothered by excess perspiration in the socket, 24% reported being “extremely” or “very” bothered by skin irritation as well (Dillingham, 2001). In another study with 97 user participants, the most common self-reported problem associated with prosthesis use that led to reduction in quality of life was excess heat and sweating (72%). The next most common source of discomfort was skin irritation (62%) (Hagberg, 2001). Moisture reduces skin strength, and increases friction and the opportunity for invasive microbial, bacterial and fungal organisms to invade the macerated and abraded tissues in contact with the stump socket and initiate infection. Infections of the skin are common in the residual limb (Meulenbelt, 2007).

Current popular prosthesis interface methods include suction and pin lock suspension. Suction prosthesis may be worn with or without a silicone or gel liner. Pin lock suspensions always make use of a silicone or gel liner. In either case the residual limb interfaces with the prosthesis through a thin membrane of silicone or gel which serves to grip the limb with its tacky rubbery surface. Liners have the added benefit of cushioning the residual limb. Current liners are primarily made of homogeneous sealed sheets of solid silicone, polyurethane, or thermoplastic elastomers (Klute, 2010). These materials are highly impermeable to moisture (Hachisuka, 2001). When excess moisture is present the interface materials lose their grip on the residual limb and slippage occurs.

To address this need in the community, we propose to develop a moisture permeable prosthetic interface. Product development using systems engineering principles dictates that the first step is to compile a list of needs from all stake holders starting with the end users.

INTRODUCTION

The ultimate beneficiary of a development project for a novel assistive technology is the end user. For this reason, systems engineering, a systematic procedure for ensuring the greatest possible chance of success, has been used. As seen in Figure 1, the development cycle of a product begins with a need in the community. Once the need has been established, conceptual design of the solution to meet that need may begin. The first step in the conceptual design is the collection of the requirements from all stakeholders. This includes all people who will be using the device or producing it or working with it. The purpose of the present study is to collect end user needs for that larger development project of a moisture permeable prosthetic interface.

Need	Conceptual Design	Preliminary Design	Detailed Design and Development	Construction or production

Figure 1: Product Development Phases

Table 1: Stakeholders, and Needed Information

Stakeholders:	Information Needed:
Manufacturers	manufacturability, commercially available materials, scalability
Clinicians	demand, complications, indications & contra indications, expected outcomes, existing alternatives,
END USERS	comfort and use, and triggers for sweating, consequences of sweating, current coping mechanisms, acceptable cost, quantity of sweat, durability
Insurers	cost coverage, product reimbursement amounts, product categorization
Competitors	competing products, market information

Many of the stakeholder requirements, such as the requirements of the insurers may be obtained directly from publically available materials published on their websites. End user requirements however must be learned directly from the end users themselves and only from them. This is in keeping with use of Participatory Action Design as outlined by Cooper et al 2006 (Cooper, 2006). Many of the requirements, however, are derived from physiological constraints and as such a thorough literature review will be done to compile a list of target metrics. This will help to form a basis by which to judge the success or failure of the product development process. Only the needs and requirements of the end users are the focus of this paper.

METHODS

The collection of end user need was accomplished in this study through a mixed interview/focus group qualitative data collection study. An application was submitted to the Institutional Review Board (IRB) at the University of Pittsburgh. As this study did not collect any personally identifiable information about the participants the IRB cleared the study as exempt from review. The IRB cleared all study materials and recruitment materials.

Climate and temperature are considered to be important factors contributing to the amount of sweating experienced by prosthetic users. For this reason data collection sites in cool climates as well as in warm climates within the United States were considered. Pittsburgh PA, the location of our university was taken to be the location of the cool climate data collection as it is located in a region of the United States which experiences large amounts of annual snow fall.

A total of four prosthetics clinics were contacted with requests for cooperation in temperate climates within the United States. The sites were selected using climate data from city-data.com using a combination of hottest summers, warmest average annual temperatures, or most humid climates. Of the four sites contacted one site was in Florida, one site was in Louisiana, one site was in California, and one site was in Hawaii. Ultimately only Advanced P&O of the Pacific, Inc. located in Honolulu Hawaii agreed to collaborate with us and assist with patient recruitment as well as provide the space for the interview. Recruitment was done using posted flyers in prosthetics clinics. Eligibility for participation was being at least 18 years of age and having experience using prosthetic gel liners. As a token of thanks participants were given a gift card to Target worth 10 dollars.

Interviews and focus groups were done in a private setting and all conversations were audio recorded. Recorded conversations were then transcribed into Microsoft Word for analysis. No personally identifiable information except for sex and age group was collected. For the purpose of transcription pseudonyms were created. The lone participant in Honolulu was codified as “P”. In Pittsburgh the participants were codified as “P1”, “P2”, and “P3”. In both sites the facilitator was codified as “F”. Using the codes listed below a directed content analysis approach was used to analyze the data (Hsieh, 2005). The codes (Table 2) were derived before and during the data analysis. Directed analysis was chosen because the engineers had preformulated specific questions they wanted to get answered prior to the commencement of the data collection (see Table 1). These involved parameters such as cost, quantity and durability which are all critical design parameters they would need for the next phase of development, the preliminary design phase. Four participants were interviewed across both sites. In Hawaii (site1) one female middle aged participant was interviewed. In Pennsylvania (site2) two middle aged men, ad one senior man participated in a focus group.

Table 2: Code Book for Analysis

Code	Meaning
Comfort	Expected comfort of current or future interfaces
Trigger	Related to the triggers which cause excessive sweating
Consequence	Consequences of excessive moisture accumulation within the prosthetic socket
Coping	When excessive sweating occurs within the prosthetic socket what are the coping mechanisms or skills used?
Cost	Related to how much should a prosthesis with this interface cost
Quantity	Related to quantity of sweat
Durability	Related to expected durability of interfaces

RESULTS

Examples of transcript excerpts from the sessions are given below followed by major findings:

Example Transcript Excerpt from Honolulu (Site1):
F "What would you say is your main complaint in using the liner in regard to moisture or any other topic."
P "Just that it led to the feeling of losing full contact and I don't like that."

Example Transcript Excerpt from Pittsburgh (Site2):
F "Have you ever felt that there was a pool of sweat, where if you inverted it you would get some drops out."
P3 "Yes"
P2 "Yes"
P1 "Absolutely"
P2 "I have taken my liner off a couple times and there's like a half a cup of sweat in there."

Major Findings Summarized:

Comfort:

Factors affecting liner comfort included mechanical compliance of the interface, fit of the socket following weight loss or limb atrophy, slippage of the prosthesis about the residual limb, and lubrication. Different types of materials and cloths may be used as long as they do not result in increased friction and irritation of the residual limb. All Participants across both sites affirmatively stated that they would anticipate people in general would tolerate greater interface care requirements for more complex prosthetic liners if they provided improved comfort.

Trigger:

All participants said both increase in physical activity as well as increase in climate temperature led to an increase in sweating into the prosthetic socket. Participant P at site1, and Participants P1, and P2 all stated that warmer climates rather than physical activity contributed more greatly to their sweating into the liner.

Consequence:

All Participants at both sites stated that the greatest problem related to the excessive accumulation of sweat was the loss of a secure linkage to the prosthetic limb. This led to feelings of fear, loss of balance, and unwanted movement of the prosthetic limb. Excessive pooling of sweat in the liner was also deemed to result in slippage of the limb inside to the socket leading to soft tissue irritation and blisters.

Coping:

P2 at site2 stated that his limb rotated inside the prosthetic liner, but that the pin lock suspension mechanism allowed him to easily reposition his leg. Participant P1 stated he always tried to carry a towel with him in order to dry off his socket. Participants P1 and P3 at site 2 stated that they would need to physically remove the socket to allow it to dry and get relief from excessive moisture With P3 further indicating public restrooms as a location where to do this.

Cost:

All participants at site 2 reached consensus that future interfaces should be covered by insurance and they should not cost in excess of what current liners are valued at.

Quantity:

All Participants at both sites reported significant pooling of sweat in the prosthetic socket. Participant "P" at site1 (Honolulu HI) reported a few table spoons of sweat. Participant P2 at site2 reported half a cup of sweat.

Durability:

At site2 all participants reached consensus that a conventional prosthetic should last at least a year to be deemed satisfactory. All participants at site2 agreed that a prosthetic interface which lasts half as long, but which costs half as much, would also be acceptable. P1 who used hand sanitizer as a lubricant reported liners lasting short of six months. P2 who reported using Vaseline as a lubricant reported no cracking in the interface but did experience delamination of the interface layers.

DISCUSSION

Interesting results can be obtained using this interview/ focus group method. For example the observation that P1 using an alcohol based lubricant reported dry cracking liners. The fact that alcohol and free floating silicone oil are miscible may explain that. Oil based lubricants would be expected to solvate silicone polymer chains and might explain the delamination reported by P2. So a careful analysis of the data indicated two modes of failure with two separate causes. To confirm these hypotheses additional testing would have to be done.

Once a satisfactory list of user requirements has been compiled they will be used to populate the stakeholder requirements document (SRD) along with the manufacturability constraints, the competition's constraints, the clinician's recommendations and all the other needs and constraints of the stakeholders. The SRD is a critical document which will be used to determine product specifications, design metrics, and measures of effectiveness. Without these engineers are unable to effectively design an interface which meets all the requirements for success and the product development effort is at risk of failure.

The user needs and requirements collected have been translated into a list of preliminary design metrics for use by rehabilitation engineers and are as follows:

Table 3: Preliminary Engineering Design Metrics

1	The prosthetic interface should provide at least one year of normal use, although a cheaper, less durable liner would also be acceptable.
2	The primary measure of effectiveness (MOE) of a moisture permeable prosthetic interface should be its ability to improve linkage between the residual limb and the prosthetic socket.
3	The out of pocket cost for the end user should not exceed the cost of currently available products even in spite of the improved outcomes.
4	The product needs to meet the requirements necessary for it to be covered by insurance. The published ceiling and floor prices for Medicare/Medicaid reimbursement for similar products are $829 and $476.
5	A composite of several materials touching the skin would be acceptable as long as it does not result in increased skin irritation.
6	Over the course of a day the interface should remove anywhere from 30mL to 120mL of sweat.

Study Limitations:

The participants in this study were not randomly selected and the data was collected in a non-uniform way. The goal of the study was to generate ideas and learn things about the end user experience that could not be learned any other way. All end users are sure to have their individualized complications with prosthetic limbs and moisture. No detailed demographic data was collected on participants. The inclusion criterion for participation in the study was broad.

Future Work:

Parallel studies to this one are currently under way to establish the remaining stakeholder needs. This includes interviews with clinicians, industry leaders and competitors.

The second phase of the development, preliminary design, has also started in parallel using data already collected from stakeholders. Feasibility analysis materials identification and computer modeling have all begun, but it is not until all the target metrics and specifications have been translated from the stakeholder needs can final interface configurations be constructed and tested.

CONCLUSION

The mixed focus group interview format proved effective for quickly gathering qualitative data on a heretofore relatively I'll defined topic. The insights gathered herein provide a set of preliminary design metrics which engineers can use to begin the preliminary design phase of the product development effort. The directed content analysis approach allowed engineers to preformulate specific questions to be asked of the participants, and therefore predetermine codes for codification of the data. The analysis was also flexible enough to observe unexpected and interesting results. More research is needed to improve the accuracy of the preliminary design metrics.

Excessive pooling of sweat in the liner is a danger to users of prosthetic limbs as it reduces their stability and increases their chances of skin irritation. Inclusion of end users from the outset of product development has yielded useful information, verified the need reported in the literature and provided requirements for future product development efforts.

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