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Lower-limb amputee needs assessment using multistakeholder focus-group approach

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Abstract—To assess the needs of lower-limb amputees and identify differences between diabetic dysvascular amputees and traumatic amputees, we held a multistakeholder focus-group workshop whose participants included veteran lower-limb amputees, clinicians, researchers, and prosthetic device manufacturers. We conducted the initial workshop sessions as traditional focus-group meetings with homogeneous participant groups generating lists of issues relevant to the individual groups. Subsequent sessions assembled heterogeneous participant groups for a two-phase approach: Discovery and Codesign. The Discovery phase used observation and discussion to elicit specific needs. The Codesign phase focused on emergent topics and explored potential solutions. The participants identified needs associated with desired improvements to the socket system, foot and ankle components, and alignment with the residual limb. One need was a comprehensive understanding of the recovery path following amputation that could be addressed through enhanced education and communication. Another need was remote monitoring systems that could potentially improve quality of care. No dichotomy of needs between diabetic dysvascular amputees and traumatic amputees was evident among the participants of this workshop. The lively, open-ended discussions produced numerous suggestions for improving amputee quality of life that are listed to facilitate future research and development.

Key words: amputation, amputee, artificial limb, diabetes, focus group, lower limb, needs assessment, prosthesis, rehabilitation, trauma.

INTRODUCTION

The loss of a lower limb can profoundly influence an individual's quality of life (QOL). Observations of lower-limb amputees showed limited mobility, greater metabolic demands, and a disproportionately high incidence of pain and discomfort in comparison with nondisabled individuals [1–4]. Identifying and prioritizing the needs of lower-limb amputees may, through meaningful research and development, improve technology and care that result in a higher QOL.

Importantly, the needs themselves and their priority may depend on individual patient characteristics. One section of the population of lower-limb amputees is older and at greater risk for diabetes and vascular disease than the general U.S. population [5–8]. The Veterans Health Administration performs about 5,000 lower-limb amputations each year on patients with these characteristics [7].

Abbreviations: LLANA = lower-limb amputee needs assessment, NIDRR = National Institute on Disability and Rehabilitation Research, QOL = quality of life, VA = Department of Veterans Affairs.

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In contrast is another group who have been injured in the current military conflicts in Iraq and Afghanistan. Currently fewer than one thousand in number [9], these patients are likely to be younger [10] and to have met military standards of physical fitness prior to amputation [11]. While the disparity between these two patient populations is readily apparent and some of their needs may be mutually exclusive, other needs may extensively overlap.

Consensus conferences are one approach to assessing needs and setting priorities for topics of broad public health importance. In recent years, several such conferences have been convened with the mission of defining and prioritizing issues important to lower-limb amputees [12–16]. These conferences employ plenary and breakout sessions and rely on both published evidence and expert opinion to form a consensus statement.

An alternative approach to exploring the needs of a homogenous group of patients involves the use of focus groups. A permissive environment and skilled facilitators can enable the participants to share opinions and perceptions through a variety of discussion formats. Carefully planned group interviews and discussions can encourage participants to interact and allow insights to coalesce into findings [17]. The choice and selection of focus-group participants are key elements of the approach and can define the scope of the findings. As care and self-care of the lower-limb amputee are both multidisciplinary and lifelong, potential focus-group participants could include prosthetic users; physiatrists; prosthetists; researchers; prosthetic device manufacturers; psychologists; and allied healthcare providers, such as physical therapists and nutritionists. Expanding beyond the traditional single-stakeholder focus-group approach to include additional stakeholders in amputee healthcare necessitated a more comprehensive method of eliciting needs and concepts for solutions.

This article presents and discusses the results of a lower-limb amputee needs assessment (LLANA) workshop held in Seattle, Washington, on October 30 and 31, 2007. The workshop identified the needs of lower-limb amputees and captured the concepts, choices, and decisions that emerged within both homogeneous and heterogeneous discussion groups. Veteran prosthetic users' perspectives were balanced through the participation of clinicians, researchers, and prosthetic device manufacturers using a multistakeholder focus-group approach.

METHODS

The workshop had three goals. The first goal was to qualitatively assess, with specific details, the needs, concerns, interests, and perspectives of the prosthetic users about the performance of their devices. The second goal was to assess a basic working hypothesis in research and development that the needs of diabetic dysvascular amputees are different from those of traumatic amputees. The third goal was to hold open-ended discussions on emergent issues that could shape future directions of research and development across the different professions represented at the workshop.

Representatives from four groups participated in the 2-day workshop: veteran lower-limb prosthetic users (n = 5 diabetic dysvascular amputees [mean ± standard deviation = 63 ± 6 years; 4 unilateral transtibial and 1 bilateral transtibial], n = 7 traumatic amputees [53 ± 16 years; 4 unilateral transtibial, 2 unilateral transfemoral, and 1 unilateral knee disarticulation]), clinicians (n = 3 prosthetists and n = 3 physiatrists), researchers (n = 9), and prosthetic device manufacturers (n = 4). All workshop sessions were moderated and recorded by personnel from Water Cooler Logic Inc or from one of the two sponsoring Department of Veterans Affairs (VA) Rehabilitation Research and Development Centers. The multistakeholder modified focus-group approach used in the workshop was developed by Water Cooler Logic Inc in collaboration with the VA beginning in 2001. The process, known as Water Cooler Logic©, is a method of qualitative discovery, research, and social intervention that integrates the aims and principles of change management with organizational learning. Water Cooler Logic is built on realities within the social dimensions of work, learning, and knowledge. This approach also identifies and leverages the largely unrecognized contributions of informal work and learning. We summarize the approach in the following paragraph.

We conducted initial workshop sessions as focus groups with homogeneous populations that produced lists of needs. Subsequent sessions used several other formats that brought the members of the four groups into common discussions and produced both more detailed needs statements and preliminary concepts for solutions. The organization of the subsequent sessions was based on the first two phases of the Water Cooler Logic process: Discovery and Codesign. The Discovery phase is the observation and discussion of issues by current or potential prosthetic

users of a technology or those who either affect or will be affected by it. The Codesign phase begins with the use of divergent thinking by participants to scan a wide range of options, followed by convergent thinking to classify and group the resulting possibilities into practical solutions and products. We chose the specific session formats to create a gradual progression from the elicitation of needs and concerns (Discovery [Day One]) to discussion of specific design ideas (Codesign [Day Two]). The workshop progressed through the following formats: (1) open-ended, facilitated discussions among like-member groups (i.e., prosthetic users, clinicians, researchers, manufacturers); (2) three-person interviews, in which members from one group were interviewed by two others from different groups; (3) sessions in which small groups focused on emergent topics; and (4) informal café-style discussions, proposed and organized by interested participants, on self-chosen topics at the end of the workshop.

Plenary reports were presented following each discussion period. Facilitators scribed the plenary presentations, posted large-print summaries, and took additional notes on the discussions prior to the plenary sessions.

RESULTS

Discovery (Day One)

Veteran Lower-Limb Prosthetic Users

While generally positive about their mobility, all prosthetic users had difficulties or problems at all stages in the processes of selecting, fitting, customizing, and using their prosthesis. Specific problems cited included socket fit, lack of flexibility and function in the ankle and foot components, alignment, attachment or suspension, and usability. Concerns also emerged regarding prescriptions that were not integrated optimally across all components and problems with maintenance and longevity. Many prosthetic users expressed concern about limited access to new prosthetic devices and the need for comprehensive rehabilitation services that treat each amputee as an individual.

Clinicians

Three physiatrists and three prosthetists identified two broad areas in which either gaps in knowledge or current guidelines inhibit cohesive, consistent clinical practice. First, little is known about how amputees actually use their prostheses. Other than self-report, limited information exists on duration of use, level or amount of activity, or details on specific activities performed during prosthesis use (e.g., ambulating on stairs, hills, uneven terrain). Second, no common national guideline exists in the United States for the continuum of prosthetic care from prescription to physical and occupational therapy. The clinician group also noted that the social and psychological well-being of patients preamputation has not been adequately addressed. Ineffective communication may also affect the success of care because the fundamental aspects of prosthetic fit have a different meaning to the different stakeholder groups.

Researchers

The research group members identified three key areas in which existing knowledge is limited. The first area involved aspects of the user experience. Little is known about the spectrum of use, the amputee "lifestyle," and psychological states. The researchers noted both a need for an appropriate match between technology and the needs of the individual patient and that control of advanced prostheses should be intuitive. The second area was specific to the prosthesis. Many problems with prostheses remain challenging because of the difficulty in measuring stability, socket fit, and socket comfort. Last, the role of economic factors in prosthetic prescription decisions has not been adequately studied.

Manufacturers

Prosthetic device manufacturers indicated that relatively few opportunities exist for them to communicate directly with amputees on prosthesis design, development, or performance. The time for information to travel from the clinic to the industrial designers can be very long. Also, an unrecognized issue is that manufacturers, payers, and clinicians are all involved in a large cycle, but the prosthetic user is rarely part of it.

Summary

Following the homogeneous group discussions, the needs and concerns were classified into four areas as presented in **Table 1**: technical goals, education, communication and collaboration, and system of care.

Codesign (Day Two)

The highest priority topics emerging from Day One formed the subjects of the 11 1-hour Codesign sessions

Table 1.
Key needs of participating stakeholder groups.

Group	Category of Need			
	Technical Goals	**Education**	**Communication & Collaboration**	**System of Care**
Prosthetic Users	Ideal "adaptable" socket and suspension system that adjusts to heat, activity, and variation in limb shape. More functional feet and ankles to accommodate greater variety of terrain, activity, and footwear types. Improvements to alignment systems.	Information about available prosthetic devices, pre- and postoperative care, community involvement in rehabilitation (prosthetists, physical therapists, occupational therapists, chiropractors, etc.), and expected outcomes.	Community and information resources: Regular updates on support groups, networks of prosthetic users, and mentoring by other amputees.	Coordinated multidisciplinary care across all stages of rehabilitation. Access to new devices. Active case management.
Clinicians	Evidence on relationship between outcomes, alignment, prosthetic components, and amputation level.	Gait and alignment training.	Measurements of daily prosthesis use to guide prescription practice. Multicenter (large sample size) studies for evidence-based practice.	Standards to optimize surgical and rehabilitative care with freedom for individual case management.
Researchers	Adaptive socket technology, liner materials, cooling and evaporation systems, actuators and sensors, and alignment measuring systems.	Research translated into clinical guidelines.	Multicenter (large sample size) studies for evidence-based practice.	Automated monitoring of functional outcomes.
Manufacturers	Meaningful outcome measures for new innovations and technologies.	Continuing education for clinicians. New product awareness.	Clinicians' willingness to be open-minded.	Greater access to prosthetic users for assessing product requirements and performance.

shown in **Table 2**. Driven by the amputees' emphasis, socket design was addressed in 3 of 11 sessions. The second priority was foot and ankle function, covered in two sessions. Alignment issues also formed the focus of two sessions. Single-session topics included the recovery path from amputation, remote monitoring systems, communication and education among stakeholders, and the formulation of a workshop consensus statement.

Socket Design

The key functions of the socket are to translate force and motion and provide sensation and comfort. Ideally, a socket should offer temperature, moisture, and shape control; ease of handling (i.e., easy to put on and adjust); good suspension to effectively connect limb, prosthesis, and ground; minimized potential of injury; and desirable cosmesis.

Currently, available sockets create problems associated with excess heat and humidity at the interface, do not adapt to the shape of the limb or its daily variations in

Table 2.
Codesign sessions. In round 1, each group spent 1 hour discussing topic and then returned to report their ideas to all. In round 2, groups could choose to continue topic from round 1 or begin anew. Finally, participants could host café-style sessions of about 30 minutes to continue discussing existing topic or start new one.

Round 1	Round 2	Café-Style Discussions
Socket Design I	Socket Design III	Remote Monitoring Systems
Socket Design II	Recovery Path	Connections: Getting Stakeholders Together
Foot and Ankle I	Foot and Ankle II	Consensus Statement
Alignment I		Alignment II

shape and volume, require a fitting process that is painstaking and time-consuming, and can produce excess pressure and friction on the residual limb, which can result in problems with the skin and deeper tissue, discomfort, and pain. Parts for prosthetic sockets can wear out at different rates based on manufacturer and use, and once a part is beyond its normal life span, it may make the whole assembly unstable. These issues and ideas are not radically new, and a number of possible solutions can be, or have been, offered. However, socket systems problems have not been addressed in any systematic way, and an ideal "adaptive" socket has yet to be manufactured. Among the possible implementation barriers, participants cited lack of funding, small market size, high costs, unrefined technology, and intellectual property restrictions. They looked to availability of new materials as opportunities to reexamine old ideas. Most important, they saw the VA as an organization to take a long-term view of prosthetic technology, where investments of resources might not produce clinically meaningful results for 5 years or more. Participants agreed that progress will require collaborating across clinical, professional, and institutional boundaries; sharing knowledge; and creating tools and systems for unbiased objective evaluations of technology.

The participants in the Codesign sessions suggested that solutions to socket and suspension problems might take one of two approaches. First, adapting the limb to the socket might improve fit through vacuum-assisted suspension systems or perhaps a physiological or neurological intervention (speculation) that would cause the body to retain volume in certain areas. Second, adapting the socket to the limb could employ an automatic bladder system or even a mechanical buckle adjusted by the user. Both approaches would benefit from the development of an in-socket objective measurement of fit (or limb volume) rather than rely on user perception alone. **Figure 1** summarizes the needs generated in the three Codesign sessions on socket design and approaches to fulfilling them.

Foot and Ankle

In the Discovery sessions, the prosthetic users expressed a desire to extend their activities to running, cycling, hiking, and driving. These and other activities are often limited by the mechanical capabilities of prosthetic feet and ankles. In the Codesign sessions, disadvantages of current technology mentioned were lack of an ankle that allows donning and doffing boots, a foot that does not rotate to facilitate entering and exiting cars, and limited multiaxial motion that makes ambulation on uneven terrain difficult. Participants expressed concern that a "weight-balance trade-off" will always exist in whatever new technology is introduced. **Figure 2** summarizes the requirements and potential solutions developed in the two Codesign sessions on the prosthetic foot and ankle.

Alignment

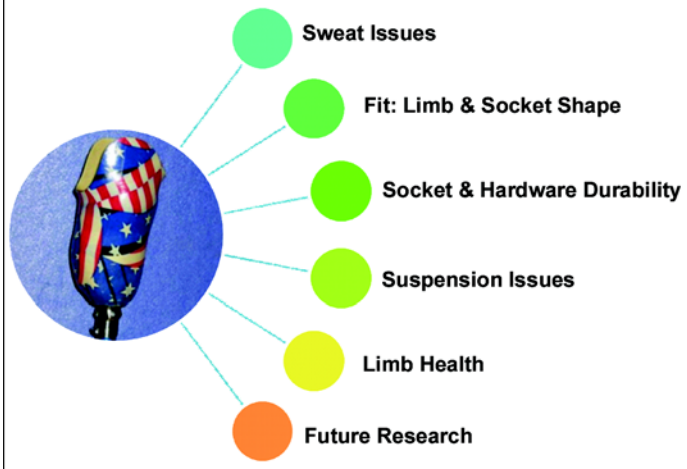
While all groups agreed that body alignment is crucial, the prosthetists expressed particular concern about the issues of aligning the individual components of prostheses. Researchers cited the importance of body alignment within the gait cycle as a contributor to optimal function of prostheses. **Figure 3** summarizes issues and concepts discussed in the alignment sessions.

Recovery Path

All groups, but especially the physiatrists and prosthetic users, strongly advocated for a more comprehensive understanding and better guidelines for an amputee's overall recovery path. Four phases of recovery were identified: preoperative care (for dysvascular amputees), surgery, postoperative care, and mentoring. For a person with diabetes, education on preventing amputation needs to be integrated into a total self-care regimen. Once the patient with diabetes has agreed to an amputation, education about the operation and its consequences must begin. In the case of a traumatic amputation, education must start immediately afterward. **Figure 4** summarizes needs and suggestions that arose in recovery path discussions.

Remote Monitoring Systems

Several participants organized a café-style discussion on the potential for remote measurement in overall prosthetic care. They saw both diagnostic and real-time feedback value in remote measurement technologies. Data on prosthetic usage (e.g., step count, magnitude of foot-ground reaction forces, number of falls and stumbles, moisture, socket temperature, wear time, and socket pressure) could become the basis for improved prostheses. Simple measures of durability and reliability could be used to provide "consumer reports" style evaluations. Advanced onboard systems could communicate with healthcare providers monitoring prosthesis use to signal events that would require intervention, such as replacement of device components. **Figure 5** summarizes the recommendations of the group that discussed remote monitoring systems.



Sweat Issues
- o Create sockets and/or liners of "breathable" materials
- o Develop cooling system involving liquids, gases, Peltier devices, catalysts, or kinetics
- o Physiologically eliminate sweating using pharmacological measures
- o Use psychological measures to reduce perceived discomfort

Fit: Limb & Socket Shape
- o Control limb volume, e.g., through isometric exercise
- o Adjust limb volume physiologically or neurologically. Trick body into retaining fluid in particular areas (research area)
- o Adapt socket to residual limb using polymers that react to magnetic fields, air bladders, and low-tech mechanical methods, such as buckles or laces that user can fine-tune

Socket & Hardware Durability
- o Improve fabrication techniques, quality, and compatibility of component materials
- o Require manufacturers to provide up-to-date information on liner modifications
- o Reduce wear on liners and sleeves by ensuring optimal socket fit
- o Educate amputees on liner care to lengthen life, reduce smell, and improve limb health
- o What is life of liner? How to care for it? (research area)

Suspension Issues
- o Reduce wear of pin-lock suspension system
- o Reduce donning and doffing times
- o Provide auxiliary suspensions for special activities, e.g., competitive sports
- o Develop mileage/dependability rating for suspension components
- o Improve vacuum-assisted suspension systems to be more user-friendly and easier to fit

Limb Health
- o Develop self-care hygiene protocol that best preserves skin integrity
- o Enable greater awareness of limb volume and moisture by employing existing or new sensors
- o Develop systems that detect pistoning between residual limb and prosthesis
- o Explore effectiveness of revision surgery
- o Explore use of bioengineered tissue instead of natural tissue (research area)

Future Research
- o Develop flexible sockets to maintain more natural range of motion
- o Explore alternative materials for limb-contacting surfaces
- o Study new materials that can make sockets more adaptable: magnetic-rheological fluid, phase change, pneumatics, piezoelectric polymers, shape memory, and disposable materials
- o Study other ways to connect to artificial limb: osseointegration, magnetic linkage, adhesive systems, and partial limb regeneration

Figure 1.
Key outcomes of Codesign sessions on improving sockets and suspension systems. Mixture of ideas are shown for approaching key problems of prosthetic socket and suspension systems. Issues are diverse and may best be handled through research, engineering, or clinical strategies.

DISCUSSION

The goals of this 2-day workshop were to assess the needs of lower-limb amputees, identify differences in needs between diabetic dysvascular and traumatic amputees, and describe future research and development intended to address these needs. The workshop was a guided cooperative effort of four stakeholder groups involved in amputee rehabilitation. These stakeholders were the prosthetic users themselves, clinicians, researchers, and prosthetic device manufacturers. One limitation of this approach is that only a small sample population represented each group of stakeholders. In addition, the somewhat unexpected emphasis on the recovery path following amputation revealed the absence of other involved stakeholders, such as psychologists and physical therapists.

The LLANA focused qualitatively on the needs, concerns, interests, and perspectives of users with regard to the performance of their prosthetic devices. Socket and suspension issues have been a long-standing topic of research and development in the prosthetics field. The National Institute on Disability and Rehabilitation Research (NIDRR) Rehabilitation Engineering Research Center on Prosthetics and Orthotics conducted a state-of-the-science meeting entitled "Research in prosthetics and orthotics: Are we addressing clinically-relevant problems?" in February 2006 [12]. This meeting identified issues that are of interest to prosthetists and orthotists but not currently receiving sufficient research attention. A consensus among the approximately 50 clinicians and researchers was that a better understanding is needed of how socket design affects fit, suspension, and comfort.

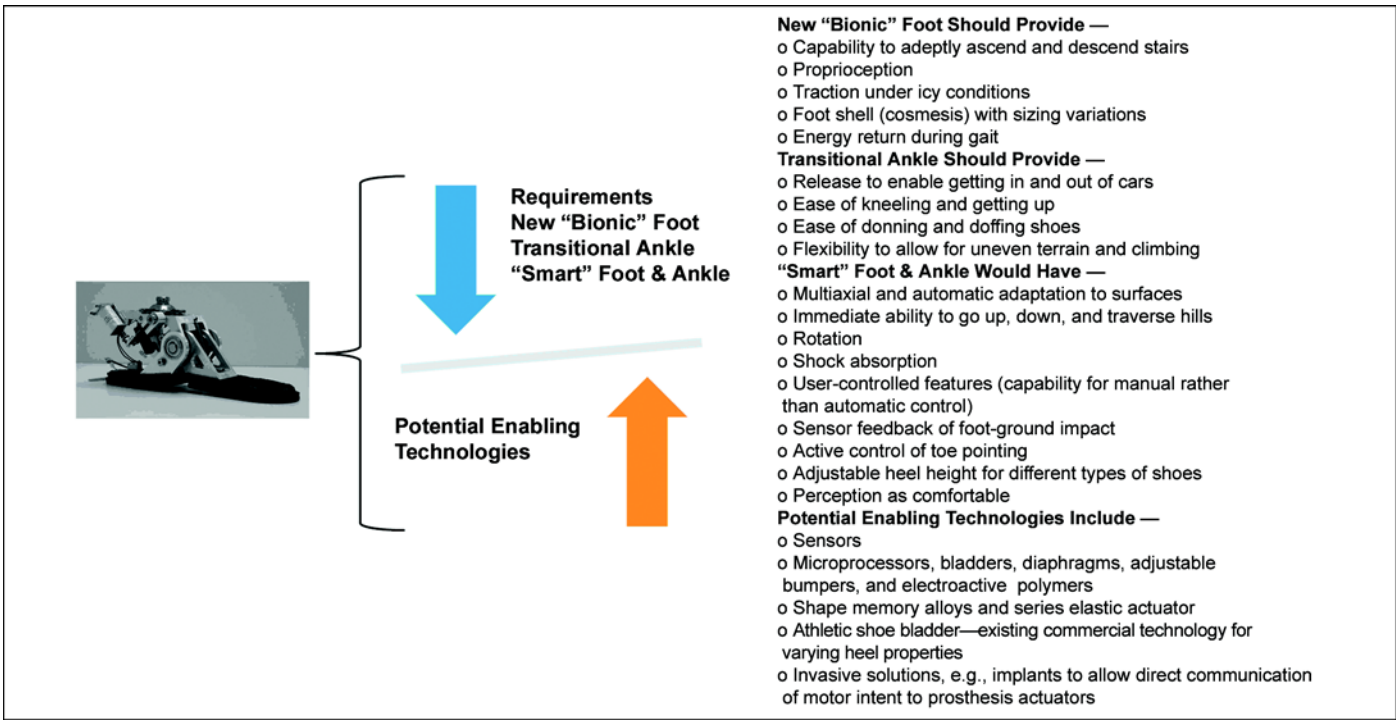


Figure 2.
Key outcomes of Codesign sessions on improving prosthetic foot and ankle. Sessions focused on delineating requirements that prosthetic users proposed for improved feet and ankles.

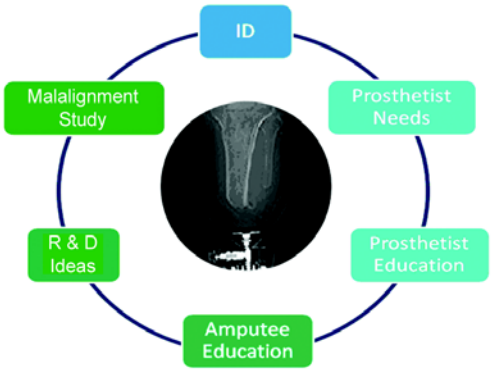
The attendees also agreed that a better understanding is needed of the relationship between limb shape, suspension choice, and alignment. The findings of the LLANA workshop concur with these results.

One of the key barriers to socket system improvement is measuring subjective metrics. Fit, comfort, and stability are difficult to quantify but necessary for product development or comparison. A 3-day consensus conference on outcome measures in lower-limb prosthetics attended by 17 clinicians and researchers highlighted the problem of obtaining reliable results [13]. Participants agreed that a better understanding is needed of how to use existing instruments to predict and optimize amputee rehabilitation, compare existing socket systems, and develop improvements.

The LLANA workshop participants suggested that improving sockets and suspension will rely on understanding and defining the fundamental problems, that new instruments are needed to provide appropriate metrics and that further experiments with new technologies represent the next step. A planned state-of-the-science conference by the American Academy of Orthotists and Prosthetists on the lower-limb socket interface will likely facilitate further development [18].

Issues with the foot and ankle have also been long-standing topics of research. The foot and ankle mechanisms session at the NIDRR consensus meeting also addressed the following: attendees agreed that articulating and propulsive feet are an enhancement needed for currently available prosthetic feet [12]. Furthermore, both this consensus meeting and another [15] concluded that a need exists for real-world testing of prosthetic components with metrics related to daily use to provide clinicians with useful information. LLANA workshop participants echoed these findings with discussions of numerous design objectives and suggestions for real-world test environments.

Beyond issues related to socket design and prosthetic foot and ankle interventions, topics also emerged on alignment, the recovery path following amputation, and remote monitoring systems (measurement, diagnosis, and feedback). Alignment remains a challenging problem for clinicians, because separating socket-limb alignment issues from component alignment issues can be difficult. The daily alignment process also remains challenging for



ID
- o Alignment problems are difficult to separate from socket and component problems
- o Pin alignment is not precise or consistent
- o Daily donning variations (user alignment changes) affect overall alignment
- o Manufacturer's preferred alignment settings are designed to maximize durability, not necessarily performance

Prosthetist Needs
- o Better understanding of alignment at all amputation levels
- o Better understanding of how different lifestyles and performance at different levels affect alignment choices
- o Modeling to decide among many different possible ways to adjust components

Prosthetist Education
- o Gait alignment training and resources
- o Ways to reduce or prevent limb volume fluctuations and effect on alignment
- o Ways different components require different alignment

Amputee Education
- o Effect of alignment issues on amputee function
- o Prosthetist's vocabulary to improve communication
- o Care, use, and adjustment of prosthesis
- o Instructional videos

R & D Ideas
- o Develop protocol to identify and achieve recommended alignment—Multicenter study?
- o Predict modeling
- o Study effect of pseudojoint on alignment
- o Study gait and alignment using standard measurement techniques: photography, video, laser X-rays, gait kinematics, electromyography, pressure sensors, force plates, and energy cost measures
- o Use animation technology as a teaching tool for clinicians and prosthesis users

Malalignment Study

Study relationship between amputation level, prosthetic foot-ankle, and malalignment of—
- o 2° dorsiflexion
- o 2° plantar flexion
- o 2° inversion
- o 2° eversion

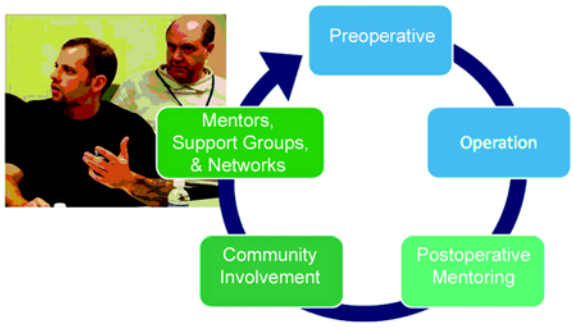
Figure 3.
Key outcomes of Codesign sessions on alignment. Prosthetists and manufacturers were principal stakeholders concerned with alignment issues. ID = Issues Identified, R&D = Research & Design.

prosthetic users because it is neither precise nor consistent. The degree of malalignment and its effect on outcomes are also open questions. Many variables contribute to an optimal alignment, yet the sensitivity of these variables to outcome metrics is unknown.

Prosthetic users clamored for more information on the recovery path following amputation. They recommended amputees be given comprehensive information about the entire process to understand their treatment, rehabilitation, and the range of possible outcomes. They wanted to know who could best help them and what their choices might be. Few had mentors or participated in support groups but most desired the opportunity. All agreed that the ultimate responsibility for their care lies with themselves, emphasizing why detailed information about each phase in the recovery path is so important.

Participants of the café-style session on remote monitoring systems suggested numerous ideas for new products and devices that might improve amputee care. They suggested systems that could indicate alignment problems, predict and prevent residual-limb skin injuries, optimize prosthesis performance, and track actual use. The participants were mindful of data security issues and concerns regarding selection of data recipients but felt the clinical use of remote monitoring would resolve issues of privacy naturally.

The second goal of the LLANA workshop was to identify differences in needs between diabetic dysvascular and traumatic amputees. While these two groups have great differences in etiology, the differences did not manifest in needs between the two amputee groups participating in the workshop. Neither the Discovery (Day One) nor the Codesign (Day Two) session produced any meaningful discussion regarding the working hypothesis that differences exist between these two groups that should translate to differences in their rehabilitation. One veteran prosthetic user explained this quite well with the statement "My amputation was due to my diabetes, but it was



Preoperative
- o Show video on operation, recovery path, treatment, and possible outcomes
- o Introduce patient to support and peer groups and possible mentors
- o Provide lifestyle advice (e.g., what to expect, how to prepare for change)
- o Include family members!

Operation
- o Understand surgical options
- o Understand healing times
- o Understand prosthetic options
- o Include family members!

Postoperative Mentoring
- o "It is not so bad"
- o "I can function as I wish without buying a wheelchair or redoing house"
- o "I can get back to my job and I have rights as a disabled person"
- o "I can get financial assistance"
- o Include family members!

Community Involvement
- o Physical therapist helps strengthen muscles and teaches standing and walking posture
- o Prosthetist gets patient walking with or without cane
- o Peer group—other amputees can tell patient how to adjust and improve functional abilities
- o Others can help in recovery (e.g., massage therapist, chiropractor, and trainer)
- o Ultimate responsibility lies with amputee; that is why having knowledge is so important!
- o Case management is needed to integrate different clinician and caregiver functions

Mentors, Support Groups, & Networks
- o Match mentors to new amputees based on age, activity level, expectations, and etiology
- o Join or start mentoring program to pass on what patients know and help others via VA, Amputee Coalition of America, Web sites, and blogs (e.g., Disaboom.com)
- o Share information and tricks for success, improve mental health, and involve family and friends
- o Participate in athletic activities (e.g., Special Olympics, Paralympic Games, and Senior Games)
- o Attend annual rehabilitation, orthopedics, or diabetes meetings
- o Offer potential network participants options to be involved in research, product testing, mentoring, and support groups

Figure 4.
Key outcomes of Codesign session on recovery path for amputees. Mostly veteran prosthetic users and clinicians participated in these sessions. VA = Department of Veterans Affairs.

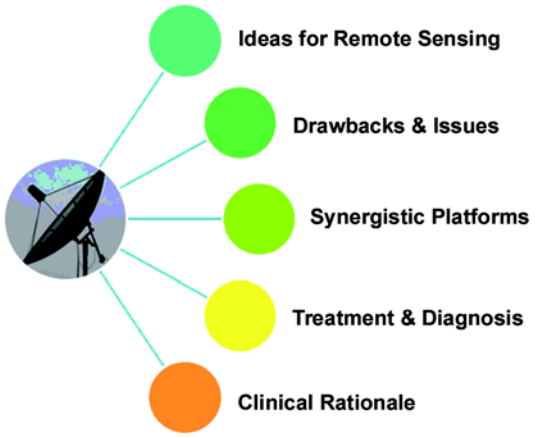
traumatic to me." We identified no mutually exclusive issues, only issues of graded importance between the diabetic dysvascular and traumatic amputees.

The third goal of the LLANA workshop was to describe future research and development directions that would provide solutions to the unmet needs of lower-limb prosthetic users. The participants suggested four areas of need: technical goals, education, communication and collaboration, and system of care.

Technical goals for future research are related to the persistent, unmet needs of prosthetic users. These needs include fit, comfort, function, stability, and performance. Research must also define functional outcome measures and relate them to subjective dimensions of prosthetic use. Dissemination might take the form of a "consumer reports" publication with research results on both new and currently available prosthetic components to help users and clinicians decide on appropriate prescriptions.

A future emphasis on the education of prosthetic users and their families is needed to allow them to be more informed consumers about prosthetic interventions, their own rehabilitation, vocational training, and lifelong fitness. Suggested approaches included short instructional videos that introduce technical terms and demonstrate healthy biomechanics, consumer-oriented publications that include technical glossaries, support groups, mentoring networks, and informational Web sites. Clinicians also need expanded educational opportunities to learn how to incorporate new technologies and research results into clinical practice. Suggested approaches included conferences, publications, workshops, technology evaluations, and Web sites.

All stakeholder groups felt that enhanced collaboration and communication could improve future lower-limb amputee care. Evidence-based guidelines demand larger sample populations, which in turn require multisite experimental protocols. A 2-day consensus conference on the



Ideas for Remote Sensing
- o Measure normal baseline pattern—pattern deviations would send alert
- o Include metrics such as alignment, orientation, step count, turning rate, temperature, pH, moisture, bioimpedance, and hours worn
- o Could use orientation as fall detector
- o Provide capability for user comments (i.e., voice recorder for specific events)
- o Base motivation and marketing to payers on reducing injury and costs
- o Consider open source standard and data bus design

Drawbacks & Issues
- o Cost of monitoring data
- o Level of automation (e.g., triggers that would notify caregivers)
- o Reimbursement (create current procedural terminology codes)
- o "Big Brother" concerns—report to physician/provider or report to user only?
- o Who can turn system on or off?
- o Data security and protected health information (Health Insurance Portability and Accountability Act [HIPAA])
- o User may not take enough responsibility
- o Waterproof
- o Complexity
- o Durability
- o Reliability
- o Power requirements: batteries, battery charging, and kinetics
- o Weight vs function, power, and size
- o Fee-based

Synergistic Platforms (Related Applications)
- o Diabetic shoes—ulcer hotspots
- o Wheelchair seating
- o Elderly or Parkinson patient monitoring
- o Search and rescue signals (e.g., natural disasters, outdoor enthusiasts)
- o Automobile On-Board Diagnostic systems
- o Military and space applications
- o Remote weather and irrigation systems
- o Software updates (e.g., microprocessor knees)

Treatment & Diagnosis
- o Capability of reprogramming prosthesis in field (e.g., microprocessor knees)
- o Local adaptation

Clinical Rationale
- o Averts visits to prosthetists
- o Minimizes downtime
- o Encourages replacement of liners before they cause skin breakdown
- o Enables monitoring agency to continually assess function, reliability, and durability of prostheses

Figure 5.
Key outcomes of café-style session on remote monitoring systems. Researchers were enthusiastic about this topic and assembled notes on why and how to develop remote monitoring systems for lower-limb amputees.

biomechanics of partial foot amputation reached a similar conclusion [14]. The attending 11 clinicians and researchers concluded that small sample sizes result in insufficient experimental evidence to justify prescribing interventions. Larger sample populations would also strengthen recommendations and help validate standards. Likewise, the workshop participants opined that clinical practice would benefit from guidelines across the continuum of amputee care. Such guidelines would provide an outline for care with sufficient autonomy of practice. The continuum of care is expansive, extending from preoperative care through prescription practice and to vocational and recreational training. Importantly, the process must be able to introduce the latest knowledge into clinical education.

To improve the QOL and rehabilitative care of lower-limb amputees, an ongoing and comprehensive system of care is needed to match the wide spectrum of technical prosthetic solutions with the wide spectrum of users and their lifestyles. Clinicians, prosthetists, and manufacturers need to work together with the amputee to ensure optimal outcomes. Support groups and amputee mentoring can provide the amputee and his or her family with invaluable peer information.

CONCLUSIONS

The multistakeholder focus-group workshop convened to assess the needs of lower-limb amputees, and it identified issues with the socket system, the foot and ankle components, and alignment with the residual limb. Needs associated with the socket system included

improving patient comfort, solving problems associated with limb and socket shape, enhancing durability, and preventing injuries. Needs for the foot and ankle components included propulsive systems, proprioceptive systems, and enhanced ability to perform daily activities such as donning and doffing shoes and walking on uneven terrain. Alignment needs included better tools for clinicians, improved communication between amputees and clinicians, and knowledge about the relationship between alignment and outcomes. Also among the needs of the lower-limb amputees was a comprehensive understanding of the recovery path following amputation. The amputee has the last word on his or her own care. Understanding the treatment options, rehabilitation process, and range of possible outcomes is essential for effective case management. Finally, the need for remote monitoring systems may exist and could provide a cost-effective QOL improvement for the amputee. Importantly, we found no dichotomy in needs between the diabetic dysvascular amputees and the traumatic amputees identified at this workshop.

The Water Cooler Logic approach facilitated, guided, and documented open-ended discussions on emergent issues that produced numerous suggestions for research and development. Advances in technology and componentry were deemed as important as patient education and awareness of the amputation recovery path as a means to improve amputees' QOL. Many participants expressed the desire to meet again to extend these discussions and include other experts, such as psychologists.

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