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# Upper Extremity Prosthesis User Perspectives on Unmet Needs and Innovative Technology

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## Abstract

The needs of individuals with upper limb amputation and congenital limb difference are not being fully met by current prostheses, as evidenced by prosthesis rejection, non-wear, and user reports of pain and challenging activities. Emerging technologies such as dexterous sensorized robotic limbs, osseointegrated prostheses, implantable EMG electrodes, and electrical stimulation for sensory feedback have the potential to address unmet needs, but pose additional risks. We plan to assess upper limb prosthesis user needs and perspectives on these new benefits and risks using an extensive quantitative survey. In preparation for this survey, we report here on qualitative interviews with seven individuals with upper limb amputation or congenital limb difference. Unstructured text was mined using topic modeling and the results compared with identified themes. A more complete understanding of how novel technologies could address real user concerns will inform implementation of new technologies and regulatory decision-making.

## I. Introduction

A number of technical innovations have arisen in upper extremity prosthetic research in recent years, including osseointegration for prosthetic attachment [1–2], highly dexterous

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robotic limbs [3–5], implanted sensors for improved prosthetic control [6–7], and electrical stimulation for the restoration of naturalistic sensation [7–9]. Prosthesis user perspectives on the improved benefits and increased risks that result from these technologies can inform device development, clinical trial design, regulatory benefit-risk assessments [10], and clinical practice. We are therefore developing a survey to determine unmet needs for people with upper extremity amputation, in addition to perspectives on these new benefits and risks.

Previous surveys have informed advances in myoelectric prosthetic control and socket design, emphasizing the need for more comfort and functionality compared to the harness socket designs used with body-powered hooks [11]. Prosthesis rejection dropped from 30% among veterans of the Vietnam War (mean age 60) to 22% among veterans and service members from Operation Iraqi Freedom/Operation Enduring Freedom (mean age 30) [12], perhaps related in part to improvements in myoelectric prostheses. Similarly, with the advent of invasive technologies, which face higher regulatory hurdles than previous prosthetic technologies, input from prosthesis users will help guide implementation and could be informative when assessing benefit-risk tradeoffs. A recent survey demonstrated that surgical interventions are not a deterrent to potential brain-computer interface users [13]. We aim to generate quantitative information about the risks people with amputation will accept in exchange for increased function, decreased pain, or improved quality of life. To prepare for this planned survey, here we report on an initial qualitative landscape assessment of the unmet needs of people with upper extremity amputation.

## II. Methods

This study was approved by the U.S. Food and Drug Administration Institutional Review Board, the Research Involving Human Subjects Committee. All participants gave informed consent to participate in this study. For pilot qualitative work, 7 participants (2 female; ages 41 to 65) were interviewed about their daily experiences with amputation and, if applicable, prostheses. Subject demographics are summarized in Table I.

Interviews, which lasted 60–90 minutes, were structured around open-ended questions about participants' typical daily activities. Open-ended questions were used to avoid bias in the responses due to priming. Particular attention was paid to any challenging or frustrating activities or situations in which participants experienced limitations. When limitations were relevant to novel prosthesis technologies (osseointegration, implantable devices, or sensory feedback), participants were asked briefly about their perspectives on these technologies. Interviews were recorded and transcribed for content analysis and text mining. One interview transcript was truncated due to a recording failure.

Initial coding identified challenges and limitations, including pain and overuse injuries, and concepts related to novel prosthetic technology. Here we report themes that emerged in both categories.

Additionally, we used topic modeling, a form of text mining, as an alternative approach to examining themes in participant responses. This form of unsupervised machine learning can evaluate large bodies of unstructured text to generate topics, defined as clusters of terms that frequently appear together. Full transcripts from six interviews were stripped of punctuation and used to construct a corpus of documents. A list of stopwords was empirically selected, based on high frequency and low relevance, and was excluded from the analysis. The Porter Stemming Algorithm was applied to truncate words to their stem. Topic modeling was carried out in Gensim using Latent Dirichlet Allocation (LDA) [14].

## III. Results

### A. Challenges and Limitations

As participants narrated a walkthrough of a typical day, a number of consistent challenges and limitations emerged. Table II summarizes the most common themes in the interviews. Discomfort or pain on both the side with amputation or limb difference and, when applicable, the intact side, was mentioned frequently. Difficulty with precise hand or finger movements was a common challenge, both during activities of daily living and when using computers or handheld electronics. Recent bilateral amputation (participants with bilateral amputation were both two years from time of amputation) was, as anticipated, significantly more disabling than recent unilateral amputation, and led to the need for a caregiver throughout the day.

In many cases, prostheses were worn in the home environment and in social settings, but it was most common to wear a prosthesis in a work or professional environment. Typing was a common work-related activity that presented some difficulties for many participants. In some cases, assistive technology, such as voice recognition software, was used or considered to address this challenge.

Participants expressed both negative and positive emotions during the interviews. The most common negative emotion was frustration, which was often experienced when confronted with a challenge or limitation. A common positive emotion was a feeling of being “whole,” in connection with ability to function or acceptable cosmesis.

### B. Perspectives on Prosthetic Technology

Although the interview focus was not on novel prosthetic technologies, they were discussed when it was natural to do so during the conversation. Table III summarizes desired benefits and features associated with novel prosthetic technologies that emerged in at least two interviews. The most commonly expressed desires were lighter weight devices, more comfortable device socket and attachment approaches, and the need for more functionality for activities of daily living. In two interviews, participants reflected on whether they would consider an additional surgery in exchange for some of these benefits. Both emphasized the need to weigh the potential benefits, particularly increased function, against the drawbacks involved in surgery. Their level of concern was variable. One participant was more wary of surgery:

> “I would be reluctant to do any kind of surgical intervention because I don’t know if I could get improved function. I would have to be super convinced that my function would be improved with the surgery.”

The other participant reflected that he was not afraid of surgery, but would weigh the potential benefits and increased functionality against the postsurgical recovery and training time. These responses underscore the potential for heterogeneity in individuals' approaches to weighing benefits and risks, which may be quantified in a larger population of individuals with a quantitative benefit-risk tradeoff survey.

### C. Topic Modeling

Selected topics from the topic modeling analysis are shown in Table IV, and include using a prosthesis to do small tasks, comfort of the myoelectric socket, and playing with children. Selected quotes are also included to demonstrate the relevance of the generated topics.

## IV. Discussion and Conclusion

Here we summarized qualitative results about individuals' experiences with amputation or congenital limb difference, with a focus on challenges or limitations that may be addressed by emerging technologies. This initial qualitative work will inform the development of a larger survey on the perspectives of individuals with amputation or congenital limb differences on specific benefits and risks expected from novel prostheses.

Prosthesis users and individuals who have rejected prostheses have previously been surveyed about specific technologies they would like and specific lists of activities they find difficult [11]. These approaches do not fully capture user needs, because it is difficult for users to map technical advancements or specific device features to their individual experiences with a prosthesis. This difficulty was expressed during several of the interviews we conducted, for example when one participant reported:

> "I wish that I had the opportunity to try out something like this a long, long time ago to see if it would be a good fit for me, and I think that's one thing that's lacking right now."

This work therefore extends the results of these studies in two ways. First, prosthesis users are asked about their day-to-day experiences, with a focus on understanding not only what high-level activities are affected by amputation and prosthesis use, but also the specific challenges and limitations involved. This focus will advance the mapping of unmet user needs to novel technical capabilities. Second, recent and emerging developments in prosthetic technologies were unavailable at the time of most previous surveys, so it was not possible to specifically address the benefit-risk tradeoffs that will apply to these new devices.

In light of the qualitative data collected in this study, we can generate hypotheses to test in a larger survey. Participants, particularly those with above-elbow amputation, expressed dissatisfaction with socket fit and prosthesis weight, leading to pain and discomfort, and a resulting impact on prosthesis wear time and overall functionality. For such participants, the risks of osseointegration, such as infection, may be outweighed by the removal of the socket, restoration of full range of motion, and differences in how prosthesis weight is distributed. These considerations may therefore be presented in the quantitative survey.

The most persistent theme in the interviews was pain due to overuse syndrome, which in some cases resulted in concerns about current and future impact on quality of life and ability to work. Therefore, some risks may be acceptable to some upper extremity prosthesis users to obtain a prosthetic limb with superior dexterous function, control, fluidity of use, and operation speed, in order to decrease overuse of the intact hand. This possibility may be tested with the quantitative survey.

Another consistent theme was the high value to participants of feeling “whole” or “complete,” which was sometimes related to prosthesis use for both functional and cosmetic purposes. Questions in the quantitative survey may therefore probe the potential value of sensory feedback in the context of a natural-feeling limb or body schema.

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## References

1. Tsikandylakis G, Berlin Ö, Brånemark R. Implant survival, adverse events, and bone remodeling of osseointegrated percutaneous implants for transhumeral amputees. Clinical Orthopaedics and Related Research. 2014; 472(10):2947–2956. [PubMed: 24879569]
2. Ortiz-Catalan M, Håkansson B, Brånemark R. An osseointegrated human-machine gateway for long-term sensory feedback and motor control of artificial limbs. Science Translational Medicine. 2014; 6:257.
3. Resnik L, Klinger SL, Etter K. The DEKA Arm: Its features, functionality, and evolution during the Veterans Affairs Study to optimize the DEKA Arm. Prosthetics and Orthotics International. 2014; 38(6):492–504. [PubMed: 24150930]
4. Borgia M, Latlief G, Sasson N, Smurr-Walters L. Self-reported and performance-based outcomes using DEKA Arm. Journal of Rehabilitation Research and Development. 2014; 51(3):351. [PubMed: 25019659]
5. Collinger JL, et al. High-performance neuroprosthetic control by an individual with tetraplegia. The Lancet. 2013; 381(9866):557–564.
6. Pasquina PF, et al. First-in-man demonstration of a fully implanted myoelectric sensors system to control an advanced electromechanical prosthetic hand. Journal of Neuroscience Methods. 2015; 244:85–92. [PubMed: 25102286]
7. Clark, GA., et al. Using multiple high-count electrode arrays in human median and ulnar nerves to restore sensorimotor function after previous transradial amputation of the hand. Engineering in Medicine and Biology Society (EMBC), 2014 36th Annual International Conference of the IEEE; IEEE; 2014.
8. Tan DW, et al. A neural interface provides long-term stable natural touch perception. Science Translational Medicine. 2014; 6(257)
9. Raspopovic S, et al. Restoring natural sensory feedback in real-time bidirectional hand prostheses. Science Translational Medicine. 2014; 6(222)
10. Ho MP, et al. Incorporating patient-preference evidence into regulatory decision making. Surgical Endoscopy. 2015; 29(10):2984–2993. [PubMed: 25552232]
11. Biddiss E, Beaton D, Chau T. Consumer design priorities for upper limb prosthetics. Disability and Rehabilitation: Assistive Technology. 2007; 2(6):346–357. [PubMed: 19263565]
12. McFarland LV, et al. Unilateral upper-limb loss: satisfaction and prosthetic-device use in veterans and service members from Vietnam and OIF/OEF conflicts. Journal of Rehabilitation Research and Development. 2010; 47(4):299. [PubMed: 20803400]

13. Engdahl SM, Christie BP, Kelly B, Davis A, Chestek CA, Gates DH. Surveying the interest of individuals with upper limb loss in novel prosthetic control techniques. Journal of Neuroengineering and Rehabilitation. 2015; 12(1):1. [PubMed: 25557982]
14. Blei DM, Ng AY, Jordan MI. Latent dirichlet allocation. The Journal of Machine Learning Research. 2013; 3:993–1022.

## TABLE I

Subject Demographics

| Subject | Amputation level | Dominant limb before amputation | Dominant limb at time of interview | Years since amputation | Current prostheses | Frequency of prosthesis use |
|---|---|---|---|---|---|---|
| 1 | Transradial | Right | Right | 8 | Myoelectric hand; adaptive (sports) | Daily |
| 2 | Transradial | Right | Right | 36 | Myoelectric hand; myoelectric hook; adaptive (sports) | Daily |
| 3 | Transhumeral | Right | Left | 3 | Cosmetic; myoelectric hand | Monthly |
| 4 | Bilateral transradial | Right | Right | 2 | Adaptive (weight-lifting); body-powered hook | Weekly |
| 5 | Congenital transradial | N/A | Right | N/A (Congenital) | Myoelectric hook; adaptive (weight-lifting, yoga) | Daily |
| 6 | Transradial | Left | Left | 4 | Body-powered hook; myoelectric hand; myoelectric hook | Daily |
| 7 | Bilateral transhumeral | Right | Left | 2 | Myoelectric hands | Daily |

## TABLE II

Common Themes

| Theme | Comments |
| --- | --- |
| Discomfort or pain on side with amputation or limb difference | Prosthesis sockets and harnesses were a source of discomfort or pain. Additionally, device weight and effort required to use prostheses resulted in fatigue in the arm, shoulders, and back. |
| Overuse syndrome | Compensatory movements and overuse of the sound side led to pain. In some cases, concern was expressed about future disability if pain continued to increase. Pain in the form of tendinitis, arthritis, and/or carpal tunnel was common. |
| Wholeness | Prosthesis users expressed successful function or appropriate cosmesis as feeling “whole.” This theme emerged in conversation about being able to function independently; being whole in their relationships and function within their family; and being whole in a professional, social, or public setting. |
| Difficulty with precise hand or finger movements | Several participants expressed frustration with at least one daily activity in which the precision of prosthesis movements was inadequate. Examples included typing on a keyboard or phone, using silverware to eat, and buttoning or unbuttoning shirts or pants. |
| Prosthesis use in a professional environment | Participants mentioned using their prostheses at work. Certain activities, such as typing, were said to be tiring and could lead to overuse and pain in the sound limb. |
| Impact of recent bilateral amputation | Participants with bilateral amputation were both recent amputees. They indicated a need for assistance throughout the day to accomplish activities of daily living, whereas individuals with recent unilateral amputation required very little or no assistance. Participants with recent bilateral amputation reported that they engage in little physical activity because they require assistance with many tasks, leading to some social isolation and frustration with the inability to engage in activities that were possible prior to amputation. |

## TABLE III

Perspectives on Novel Prosthesis Benefits

| Desired Benefit | Raised in interviews (out of 7) |
|---|---|
| Lightweight | 6 |
| More comfortable or secure attachment or socket | 6 |
| More functionality for daily tasks | 6 |
| Improved gripping and lifting strength | 5 |
| More resistant to environmental exposure (esp. water) | 4 |
| Compatible with multiple terminal devices | 4 |
| Improved control of device | 4 |
| Decreased need for compensatory movements | 3 |
| Decreased time between intention to move and actual movement | 3 |
| Easier to don and doff | 3 |
| Takes less time to do daily tasks | 3 |

## TABLE IV

Selected Topics and Example Interview Excerpts

<table>
<tr><th colspan="3">Topic: hand thing prosthesis help something work up way stuff little</th></tr>
<tr><td colspan="2">“They did not think that there was ever going to be a prospect of prosthetics in my life, but there are. So it’s very helpful for me. For me to be able to do little things makes a huge, huge difference.”</td><td>“Throughout the day, if I don’t want to sit on the dark or if I want the light on or off, I’m able to do that myself. Little things like that make a big difference to me.”</td></tr>
<tr><th colspan="3">Topic: prosthesis little off device use wear socket limb myoelectric</th></tr>
<tr><td colspan="2">“…there’s a number of things that go into the comfort of a prosthesis. Number one is the socket. Where the prosthesis touches your skin. But also for a cable operated system it’s the strap system. And the fact that I’m able to go harness free now with a myoelectric…”</td><td>“The thing is it’s so big on the top part where the socket is that sometimes it’s restraining what kind of clothes I can wear.”</td></tr>
<tr><th colspan="3">Topic: little pain use feel kid play sometimes off wanna hold</th></tr>
<tr><td>“…it’s great to have for a lot of the stuff that matters to me, like holding my kids’ hands, being able to carry them…”</td><td>“…when I go to play sports with the kids, I’ll wear my prosthesis…”</td><td>“…the prosthesis that they made for me is for specific activities, and I’m able to use a lacrosse net to play catch with my kids…”</td></tr>
</table>