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Stakeholder Perspectives for Possible Residual Limb Monitoring System for Persons with Lower-Limb Amputation

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Abstract

Purpose: To gather ideas from lower-limb prosthesis users and certified prosthetists regarding possible residual limb monitoring system features and data presentation. We also gathered information on the type of residual limb problems typically encountered, how they currently manage those problems, and their ideas for methods to better manage them.

Materials and Methods: Two focus groups were held; one with certified prosthetists and another with lower-limb prosthesis users. Open-ended questions were used in a moderated discussion that was audio recorded, transcribed, and assessed using Applied Thematic Analysis.

Results and Conclusions: Seven individuals participated in each focus group. Prosthetists came from a mix of practice settings, while prosthesis users were diverse in level of amputation, etiology, and years of experience using lower-limb prostheses. Residual limb problems reported by participants were consistent with those in the literature. Participants suggested better managing residual limb problems through improved education, better detection of residual limb problems, and using sensor based information to improve prosthetic technology. Participants' favored short-term use of a possible residual limb monitoring systems to troubleshoot residual limb problems, with temperature and pressure the most frequently mentioned measurements. Participants described that an ideal residual limb monitoring system would be lightweight, not interfere with prosthesis function, and result in benefits with regard to prosthetic care and socket function that outweighed inconveniences or concerns regarding system use. A potential positive of system use included having objective data for reimbursement justification, although it was pointed out that the residual limb monitoring system itself also needed to be reimbursable.

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Authorship Contributions

Declaration of Interest

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Keywords

lower-limb prosthesis; residual limb monitoring; focus groups; prosthetic interface; amputation rehabilitation

Introduction

Many people who use lower-limb prostheses experience residual limb problems from the stresses created by the prosthetic socket, especially when the socket does not fit well or the suspension mechanism does not sufficiently limit relative motion between the socket and limb [1]. Residual limb problems common across levels of lower-limb amputation include skin irritation and breakdown, heat and sweating [2], and dermatitis and infections [3, 4] that may lead to reduced prosthesis use [5], mobility [5] and quality of life [2]. Current clinical management of socket fit and suspension issues to reduce residual limb problems is based primarily on prosthesis user feedback and visual inspection of the residual limb [6]. With a large proportion of amputations due to vascular issues and diabetes [7], and accompanying sensory impairments and older age, the ability to rely on prosthesis user feedback may be compromised. While a residual limb monitoring system would be of use for all persons with lower-limb amputation, it might be of particular benefit for persons with diabetic amputations given the more serious consequences of socket fitting issues.

It has been suggested that sensing and monitoring technologies may be used to improve prosthetic rehabilitation by providing prosthetists the ability to monitor a prosthesis users' status, progress, and outcomes more frequently, enabling them to make more informed and timely decisions based on meaningful, objective data [6]. Specific to the issue of residual limb problems, sensing and monitoring tools are needed that can be used to assess the residual limb inside the socket and assist the prosthesis user and prosthetist in diagnosing and managing socket issues before problems arise. While attempts have been made to measure inside the socket [3, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18], the instruments used included bulky sensors [14, 17, 18], wires [3, 8], cables [9, 10, 11, 12, 13, 15, 17, 18], and/or required holes in the socket [11, 14], which disrupts the environment within the socket and compromises the value of the measurements. Additionally, such instruments are not feasible for every day clinical use. It is likely that prosthetists and prosthesis users will have limited tolerance for sensing and monitoring tools that are difficult to integrate into a prosthesis, have cumbersome software, produce data that is challenging to interpret, and lack cost-effectiveness [6]. Ultimately, use of sensing and monitoring tools must lead to improvements in quality and/or efficiency of care if they are to become a cost-effective solution for use in clinical care.

Hence, there is growing interest in developing sensing and monitoring tools to assess inside the prosthetic socket in a clinically- and user-friendly manner. For example, flexible 3D printed sensors [17, 18], instrumented liners [19, 20], and removable instrumented inserts [21] have been described. Our own work developing a residual limb monitoring system involves the use of epidermal electronics, which were developed for skin-based monitoring [22]. These 'skin-like' sensors are thin (2 mm), flexible, waterproof, wireless, and can

monitor various modalities including temperature, sweat, electrocardiogram, pressure, stress-strain, etc. They have the potential to be worn unnoticed on the residual limb within a prosthetic socket, forming the basis of a residual limb monitoring system that could be attached to any prosthesis for either short- or long-term monitoring. Similar to Hafner and Sanders [6], we envisage that integration of such a system into clinical practice would allow for multidimensional, bidirectional exchange of information between the prosthesis user and prosthetist.

However, when it comes to development and use of residual limb monitoring systems in prosthetics, there is limited information on the needs and wants of end users. In a focus group with prosthesis users, clinicians, researchers and manufacturers designed to assess their needs and perspectives on prosthetic care, Klute et al. [23] indicated that there was general support for the concept of monitoring systems. However, the information provided did not describe the features of such a system that would make it attractive and useful to end users or what concerns they may have regarding use of such a system. Ethical issues related to monitoring technologies have been suggested [24, 25], some of which may apply to monitoring of prosthesis users [6]. Issues raised with regards to monitoring of elderly people include loss of privacy and autonomy, stigma, reduced human contact; and technology obtrusiveness, personalization, affordability, and safety [24]. Other potential issues described by Rigby et al. [25] relate to practitioners' responsibility for monitoring and reporting outcomes, misuse or misinterpretation of collected information by third parties, and inclusion of monitored data in the medical record.

Our long term goal is to incorporate skin-like sensors into a residual limb monitoring system for use in clinical settings. Hence, to inform development and ensure that the residual limb monitoring system serves the needs of end-users, the aim of this study was to gather information from lower-limb prosthesis users and certified prosthetists regarding their ideas for system features and data presentation. In doing so, we also gathered information on the type of residual limb problems they typically encounter, how they currently manage those problems, and their ideas for methods to better manage them.

Materials and Methods

Participants

Two focus groups were held; one with certified prosthetists (Certified Prosthetist Group) and another with lower-limb prosthesis users (Prosthesis User Group). The University's Institutional Review Board approved the study and all participants provided informed consent prior to participation. Eight participants per focus group were recruited from among lower-limb prosthesis users and prosthetists in the Chicago area. This recruitment target was based on previous recommendations that a focus group of this size is large enough to generate fruitful discussion and small enough for everyone to contribute [26]. Participants were recruited using flyers, emails, phone calls, and word of mouth. Individuals needed to be 18–80 years, able to speak, read and comprehend English, and able to travel to attend the focus group. Participants in the Certified Prosthetist Group needed to be currently practicing certified prosthetists or prosthetist-orthotists with at least two years of clinical experience with lower-limb prostheses. Participants in the Prosthesis User Group needed to be currently

using a lower-limb prosthesis on a daily basis. We tried to ensure that there were different levels of time in practice and practice settings among prosthetists, different levels of major lower-limb amputation and etiologies among prosthesis users, and male and female representation in both groups.

Data Collection

A moderator guided both focus groups using eight open-ended questions (see Table 1) that solicited information about residual limb problems and their management; how prosthesis users and clinicians might want to measure conditions within the socket; and how a residual limb monitoring system might best be configured for the end user. Each participant had the opportunity to respond to each question using random sequencing. To avoid biasing responses, participants were not informed at the outset about the existence of the skin-like sensors [22] that are the focus of our development efforts. Discussions were audio recorded and transcribed, resulting in one transcript per focus group.

Data Analysis

We used Applied Thematic Analysis [27, 28, 29], an exploratory, content-driven approach for assessing textual data, to analyze the transcripts. Systematic analysis of the transcripts was managed by the first author through four phases: (1) initial coding (defined as a textual description of the semantic boundaries of a theme or a component of a theme [29]), (2) codebook creation, (3) focused coding using the codebook, and (4) consensus generation regarding themes/repeating ideas [27, 28, 29, 30, 31, 32]. All four authors analyzed the transcripts, reducing them to coded text that helped identify patterns that represented themes corresponding to the stakeholder's perceptions, feelings, knowledge, and behavior with respect to the study aims.

Initial Coding (phase 1)—Initial coding was performed to develop a codebook for use in focused coding [29]. In this phase, the investigators read and re-read the transcripts to familiarize themselves with the data, individually noting keywords, trends, themes, and/or ideas.

Codebook Creation (phase 2)—By synthesizing initial coding efforts, a codebook was created in Excel (Microsoft, Redmond, WA) to serve as a framework for systematically coding the text [30, 31, 32]. For manageability the number of codes was limited to 40, with each code being described by five definitional attributes: code category, short description of code, code definition, and example text from the transcripts that indicated how the code could be applied [31]. Investigators reviewed and edited the initial codebook until all agreed that each code was explicit enough for application.

Focused Coding (phase 3)—Investigators performed focused coding individually by tagging segments of text with codes from the codebook using QDA Miner Lite (Provalis Research, Montreal, CA) qualitative analysis software. Coded text was exported and arranged into Excel spreadsheets by seven attributes: transcript group (Certified Prosthetist or Prosthesis User), code category, code name, and each of the four investigator's corresponding coded text from the transcripts. Disagreements in the independently coded

text were addressed by consensus. First, investigators were sent the spreadsheets to individually review text with disagreement and re-consider their code against that of other investigators. This individually reconciled text was collated and, where there was full agreement, the text and corresponding code was kept for further analysis. If disagreement remained, the investigators discussed each code until there was consensus on whether or not the coded text should be kept for further analysis.

Consensus on Themes (phase 4)—The last phase of analysis assessed the coded text for themes and repeating ideas that described the stakeholder's perceptions, feelings, knowledge, and behavior with respect to the study aims. For example, under the code 'Skin' in the category 'Residual Limb Problems', responses about rashes, sores, and blisters were grouped into the theme 'skin breakdown'.

Results

Of the sixteen individuals initially recruited to participate in the focus groups, fourteen individuals ultimately participated. As shown in Table 2, participants in the Certified Prosthetist Group (n=7) came from a mix of practice settings and had 4 to 33 years of clinical experience. Participants in the Prosthesis User Group (n=7) included people with both transtibial and transfemoral amputation with different etiologies (e.g. trauma, vascular, infection, or congenital) who had <1 to 40 years of experience using lower-limb prostheses.

The final codebook (Supplemental File 1) contained 31 codes with definitions and example text organized under six major thematic categories across both focus groups: residual limb problems encountered, current management of residual limb problems, proposed methods to better manage residual limb problems, receptivity towards a residual limb monitoring system, vision for a residual limb monitoring system, and residual limb monitoring system configuration suggestions (Supplemental File 2). Table 1 provides a summary of these categories and codes.

Theme 1: Residual Limb Problems

Residual limb problems encountered referred to those that occurred at the residual limb within the socket. The most frequently encountered residual limb problems mentioned by both focus group participants were skin problems, limb volume fluctuation, pain, and increased temperature within the prosthetic socket. For example, one prosthesis user stated, *"I would say that my prosthetic adds about 20 degrees to my body temperature... There's no air flow"* (Subject 6, Prosthesis User Group). Prosthesis users also frequently mentioned discomfort, citing lack of liner breathability, bulk behind the knee, weight, and *"clunkiness"* (Subjects 5 and 6, Prosthesis User Group) of the prosthesis as factors that contributed to residual limb discomfort when using a prosthesis.

Theme 2: Management of Residual Limb Problems

Management of residual limb problems referred to any approaches currently used to address residual limb problems including methods of patient-clinician communication, patient education activities, problem solving techniques, and factors that influence the ability of the

prosthesis user to self-manage residual limb problems, such as issues with patient-reliability. There was broad consensus across both groups that sharing pictures and videos was currently the most effective method of communicating about residual limb problems, and in-clinic troubleshooting was an effective, albeit time-consuming, problem-solving technique. As methods to manage residual limb problems, some prosthesis users also described intermittently taking off their prosthesis, sitting and resting to relieve pain or discomfort, wiping down the liner and/or socket when a lot of sweat accumulated or, conversely, coping with the residual limb problems until they reached their destination and could take the prosthesis off or rest. One prosthetist described managing residual limb problems as being *“very patient specific...there is a trend in etiologies that result in challenges for the patient to be able to self-inspect...to have sensation, their eyesight, their ability to feel, to move their fingers”* (Subject 2, Certified Prosthetist Group). Another prosthetist remarked, *“It’s a lot harder if it’s a brand new amputee. They don’t necessarily have their sensation under control”* (Subject 1, Certified Prosthetist Group).

Theme 3: Proposed Methods to Better Manage Residual Limb Problems

Proposed methods to better manage residual limb problems referred to any suggested improvements for managing residual limb problems. To improve current methods of managing residual limb problems, participants from both groups suggested better patient education, having objective information, being able to better detect residual limb problems, and improving prosthetic technology. Better patient education as recommended by the prosthetists included peer support, continued practice with prosthetic management, and age-appropriate education. For example, one prosthetist remarked, *“it’s probably something most prosthetists could spend a lot of time improving, as to how we educate our patients to make sure that these problems can be averted. But that takes a lot of time and it takes a lot of effort”* (Subject 6, Certified Prosthetist Group). This sentiment was echoed by a prosthesis user who explained, *“...being a new amputee, there were so many things that came up that I had not a clue. I don’t know if this is normal. I don’t know what this is. How long will this last? I only wish there was a book for the new amputee”* (Subject 1, Prosthesis User Group).

Regarding the ability to better detect residual limb problems, participants in both groups asserted the need to detect emerging issues as they occur and to identify problems sooner. One prosthetist explained they wanted to detect problems before they *“get severe and waiting 2 or 3 months for the wound to heal”* (Subject 4, Certified Prosthetist Group). This idea was echoed by a prosthesis user who suggested when problems occur it would be helpful to *“Get a warning alarm and get in there in time. Not have to wait two weeks. Or after it’s too late”* (Subject 2, Prosthesis User Group). Desirable objective information included having quantifiable data or a tool that one prosthetist described as *“taking it out of the patient’s hand or the CP [certified prosthetist] relying on patient feedback”* (Subject 2, Certified Prosthetist Group). Similarly, a prosthesis user described that objective information would be helpful to document *“something that happens outside the prosthetist’s presence that you’re trying to explain”* (Subject 2, Prosthesis User Group).

There were diverse viewpoints regarding technology to better manage residual limb problems. Some prosthetists suggested the development of a sock management tool or

trouble-shooting app, or a device that would give the prosthetists “*x-ray vision*” (Subjects 1 and 5, Certified Prosthetist Group) of residual limb conditions within the socket. Whereas, some prosthesis users suggested they wanted technologies that could control temperature, get rid of sweat, or adjust the shape of the prosthesis automatically in real-time, as well as breathable liners that are either more durable or disposable. While not directly related to a residual limb monitoring system, there was consensus among prosthesis users that they wanted softer, more flexible socket materials, and lighter weight prostheses to address residual limb problems, with one prosthesis user emphasizing “*lighter weight. That’s what I want to see so badly*” (Subject 4, Prosthesis User Group).

Theme 4: Receptivity Towards a Residual Limb Monitoring System

Receptivity towards a residual limb monitoring system referred to the participants’ feelings and thoughts about using a residual limb monitoring system should one exist, and responses included health concerns, potential benefits, potential inconveniences, and potential for use in reimbursement justification. Some prosthesis users were concerned about potential injuries from using sensors on the skin for long time periods. One prosthesis user was particularly vocal about cancer as a potential health issue from using a residual limb monitoring system long-term on the residual limb, stating that they “*don’t like all these waves and stuff going through us*” (Subject 4, Prosthesis User Group). Another prosthesis user said their willingness to use a residual limb monitoring system would depend on “*...the benefits. If it’s going to change your life, then you do what you have to...if I’m having intense pain or whatever, and this will relieve it. Or lead to the relief of it, I’m willing to go an extra step*” (Subject 5, Prosthesis User Group).

With regard to short-term use, there was consensus among both groups that a residual limb monitoring system would be beneficial for troubleshooting interface problems in the clinician’s office. In this scenario, a majority of the prosthetists and some prosthesis users stated they would be comfortable with placing sensors directly on the skin because they thought it would provide more accurate information. However, for long-term use, prosthesis users preferred for the sensors to be integrated into the liner or socket or located on the outside of the interface. In this scenario, participants described that a residual limb monitoring system could be used to monitor daily activities and assist the prosthetist and prosthesis user in troubleshooting socket issues outside of the clinician’s office. For example, one prosthetist stated, “*we’re looking at a device that can measure very specific things, that’ll give us more information, that’s very detailed, so ultimately we have better patient outcomes, better clinical decisions can be made versus ‘hey yeah that looks a little looser, it looks a little tight, or how does it feel?’*” (Subject 3, Certified Prosthetist Group). Another prosthetist noted that the system would not be able to replace the clinician, stating, “*the recommendations would have to be very targeted and accurate, or not be recommendations at all and just say, ‘hey something’s going on, do you need to reach out? Or do you want to send a profile to your prosthetist to discuss this?’*” (Subject 2, Certified Prosthetist Group).

Theme 5: Vision for a Residual Limb Monitoring System

Vision for a residual limb monitoring system referred to capabilities and uses of a residual limb monitoring system suggested by participants, including length of use, sensor characteristics and locations, desired measurements, and measurement sites, and system goals. There was broad agreement across participant groups that while using a residual limb monitoring system for long-term monitoring would be ideal, short-term monitoring was preferred. Short-term use was described by some prosthetists as a couple of days or only in the clinician's office. By way of explanation for this preference one prosthetist stated, *"the duration of how long we are asking them to collect this information could affect how compliant patients are with using it"* (Subject 5, Certified Prosthetist Group). Regardless of the length of use, there was consensus across all participants that the sensors need to be *"virtually invisible"* (Subject 2, Prosthesis User Group) and the number of components in the residual limb monitoring system minimal. For example, one prosthetist suggested that the sensor be *"small enough not to interfere with function of the leg"* (Subject 3, Certified Prosthetist Group).

Desired measurements identified by participants included shear, moisture, duration of prosthesis use, step count, volume changes, amount of socket pistoning, consistency of socket fit, nerve activity, skin integrity, and alignment, with temperature and pressure being mentioned most frequently by participants. Prosthesis users' suggestions for measurement sites on the residual limb extended from the distal end to every part of the limb. The prosthetists concurred that the distal end was a very important measurement site, with some prosthetists adding that measurements should be taken over bony prominences and weight bearing areas.

With regard to using a residual limb monitoring system, some participants from both groups acknowledged potential inconveniences such as the likely cost of a residual limb monitoring system, technological issues that may occur during use, and the interpretability of the resulting data. Potential positives of system use included being able to more effectively troubleshoot socket issues, document quantitative data regarding the residual limb, and having objective data for reimbursement justification, although it was pointed out that the residual limb monitoring system itself also needed to be reimbursable. Potential benefits mentioned collectively by both groups were developing a better understanding from monitoring daily patterns of change within the residual limb, lessening the time spent in the clinic, and using the data to document activity levels in the community.

Theme 6: Suggestions for Configuration of Residual Limb Monitoring System

Residual limb monitoring system configuration suggestions referred to how the participants thought the monitoring system could best be configured, including how participants would like to be alerted to residual limb problems, what type of data might be collected, and how that data could be stored, shared, and viewed. Both participant groups suggested that data should be collected wirelessly on a mobile phone app. Additionally, some participants from both groups recommended synching and storing data in real-time. Some prosthesis users suggested they would like to view data with videos, charts, and plots color-coded to represent problem severity. One prosthesis user described this as a *"color level thing, like*

she had this many peaks, you know, red, in this month... You know, you had two peaks, you had this at yellow level. You had this at, like, green level" (Subject 4, Prosthesis User Group). Participants from both groups also stated that alerts should be customizable, noting that, *"having too many alerts can be overwhelming"* (Subject 6, Prosthesis User Group). Some prosthesis users agreed that data should be shared automatically with the prosthetist, while others were unsure. Additionally, while some prosthesis users indicated they would like data stored on a website, one prosthetist stated they would like *"some mechanism to include it in the medical record"* (Subject 6, Certified Prosthetist Group) and another prosthetist wanted *"a way to export the data, print it, and file it"* (Subject 3, Certified Prosthetist Group).

Discussion

The purpose of this study was to gather information that would inform development of a residual limb monitoring system, ensuring that it serves the needs of end-users. Hence, we gathered information from lower-limb prosthesis users and certified prosthetists regarding their ideas for system features and data presentation. In addition, we gathered information on the type of residual limb problems they typically encounter, how they currently manage those problems, and their ideas for methods to better manage them. This information allowed us to confirm that the residual limb problems encountered by participants in our focus groups matched those typically reported in the literature, including volume fluctuation, skin breakdown, increased temperature in the socket, and sweating [2, 3, 4, 5, 16, 33, 34, 35]. While all participants perceived value in using a residual limb monitoring system, participants in the Certified Prosthetist Group spoke mostly about the need to develop methods to detect residual limb problems before they occur, while the Prosthesis User Group spoke mostly about advancements they want made to prosthetic socket technology that would solve their residual limb problems (e.g., having air conditioning inside the socket or lighter prosthetic components). While the development of such technologies may not be related directly to the idea of a residual limb monitoring system, they still require in-socket sensing for operability (e.g. determining when to activate an air conditioner inside the socket would require sensing of in-socket temperature).

Suggestions for system configuration and data presentation also varied between the groups, with prosthesis users particularly concerned about the cost and safety of using a residual limb monitoring system. However, all participants agreed that they would use a residual limb monitoring system if they derived a perceptible benefit and it was relatively easy to use, consistent with previous studies [6, 23] and hypotheses [6]. Although our participants acknowledged that using a residual limb monitoring system long-term would be ideal, given potential drawbacks such as health concerns, they were only prepared to use it short-term. It seemed that if a residual limb monitoring system were developed for long-term use, prosthesis users would need reassurance regarding safety and benefits. Such reassurance may not be immediately necessary given that the current state of technology, such as limited battery life [6], makes long-term monitoring a challenge.

For all our participants the most frequently mentioned measurements were pressure and temperature at the socket-limb interface. Similar to Klute et al. [23], we heard that prosthesis

alignment, step count, temperature, moisture, and duration of prosthesis wear were among desired measurements for a residual limb monitoring system. While prosthetists agreed that the best measurements would be those taken directly on the skin of the residual limb, participants' concerns about safety and prosthetists' concerns about ease of use led to a preference for mounting the sensors in the liner or socket, similar to the approach to monitoring proposed by Laszczak et al. [17, 18] and Wheeler et al. [19, 20].

The expectations and concerns of prosthetists and prosthesis users regarding a residual limb monitoring system echoed many of the considerations and hypotheses expressed by Hafner and Sanders [6]. For example, prosthetists described that sensing systems should complement or extend prosthetists existing skills and knowledge, augmenting traditional methods of care, while prosthesis users described ethical concerns regarding how monitoring might diminish their autonomy, especially with regards to unfettered data sharing with the prosthetist. The issue of health concerns and the impact that had on the preference for duration of monitoring was not mentioned as an issue in the ethical reviews we found regarding monitoring technologies [6, 24, 25], but is similar to concerns about the effect of cell phone use on health [36, 37].

The main limitation of this study was that we held only two focus groups, with each group representing different end-users of a residual limb monitoring system (certified prosthetists and lower-limb prosthesis users). This may have limited our ability to reach data saturation regarding new information with regards to the identification of themes [38]. Additionally, the majority of our prosthesis users had amputations of traumatic origin and their ideas may not represent those of prosthesis users with vascular amputations. However, given that our results regarding the residual limb problems experienced were similar to those of previous studies [6, 23] we are confident the information is sufficiently useful to inform our development of a residual limb monitoring system based on skin-like sensors [22] as an example, and may be useful to other researchers focusing efforts on similar endeavors [17, 18, 39].

In developing a residual limb monitoring system focus group participants described that the benefits of system use needed to outweigh any inconveniences, such as reimbursement. Having objective data about socket issues should facilitate reimbursement justification for socket/liner/suspension repairs or replacements, however to be a viable clinical tool use of the residual limb monitoring system itself would also need to be reimbursable. However, reimbursement for a residual limb monitoring system would likely be challenging in the current health care environment where prosthetists are only reimbursed for the device delivered and not for services provided in managing residual limb health. Despite this reimbursement structure, prosthetists are under the same pressure as other health care professionals to provide evidence to support reimbursement requests and as such a residual limb monitoring system could be useful. It is possible that for short-term monitoring, which was preferred by focus group participants, many system components could be reused between patients, and therefore costs minimized. As such, prosthetists and prosthesis users might be willing to bear the costs themselves until such time as reimbursement was available if the benefits were sufficiently meaningful.

Reimbursement justification was one obvious use for quantitative data about residual limb problems that necessitate socket/liner/suspension repairs or replacements. All the desired variables identified by participants (e.g. shear, moisture, duration of prosthesis use, step count, volume changes, amount of socket pistoning, consistency of socket fit, nerve activity, skin integrity, alignment, temperature and pressure) could be used to justify changes in the socket or prosthesis. The same data could also be used to alert users that a problematic change in socket fit has occurred (e.g. increased distal end pressure, increased shear) and should be acted upon quickly in order to avoid developing a residual limb problem. Such an alert could prompt the user with a recommended adjustment or to contact their prosthetist. A simultaneous alert could be sent to the prosthetist who could then provide guidance by email or text. Other data use was alluded to by prosthesis users' desire for better prosthetic technology; that is the ability to use socket monitoring to automate actuation of technologies that address socket problems like cooling, sweat evacuation, or volume adjustment. Many of these scenarios for data use would require the development of smart data analytics in conjunction with sensors [6]. An example of these type of analytics already emerging in prosthetics is related to the use of systems such as the Europa+ (Orthocare Innovations, Edmonds, WA) that assesses the dynamics of gait and recommends alignment changes via mobile app based on on-demand monitoring of distal socket moments [40, 41, 42].

In conclusion, focus groups were used to gather information from end-users of a residual limb monitoring system regarding their ideas for the features of a residual limb monitoring system. We confirmed that our participants experience the same types of residual limb problems as previously reported by persons with lower-limb amputation and discovered that temperature and pressure at the socket-limb interface were the most frequently mentioned measurements desired of a system, with short-term use preferred for trouble-shooting socket problems due primarily to prosthesis users' health concerns with sensor use and prosthetists' concerns with compliance with monitoring. In developing a residual limb monitoring system users insisted that the benefits of system use needed to outweigh any inconveniences and that an ideal residual limb monitoring system would be lightweight and not interfere with prosthesis function.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Implications for Rehabilitation

- Stakeholders suggested better managing residual limb problems through improved education, better detection of residual limb problems, and using sensor based information to improve prosthetic technology.
- Stakeholders favored short-term use of a possible system to troubleshoot residual limb problems, with temperature and pressure the most frequently mentioned measurements.
- Stakeholders described that an ideal residual limb monitoring system would be lightweight, not interfere with prosthesis function, and result in benefits with regard to prosthetic care and socket function that outweighs any inconveniences or concerns regarding system use.
- Stakeholders indicated that a potential positive of system use included having objective data for reimbursement justification, although it was pointed out that the residual limb monitoring system itself also needed to be reimbursable.

Table 1

Focus group guiding questions and resulting codes and themes

Questions	Resulting Codes	Themes
1. What problems or issues do you experience with your residual limb?	Discomfort Hygiene Pain Sensation Skin Temperature Volume	Residual Limb Problems (RLPs)
2. What do you do when you experience problems with your residual limb?	Communication Education Influencing Factors Patient-reliability Problem Solving	Management of RLPs
3. What could be done to help you better manage your residual limb problems?	Better Education Detection Objective Information Technology	Proposed Methods to Better Manage RLPs
4. If your residual limb health could be measured and monitored, what would you like to see measured or monitored?	Desired Measurements Length of Use Measurement Sites Sensor Characteristics Sensor Location	Vision for a Residual Limb Monitoring System (RLMS)
5. People now use devices like a Fitbit or pedometer to measure and monitor health and fitness related activities such as sleeping habits or distances walked in a day. How would you feel about wearing some kind of electronic sensor system to measure conditions such as pressure, temperature or moisture?	Potential Benefits Potential Inconveniences Health Concerns Reimbursement Justification	Receptivity Towards a RLMS
6. If this type of information were available, how would you want to view it (e.g. on your iPhone)?	Alert Data Collection Data Sharing Data Storage Data Viewing	Suggestions for Configuration of RLMS
7. Are there any circumstances where you think this type of information might be useful?	System Goals	Vision for a RLMS
8. As our last question, I'd like to ask each of you to summarize what we have talked about today. Imagine that you have one minute to tell the President what we've talked about today. What would you say?		

Table 2

Focus group participant characteristics.

Subject	Certified Prosthetist Group			Prosthesis User Group		
	Gender	Practice Setting*	Years as a CP/CPO	Gender	Amputation Level	Etiology/ Years since amputation
1	F	a	4-5	F	TTA	trauma < 1
2	F	c	4-5	M	TTA, PFA, TRA, PHA	infection 10
3	M	c	4-5	F	TTA	congenital > 40
4	M	b	5	F	TTA	trauma 15
5	F	c	9	F	TTA	vascular 12
6	M	c	13	F	TFA	trauma > 20
7	M	b	33	M	TFA	trauma 13

* Practice Setting: a. Multi-facility orthotics and/or prosthetics practice, publicly owned; b. Multi-facility orthotics and/or prosthetics practice, privately owned; c. Hospital or rehabilitation center [43].
F=female; M=male; CP=Certified Prosthetist; CPO=Certified Prosthetist-Orthotist; TTA=transfemoral amputation; PFA=partial foot amputation; TRA=transradial amputation; PHA=partial hand amputation; TFA=transfemoral amputation.