JRRD Volume 51, Number 1, 2014
Pages 1–14

Considerations for development of sensing and monitoring tools to facilitate treatment and care of persons with lower-limb loss: A review

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Abstract—Sensing and monitoring technologies offer enormous potential to enhance the quality of healthcare provided to persons with lower-limb loss. Incorporation of these technologies into the rehabilitation process creates opportunities for a multidimensional exchange of timely, relevant, and meaningful health information between patients, their prostheses, and healthcare providers. Here, the authors envision a conceptual model for enhancing prosthetic rehabilitation through use of integrated physical and/or biological sensors and remote monitoring methods. Several specific applications that target treatment, diagnosis, and prognosis of health issues faced by persons with limb loss are proposed in an effort to demonstrate how collecting and using objective data can facilitate clinical decision making. Contemporary integrated sensors that may be used in these applications are reviewed and their limitations discussed. It is hoped that the considerations proposed here may serve to stimulate development of clinically useful monitoring and sensing technologies and promote their integration into routine amputation rehabilitation.

Key words: ambulatory monitoring, amputee, diagnosis, limb loss, outcome assessment, prognosis, prosthesis, remote sensing technology, therapy/treatment, wireless sensors.

BACKGROUND

Recent estimates suggest that more than 1.75 million people living in the United States have experienced limb loss, primarily resulting from dysvascular disease, trauma, or cancer [1]. Moreover, the prevalence of limb loss is expected to more than double (to 3.6 million people in the United States) over the next four decades as the population ages and the expected increases in adverse health conditions such as obesity, diabetes, and dysvascular disease manifest [1–3]. Although digit (i.e., finger or toe) amputations comprise a majority of these estimates, approximately 42 percent of these cases are considered to be “major” limb amputations that occur in more proximal areas of the body. Furthermore, most (i.e., more than 90%) major limb loss occurs in the lower limb proximal to the toes [1]. Given the critical role that the lower limb plays in balance, transfers, and ambulation, it is not unexpected that severe physical impairment in the lower limb significantly decreases an individual’s ability to function at home and in the community [2–4].

Recovery from major limb loss is a lifelong, personal struggle that requires the attention and experience of a multidisciplinary clinical team of physicians, therapists, and prosthetists [5]. Rehabilitation following an amputation commonly includes the prescription of a prosthetic limb in an effort to address patients’ specific functional, vocational, and recreational needs. However, even with the use of a prosthesis, persons with lower-limb loss face a lifetime of functional limitations and continual health threats, including decreased balance [6–10]; increased metabolic energy expenditure while walking [11–13];

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http://dx.doi.org/10.1682/JRRD.2013.01.0024

decreased walking speed [12,14–15]; gait asymmetries [14,16–17]; increased frequency of stumbles and falls [9,18]; reduced activity level [19–21]; difficulty negotiating uneven terrain, hills, and stairs [5,22–24]; skin breakdown [25–27]; joint degeneration [28–30]; and pain [31–34]. These issues collectively contribute to a significantly reduced health-related quality of life [25,35–38] among individuals with lower-limb loss when compared with individuals without amputation [39–40]. From a healthcare system perspective, the postamputation rehabilitation process is also time-consuming [4] and expensive [41]. Therefore, strategies and/or tools to facilitate the treatment and lifelong management of limb loss are needed to address the medical needs of this rapidly growing patient population.

Postamputation rehabilitation is intended to address patients' functional needs through therapeutic (e.g., gait training) and prosthetic (e.g., specific components) interventions as well as to mitigate medical conditions (e.g., skin breakdown) that threaten patients' long-term welfare. The selection of appropriate and timely rehabilitative interventions traditionally relies upon the experience of the clinician with input from the patient. This "experience-based" approach to amputee care may be visualized as a one-dimensional exchange of information between the practitioner and patient during regularly scheduled clinical visits (**Figure 1**). The information obtained may include the patient's physical presentation, results of administered clinical tests, and/or subjective responses to posed questions. These insights enable the practitioner to assess a patient's status, observe longitudinal changes, and make treatment recommendations. These data are often collected retrospectively, infrequently (i.e., during scheduled visits), and in a controlled clinic environment that may not well reflect real-world conditions (i.e., a patient's free-living environment). Experience-based care is also predicated on patient self-report and, as such, may be affected by limitations inherent in subjective survey instruments, such as generalization, comprehension, perception, honesty, and recall [42–46]. These concerns may be pronounced among persons with limb loss who experience cognitive impairments due to diabetes [47] or peripheral arterial disease [48]. Ultimately, these compounding issues may precipitate a reactionary and iterative approach to amputee care that is inefficient, time-consuming, and expensive.

An extension of experienced-based care (as described previously) is an evidence-based approach, where a practitioner develops a treatment plan through the use of both sound clinical experience and best available empirical evidence (**Figure 2**) [49]. The intervention is then applied and clinical outcomes are later evaluated and revised, as necessary, using feedback from the patient. Although this form of healthcare considers objective data (in the form of published research) in the derivation of the treatment plan, retrospective clinical assessment using traditional, in-clinic outcome measures [50] is still subject to those same limitations (i.e., subjectivity, infrequency of assessment opportunities, and compromised

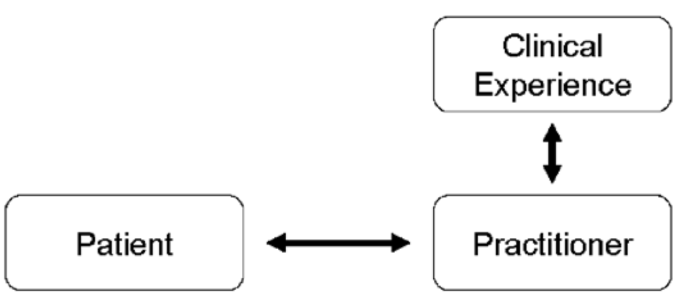

Figure 1.
Traditional model of amputee rehabilitation, where experience informs clinical decisions and is augmented by information obtained from patient.

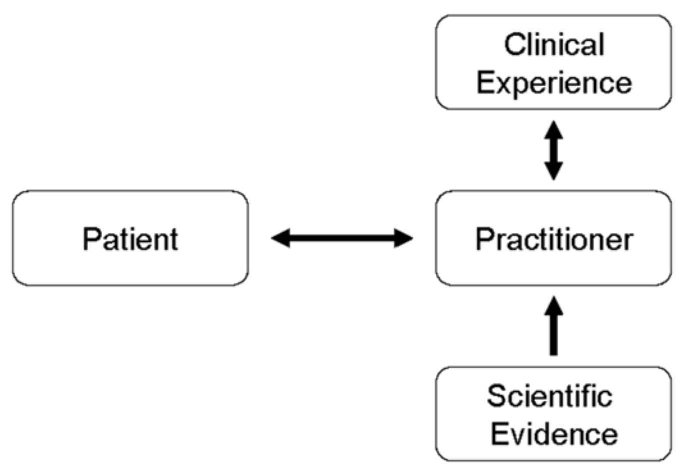

Figure 2.
Evidence-based model of amputee rehabilitation, where both scientific evidence and clinical experience are incorporated into clinical decision-making process, augmented by information obtained from patient.

cognitive status of patients) present in the aforementioned experience-based approach.

Limitations to these contemporary experience- and evidence-based models of care could potentially be addressed through direct and objective assessment of patients' outcomes *throughout* the rehabilitation process. Sensing and monitoring technologies have the potential to affect patient care by providing practitioners with the ability to monitor a patient's status, progress, and outcomes more frequently and could enable them to make more informed (and timely) decisions based on meaningful, objective data. The collected patient-specific information could then be used to help prescribe, change, and/or justify therapies and interventions and better ensure patients are receiving optimal care for their specific needs. Data obtained using sensing and monitoring technologies would complement clinician expertise and existing empirical evidence, thereby enhancing the overall quality of care provided to patients. Further, evidence obtained in this manner could be used to more efficiently and effectively allocate appropriate resources to a growing population of people facing acute physical limitations and medical issues.

The purpose of this article is to review existing solutions for collecting and using objective data to support and/or facilitate clinical decisions related to prosthetic rehabilitation as well as to suggest new strategies for applying this information in routine clinical practice. It is believed that the use of novel solutions for the purposes of restoring and optimizing function following limb loss will promote healthier lifestyles, improve quality of life, and decrease individuals' reliance upon physical, personal, and financial assistance.

EXISTING STRATEGIES AND TECHNOLOGIES

Periodic (e.g., pre- and postintervention) assessment of clinical outcomes is standard practice in most rehabilitation settings. However, continuous or perpetual assessment of outcomes in other settings (e.g., at home or in the community) is far less common. Advances in sensing and remote monitoring technologies have encouraged adoption of modern telemedicine solutions in wellness applications (e.g., weight loss and physical activity) and chronic conditions (e.g., diabetes, asthma, and heart failure) [51–54]. This form of healthcare offers a variety of potential benefits, including reduced numbers of clinical visits, reduced numbers of hospitalizations, reduced medical costs, and increased quality of life [55–57]. However, to date, application of remote monitoring technologies for the purposes of evaluating functional outcomes in areas such as amputee rehabilitation or prosthetic management has received little attention.

Conceptually, the use of remote monitoring technologies may be better suited to measuring functional outcomes in persons with limb loss than nondisabled users. Existing sensing devices are typically worn on the wrist, waist (i.e., belt), ankle, or other bodily location [58]. On nondisabled users, placement of the device in these locations often necessitates that the user remove and replace the device for activities such as bathing or sleeping. Nondisabled users may also selectively discontinue wear of a sensing device for aesthetic reasons (e.g., going out in public or formal dress occasions). As such, adherence to a regular protocol of removal and reapplication is needed to obtain useful, perpetual data.

For persons with limb loss, a prosthesis provides an ideal vehicle for sensing technologies, particularly for purposes such as ambulatory monitoring. Because a prosthesis is typically removed for sleeping and bathing, attaching sensors to or integrating them within a prosthesis seems to be a logical means to overcome the aforementioned compliance limitations to remote sensing identified in nondisabled users, especially because the modest addition of weight required for such devices would not appear to affect movement or energy expenditure [59–61].

Efforts to obtain and provide practitioners with information about prosthetic patients' activity in their free-living environments have resulted in the development of several different monitoring devices, only some of which are intended to be attached directly to a prosthesis. These existing products may be loosely grouped under two categories (i.e., accelerometer-based and strain-gage–based), depending on the device's inherent sensing technology.

Accelerometer-based devices have been used to approximate activity through measurement of step counts [62–65]. Data collected with accelerometer-based devices is collected perpetually, stored locally (i.e., on the unit), and then retrieved later. Numerous accelerometer-based activity monitors have been described in the literature [66]. Accelerometer-based devices require low power and accurately measure steps across a range of walking speeds. However, commercial step-monitoring devices developed to date have limitations. Step counts provide limited clinical information as to *how* the prosthesis is used or how activities affect the user. Thus, prosthetic interventions (such as shock-absorbing pylons or microprocessor-controlled prosthetic knees) that are designed to alter loading patterns, demonstrate no clinical effect when step counts are used as an outcome [67–68]. Further, because step monitors are sensitive, stand-alone devices, they must be properly oriented on the patient to collect accurate data. Failure to wear the device properly results in incomplete or erroneous information.

Recent advances in low-power sensor technologies and signal processing techniques have enabled researchers to overcome the aforementioned limitations and also to expand the capabilities of accelerometer-based devices to measure a variety of postural positions (e.g., sitting, standing, lying down) and physical activities (e.g., walking, sit-to-stand transitions) [69]. Modern accelerometers are now sufficiently sensitive to be used as inclinometers (e.g., to measure the angle of the pylon relative to vertical) [70]. Angulation data are proving clinically useful to help distinguish sitting, standing, walking, and doffing, facilitating characterization of amputee activity outside the clinic [71].

Strain-gage–based devices that are attached directly to the prosthesis have been developed to measure prosthetic pylon forces and moments [72–76]. Pylon force and moment data may provide information about gait abnormalities, prosthesis misalignment, or improper componentry that put the prosthesis user at risk of falling or other injury. Strain-gage devices require more power than accelerometer devices, but provide additional information (i.e., up to three forces and three moments) regarding how the prosthesis is loaded. Given the power required to operate strain-gage–based devices, they are used to collect data perpetually only when tethered to a power supply or run on batteries for short-term intervals (e.g., up to 7 h [iPecs Lab, College Park Industries; Fraser, Michigan]). Hence, strain-gage–based prosthetic sensors have been limited to short-term use in research settings [67–71]. Other limitations with specific strain-gage technologies may include relatively low and poor resolution (i.e., low bandwidth), crosstalk, and long-term fatigue. These issues may limit a sensor's ability to pick up high-frequency events, measure with accuracy, and/or operate reliably over extended periods of time.

For monitoring outside the laboratory for long-term intervals, other sensing technologies, such as piezoelectric sensors (e.g., triaxial ICP force sensor [PCB Piezotronics Inc; Depew, New York]) or limb-socket interface pressure sensors (e.g., Pliance [Novel; St. Paul, Minnesota]) require less power and thus may be capable of longer monitoring intervals. A number of research devices have been developed to monitor shear stress at interfaces [77–84], but none are commercially available.

Although the motivations for collecting perpetual, clinically relevant information in free-living environments using existing technologies (e.g., accelerometers, load cells) are sound, current solutions are limited in their ability to accurately and efficiently measure characteristics of clinical interest to a physical rehabilitation team (e.g., types and frequencies of activities performed, gait abnormalities that might identify imminent injury). Further, existing tools often require that the practitioner learn to use complex, customized software to retrieve and interpret the data collected by the device(s). Existing solutions do not align with the needs of an efficient practice and instead often add to the overall time and expense of care provided. Efforts need to be pursued to develop comprehensive, efficient solutions with simple, yet useful, user interfaces that allow practitioners (and/or patients) to quickly and easily retrieve and interpret information of clinical interest.

NEW PARADIGM AND POTENTIAL APPLICATIONS

To address the need for objective information to support and facilitate the rehabilitation of persons with lower-limb loss, efforts should target the development of systems that interface with and disseminate information from existing and emerging remote monitoring technologies. Such systems would include, at a minimum, a sensing component, a notification strategy, and management software. The sensing unit would obtain critical, objective information directly from the device (i.e., the prosthesis) prescribed to a patient. The notification strategy would make data available to the practitioner and patient at desired intervals. The management software would allow the practitioner and user to customize how and when the data are collected and made available. Integration of such systems into clinical practice would allow for a multidimensional, bidirectional exchange of information among the patient, the practitioner, and/or the device (**Figure 3**).

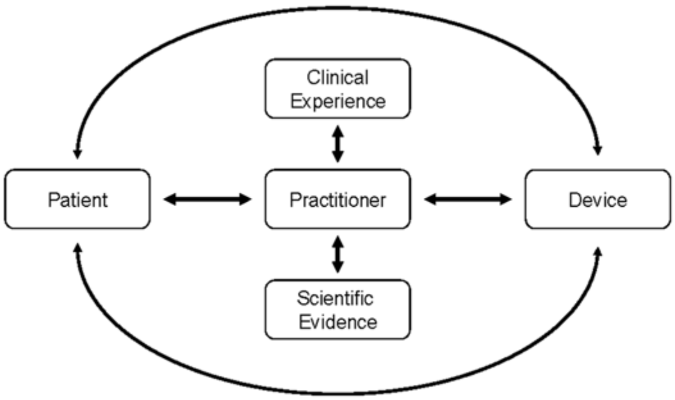

Figure 3.
Multidimensional model of amputee rehabilitation, where information is obtained from and exchanged between patient, sensing device, and practitioner. This model allows for practitioners to use objective information to make informed clinical decisions as well as potentially contribute data to growing body of scientific evidence.

A solution such as that presented here represents a paradigm shift in limb loss healthcare and offers advantages over current approaches to prosthetic rehabilitation that are based only on experience or evidence from the scientific literature. First, the practitioner can access the device to obtain knowledge of a patient's historical or present status in his or her free-living environment and community, thereby augmenting the patient-reported experience with valid and reliable data that is unencumbered with the limitations of subjective recall. Second, patients can access the device to evaluate their performance against practitioner-established goals for a personalized and interactive rehabilitation program. Engaging patients in this way is a strategy that has been recognized to improve physical activity [85] and is likely to benefit many aspects of amputee rehabilitation. Lastly, the device can monitor user performance for indications of adverse events, such as stumbles, suspension failure, or imminent skin breakdown and notify the practitioner and/or patient of unsafe behaviors. Ultimately, use of this system would be expected to better inform individualized treatment strategies and to help establish objective rationale for the prescription of specific prosthetic components intended to optimize a patient's function, health, safety, and quality of life.

The clinical applications for such a system are diverse. Here, we illustrate how one type of sensing technology (i.e., load or force sensors) could be applied to address clinical issues that span the traditional domains of evidence-based medicine (i.e., therapy/treatment, diagnosis, and prognosis). Load sensors were selected because of our familiarity with their features, limitations, and potential. However, other sensing technologies (e.g., other physical or biological sensors) could be similarly configured to address routine challenges encountered by members of the prosthetic rehabilitation team (i.e., the physician, therapist, prosthetist, and/or patient). It is hoped that these examples may stimulate discussion, development, and use of these and other sensors in prosthetic monitoring applications.

Therapy/Treatment

One application for the proposed sensing system is as a therapeutic monitor. A therapeutic monitor is used to facilitate and measure outcomes achieved through use of prescribed prosthetic interventions. When configured for such purposes, the sensing unit is temporarily or permanently integrated into the patient's prosthesis (depending on the desired length of observation) and measures important clinical outcomes, such as activity, residual-limb loads, or daily use of the prosthesis. Once the sensor is affixed to or integrated into the prosthesis, the practitioner works with the patient to establish meaningful and realistic rehabilitation targets for the outcomes of interest. The management software is then configured to record the patient's daily, weekly, and/or monthly outcomes. The notification system uploads the desired data to a server and presents it with respect to established targets using a Web-based graphical user interface. The notification frequency can be easily adjusted to suit the needs of the practitioner and/or patient. For example, the patient may desire daily updates on his or her progress, while the practitioner may only solicit summary reports during the patient's regular office visits in order to establish future rehabilitation goals. Ideally, a scalable notification system like this will allow for the desired information to be made efficiently available to both parties.

As a conceptual example of this application, consider a hypothetical patient with lower-limb loss receiving a first prosthesis and gait training in its use. During this early postoperative period, the delicate residual-limb tissues are still adapting to the stresses of the prosthetic socket [5,86–87]. Therefore, the practitioner wishes to carefully manage the amount of weight the patient bears on the prosthesis and the amount of time the patient uses the prosthesis daily so that the skin tissues can gradually grow to tolerate the stresses applied by the prosthesis. In the clinic, the practitioner affixes a load-based sensing unit to the prosthesis and then shows the patient how to incrementally load the prosthesis while using an assistive device. The practitioner instructs the patient to use the prosthesis daily and to monitor the loading daily using the Web-based notification system. **Figure 4** shows this hypothetical patient's use of the prosthesis over the first week. The feedback the patient receives from the system can be used to encourage adherence to a clinical schedule that promotes wound healing, development of healthy tissues, and increased use of the prosthesis.

As the hypothetical patient is able to tolerate larger loads, a practitioner elects to monitor the patient's activity over subsequent weeks to ensure that progress is maintained and that no setbacks occur. **Figure 5** shows the hypothetical patient's activity intensity over several months of rehabilitation. At this point in the rehabilitation process, the patient is able to tolerate increasingly longer and higher loads as the soft tissues adapt and the patient accommodates to use of the prosthesis. This activity information is useful for establishing a clinical visitation schedule or altering the training program, if insufficient progress is made.

Another related use of the therapeutic monitor is to document outcomes for the purposes of intervention assessment and justification. When applied this way, the system measures clinical outcomes before and after an intervention is provided to the patient. The management software is used to prepare a patient-specific outcomes report that shows the effect of the intervention. This report may be filed in the patient's medical file and used for later reference or sent to a reimbursement agency as justification of the intervention's effectiveness.

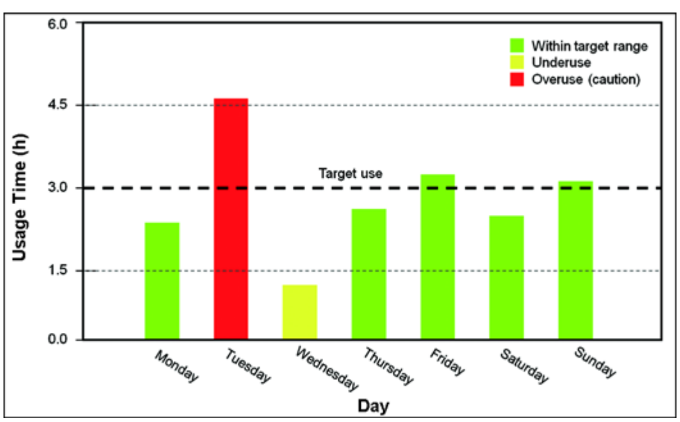

Figure 4.
Example of daily loading feedback provided to hypothetical patient who has received first prosthesis. Data shows daily performance (i.e., vertical loading) with respect to established clinical targets. Patient can use feedback to adjust loading patterns when he or she loads prosthesis too much or not enough.

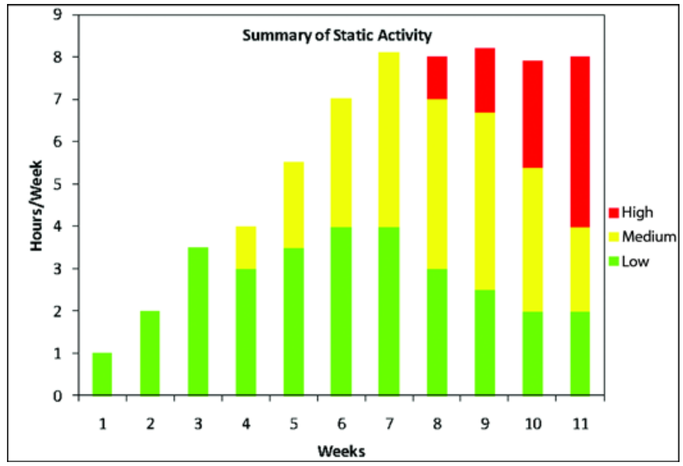

Figure 5.
Summary chart of hypothetical patient activity, highlighting time and intensity of loading. With this kind of information, practitioner can visualize patient's progress and observe unexpected changes in patterns that may require intervention.

Given the relative paucity of research evidence related to many lower-limb prosthetic interventions, data collected using the therapeutic monitor is expected to facilitate development of information databases that illuminate differences among individuals with different clinical characteristics and among those interventions that most effectively address the limitations inherent to major limb amputation. Further, a database of this type of objective data will support development of evidence-based clinical practice guidelines and establish appropriate expectations for contemporary rehabilitation techniques.

Diagnosis

A second potential application for the proposed system is as a clinical diagnostic instrument. As before, the sensing unit is temporarily or permanently attached to the prosthesis. In its diagnostic configuration, the management software is used to instruct the system to collect and store the objective sensor data onboard the unit in resident memory. Manual or wireless download of the data directly to a personal computer is then initiated when the patient attends clinic. A software-based notification strategy is used to display the collected diagnostic data and allows the practitioner to extract features of clinical interest. This information is then compared to the patient's self-report information in order to identify and remedy user problems such as skin breakdown, pain, or falls. The practitioner uses the obtained sensor data to determine whether the reported problems are the result of activity, intensity, frequency, suboptimal alignment, or suboptimal socket design. In this configuration, the system is used to quickly and efficiently diagnose and treat problems before they lead to more adverse issues.

In a diagnostic configuration, the sensor system may also be used in the clinic to assist in the selection of optimal prosthetic componentry. Consider use of the aforementioned kinetic sensing system for the purposes of prosthetic component selection. A hypothetical patient attends clinic and complains of discomfort and balance problems. The practitioner attaches the sensing system to the patient's prosthesis and requests that he or she stand quietly still for 30 s while the diagnostic monitor records data. The practitioner removes the monitor and downloads the data to a personal computer or wirelessly sends it to a personal computer. Experience with static standing in healthy amputees has prepared the practitioner to expect stable kinetic data like that shown in **Figure 6(a)**. The hypothetical patient, however, presents with kinetic data like that shown in **Figure 6(b)**, suggesting rapid weight shifts. Excessive weight shifting during everyday activity is indicative of balance problems* and is a possible indicator of instability. The practitioner uses this knowledge and the data made available by the sensing system to initiate a conversation with the patient and to perform a physical evaluation. The results of this hypothetical patient interaction show that the patient exhibits poor sensation and proprioception, likely induced by sleeplessness and medications. The practitioner recommends exchanging the patient's existing multiaxial foot with a rigid, fixed ankle foot until the medical issues are resolved. To confirm the decision, the practitioner again attaches the sensor, asks the patient to stand, and records data. The data download, as shown in **Figure 6(c)**, shows

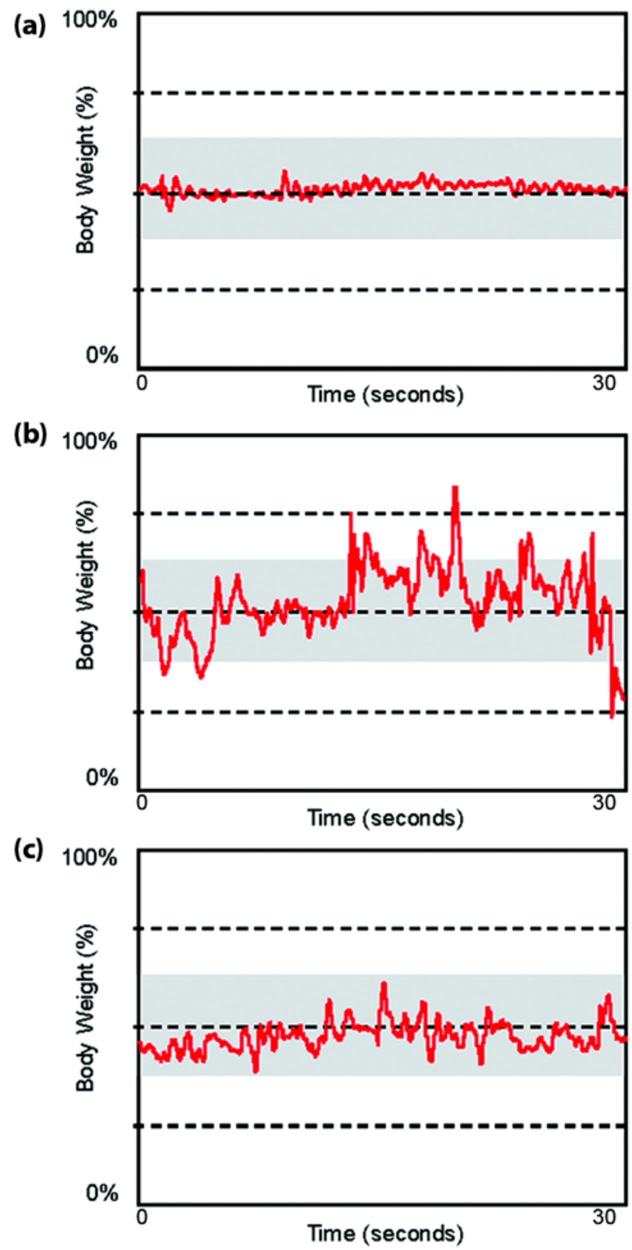

Figure 6.
Static stability for hypothetical patient, as indicated by relative loading of prosthesis during 30 s of quiet standing. Gray area represents suggested zone of stability for static standing. Sensor data are expected to help differentiate between patients and conditions, for example **(a)** healthy transtibial amputee, **(b)** patient that presents with poor proprioception and balance when wearing multi-axial foot, and **(c)** patient that presents with poor proprioception and balance after transition to solid-ankle foot. Pattern in **(c)** shows that patient is more stable wearing solid-ankle foot. Data were collected using piezoelectric force sensor positioned in prosthesis.

*Sutter JD. Electronic "iShoe" aims to prevent falls [Internet]. CNN.com. 2010 Jul 1. Available from: http://www.cnn.com/2010/TECH/03/03/ishoe.mit.award/index.html that standing stability is markedly improved. The hypothetical patient is then referred to his or her managing physician to discuss the sleeplessness issues and return for another prosthetic evaluation in a week. As shown, the sensor system facilitates diagnostic skill, supports evidence-based practice, and improves the overall quality of care provided. Use of sensing technologies in this manner represents an unchartered area of research in prosthetics as well as in portable gait characterization of nonamputees [88].

Prognosis

A third potential application of the proposed system is as an autonomous prognostic monitor. In this configuration, the sensing unit is permanently integrated into the prosthesis and used to monitor the user's performance for signs of adverse behaviors (i.e., stumbles, excessive pistoning) that require the user and/or practitioner's attention. The practitioner configures the management software to provide active, perpetual feedback to the user through the desired mechanism (e.g., auditory, vibratory, or text message to the user's smartphone) and to send summary reports to the practitioner on a weekly basis. In the event that adverse condition predictors are detected, the system notifies the patient, thus allowing the user to change behavior or seek assistance before the adverse event, fall, or skin breakdown occurs. Similarly, summary reports sent to the practitioner can be used to ensure the user is safely using his or her prosthesis or to prompt a clinic visit in the event problems are detected. In this configuration, the sensor system serves as an "advanced warning system" that helps to reduce the likelihood of harm and the personal and economic outcomes associated with such injuries (i.e., hospitalization, prosthetic disuse, medical leave from work). Other quantitative measures may be useful; for example, sensors might measure limb-socket slip or excessive skin strains.

Consider the example of a hypothetical patient with a recent amputation, fitted with his or her first prosthesis. A prosthetic pylon with the integrated sensor system is affixed to the patient's temporary prosthetic socket. The sensor is a highly sensitive dynamic force sensor capable of measuring high-frequency fluctuations in force that occur when the residual limb slides relative to the liner or socket. During the initial visit, the practitioner adjusts the prosthetic socket until an acceptable fit is achieved. Using the management software, the practitioner sets the sensing unit to detect slip between the prosthetic socket and the residual limb. While with the patient, the practitioner adjusts the sensitivity of the slip monitor so that the system detects undesirable limb-socket displacements. The practitioner instructs the system to send weekly notifications of progress. After 1 week, the notification system relays a report (**Figure 7**) to the practitioner. As shown, the patient's activity has increased as he or she has grown accustomed to using the prosthesis. However, after several days of use, slip has started to regularly occur, likely due to reduced edema in the residual limb as the limb heals and accommodates to the mechanical stresses of the prosthetic socket. This result prompts the practitioner to contact the patient and schedule an appointment and adjust the prosthetic socket with pads so as to minimize slip and prevent soft tissue damage. As shown, the system helps the practitioner to provide timely intervention in order to prevent placing the patient at undue risk. This configuration presents a cost- and resource-efficient strategy for providing effective prosthetic care.

INTEGRATING SENSING TECHNOLOGIES INTO CLINICAL PRACTICE

The previous examples illustrate the potential for sensing and monitoring technologies to change how we

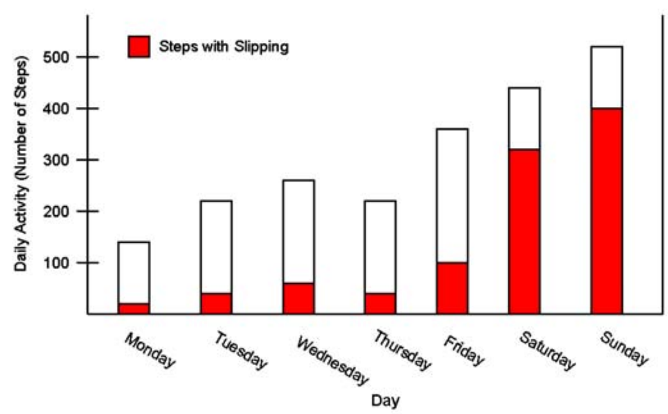

Figure 7.
Step activity and limb-socket slippage for hypothetical patient. Practitioner-generated report shows that after 5 d of use slip occurs regularly. This suggests that clinical intervention is necessary to avoid residual-limb tissue breakdown or falls due to poor suspension.

approach and apply rehabilitation interventions. Physical and biological sensors can provide practitioners and patients with information that is objective, reliable, and presently unavailable to them. Notification strategies can communicate the obtained information more rapidly and efficiently than is possible with routine office visits. Management software can customize the type and timing of information so that it meets the needs of the recipients. Integration of these systems into lower-limb prostheses can enrich a practitioner's toolkit and facilitate provision of individualized, efficient, and evidence-based care for persons with lower-limb loss.

It is important to acknowledge that sensing and monitoring technologies should not be viewed as a strategy for replacing the experience of qualified practitioners or eliminating clinician-patient interactions. Attempting to substitute clinicians' experience and/or judgment with these nascent technologies may worsen, rather than enhance, clinical care. Instead, sensing systems should be envisioned as tools to complement or extend practitioners' existing skills and knowledge. Future efforts should therefore explore how best to apply these systems so as to augment traditional methods of care.

We recognize that challenges to incorporating sensing technologies into routine clinical practice remain. For devices such as those exemplified previously to be successful, they must avoid adding to the burden of a clinical provider. Practitioners working in a busy clinical environment will have limited tolerance for devices that are difficult to integrate into a prosthesis, software that is cumbersome to use, or data that is challenging to interpret. Integration of devices into clinical practice must also be cost-effective. The additional time and expense associated with use of these technologies must be offset by improvements in the quality of care (e.g., selection of optimal componentry, shorter rehabilitation period, and/or more reliable documentation) or an increased efficiency of healthcare resources (e.g., time required to diagnose problems, frequency of patient visits, and/or reduced occurrence of adverse events).

Lastly, monitoring of prosthetic users by practitioners and transmission of patient data are certain to raise a variety of ethical concerns. Although an in-depth review of ethical issues related to health monitoring in prosthetic applications is beyond the scope of this review, discussions related to responsibility of action, liability, compliance, social stigmas, ownership, data integrity, and privacy of health information in other healthcare fields are common [89–93]. Zwijsen and colleagues recently conducted a thorough review and discussion of ethical issues related to monitoring technologies [90]. They noted three primary themes related to monitoring elderly adults that would likely also apply to prosthesis users. Themes included the personal living environment (e.g., issues of privacy, autonomy, and obtrusiveness), the outside world (e.g., issues of stigma and reduced human contact), and design and application of the device (e.g., issues of technology personalization, affordability, and safety). Other concerns, such as a practitioners' responsibility for monitoring and reporting negative outcomes, misuse or misinterpretation of collected information by third parties, and inclusion of monitored data in patients' permanent medical record were not identified in that review, but have been raised elsewhere [93]. Consideration and resolution of these issues may be warranted before sensing and monitoring technologies are universally adopted for prosthetic users. Once ethical concerns are addressed, sensing and monitoring technologies would appear to have enormous potential for enhancing prosthetics practice and improving the lives of persons with lower-limb loss.

CONCLUSIONS

Rehabilitation of persons with lower-limb loss is enhanced with knowledge of patients' functioning and health. Advances in sensing and monitoring technologies have made obtaining such information directly from prosthetic patients possible across a variety of settings (e.g., hospitals, prosthetic clinics, homes, and communities). Sensors can acquire useful and meaningful health information perpetually and remotely, but often require patients to remain compliant with application and wear recommendations. Integrating sensors into prosthetic limbs overcomes many limitations to use of stand-alone sensor devices for health monitoring. However, sensing technologies have yet to be integrated into routine clinical practices or used regularly to enhance the quality of care provided to persons with limb loss. However, a growing prevalence of available sensors and emergence of novel technologies will serve to promote these and related health applications.

Here, a multidimensional model of rehabilitation that embraces use of sensing and monitoring technologies for communicating information between (or among) prosthetic devices, patients, and their healthcare providers is proposed. Several hypothetical clinical situations are presented to illustrate how information from physical and biological sensors could be used to promote successful outcomes for prosthetic patients. Although challenges to development of efficient, cost-effective sensor systems for prosthetic applications remain, they can be addressed. Thoughtfully developing and integrating sensor systems into clinical practice has the potential to enhance the quality of care provided to persons with limb loss and to promote prosthetic users' function, health, and quality of life.

ACKNOWLEDGMENTS

Author Contributions:
Review concept and design: B. J. Hafner, J. E. Sanders.
Drafting of manuscript: B. J. Hafner, J. E. Sanders.
Critical revision of manuscript for important intellectual content: B. J. Hafner, J. E. Sanders.
Financial Disclosures: The authors have declared that no competing interests exist.
Funding/Support: Funding for Drs. Hafner and Sanders was provided in part by the National Institutes of Health (R01HD069387) and the Department of Defense (W81XWH-10-1-1035).

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Submitted for publication January 27, 2013. Accepted in revised form July 9, 2013.

This article and any supplemental material should be cited as follows:
Hafner BJ, Sanders JE. Considerations for development of sensing and monitoring tools to facilitate treatment and care of persons with lower-limb loss: A review. J Rehabil Res Dev. 2014:51(1):1–14.
http://dx.doi.org/10.1682/JRRD.2013.01.0024

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