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PRINCIPAL INVESTIGATOR: Joan E Sanders PhD

RECIPIENT: University of Washington

Seattle, WA 98195

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Joan E Sanders PhD

jsanders@u.washington.edu

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14. ABSTRACT

The purpose of this research is to integrate a novel limb fluid volume measurement instrument into clinical prosthetics, and then to evaluate its effectiveness to enhance prosthetic design and fitting. An observational cohort study and a randomized control trial are conducted. During this funding period, strategies were created and implemented to test the instrument on trans-tibial prosthesis users at remote locations. A novel system developed to monitor user activities (walking, standing, sitting, and doffing) in participants' free living environments for 2 to 4 weeks proved effective, and helped to characterize impact of socket modification/replacement on patient-centered outcomes. In general, socket modification/replacement slightly enhanced walking and standing activities, and enhanced limb fluid volume gains during walking. Limb fluid volume changes during resting were mixed. Self-reported outcomes generally improved with socket modification/replacement. A next step is to analyze collected data to address study hypotheses, and to extend participant recruitment and data collection to other remote facilities.

15. SUBJECT TERMS

None listed

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1. **INTRODUCTION**

The purpose of this research is to make prosthetic limbs more comfortable for Service members, Veterans, and civilians who have experienced limb amputation. Often a prosthesis will not fit well because the amputee's residual limb changes volume within the prosthetic socket. The proposed effort addresses the problem of changing limb volume by bringing a new diagnostic system to amputee patient care. We use a small portable instrument to measure where, when, and by how much limb volume changes. The focus in this application is use of the system for clinical diagnosis and treatment of volume problems common in people with limb loss. In this research we first conduct testing with prosthesis users to establish how well different volume management solutions work and how they relate to data measured from the system. That insight helps us determine how best to use the technology in clinical care. We then ask practitioners to test the system in their clinics to determine if it is a useful clinical tool for prosthetic fitting and if it reduces the total time required to achieve a successful prosthetic fit. Results of these studies provide valuable information about what clinical interventions work best and which prosthesis users are likely to benefit from each.

2. **KEYWORDS**

Diagnosis, residual limb, accommodation, bioimpedance analysis, extracellular fluid volume, prosthetic socket, amputee, skin breakdown, elevated vacuum, suction socket, interface stress, volume fluctuation, activity monitor

3. **ACCOMPLISHMENTS**

What were the major goals of the project?

The major goals of the project were to: (1) conduct a prospective observational cohort study to characterize how volume management solutions affect limb fluid volume fluctuations; and (2) to conduct a randomized control trial to characterize the effectiveness of a limb fluid volume monitoring system (developed under prior Department of Defense funding) towards enhancement of patient care and outcomes.

Major tasks, as per the approved SOW, are listed below.

Major Tasks
Aim #1. Prospective Observational Cohort Study
Task 1.1. Obtain Human Subjects approval for Aims 1 and 2
Task 1.2. Recruit practitioners
Task 1.3. Fabricate additional bioimpedance units
Task 1.4. Automate electrode assembly/fabrication
Task 1.5. Recruit subjects (~6/month for 9 months; n≥55)
Task 1.6. Conduct pre-implementation testing
Task 1.7. Monitor activity during interim 2-4 weeks
Task 1.8. Conduct post-implementation testing
Task 1.9. Process collected data
Task 1.10. Address hypotheses
Aim #2. Randomized Control Trial
Task 2.1. Recruit practitioners (~4/month for 5 months; n≥20)
Task 2.2. Recruit subjects (~10/month for 6 months; n≥60)
Task 2.3. Randomization and blinding
Task 2.4. Monitor subject activity
Task 2.5. Conduct pre-implementation testing
Task 2.6. Present and explain bioimpedance data to practitioner
Task 2.7. Practitioner recommends and carries out accommodation
Task 2.8. Collect data to assess effectiveness
Task 2.9. Address hypotheses

What was accomplished under these goals?

Aim #1.

Task 1.1. Obtain Human Subjects approval for Aims 1 and 2

A University of Washington IRB application was submitted on October 23, 2015, and approval was granted on March 23, 2016. A HRPO application was submitted on April 28, 2016, and approval was granted on October 21, 2016.

Minor modifications were made to the IRB as summarized in TABLE 1 below.

TABLE 1. IRB modifications.

Version	Date Approved	Description
0	3/23/2016	Initial application
1	4/20/2016	Modified consent forms to clarify funding source and to allow offsite locations
2	9/27/2016	Added FDA regulation to study Added offsite demonstration to recruitment methods
3	12/12/2016	Updated session protocol details, e.g. session timing and device used for activity monitoring
4	4/21/2017	Added Ability P&O as an engaged institution Added remote consenting Added new protocols for Aim 1 & 2

Task 1.2. Recruit practitioners

To facilitate recruitment, we held a meeting at the University of Washington (UW) (December 8, 2016) to present and discuss the study with active practitioners in the region. We provided continuing education credits so as to facilitate attendance. Afterwards, we visited 3 local clinics of practitioners unable to attend the meeting and conducted a similar presentation.

Before the meeting, we conduced test sessions on 3 amputee participants so that we had data to show and discuss at these interactions. Approved study procedures were carried out: medical history survey; questionnaires PEQ/SCS completed; intake form completed; electrodes for fluid volume monitoring placed on limb; 5 cycles of sitting/standing/walking (90 seconds each activity) conducted; 10-minute doff conducted. After the 5-cycle the participant completed activities of his or her choosing (unstructured protocol) around campus for 3 hours while accompanied by research staff. A low-sodium lunch was provided. The participant then returned to the lab to repeat the 5-cycle and 10-minute doff. The session ended and electrodes were removed.

At the meeting with practitioners, after presentation of the study goals, testing procedures, practitioner roles, data from the 3 participants, and a question and answer session, practitioners completed a survey to rate their interest in the project and to provide basic information about potential participants who were patients under their care (APPENDIX 1).

Results from the survey of 34 prosthetist attendees demonstrated enthusiasm levels shown in FIG. 1. Overall, prosthetists expressed high enthusiasm (average score 81%) with the majority of surveyed prosthetists scoring enthusiasm over 82% (shown by the skew to the right in FIG. 1). Attendees were inquisitive about the technology and excited for the potential utility of the device.

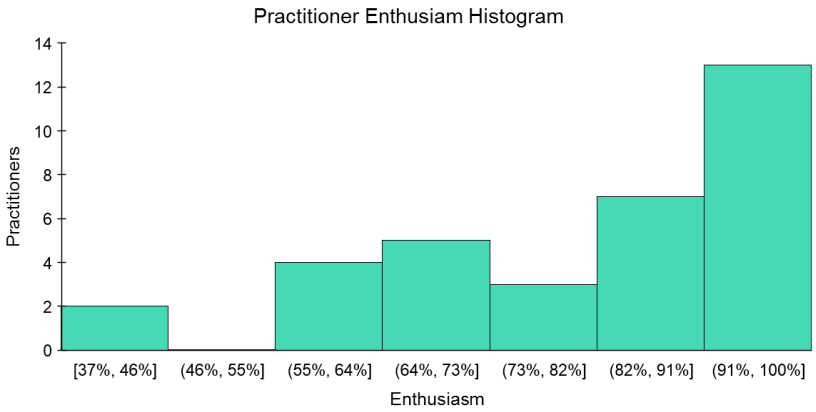


FIG. 1. Results from practitioner interest survey.

Task 1.3. Fabricate additional bioimpedance units

Circuit boards populated with components were ordered for four additional bioimpedance units; and two units were assembled. The unit fit within a 15 cm x 11 cm x 3.6 cm enclosure mounted on a waist belt (FIG. 2).

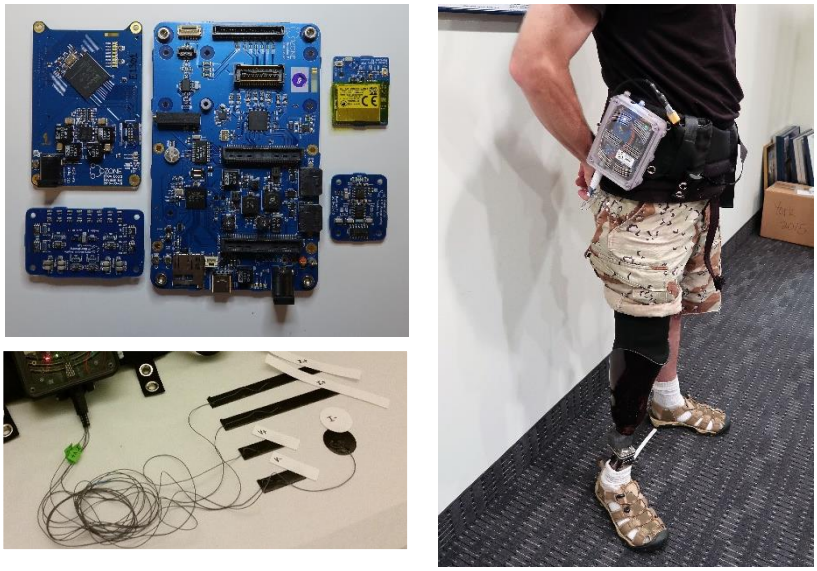


FIG. 2. Bioimpedance unit for monitoring limb fluid volume. Top left: electronic circuit boards that make up the system. Bottom left: electrodes placed on residual limb. Right: A participant wearing the unit in a study.

Task 1.4. Automate electrode assembly/fabrication

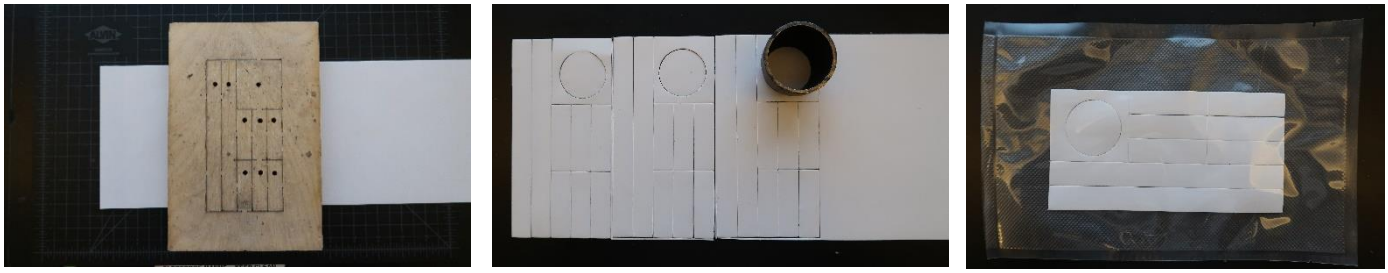


FIG. 3. Fabricating electrodes. Left: die used to cut electrodes. Center: three sets of electrodes cut. Right: single set ready for leadwire attachment.

Muliple sets of electrodes were punched from a preassembled base of electrode material (FIG. 3). These electrodes were stored in sealed packages then attached to wired harnesses when needed. Assembly of harness plugs and wires was sourced to an outside vendor using specificiations determined from previous in-lab assembly protocols. Harnesses were shipped to us ready to be connected to electrodes.

Task 1.5. Recruit subjects

We posted flyers in 15 prosthetist offices, and attended 2 local amputee events and support group meetings. We also recruited subjects off of our registry of 65 potential subjects who have previously agreed to be added to the registry.

Task 1.6. Conduct pre-implementation testing

The pre-implementation protocol for Aim #1 proceeded in 4 steps:

- The participant completed a Medical History Survey (APPENDIX 2), Intake Form (APPENDIX 3), an AM Query Form (APPENDIX 4), and a PEQ form (APPENDIX 5)
- The participant completed an AM limb fluid volume monitoring session, which took about 30 minutes, that included 5 cycles of sitting for 90s, standing for 90s, and walking on a treadmill for 90s
- The participant then left the lab with the researcher for 4 hours, conducting an unstructured protocol
- The participant returned to the lab and completed a PM limb fluid volume monitoring session, identical to that in the AM, and completed a PM Query Form (APPENDIX 6).

Tests were conducted on 6 participants. Results from those efforts demonstrated that the time between pre- and post- modification sessions (4 weeks) was too short. Modifications took longer than expected, and as a result the 4-week between-session time frame stated in the consent form could not be met. Some restarts were required because of this issue. Subsequently, we changed the consent forms to allow up to 12 weeks between sessions. We also changed our thinking of when to start recruiting potential participants in line for socket replacement or modification. Instead of attempting to target participants before they had seen their prosthetist for casting, we decided to wait until after the potential participant visited their prosthetist and had a cast made of their residual limb. This change ensured that patients were approved for the procedure, and that both parties were prepared for the new socket process. This eliminated delays related to insurance and pushed the first test session further down the socket development timeline, reducing time between test sessions. We found that close follow-up with participants and prosthetists was important to properly coordinate study sessions and ensure timely clinical visits.

In analysis of collected data, we found that the unstructured protocol made it difficult to compare results among participants, limiting significance of the study. This determination lead us to create a more structured protocol specification, which is listed in TABLE 2.

To determine appropriate activity for the structured protocol for individual participants, we added 2 weeks of activity monitoring to the start of testing. The revised management plan for Aim #1 is summarized in FIG. 3 below.

TABLE 2. Revised protocol for Aim #1. Lunch was provided during one of the Rest periods.

AM	5-Cycle
	Doff
Cycle 1	Low Activity
	High Activity
	Rest
Cycle 2	Low Activity
	High Activity
	Rest
Cycle 3	Low Activity
	High Activity
	Rest
PM	5-Cycle
	Doff

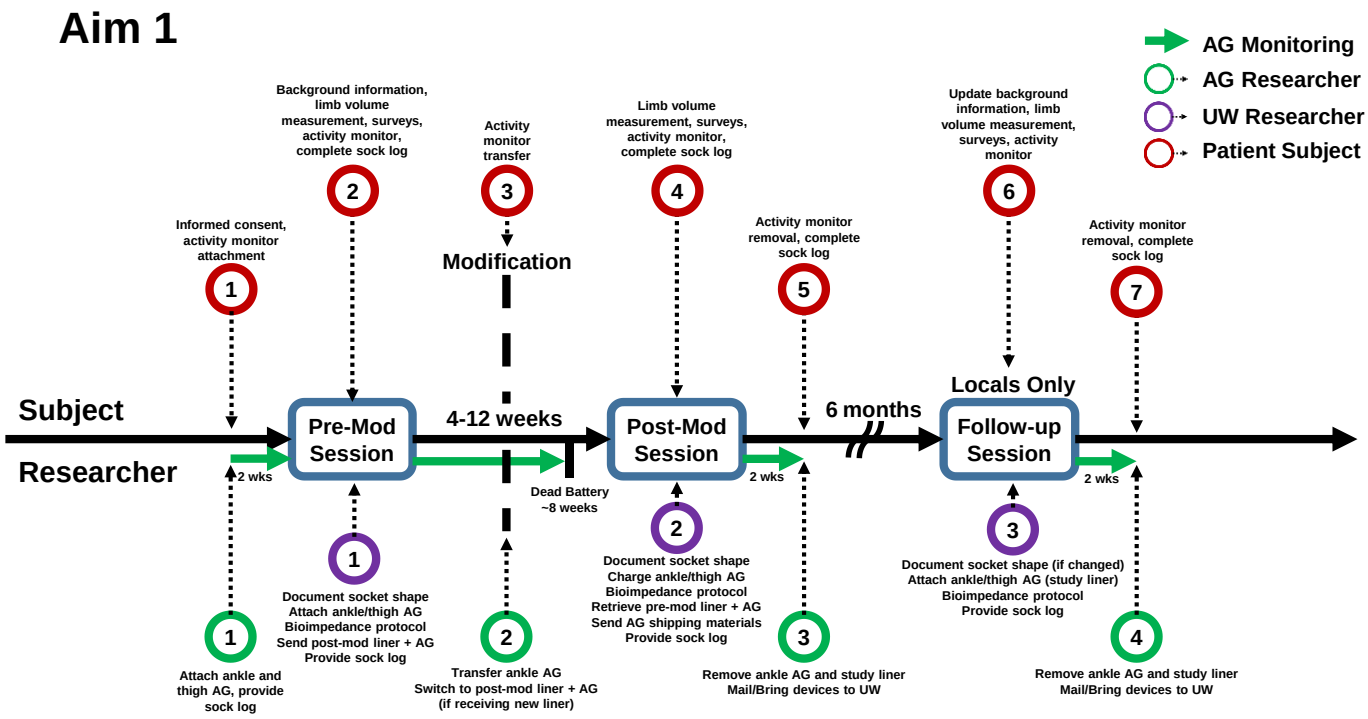


FIG. 3. Aim #1 management plan flowchart.

A total of 8 participants started the Aim #1 protocol, and 4 have completed testing.

Task 1.7. Monitor activity during interim 2-4 weeks

To monitor activity during the interim 2-4 weeks between test sessions, we developed a method to apply two 3-directional accelerometers to the affected limb, and then implemented an algorithm to calculate times of standing, sitting, and walking from collected data [J Prosthet Orthot 2016; 28:68-77]. Redfield's algorithm [J Rehabil Res Dev. 2013; 50:1201-12] was used for doff detection. One accelerometer was fastened to the pylon of the prosthesis and the other to the proximal aspect of the wearer's elastomeric liner.

Novel methods needed to be developed to affix accelerometers to elastomeric liners since participants were to wear the accelerometers for weeks at a time. A technique was needed that ensured the accelerometer did not come off during the 2-4 weeks of monitoring, did not interfere with normal liner donning and doffing, and was comfortable to prosthesis users. We initially disassembled the selected accelerometer (ActiLife ActiGraph GT3X+BT and GT3X+, Pensacola, Florida) so that the parts could be arranged into a low profile package. However, that strategy proved problematic because of concerns about battery safety (recent battery combustion problems of cell phones highlighted this issue). We changed our strategy to: pot the entire accelerometer package, and affix it to the anterior proximal aspect of the liner. A number of materials were attempted for embedding the accelerometer (TABLE 3). PMC121/30 Dry was selected for its moderate rigidity and minimal oil content.

TABLE 3. Materials attempted for embedding the accelerometer

Product	Manufacturer	Comments
Dragonskin 30	Smooth-On, Macungie, PA	Silicon compound, flexible but difficult to adhere to liner
Vytaflex 10	Smooth-On, Macungie, PA	Low rigidity polyurethane compound, exudes some oil after curing (too soft, too oily)
Vytaflex 50	Smooth-On, Macungie, PA	High rigidity polyurethane compound, exudes minimal oils
*PMC121/30 Dry	Smooth-On, Macungie, PA	Medium rigidity polyurethane compound, exudes minimal oils. Chosen for its moderate rigidity and minimal oils

*Material selected for use

We tested several different materials for adhering the potted assembly to the liner (TABLE 4). Loctite 454 was selected for its high bond strength and minimal restriction on liner deformation.

TABLE 4. Materials attempted for adhering potted assembly to liner

Product	Manufacturer	Comments
PLUSeries 60 Second Adhesive	Fabtech Systems, Everett, WA	Highly rigid upon curing, adheres well but restricted liner
*Loctite 454 Adhesive	Loctite, Düsseldorf, Germany	General purpose cyanoacrylate adhesive, rigid when cured but much thinner bond thickness than PLUSeries adhesives Chosen for its high bond strength and minimal liner restriction
Loctite 409 Adhesive	Loctite, Düsseldorf, Germany	General purpose cyanoacrylate adhesive, slower cure time than 454
E6000 Permanent Craft Adhesive	Eclectic Products, Eugene, OR	Epoxy adhesive designed for various surfaces, flexible when dries, bond strength not strong enough and ActiGraph peeled off too easily

While the strategy of potting the accelerometer and adhering it to the liner was effective, the liner was destroyed from this process and could not be re-used. In an effort to create a more cost-effective strategy, we pursued a temporary attachment method so that the liner could be used again. The two methods we tried included:

Dissolving the Loctite glue: We tried various solvents, but found that while strong solvents removed the Loctite glue, they also removed the fabric liner backing from the elastomer as well. Weak solvents did not effectively remove the Loctite glue.

Using Fabri-Loc adhesive bonding net: We attempted to use this material by first adhering it to the embedded accelerometer backing, and then adhering the Fabri-Loc adhesive bonding net to the liner. The bond was not strong enough and failed after several days.

The final procedure for adhering accelerometers to elastomeric liners is listed in APPENDIX 7.

A total of 7 Aim #1 participants were monitored with this instrumentation between test sessions.

Task 1.8. Conduct post-implementation testing

The protocol for post-implementation testing was the same as that for pre-implementation testing. The prosthesis components that were modified by the practitioner as part of treatment were noted and documented by research staff.

Task 1.9. Process collected data

Bioimpedance test data were processed using De Lorenzo's form of the Cole model [J App Physiol. 1997; 82:1542-58], and converted to extracellular fluid volume using a limb segment model. A stand point after the first cycle during the morning 5-cycle test was used as reference for calculating subsequent percent limb fluid volume change.

Processing algorithms for data from the activity monitors were modified to run more efficiently so that large datasets could be processed in a timely manner. By refactoring the code, we were able to reduce the time to process 4 week data sets from several hours to less than a minute. The code was also modified to resample and synchronize datasets in order to account for clock drift between the two accelerometers.

A visual display was developed to present processed data. Data for each day were shown, with summary statistics in a column at the right (FIG. 4).

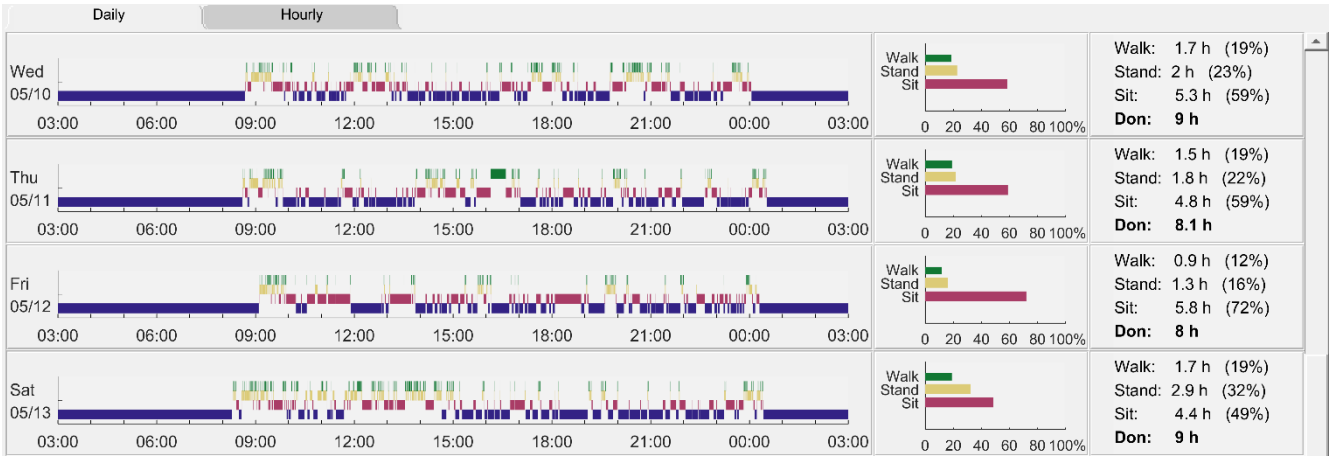


FIG. 4. Sample of processed activity monitor data.

A summary of participants tested in Aim #1 is listed in TABLE 5.

TABLE 5. Participants tested in Aim #1.

#	Pre-Mod Session	Post-Mod Session	Completed?	Notes
1	11/9/2016	X	N	Delayed due to late socket pick-up
2	1/25/2017	2/24/2017	Y	
3	1/12/2017	2/3/2017	Y	
4	2/13/2017	X	N	Delayed due to bad test socket
5	1/23/2017	X	N	Delayed due to insurance approval
6	3/27/2017	4/20/2017	Y	
7	4/10/2017	5/4/2017	Y	
8	4/11/2017	X	N	Withdrew due to activity monitor use

Task 1.10. Address hypotheses

Of the participants that completed Aim 1, three received a new socket as their modification (#2,6,7) and one received socket pads and relief as modification (#3). We present findings from Participant 3 below to illustrate data interpretation.

The modifications included tibial crest relief, fibular head relief, large posterior pad, and a posterior trim line reduction. These modifications resulted in the participant reducing socks by one ply. Though these modifications were intended to improve the prosthesis, the Socket Comfort Score (SCS) was unchanged and all Prosthesis Evaluation Questionnaire (PEQ) scores (satisfaction, ambulation, residual limb health, utility, and well-being) were lower following the modification. This participant did not experience large daily volume changes either pre- or post-mod, though the post-mod data did show higher rates of loss anteriorly during the AM and PM sections. Additionally, while six-day averages of activity were largely unchanged, the participant did decrease weight-bearing post-modification by about 5%. Overall, the modification strategy was not successful in that patient outcomes were not improved. Our results indicate that this particular participant may have benefited more from a new socket instead of a modification. The participant's fluid volume profile was defined by loss of volume during walking and standing and gain of volume during resting. Speculating as to how the specific modifications may have impacted fluid volume results, we believe the tibial and fibular head relief removed pressure from the bony areas but redistributed it to soft tissue and perhaps were the cause of greater overall fluctuation. Additionally, the posterior pad could have set the limb further anteriorly, causing the observed higher rates of fluid volume loss in that region. The knowledge gained could

be useful to treatment of this patient and to treatment of other patients with similar limb qualities and similar pre-modification limb fluid volume profiles.

Aim #2.

The Aim #2 protocol and management plan for the treatment and control arms are summarized in FIG. 5.

Task 2.1. Recruit practitioners

We recruited practitioners outside of the Pacific Northwest so as to enhance the number of potential participants. Extending from interaction with about a dozen practitioners from prosthetics offices Dr. Sanders visited in the east and southeast in August 2016 (before the grant started), we recruited a clinic with multiple branches to participate (Ability Prosthetics and Orthotics). In October 2016 we travelled to a quarterly meeting of the clinic (in Gettysburg, Pennsylvania), arriving a day early so as to collect data from a participant there. We presented data from that session at the meeting; the participant also attended and had his residual limb instrumented for limb fluid monitoring so that practitioners could see limb fluid volume data in real time projected on the screen. This strategy proved highly effective in generating enthusiasm and participation in the project.

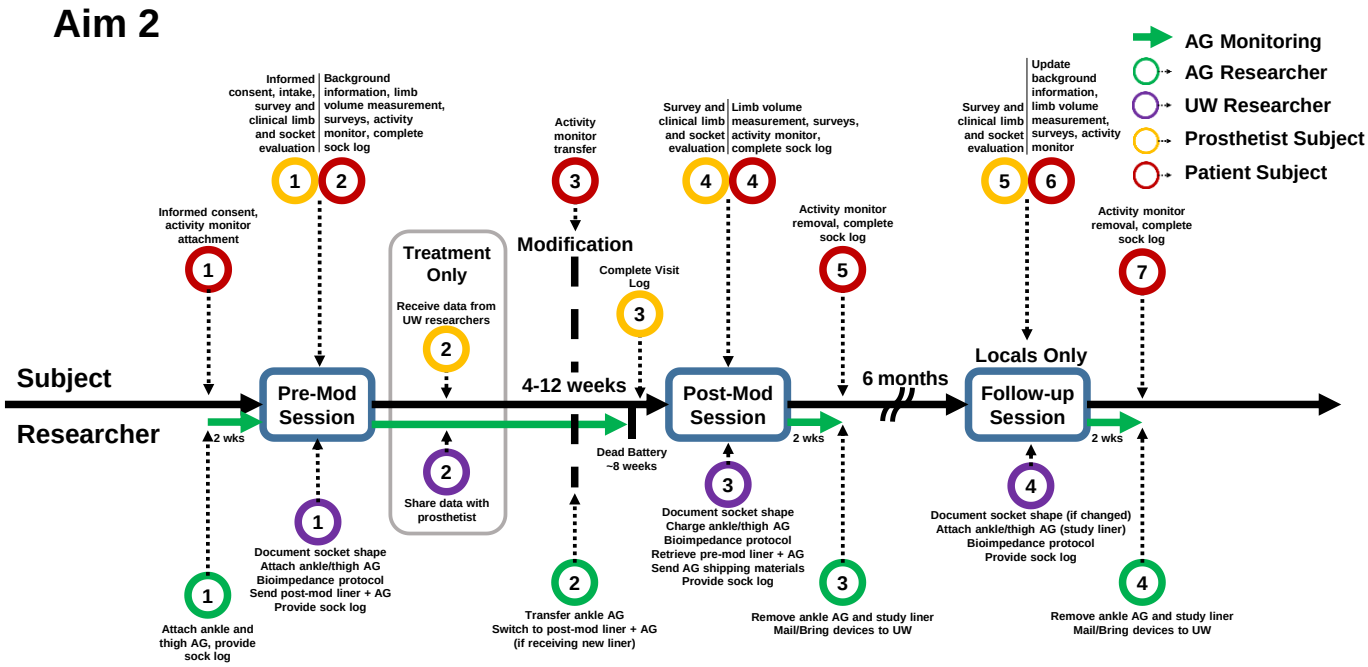


FIG. 5. Aim #2 management plan flowchart.

Task 2.2. Recruit subjects

Participants were recruited locally and through the Ability P&O clinics using recruitment flyers. Ability distributed material provided to them at the meeting and posted information about the study on their website.

The Clinical Outcomes & Research Director at the Ability P&O network of clinics helped to identify patients who were in line to receive a new socket. Additionally, prosthetists were instructed to think of patients who may soon be receiving a new socket. The Research Director then contacted that patient's prosthetist asking if the prosthetist could pass on the study information from our flyer to the patient. The Research Director conducted further discussions with the patient if needed. Next, if the patient was interested in participating, the person contacted the study team Research Prosthetist. The study team Research Prosthetist carried out

pre-screening as she would for any participant, based on inclusion and exclusion criteria.

Task 2.3. Randomization and blinding

A block randomization method was used to randomize 60 participants into the treatment or control group, resulting in equal sample sizes. A disadvantage of block randomization is that it may become predictable and result in bias. To reduce the risk of selection bias and help prevent the group allocation from becoming unconcealed to study personnel, block size was randomized to 4 and 6 participants. These block sizes were selected as a multiple of the total subjects (60) and in smaller increments to more easily control balance. The schedule manager used the online services on the website Randomization.com (http://www.randomization.com) to generate the randomization scheme. Participants who withdrew or were withdrawn from the study were not replaced.

All participants were blinded to their group assignment during the entire study period. Prosthetists did not discuss group assignment with participants. The prosthetist did not disclose or show how he/she decided on the modification strategy. Data was not presented in real time or discussed verbally with participants or with the practitioner while the participant was present so as to avoid informing the participant of his or her group assignment. Participants were notified of their group assignment upon exiting the study.

Task 2.4. Monitor subject activity

For local testing, the participant came to the UW lab, and the research staff affixed the accelerometers to the participant's prosthesis and liner and initiated data collection. Research staff travelled to the remote site for the first set of participants to apply accelerometers to those participants. We subsequently created and provided to prosthetist participants a document and an instructional video of the procedures to mount the accelerometers (the document is provided in APPENDIX 7). Subsequent accelerometers for data collection before the first limb fluid volume test day were mounted by practitioner participants. The participant was also provided with a sock log (APPENDIX 8) to track their socket use for the 2-week period.

The 2 weeks of activity data collected before the first limb fluid volume test day were used to characterize participant activity and to select an appropriate between-session protocol for limb fluid volume monitoring during pre-implementation testing. The pre-session activity data were processed to determine the participant's average daily activity (average hours active/24 hours) over the 2 weeks of collection. The average daily activity was then normalized to 15-hours to determine the time of prosthesis use that was spent active, termed "adjusted activity." 15 hours was previously determined a representative average daily prosthesis use [J Prosthet Orthot. 2017; submitted]. This adjusted activity was used to match participants with one of four protocols featuring comparable percent time walking, as defined in TABLE 6.

TABLE 6. Between session protocol options.

Adjusted Activity	Protocol	Walking Protocol
<11.0%	Dx1	5%
11.0%-15.9%	Dx2	11%
16.0%-20.9%	Dx3	16%
≥21.0%	Dx4	21%

Task 2.5. Conduct pre-implementation testing

The pre-implementation protocol for Aim #2 proceeded in 4 steps:

- The participant completed a Medical History Survey (APPENDIX 2), Intake Form (APPENDIX 3), and a PEQ form (APPENDIX 5).
- The prosthetist completed an Intake Form (APPENDIX 9) a Limb Socket Evaluation Form (APPENDIX 10), and a Prosthetist Survey 1 (APPENDIX 11).

- The participant completed an AM limb fluid volume monitoring session, which took about 30 minutes, that included 5 cycles of sitting for 90s, standing for 90s, walking on a treadmill for 90s, and doffing for 10 minutes.
- The participant then left the lab with the researcher for 4 hours, conducting a structured protocol based on the person's activity as determined from the 2 weeks of collected activity data. The test procedure was the same as that used in Aim #1 (TABLE 2), but with the durations of activity within each section adjusted according to the selected protocol (Dx1, Dx2, Dx3, or Dx4) (TABLE 6).
- The participant returned to the lab and completed a PM limb fluid volume monitoring session, identical to that conducted in the AM.

Task 2.6. Present and explain bioimpedance data to practitioner

For participants in the treatment arm, collected pre-implementation test data were processed and analyzed by the research team, a video conference call was scheduled with the practitioner, results documents were emailed to the practitioner, and data were presented and discussed with the practitioner at the video conference call. Video conference calls were conducted less than a week after pre-implementation test data were collected.

For the research team to analyze collected data, the following documents were prepared:
- a clinical summary of participant history and the reason for socket modification or replacement
- a summary of the 2 week activity data
- a summary of the limb fluid volume data

An example analysis package for a participant is presented in APPENDIX 12.

The research team generated a report that was then shared with the practitioner during the video conference call. An example of data provided is shown in FIG. 6.

Conference calls helped us to understand prosthetist's perception of the data. Through these calls we learned how to better present the results to prosthetists – what made sense and what was confusing to them. We were able to answer questions and clarify information. Prosthetists appeared to benefit from examples provided by the research prosthetist of how they may use the information to inform clinical care, particularly without unblinding the participant. The calls gave researchers a preview of how the prosthetist was planning to use the information, for example through socket modifications, or through behavioral suggestions and volume management strategies.

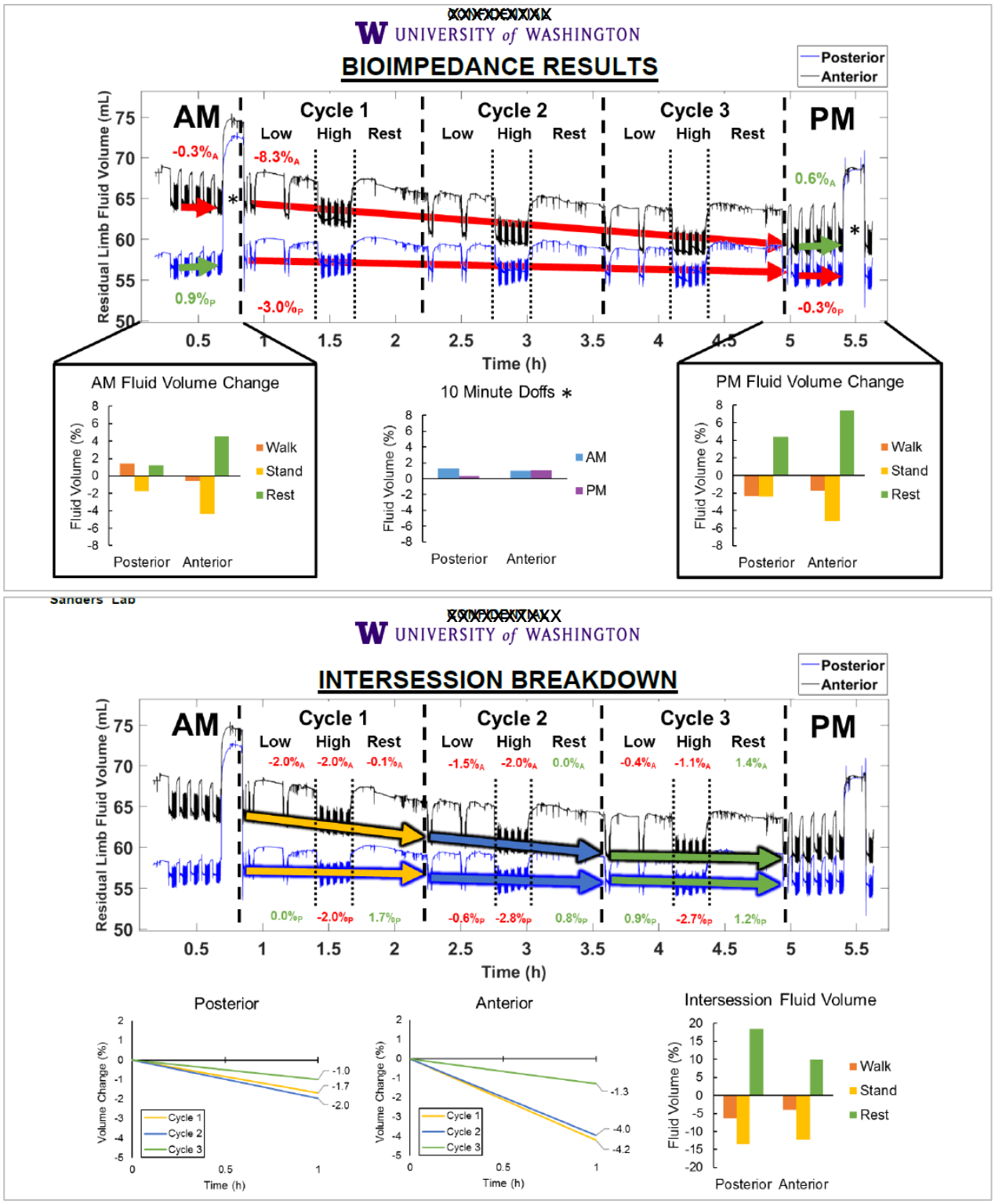


FIG. 6. Sample of data shared with practitioners in the treatment arm of Aim #2.

Task 2.7. Practitioner recommends and carries out accommodation

For participants in the treatment arm, the practitioner carried out the accommodation plan, using insight gained from limb fluid volume monitoring in their thinking.

Task 2.8. Collect data to assess effectiveness

Participant practitioners completed the survey presented in APPENDIX 13A,B. The following questions were asked for participants in the treatment arm:

- Describe your impression of the bioimpedance results
- Describe how you used the results to inform your clinical decisions
- How would you rate the utility of the bioimpedance results in designing the socket for your patient?
- How would you rate the utility of the bioimpedance results in choosing volume management strategies for your patient?
- Overall, to what extent did the bioimpedance results affect how you addressed the patient's issues?
- To what extent did bioimpedance results improve your ability to communicate with your patient?
- To what extent did bioimpedance results improve your patient's clinical outcomes?
- How likely would you be to request bioimpedance results for each of your patients?
- Which bioimpedance information was most useful to you?
- What additional volume information would you find useful towards assessing socket fit, improving socket design, or recommending volume management strategies?
- To what extent did the presentation and discussion of bioimpedance information improve your understanding of the information?
- How would you recommend improving the presentation and discussion of bioimpedance information?

Summaries of amputee participants and participants practitioners tested in Aim #2 are presented in TABLES 7 and 8.

TABLE 7. Participants tested in Aim #2.

#	AG Placement	Pre-Mod Session	Post-Mod Session	Completed?	Notes
1	5/2/2017	5/15/2017	7/17/2017	Y	
2	5/2/2017	5/14/2017	7/14/2017	Y	
3	5/2/2017	5/17/2017	7/19/2017	Y	
4	5/2/2017	5/13/2017	9/23/2017	Y	
5	5/3/2017	5/12/2017	X	N	Suspended, subject incarcerated
6	5/3/2017	5/16/2017	7/13/2017	Y	
7	5/22/2017	5/22/2017	6/16/2017	Y	Activity determined previously
8	5/25/2017	X	X	N	No modification made
9	6/14/2017	X	X	N	Missed session, proceeded with mod
10	7/11/2017	7/20/2017	9/22/2017	Y	
11	7/5/2017	7/16/2017	9/24/2017	Y	
12	7/7/2017	7/21/2017	9/27/2017	Y	
13	7/11/2017	7/18/2017	9/28/2017	Y	
14	7/25/2017	X	X	N	Skin breakdown before session

TABLE 8. Participant practitioners tested in Aim #2.

#	Group	Pre-Mod Session	Post-Mod Session	Completed?	Notes

1	Control	5/15/2017	7/14/2017	Y	
2	Treatment	5/12/2017	X	N	Suspended, subject's patient incarcerated
3	Treatment	5/17/2017	7/19/2017	Y	
4	Treatment	5/17/2017	9/26/2017	Y	
5	Control	5/15/2017	7/17/2017	Y	
6	Control	5/16/2017	7/13/2017	Y	
7	Control	5/26/2017	6/22/2017	Y	
8	Treatment	7/19/2017	9/26/2017	Y	
9	Treatment	7/18/2017	9/25/2017	Y	
10	Control	7/20/2017	9/22/2017	Y	
11	Treatment	7/21/2017	9/27/2017	Y	

Task 2.9. Address hypotheses

Hypotheses were evaluated for the first 5 participants (#1,2,3,6,7). This small sample size provided a lopsided distribution in that only 1 participant was in the treatment group and 4 were in the control group. This distribution was improved to 5 in each group following the recent completion of 5 additional participants. Based on the first 5 subjects, we note in TABLE 9 observed changes in participants' activity, self-reported outcomes, limb fluid volume, prosthetic fit, and number of clinical visits from pre-modification to post-modification. Self-reported outcomes included the Socket Comfort Score (SCS) and the Prosthesis Evaluation Questionnaire (PEQ), including PEQ-Satisfaction and PEQ subscales (Residual Limb Health, Ambulation, Utility, and Well Being).

TABLE 9. Changes from pre-mod to post-mod.

#	GROUP	ACTIVITY	SURVEY	LIMB FLUID VOLUME	PROSTHETIC FIT	CLINICAL VISITS BETWEEN PRE- AND POST-MOD
1	Control	Little to no change	SCS increased greatly, PEQs all increased except residual limb health	Maintained volume during tests, improved gain during walking	Reduced socks by 5 ply	5
2	Control	Little to no change	High pre-mod scores, PEQ-Well-being increased, little change elsewhere	Rest intervals not as beneficial, less rapid loss early, more steady throughout the day	Increased socks by 1 ply	5
3	Treatment	Slight increase	SCS and PEQ-Utility, -Ambulation, -Satisfaction increased	Less loss during the day, improved gains during walking, less gains during rests	No change in sock ply	4
6	Control	Little to no change	Largely unchanged, slight increases in PEQ-Utility, -Residual Limb Health, and SCS	Slightly more overall loss, less recovery during doff, some benefit during rests	Increased socks by 1 ply + 1 gel sock	4
7	Control	Slight increase	Increased in all but PEQ-Well Being	Higher overall loss, increased loss during rests and	No change in sock ply, no longer	3

		standing, increased gain during walking	changes during day

What opportunities for training and professional development has the project provided?

Practitioners attending our initial presentation in Seattle received continuing education credits.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Goals during the next reporting period include:

- completion of analysis of data collected to date towards addressing Aim #1 and #2 hypotheses
- construction of additional limb fluid volume monitoring units
- identification and data collection at additional clinics for testing participants remotely, as accomplished successfully in Year 1
- dissemination of findings at conference and meeting presentations

4. **IMPACT**

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

- **What was the impact on technology transfer?**

Nothing to Report

- **What was the impact on society beyond science and technology?**

- Nothing to Report

5. **CHANGES/PROBLEMS**

- **Changes in approach and reasons for change**

Minor changes to the times between sessions were made because of slowdowns in clinical socket changes. The between-session protocol for Aim #1 was changed to a structured protocol from an unstructured protocol so that comparisons among participants could be made.

- **Actual or anticipated problems or delays and actions or plans to resolve them**

There were unanticipated problems with delays in performing clinical socket modifications or replacements that disrupted our protocols and forced restarts for some participants. To resolve this problem, the time window for socket modification or replacement was extended.

To enhance recruitment, we are trying to identify other remote locations (similar to the group in Pennsylvania) that have large numbers of participants available. The trips for remote data collection allowed us to collect much data in a short period of time, which moved the project forward quickly.

- **Changes that had a significant impact on expenditures**

Nothing to Report

- **Significant changes in use or care of human subjects**

Nothing to Report

6. **PRODUCTS**

Nothing to Report

- **Publications, conference papers, and presentations**

Data from this project were presented at the American Academy of Orthotists and Prosthetists (AAOP) Annual Meeting and Scientific Symposium in Chicago, Illinois March 1-4, 2017 in a presentation titled, “Diagnostic Assessment of Limb Fluid Volume Changes in People with Trans-Tibial Amputation: Testing a Clinical Monitoring Tool.”

- **Journal publications**
- **Books or other non-periodical, one-time publications**
- **Other publications, conference papers, and presentations**
- **Website(s) or other Internet site(s)**
- **Technologies or techniques**
- **Inventions, patent applications, and/or licenses**
- **Other Products**

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	Joan E Sanders PhD
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-8850-243X
Nearest person month worked:	1.8
Contribution to Project:	Project administration; mechanical design; analysis
Funding Support:	

Name:	Brian J Hafner PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0001-6175-1869
Nearest person month worked:	1.0
Contribution to Project:	Study design, data interpretation
Funding Support:	

Name:	Katheryn J Allyn CPO
Project Role:	Research Prosthetist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.5
Contribution to Project:	Clinical support; participant recruitment and management
Funding Support:	

Name:	Brian Larsen MS
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.8
Contribution to Project:	Data analysis
Funding Support:	

Name:	Jacob Brzostowski
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3.1
Contribution to Project:	Instrumentation preparation; data collection
Funding Support:	

Name:	Clement Gurrey
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5.4
Contribution to Project:	Mechanical design; data collection
Funding Support:	

Name:	Andrew Vamos
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4.7
Contribution to Project:	Instrumentation development; data processing, analysis and visualization
Funding Support:	

Name:	Ethan Weathersby
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3.0
Contribution to Project:	
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Summary tables for key personnel are provided below.

Changes - Other Support				
	CONTRACT/PERIOD OF PERFORMANCE/AGENCY	**STATUS**	**FUNDING**	**EFFORT (calendar months)**
SANDERS, JOAN E				
	R01HD060585-03 (Sanders) 12/01/12-05/30/18 NIH/NICHD	no change	$383,756/year direct	2.10
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020 Joint Warfighter Medical Research Program (JWMRP)	added	$960k/year direct	3.60
	W81XWH-16-1-0585 (Sanders) 09/15/2016-09/14/2019 Peer Reviewed Medical Research Program (PRMRP) Investigator-Initiated Research Award	added	$324k/year direct	1.60
	A112491 (Sanders) 07/01/2016-06/30/2018 Sandia National Laboratories	added	165.8k/year	0.10
	Total Effort (months per year)			7.40

HAFNER, BRIAN J				
	2R01HD065340 (Hafner) 02/13/2017-01/31/2022 National Institutes of Health	no change	$ 390,984.0	3.60
	R01HD060585-03 (Sanders) 12/01/12-05/30/18 NIH/NICHD	no change	$383,756/year direct	0.84
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020 Joint Warfighter Medical Research Program (JWMRP)	added	$960k/year direct	2.40
	W81XWH-16-1-0585 (Sanders) 09/15/2016-09/14/2019 Peer Reviewed Medical Research Program (PRMRP) Investigator-Initiated Research Award	added	$324k/year direct	1.20
	W81XWH-16-1-0569 (Morgenroth) 10/01/2016-09/30/2019 Department of Defense	added	$ 24,386	0.60
	W81XWH-15-1-0458 (Hafner) 9/01/2015-08/31/2018 Department of Defense	added	$ 162,249	2.76
	OPERF-SGA-2014-1 (Hafner) 04/10/2014-06/30/2016 OPERF	closed	$ 22,722	0.00
	A97186 (Hafner) 03/01-2015-02/28/2016 UW Royalty Research Fund	closed	$ 34,438	0.00
	OP140079 (Hafner) 9/01/2015-08/31/2017 Department of Defense	closed	$ 161,377	0.00
	Total Effort (months per year)			11.40

FRIEDLY, JANNA L.				
	CE-12-11-4469 (Friedly) 7/1/2013-2/28/2018 PCORI	no change	$ 536,221.0	2.16
	4UH3AR066795 - 02 (Jarvik) 1/1/2014-12/31/2017 NIH	no change	1298074	1.04
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020 Joint Warfighter Medical Research Program (JWMRP)	added	$960k/year direct	1.08
	W81XWH-16-1-0585 (Sanders) 09/15/2016-09/14/2019 Peer Reviewed Medical Research Program (PRMRP) Investigator-Initiated Research Award	added	$324k/year direct	0.54
	Evidence Based Practice Center (Devine) 10/01/16-09/20/2017 AHRQ	added		0.54
	W81XWH-15-1-0291 (Mourad) 09/15/15 – 09/14/18	added		1.08
	OP160059 (Morgan) 10/01/2017 – 09/30/2019 Department of Defense	added	$ 101,327	0.12
	P30 (Jarvik) 9/1/2017-8/31/2022 NIAMS	added	$ 519,122	1.20
	Total Effort (months per year)			7.76

CIOL, MARCIA A				
	R01 AF 059102 (Turk) 09/01/11– 07/31/18 NIH/DHHS	no change	$ 768,194	0.70
	R01AT008336 (Jensen) 09/01/14 – 06/30/19	no change	$ 534,591	1.20
	R01AT008336 (Jensen & Williams) 10/01/14 – 09/30/19 NIH	no change	$ 421,499	1.20
	R01HD060585-03 (Sanders) 12/01/12-05/30/18 NIH/NICHD	no change	$383,756/year direct	0.60
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020 Joint Warfighter Medical Research Program (JWMRP)	added	$960k/year direct	1.20
	PCS-1604-35115 (Hoffman) 08/01/17 – 04/30/23 PCORI	added	$ 2,077,520	2.40
	P30 AG034592 (Matsuda) 06/01/16 – 05/31/18 Roybal	added	$ 74,285	0.60
	A121025 (Maitland) 10/02/17 – 04/02/18 NCMRR	added	$ 62,279	0.60
	R01 HD070973 (Jensen) 07/20/12 – 05/31/17 NIH/NICHD	closed	$ 338,079	0.00
	IH-1304-6379 (Ehde) 10/01/13-09/30/16 Patient Centered Outcomes Research Institute (PCORI)	closed	$ 498,365	0.00
	R24 AG047115-01 (Ladiges) 05/01/14-04/31/17 NIA	closed	$ 236,000	0.00
	Total Effort (months per year)			8.50

ALLYN, KATHERYN J				
	R01HD060585-03 (Sanders) 12/01/12-05/30/18 NIH/NICHD	no change	$383,756/year direct	1.50
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020 Joint Warfighter Medical Research Program (JWMRP)	added	$960k/year direct	1.50
	W81XWH-16-1-0585 (Sanders) 09/15/2016-09/14/2019 Peer Reviewed Medical Research Program (PRMRP) Investigator-Initiated Research Award	added	$324k/year direct	1.50
	Total Effort (months per year)			4.50

- **What other organizations were involved as partners?**
  - **Organization Name:** Ability Prosthetics and Orthotics
  - **Location of Organization:** Exton, Pennsylvania
  - **Partner's contribution to the project**
    - **Collaboration.** Brian Kaluf, Clinical Outcomes & Research Director, facilitated practitioner recruitment and helped coordinate study visits. He also participated in video conferences between researchers and practitioners to help interpret collected data for clinical use.

8. **SPECIAL REPORTING REQUIREMENTS**

- **QUAD CHART**

A Novel Diagnostic Interface to Enhance Limb Health, Comfort, and Function

W81XWH-16-1-0585

PI: JE Sanders PhD **Org:** University of Washington **Award Amount:** $1.59 M

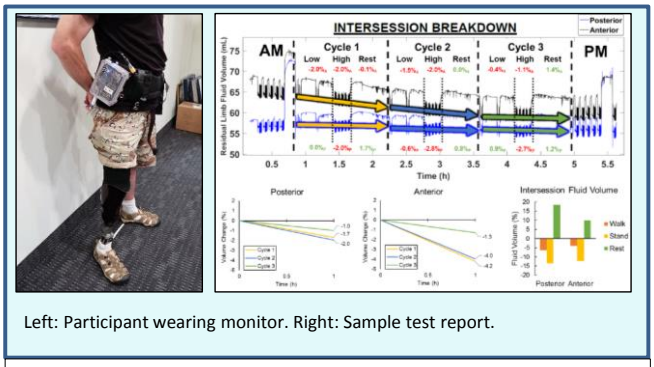
Study/Product Aim(s)

Aim 1. Conduct an observational cohort study to characterize residual limb volume accommodation strategies and associated clinical outcomes experienced by prosthetic users to determine which strategies are most predictive of optimal clinical outcomes.

Aim 2. Conduct a randomized controlled trial to compare the effectiveness of bioimpedance-enhanced and traditional prosthetic evaluation, design, and fitting practices for lower limb prosthetic users who require adjustment or replacement of their volume management system.

Approach

A portable limb fluid volume monitor is tested in participants with lower limb amputation to quantify how measured variables relate to clinical outcome. Then, impact of monitor use on design and fitting practices is evaluated in a prospective study.



Left: Participant wearing monitor. Right: Sample test report.

Accomplishment:

Timeline and Cost

Activities / CY	17	18	19
Conduct observational study			
Relate data to clinical outcomes			
Conduct randomized control trial			
Assess monitor effectiveness			
Estimated Budget (total) ($K)	**$411**	**$600**	**$578**

Updated: October 1, 2017

Goals/Milestones

CY17 Goal –
- ☐ Create additional limb fluid volume monitoring instruments
- ☐ Finalize observational cohort study and randomized control trial study procedures
- ☐ Begin studies

CY18 Goals –
- ☐ Complete observational cohort study
- ☐ Establish how measured variables relate to clinical outcomes
- ☐ Continue randomized control trial

CY19 Goal –
- ☐ Complete randomized control trial
- ☐ Characterize impact of monitor on outcome

Comments/Challenges/Issues/Concerns
- Not applicable

Budget Expenditure to Date

Projected Expenditure: $511,292
Actual Expenditure: $410,454

- **APPENDICES**
  - APPENDIX 1. Practitioner interest survey
  - APPENDIX 2. Medical history survey
  - APPENDIX 3. Intake form
  - APPENDIX 4. Participant query form – AM
  - APPENDIX 5. PEQ/SCS
  - APPENDIX 6. Participant query form – PM
  - APPENDIX 7. Actigraph attachment protocol
  - APPENDIX 8. Daily sock change log
  - APPENDIX 9. Prosthetist intake form
  - APPENDIX 10. Prosthetist limb and socket evaluation
  - APPENDIX 11. Prosthetist survey 1
  - APPENDIX 12. Example analysis package for research team
  - APPENDIX 13A,B. Prosthetist survey 2 (control, treatment)

A DIAGNOSTIC TOOL TO UNDERSTAND

A PATIENT'S LIMB FLUID VOLUME PROFILE

UNIVERSITY OF WASHINGTON RESEARCH STUDY

PRACTITIONER SURVEY

Name: _____

E-mail address: _____

Clinic Location: _____

Please rate your enthusiasm level for participation with an "X" on the line below:

Low ----------> High

Approximately what percentage of your patients had their limb amputation from:

Trauma _____ Vascular Disease _____ Other _____

Approximately what percentage of your patients have:

Vascular Disease _____ Diabetes _____ Poor Limb Sensation _____

Heart Disease _____ Cancer _____ No Major Health Issues _____

Approximately what percentage of your patients:

Smoke _____ Are Obese (BMI>30) _____

Date: _____ Participant Id#: _____

Medical History Survey

Have you experienced any of the following medical conditions?

1. Heart attack?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

2. High cholesterol?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

3. High blood pressure?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

What was your most recent blood pressure (if known)? _____ / _____ mm Hg

4. Heart failure?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

Participant Id#: _____

Medical History Survey

Have you experienced any of the following medical conditions?

5. Chest pain?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

Approximately how often do your chest pain symptoms occur?

☐ Never
☐ Very rarely (several times a year or less often)
☐ Rarely (monthly)
☐ Occasionally (weekly)
☐ Frequently (daily)
☐ Very frequently (more than once per day)

6. Heart arrhythmia/palpitation/murmur?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

Approximately how often do your chest pain symptoms occur?

☐ Never
☐ Very rarely (several times a year or less often)
☐ Rarely (monthly)
☐ Occasionally (weekly)
☐ Frequently (daily)
☐ Very frequently (more than once per day)

Medical History Survey

Have you experienced any of the following medical conditions?

7. Bypass surgery?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

8. Other heart disease?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

If YES, what are your symptoms or specific problems?

Please describe:

9. Other heart surgery?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

If YES, what was the reason(s) for surgery?

Please describe:

Participant Id#: _____

Medical History Survey

Have you experienced any of the following medical conditions?

10. Stroke?

☐ No

☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

If YES, what were your initial symptoms?

Please describe:

If YES, do you experience any ongoing problems related to your stroke?

Please describe:

11. Peripheral vascular history?

☐ No

☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

If YES, what are (were) the blockages (if known)?

Please describe:

Medical History Survey

Have you experienced any of the following medical conditions?

12. Blood clots?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

13. Circulation problems (including carotid artery blockage)?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

If YES, what are (were) the blockages (if known)?

Please describe:

14. Swelling in the legs?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, is this a current problem? ☐ No ☐ Yes

If YES, what causes the swelling (if known)?

Please describe:

Medical History Survey

Have you experienced any of the following medical conditions?

15. Diabetes?

☐ No
☐ Yes →

If YES, at what age were you diagnosed? _____ years of age

If YES, what type of diabetes? ☐ Type 1 ☐ Type 2

If YES, what medications are you taking for your diabetes (if any)?

Please describe:

If YES, what was your most recent blood sugar level?

Hemoglobin A1c _____%
Fasting glucose _____ mg/dL
Random or after meal glucose _____ mg/dL

If YES, do you have any diabetes-related problems?

☐ No
☐ Yes, with my eyes or vision (retinopathy)
☐ Yes, with my nerves or sensation (neuropathy; gastroparesis)
☐ Yes, with my kidneys (albuminuria; nephropathy; dialysis; transplant)
☐ Other

Please describe:

Medical History Survey

16. Do you <u>currently</u> smoke tobacco? (please choose the best answer)

- ☐ Not at all
- ☐ Less than daily
- ☐ Daily

17. Have you smoked tobacco in the past?

- ☐ No
- ☐ Yes →

If YES, how many years (in total) have you smoked: _____ years

If YES, did you smoke tobacco in the last 5 years?

- ☐ No
- ☐ Yes, less than daily
- ☐ Yes, daily

18. Do you <u>currently</u> use smokeless tobacco? (please choose the best answer)

- ☐ Not at all
- ☐ Less than daily
- ☐ Daily

19. Have you used smokeless tobacco in the past?

- ☐ No
- ☐ Yes →

If YES, how many years (in total) did you use smokeless tobacco: _____ years

If YES, did you use smokeless tobacco in the last 5 years?

- ☐ No
- ☐ Yes, less than daily
- ☐ Yes, daily

Medical History Survey

20. Have you experienced changes in weight in the last 12 months?

☐ No

☐ Yes →

If YES, did you gain or lose weight?

☐ Lose

☐ Gain

If YES, how much weight did you gain or lose? _____ lbs

If YES, what was the reason for your weight gain or loss?

Please describe:

THANK YOU FOR COMPLETING THIS SURVEY

Intake Form – Basic Demographics

Participant Id#: _____

Name of investigator: _____

Date: _____

Gender:

- ☐ Male
- ☐ Female

Date of birth: _____/_____/_____
month day year

Height: _____/_____
feet inches

Weight: _____ ☐ With shoes ☐ Without shoes
Pounds / Kilograms?

Ethnicity:

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

Race: *(please check all that apply)*

- ☐ White
- ☐ Black or African-American
- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander

Intake Form – Amputation Information

Date of amputation: _____/_____/_____
month day year

Reason for amputation:

- ☐ Traumatic
- ☐ Dysvascular
- ☐ Oncologic (cancer or tumor)
- ☐ Congenital
- ☐ Infection
- ☐ Other: _____

Side(s) of amputation (check all that apply):

- ☐ Right
- ☐ Left

Residual limb length (note length in cm and relative length):

_____ cm

- ☐ Less than 1/3 sound segment length
- ☐ Between 1/3 and 2/3 sound segment length
- ☐ More than 2/3 sound segment length

Intake Form – Activity Information

Medicare functional classification level (MFCL):

- ☐ MFCL-1 Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
- ☐ MFCL-2 Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
- ☐ MFCL-3 Has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- ☐ MFCL-4 Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

Typical activities (also indicate relative frequency):

Vocational:

Recreational:

Other:

Intake Form – General Medical Screen

Medications:

Current medical concerns:

Skin/material allergies:

Pain:

Contralateral involvement:

Routine medical/therapy interventions (dialysis, therapy, etc):

Prior surgeries:

Alcohol and/or tobacco use:

Intake Form – Prosthetic History

Prosthetic history (indicate changes in last 5 years):

Full prosthesis:

Sockets:

Suspension:

Componentry:

Other:

Intake Form – Prosthesis Information

Current prosthetist: _____

Existing prosthesis:

- ☐ Endoskeletal
- ☐ Exoskeletal

Use current prosthesis daily? (Add notes, as appropriate)

- ☐ Yes _____
- ☐ No _____

Estimated daily use:

_____ hours/day

Intake Form – Socket Information

Age of current socket):

_____/_____
months years

Current prosthetic socket:

- ☐ Patellar tendon bearing (PTB)
- ☐ Total surface bearing (TSB)
- ☐ Other: _____

Current socket material:

- ☐ Laminate - carbon fiber
- ☐ Laminate - other
- ☐ Thermoplastic (Polypropylene, Co-polymer, co-polyester)
- ☐ Other: _____

Socket fit quality:

Reason for last socket replacement: _____

Intake Form – Sock Information

Current prosthetic socks:

Sock ply:	Number of socks:	Sock material:
		☐ Nylon ☐ Wool ☐ Cotton ☐ Synthetic ☐ Other: _____
		☐ Nylon ☐ Wool ☐ Cotton ☐ Synthetic ☐ Other: _____
		☐ Nylon ☐ Wool ☐ Cotton ☐ Synthetic ☐ Other: _____
		☐ Nylon ☐ Wool ☐ Cotton ☐ Synthetic ☐ Other: _____

Intake Form – Liner Information

Current prosthetic liner:

Manufacturer: _____

Model: _____

Size: _____

Liner material (check all that apply):

- ☐ Silicone
- ☐ Copolymer
- ☐ Polyurethane
- ☐ Thermoplastic elastomer
- ☐ Pelite/EVA
- ☐ Other: _____

Intake Form – Suspension Information

Current prosthetic suspension:

Manufacturer: _____

Model: _____

Size: _____

Suspension type (check all that apply):

- ☐ Supra-patellar
- ☐ Supra-condylar
- ☐ Pin
- ☐ Valve
- ☐ Seal-in liner
- ☐ Sleeve
- ☐ Vacuum
- ☐ Other: _____

Intake Form – Foot Information

Current prosthetic foot:

Manufacturer: _____

Model: _____

Size: _____

Joint type (check all that apply):

- ☐ Solid ankle (no joint)
- ☐ Single-axis
- ☐ Multi-axis

Keel type (check all that apply):

- ☐ Rigid keel (e.g., SACH)
- ☐ Flexible keel (e.g., SAFE)
- ☐ Dynamic response (e.g., Seattle, Renegade)

Current shoes size: _____

Current shoes worn:

- ☐ Athletic
- ☐ Dress (loafer)
- ☐ Boot
- ☐ Sandal
- ☐ Other: _____

Intake Form – Assistive Device Information

Assistive device use (check all that apply, add notes as appropriate):

- ☐ Cane(s) _____
- ☐ Crutch(es) _____
- ☐ Walker _____
- ☐ Wheelchair _____
- ☐ Other _____

Intake Form – Typical Volume Accommodation Strategy

Typical sock use (check all that apply, add notes as appropriate):

- ☐ Nylon _____
- ☐ 1-ply _____
- ☐ 2-ply _____
- ☐ 3-ply _____
- ☐ 4-ply _____
- ☐ 5-ply _____
- ☐ 6-ply _____
- ☐ 7-ply _____
- ☐ Other: _____

Typical donning/doffing:

Donning time (beginning of day): _____ ☐ AM ☐ PM

Doffing time (end of day): _____ ☐ AM ☐ PM

Ask participant to explain reasons why they typically doff/don their socket daily:

Intake Form – Limb Inspection

Residual limb anatomy:

- ☐ Cylindrical
- ☐ Conical
- ☐ Bulbous

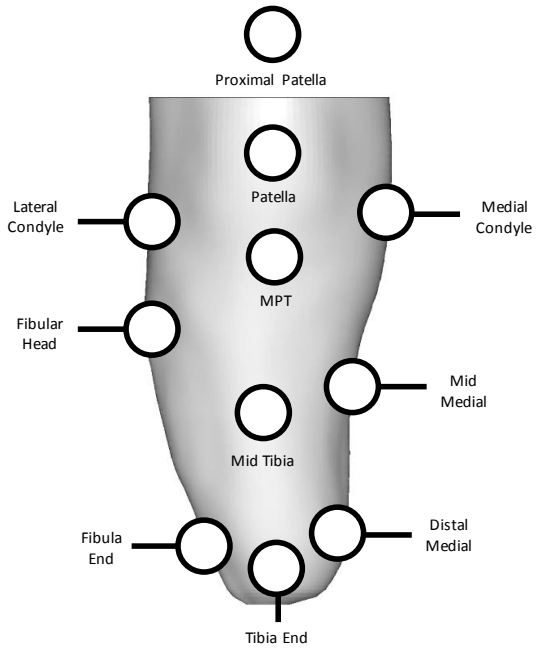
Tissue (skin/muscle) quality:

- ☐ Redundant soft tissue _____
- ☐ Large gastroc flap _____
- ☐ Patellar tendon issues _____
- ☐ Varicose veins _____
- ☐ Pigmentation _____
- ☐ Eczema _____
- ☐ Pitting edema _____
  - ☐ 1+ (barely detectable impression when finger is pressed into skin)
  - ☐ 2+ (slight indentation, 15 seconds to rebound)
  - ☐ 3+ (deeper indentation, 30 seconds to rebound)
  - ☐ 4+ (>30 seconds to rebound)
- ☐ Sock impressions _____
- ☐ Verrucous hyperplasia _____
- ☐ Skin folds _____
- ☐ Loose skin _____
- ☐ Abrasions _____
- ☐ Boils _____
- ☐ Skin infections _____
- ☐ Bone spurs _____

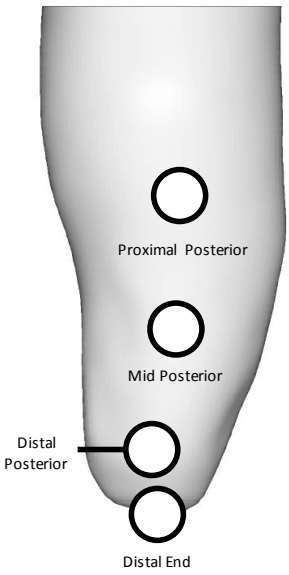
Intake Form – Limb Inspection

History of skin breakdown:

Skin sensation:



anterior



posterior

Sensation Test
(5.07 monofilament)

Indicate in Circles:
A = absent
P = present

Other notes:

Participant Query Form – AM

Participant Id#: _____

Name of investigator: _____ Date: _____

Time of AM session: _____ Time of PM session: _____

Recent changes in health (e.g., new medications, therapy, illness):

Recent changes to prosthesis (e.g., new alignment, components, etc.):

Recent socket problems (e.g., poor socket fit, skin breakdown, etc.):

Clinical Inspection of limb (e.g., skin breakdown, signs of poor socket fit, etc.):

Participant Query Form – AM

Diet / food intake before session (e.g., breakfast):

Did the participant consume any of the following (if so, describe)?

- ☐ Caffeine _____
- ☐ Alcohol _____
- ☐ Sodium _____

Other Notes:

Socket Design, Limb Health and Ability to Ambulate

Instructions

Instructions: This form contains questions related to use of your comfort, satisfaction, and use of your prosthesis. Please take your time when answering the questions and read each question carefully. Please note that some questions will refer to how you feel right now, and some question refer to how you have felt over the past 2 weeks.

If you have any questions, please stop and ask one of the study staff for assistance or clarification.

Please begin when you are ready.

Examples

How important is it to you to have coffee in the morning?

NOT AT ALL EXTREMELY IMPORTANT

Over the past two weeks, rate your morning coffee.

TERRIBLE EXCELLENT

OR check __I haven't drunk coffee in the morning in the past four weeks.

This example shows that the person who answered these questions feels that having coffee in the morning is important to him. He also thinks the coffee he has had lately has not been very good.

If he hadn't drunk any coffee in the last four weeks, he would have put a check by that statement instead of putting a mark on the line between TERRIBLE and EXCELLENT.

As in this example, make a mark across the line rather than using an X or an O. Please answer all the questions.

Socket Comfort Score (SCS)

Instructions: Please rate the comfort of your socket using the following scale (check one box for each).

On a 0 – 10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb <u>at the moment</u>?

☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
Most uncomfortable										Most comfortable

On a 0 – 10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb <u>on average, over the last 7 days</u>?

☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
Most uncomfortable										Most comfortable

On a 0 – 10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb <u>at best, over the last 7 days</u>?

☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
Most uncomfortable										Most comfortable

On a 0 – 10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb <u>at worst, over the last 7 days</u>?

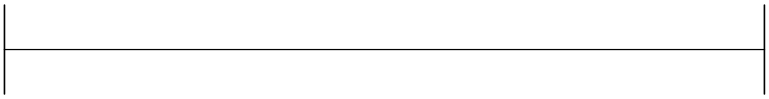
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
Most uncomfortable										Most comfortable

Prosthesis Evaluation Questionnaire (PEQ)

Instructions: Please read the PEQ instructions provided to you by the research study staff and place a vertical mark along the line at a point that indicates your response.

Prosthesis Evaluation Questionnaire – Satisfaction

Over the past two weeks, rate how happy you have been with your current prosthesis.



EXTREMELY UNHAPPY EXTREMELY HAPPY

Prosthesis Evaluation Questionnaire – Ambulation

Over the past two weeks, rate your ability to walk when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk in close spaces when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk up stairs when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk down stairs when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk up a steep hill when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk down a steep hill when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk on sidewalks and streets when using your prosthesis.

CANNOT NO PROBLEM

Over the past two weeks, rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat deck) when using your prosthesis.

CANNOT NO PROBLEM

Ambulation Average:	

Prosthesis Evaluation Questionnaire – Residual Limb Health

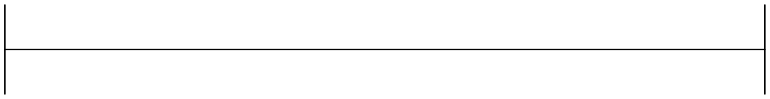
Over the past two weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket).

EXTREME AMOUNT NOT AT ALL

Over the past two weeks, rate how smelly your prosthesis was at its worst.

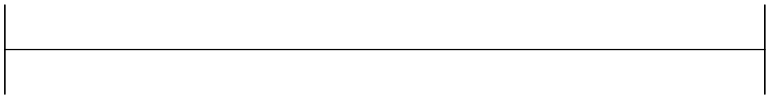
EXTREMELY SMELLY NOT AT ALL

Over the past two weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis**.**



ALL THE TIME NEVER

Over the past two weeks, rate any rash(es) that you got on your residual limb.



EXTREMELY BOTHERSOME NOT AT ALL

OR check __ I had no rashes on my residual limb in the last month.

Over the past two weeks, rate any ingrown hairs (pimples) that were on your residual limb.

EXTREMELY BOTHERSOME NOT AT ALL

OR check __ I had no ingrown hairs on my residual limb in the last month.

Over the past two weeks, rate any blisters or sores that you got on your residual limb.

EXTREMELY BOTHERSOME NOT AT ALL

OR check __ I had no blisters or sores on my residual limb in the last month.

Residual Limb Health Average:	

Prosthesis Evaluation Questionnaire – Utility

Over the past two weeks, rate the fit of your prosthesis.

TERRIBLE EXCELLENT

Over the past two weeks, rate the weight of your prosthesis.

TERRIBLE EXCELLENT

Over the past two weeks, rate your comfort while standing when using your prosthesis.

TERRIBLE EXCELLENT

Over the past two weeks, rate your comfort while sitting when using your prosthesis.

TERRIBLE EXCELLENT

Over the past two weeks, rate how often you felt off balance while using your prosthesis.

ALL THE TIME NOT AT ALL

Over the past two weeks, rate how much energy it took to use your prosthesis for as long as you needed it.

COMPLETELY EXHAUSTING NONE AT ALL

Over the past two weeks, rate the feel (such as the temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump).

WORST POSSIBLE BEST POSSIBLE

Over the past two weeks, rate the ease of putting on (donning) your prosthesis.

TERRIBLE EXCELLENT

Utility Average:	

Prosthesis Evaluation Questionnaire – Well Being

Over the past two weeks, rate how satisfied you have been with how things have worked out since your amputation.

EXTREMELY DISSATISFIED EXTREMELY SATISFIED

Over the past two weeks, how would you rate your quality of life?

WORST POSSIBLE LIFE BEST POSSIBLE LIFE

Well Being Average:	

Participant Query Form – PM

Participant Id#: _____

Name of investigator: _____ Date: _____

Time of AM session: _____ Time of PM session: _____

Clinical Inspection of limb:

Diet / food intake since AM session:

Did the participant consume any of the following (if so, describe)?

☐ Caffeine _____

☐ Alcohol _____

☐ Sodium _____

Activity since AM session (note specific activities like stairs and walking over uneven ground):

Please estimate the percent of time between sessions in each of the following categories:

Sitting: _____ %

Standing: _____ %

Walking: _____ %

Other: _____ % Describe: _____

Participant Query Form – PM

Socket doffing since AM session (note times and reasons for socket doffing):

Sock changes since AM session (note times and reasons for sock changes):

Other Notes:

INTRODUCTION

This document outlines the process for attaching two ActiGraphs, one to the prosthetic ankle and one to the liner of a transtibial amputee, and initializing the devices for data collection. Before beginning this protocol, you should have read and completed everything within the ActiGraph Setup document (software installation, loading the data collection template file, charging the ActiGraphs to be used for the current participant, etc.). The ActiGraph attachment process takes 30-60 minutes and should ideally be completed by a research assistant while the general intake of the participant is completed.

There are three separate steps outlined below:

1) Liner ActiGraph attachment
2) Ankle ActiGraph attachment
3) ActiGraph initialization

MATERIALS

General

- Scissors for cutting tapes and wrap
- Nitrile gloves
- Paper towels

Ankle Attachment

- Fully charged ankle ActiGraph
- Firm foam block for pylon attachment
- FastCap double-sided adhesive
- 3M 4016 Foam tape
- Velcro strap
- ActiGraph “pick” screwdriver
- 3M 4” Bandaging Tape

Liner Attachment

- Fitted prosthesis liner
- Fully charged liner ActiGraph w/ fabric prosthetic liner patch
- Loctite 454 Instant Adhesive Gel
- Cylindrical foam positive (for glue contouring)
- Glue applicators (Q-tip, tongue depressor)

ActiGraph Initialization

- USB Micro-B cables (2)
- Computer with ActiLife or ActiLife Lite Software installed, research template loaded, and 2 available USB ports

PROTOCOL

While a researcher is performing participant intake, have the participant doff his or her prosthesis and liner. Show the liner ActiGraph to the participant and confirm that they are comfortable with this instrument being adhered to their liner. You must also communicate to them that the device is not waterproof, only water resistant; when used properly, the ActiGraph is designed to be submersible in 1 meter of water for up to 30 minutes. Still, the participant should avoid submerging it and exposing it directly to a stream of water. Normal daily activities are fine, but they should avoid bathing with the liner on, they should never submerge it if they clean the liner, and they cannot swim with it. Complete the following sections in the order written.

Liner ActiGraph Attachment

The ActiGraph is attached to the anterior, proximal aspect of the prosthetic liner and embedded in soft rubber in order to decrease risk of damage to liners while improving comfort for the participant. Before performing these steps, put on the nitrile gloves. Loctite 454 will quickly bond to your skin and is extremely difficult to remove. Also, make sure that the ActiGraph's USB cap is open, as they can be difficult to open once adhered to the liner/prosthesis.

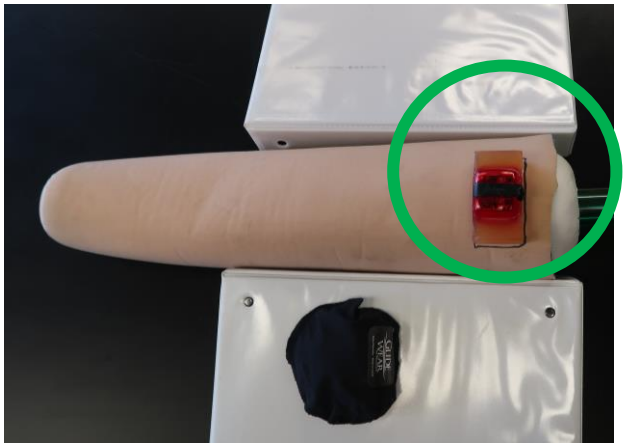


Figure 1: Correctly identified position for the liner ActiGraph – about one inch below the anterior, proximal edge of the liner.

1. Insert the cylindrical positive into the upper portion of final fitted liner. This is necessary for the liner ActiGraph to maintain its contoured shape as the adhesive dries. This also helps the ActiGraph rest more comfortably on the participant's thigh.
2. Locate the site of attachment for the ActiGraph. The top of the ActiGraph should be about an inch from the top of the liner, resting on the anterior aspect of the thigh and not over the knee. Outline the site of attachment with marker and confirm that the location is appropriate. Figure 1 demonstrates appropriate positioning and orientation.
3. Orient the ActiGraph so the USB port/black cap of the device is in the direction of the proximal end of the liner.
4. Dispense Loctite adhesive on to the bottom of the rubber that encases the ActiGraph. See Figure 2 for an ideal surface pattern. You do not want to apply an excessive amount, as large pieces of the hardened glue can be uncomfortable and possibly damage the liner.

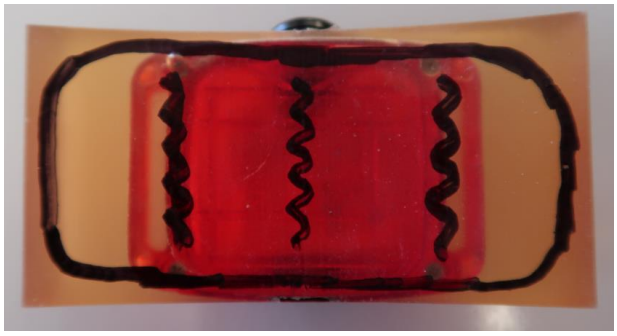


Figure 2: Loctite 454 glue pattern demonstrated with marker on the underside of the liner ActiGraph. The rounded edges reduce risk of sharp glue edges damaging the liner.

5. Immediately (and in one confident motion) press the device and adhesive into the site of attachment. Make sure the cap of the ActiGraph is oriented in the proximal direction. You only have one chance at this, as the glue sticks instantly and is nearly impossible to remove. Hold for 2 minutes; while Loctite is an "instant" adhesive and physically bonds in seconds, additional time is necessary for the chemical bond to develop.
6. Apply Loctite adhesive to the beneath free edges of the fabric patch around the base of the ActiGraph, **leaving 1 inch free on the center of the proximal side**. You will need to be able to access the USB port and close the cap once the initialization is complete. Press each edge down with the tongue depressor for 30 seconds to ensure adequate bonding. If it is difficult to get the fabric patch to adhere, you may need to apply more Loctite.

Ankle ActiGraph Attachment

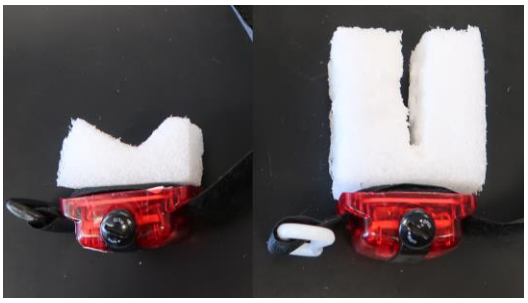


Figure 3: ActiGraphs shown with different foam padding for cylindrical ankle pylons (left) and blade style prostheses (right).

1) Identify the type of ankle pylon for the current participant. Attach an ActiGraph to the foam block that corresponds to the participant's ankle type (Figure 2) using the FastCap adhesive.

2) Place the 3M Foam tape around the ankle pylon, and then peel off the backing.

3) Locate the lateral aspect of the prosthetic ankle. Positioning and orientation is important, so ensure that the ActiGraph is upright (with black cap proximal) and lateral - see Figure 4. Press the ActiGraph and foam padding into the adhesive tape.

4) Tightly wrap the Velcro strap around the ankle, through the plastic slot on the opposite side of the ActiGraph, and then back over itself, securing it. You may have to wrap it around itself an extra time.

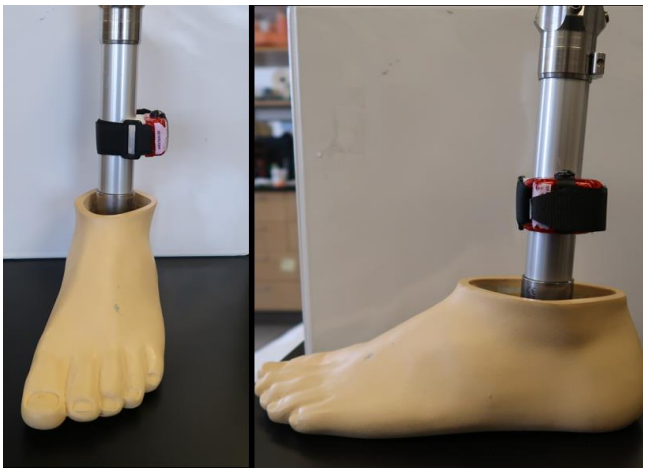


Figure 4: Ankle ActiGraph correct position demonstrated for a left leg below-knee amputee

*****BEFORE COMPLETING STEP 5, YOU MUST INITIALIZE THE ACTIGRAPH. COMPLETE ALL STEPS IN THE "ACTIGRAPH INITIALIZATION" SECTION, THEN RETURN AND COMPLETE STEP 5 TO COMPLETE ATTACHMENT OF THE ANKLE ACTIGRAPH*****

5) (AFTER INITIALIZATION) Tightly wrap the ActiGraph and pylon with medical wrap. Begin adjacent to the ActiGraph (Figure 5), then going around the prosthetic pylon. Once you reach the ActiGraph, loop around, re-wrapping in the opposite direction that you started (Figure 5). Continue around once and repeat the same process. Having crossed back twice, wrap around a few more times then cut and press once it seems adequately secured.

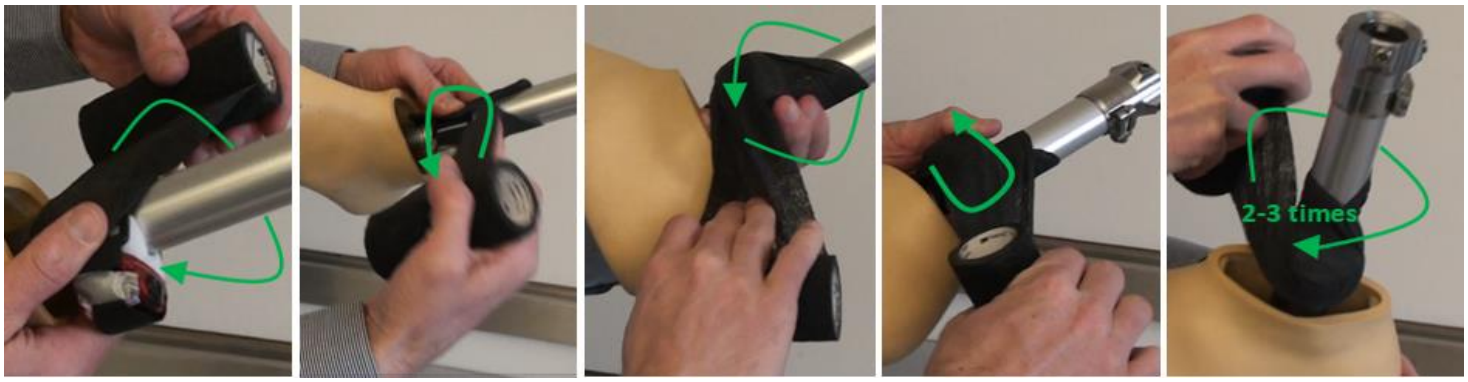


Figure 5: Sequential steps to wrap ankle pylon (left to right). Wrap very tightly in order to secure it. If the ActiGraph rotates about the pylon during the duration of the study, it can affect the quality of the activity data.

ActiGraph Initialization

1) Launch the ActiLife software.
2) Connect both ActiGraphs to the computer. If they do not show up in the device table:
   a. Click Refresh
   b. Unplug and plug the ActiGraph back into the USB port (try each end).
   c. If a. and b. do not work, wait a few minutes. If the ActiGraph battery is fully depleted, it will not be recognized by the computer and needs to be charged.
3) Take note of the specific serial number belonging to each ActiGraph. It is important that the researchers know which ActiGraph was on the ankle and which is on the liner. You need to know this for step 7.
4) Click Initialize → Regular Initialization. The "Initialize Devices" window will open.
5) Leave the date as is (the current date). Edit the time field to be 1-2 minutes ahead of the current time.
6) Click Enter Subject Info and fill in necessary fields. For Subject Name, just use the subject's anonymized three letter identifier. Then complete the Limb field (Ankle/Thigh) and the Side field (left/right leg amputee). You can ignore the Height, Weight, D.O.B., race, and gender fields.
7) Once all fields are filled out, verify that they are correct, and then click Initialize 2 Devices. If the current time caught up to the initialization time that you first entered, the software will stop you from initializing. You need to set a new time at least 1 minute ahead and click initialize. The "Initialize Devices" window will close.
8) Verify that both devices have been initialized within the Status field of the Device Table. It should read, "finished initializing" for each device.
9) Wait until the current time catches up to the time set for initialization. Once this happens, click Refresh The "Current Data Recorded" field should show the duration of data that has been collected (a few seconds), demonstrating initialization was successful.
10) Unplug both ActiGraphs. Close **both** the ankle and liner ActiGraph USB port caps using the ActiGraph "pick" screw. It may be difficult to properly thread the plastic cap. It helps to make a half rotation in the "Open" direction to align the threads, then tighten in the "Close" direction. Make sure the white O-ring is in place, as this is necessary for water resistance. The cap should be secure and level if successful (Figure 6). You should see the white O-ring.

Figure 6: Open (left), improperly closed (middle), and completely closed (right) ActiGraphs. O-Ring should not be visible.

11) Return to step 5) of Ankle ActiGraph Attachment and wrap the ankle ActiGraph.
12) **Establish the reference position for the Ankle ActiGraph. Pick up the entire prosthesis, rotate it 360° along the longitudinal axis, then set it back down so it is standing vertically (Figure 4). Wait 20 seconds with the prosthesis upright and still. Repeat two additional times.**
13) You may now return the prosthesis and liner to the participant.

DAILY SOCK CHANGE LOG

Instructions: Many individuals with limb loss add or remove socks to help improve the fit or the comfort of their prosthesis. This daily log will help us better understand when you may choose to use different socks over the next two weeks.

You are free to use any of your socks and to add and remove them throughout the day, as you wish.

It is important that you complete this log every day so that we know how you used your socks. Please be sure to fill out this form when you first put on your prosthesis during the day and then again when you take it off. If you add or remove socks differently than the fields on the form, please make a note on the reverse side of the form.

If you have any questions, contact the study staff for assistance or clarification at 206-221-5873. Thank you.

EXAMPLE

Please read the following EXAMPLE to see how to complete the DAILY SOCK CHANGE LOG:

"Bob," a study participant, wakes up, showers, and put on his prosthesis for the day at 7:00am. Bob would go fill in the first part of his DAILY SOCK CHANGE LOG as follows:

Please describe the **BEGINNING** of your day

Time	
7:00	☒ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

You see that Bob recorded the time he put on his socket (7:00) and he checked "am."

EXAMPLE (continued)

At lunch time (about noon), Bob begins to feel loose in his socket and decides to replace his MEDIUM (3-PLY) sock with a THICK (5-PLY) and a THIN (1-PLY) sock. Bob then returns home and eats dinner. After dinner (about 6:30pm), he feels a bit tight in his socket. He removes both socks and returns to his MEDIUM (3-PLY) sock for the evening. Bob would go fill in the middle part of his DAILY SOCK CHANGE LOG as follows:

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
12:00	☐ am ☒ pm	☒ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
6:30	☐ am ☒ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☒ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

You see that Bob first recorded the time he changed socks (12:00), checked "pm," and noted the total socks he changed to are thicker. He then recorded the time after dinner when he took off both these socks (6:30), checked "pm," and indicated the sock he was then wearing were thinner.

Bob removes his socket at 10:30pm and goes to bed at 11:00pm. Bob would complete his DAILY SOCK CHANGE LOG as follows:

Please describe the **END** of your day

Time	
10:30	☐ am ☒ pm
Before you took your prosthesis **OFF** (end of day)	

He records the time when he takes off his socket as 10:30, checks "pm.". Bob has correctly completed his DAILY SOCK CHANGE LOG.

DAY 1

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 2

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 3

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 4

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 5

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 6

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 7

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 8

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 9

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 10

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 11

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 12

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 13

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

DAY 14

Please describe the **BEGINNING** of your day

Time	
	☐ am ☐ pm
When you first put **ON** your prosthesis (start of day)	

Please describe any time you **ADDED or REMOVED** sock thickness during the day

Time (What time did you change socks?)		**Socks** (What socks are you wearing now?)
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks
	☐ am ☐ pm	☐ I changed to **thicker** socks ☐ I changed socks, but thickness **did not change** ☐ I changed to **thinner** socks

Please describe the **END** of your day

Time	
	☐ am ☐ pm
Before you took your prosthesis **OFF** (end of day)	

☐ Check here if you did **NOT WEAR** your prosthesis today

Prosthetist Intake Form

Date of birth: _____/_____/_____
month day year

Gender:

- ☐ Male
- ☐ Female

Ethnicity:

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

Race *(please check all that apply):*

- ☐ White
- ☐ Black or African-American
- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander

Clinic Name: _____

Clinic Location (City, State): _____

Years Practicing: _____ At Current Location: _____

Education *(please check all that apply):*

- ☐ Prosthetics certificate
- ☐ Bachelors (e.g., BPO)
- ☐ Masters (e.g., MSPO/MPO)
- ☐ Doctorate (e.g., PhD)
- ☐ Other: _____

Indicate your current clinical certification *(please check all that apply)*:

- ☐ ABC certified prosthetist (CP)
- ☐ ABC certified prosthetist-orthotist (CPO)
- ☐ BOC certified prosthetist (BOCP)
- ☐ BOC certified prosthetist-orthotist (BOCPO)
- ☐ Other: _____

Prosthetist Intake Form

Please estimate your current number of active lower-limb prosthetic patients:

Transfemoral: _____ patients

Transtibial: _____ patients

Other: _____

Estimate how many new lower-limb sockets you provide each year

Transfemoral: _____ per year

Transtibial: _____ per year

Estimate how many lower-limb socket replacements you perform each year:

Transfemoral: _____ per year

Transtibial: _____ per year

Please estimate the percent of your lower limb prosthetic patients with the following amputation cause:

Trauma: _____ %

Vascular: _____ %

Other: _____ %

Please estimate the percent of your lower-limb prosthetic patients with the following:

Vascular Disease:	_____ %	Heart Disease:	_____ %
Diabetes:	_____ %	Cancer:	_____ %
Poor Sensation:	_____ %	No Health Issues:	_____ %
Tobacco Use:	_____ %	Obesity (BMI>30):	_____ %

Which of the following modifications or volume management practices do you regularly perform or recommend to your prosthetic patients *(add details as needed)*?

☐ New sock regimen _____

☐ Periodic doffing _____

☐ New activity regimen _____

☐ New suspension _____

☐ New socket _____

☐ Socket pads/inserts _____

☐ Socket relief _____

☐ Self-care regimen _____

☐ Other: _____

Prosthetist Limb & Socket Evaluation

Describe observed tissue (skin/muscle) quality *(add details as needed)*:

- ☐ Redundant soft tissue _____
- ☐ Large gastroc flap _____
- ☐ Patellar tendon issues _____
- ☐ Varicose veins _____
- ☐ Pigmentation _____
- ☐ Eczema _____
- ☐ Sock impressions _____
- ☐ Verrucous hyperplasia _____
- ☐ Skin folds/Invagination _____
- ☐ Loose skin _____
- ☐ Abrasions _____
- ☐ Boils _____
- ☐ Skin infections _____
- ☐ Bone spurs _____
- ☐ Scar tissue _____
- ☐ Ingrown hairs _____
- ☐ Skin breakdown _____

Presence of Hair?

☐ Yes ☐ No

Overall how would you rate your patient's present limb health?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

VERY POOR VERY GOOD

Qualitative limb evaluation:

Prosthetist Limb & Socket Evaluation

Describe observed socket fit issues or concerns *(add details as needed)*:

- ☐ Too small _____
- ☐ Too large _____
- ☐ Distal end bearing _____
- ☐ Bony prominences _____
- ☐ Posterior trimlines _____
- ☐ Excessive sock use _____
- ☐ Gait deviations _____
- ☐ Non-wearing _____
- ☐ Medial/Lateral trimlines _____
- ☐ Local pressure _____
- ☐ Limb rotation _____
- ☐ Poor suspension _____
- ☐ Limb displacement _____

Overall, how would you rate the current fit of your patient's prosthetic socket?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

VERY POOR VERY GOOD

Qualitative socket fit evaluation:

Prosthetist Survey 1

Overall, how would you rate your ability to communicate effectively with this patient?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

VERY POOR VERY GOOD

Describe your most recent interaction with the patient:

Describe the design of the current socket:

Why was the current socket designed as it was?

Prosthetist Survey 1

Why is this patient receiving a socket modification or change to their volume management practices? *(check all that apply, add details as needed)*

- ☐ Volume change _____
  - ☐ Increase _____
  - ☐ Decrease _____
  - ☐ Daily fluctuations _____
- ☐ Shape change _____
- ☐ Elapsed time since last socket _____
- ☐ Wear or damage _____
- ☐ Other: _____

What socket modifications are you planning *(check all that apply, add details as needed)*?

- ☐ New socket _____
- ☐ Socket pad/insert _____
- ☐ Socket relief _____
- ☐ Suspension change _____
- ☐ Other _____
- ☐ None _____

How do you think these socket modifications will improve the patient's clinical outcomes?

What volume management strategies have you previously recommended to this patient? *(add details as needed)*

- ☐ Sock regimen _____
- ☐ Periodic doffing _____
- ☐ Activity regimen _____
- ☐ Self-care regimen _____
- ☐ Other _____
- ☐ None _____

Prosthetist Survey 1

Which, if any, of these strategies do you feel have been successful in improving clinical outcomes for this patient?

How are you now planning to modify volume management strategies, if at all? *(add details as needed)*

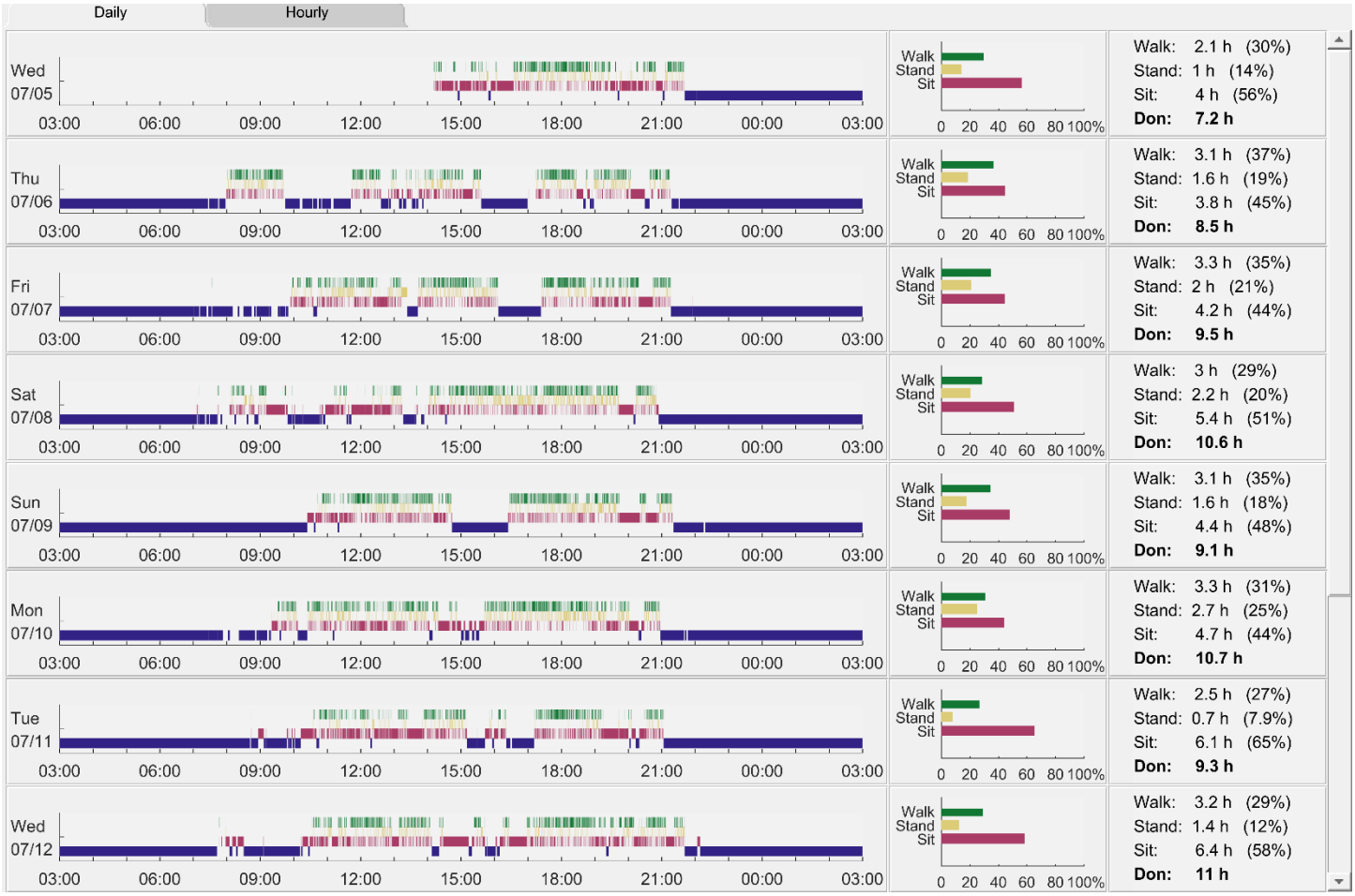
- ☐ New sock regimen _____
- ☐ Periodic doffing _____
- ☐ New activity regimen _____
- ☐ New self-care regimen _____
- ☐ Other: _____
- ☐ None _____

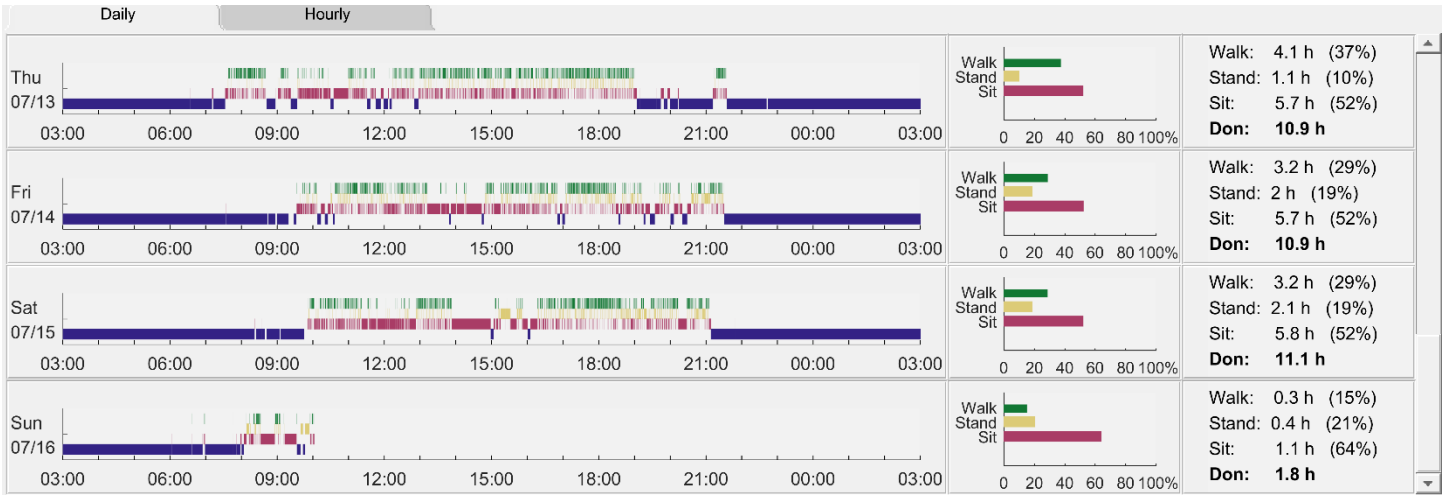
How do you think these volume management strategies will improve clinical outcomes?

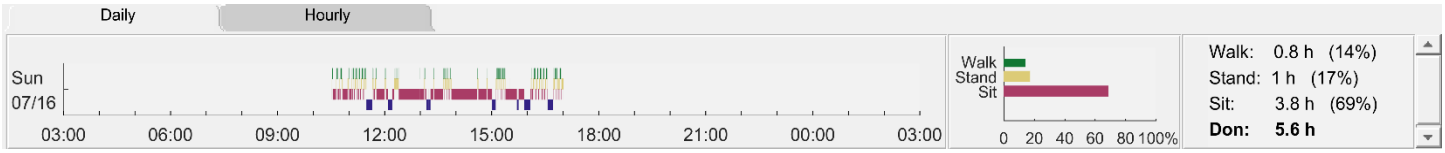
Clinical Summary

This is a 76 year old, 6', 190 lbs. male who had a left unilateral amputation 5 years ago due to an infection. Subject also suffers from arthritis, lower back pain (L3-L5 fixed), knee pain in contralateral limb (had TKR surgery), and favors contralateral side. Subject takes 150mg Lyrica and mentioned OxyContin use. He is a K-2 level ambulatory who uses a cane daily. He is retired, but appears active, tending for the dozen or so horses on his farm each day and performing other general home maintenance. He currently uses a laminated PTB socket with suspension sleeve (Ottobock) and WillowWood Alpha Hybrid liner with a gel pad in the distal end of the socket. Subject has had a posterior blister behind the knee for the past 8 months (previously open for 2 months) and some irritation from posterior brimline. He has had a hole in his liner over the blister for the past 4 months. Subject only reports doffing when experiencing excessive discomfort. He is having a new socket made since the current socket is too small (0-1 ply), with the 1 ply occasionally used to relieve rubbing on the blister. A new liner and sleeve is also planned.

Activity Summary







Conclusion - AG data and self-report: Reported wearing socket from ~7am to 9:30pm. Current AG results suggest he is highly active, but remain skeptic of this.

1. On a typical day, what time do you first **put on** your prosthesis?

   7 ☒ AM ☐ PM

2. On a typical day, what time do you **remove** your prosthesis?

   9:30 ☐ AM ☒ PM

3. Of the time during the day you are wearing your prosthesis, estimate the percent you are doing the following activities (ensure they sum to 100%):

   Sitting 10 %
   Standing 20 %
   Walking 70 %
   Total 100 %

4. Which of the following combinations best reflects the activity breakdown of an average day?:

   A. Sitting 55%, Standing 25%, Walking 20%
   (B.) Sitting 65%, Standing 20%, Walking 15%
   C. Sitting 75%, Standing 15%, Walking 10%
   D. Sitting 85%, Standing 10%, Walking 5%

5. Which of the following combinations best reflects the activity breakdown of an average day of prosthesis use?

   (A.) Sitting 7 hr
   Standing 3 hr
   Walking 2.5 hr

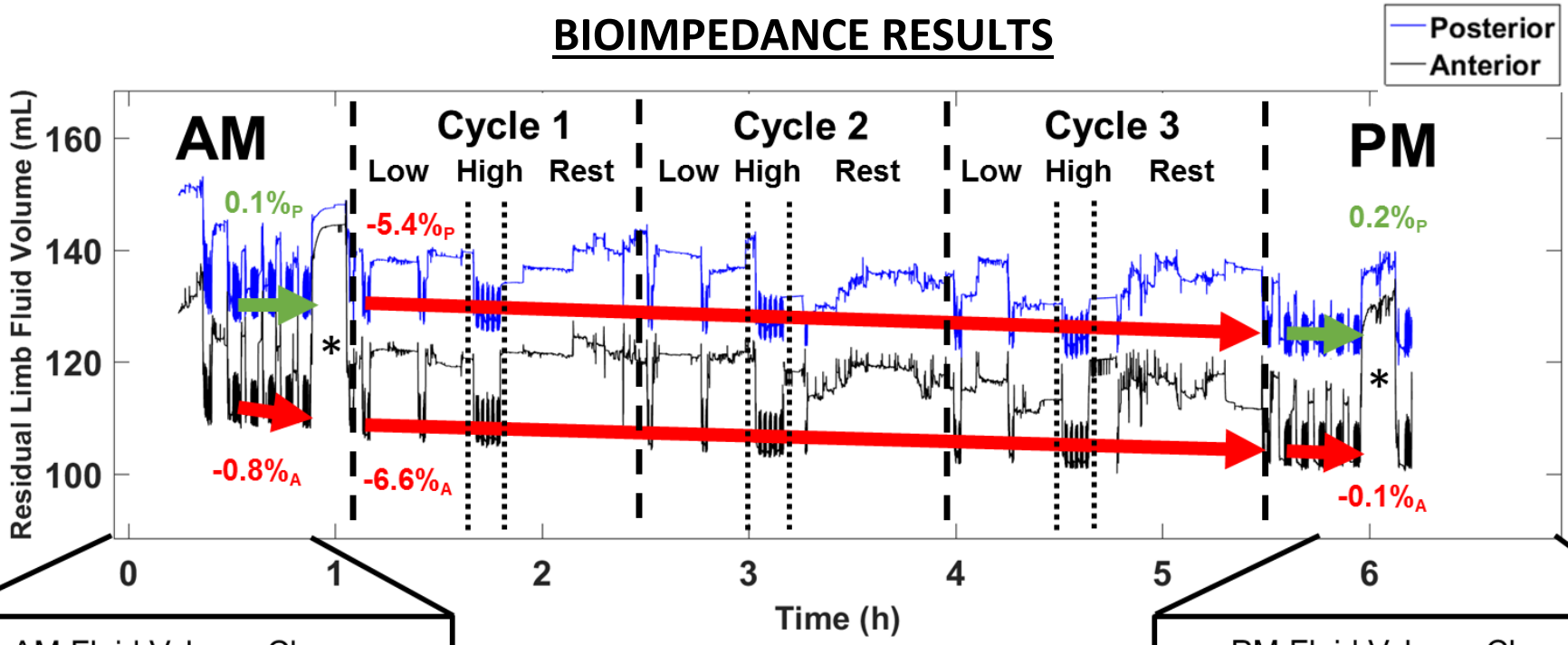
   B. Sitting 8.5 hr
   Standing 2.5 hr
   Walking 1.5 hr

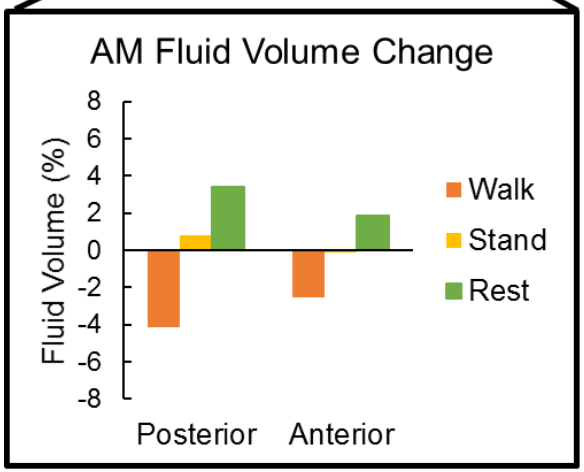
   C. Sitting 10 hr
   Standing 2 hr
   Walking 1 hr

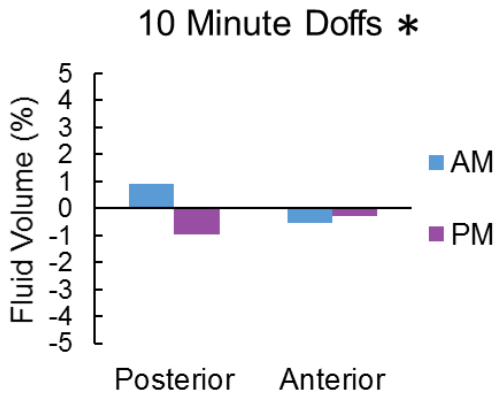
   D. Sitting 11.5 hr
   Standing 0.5 hr
   Walking 0.5 hr

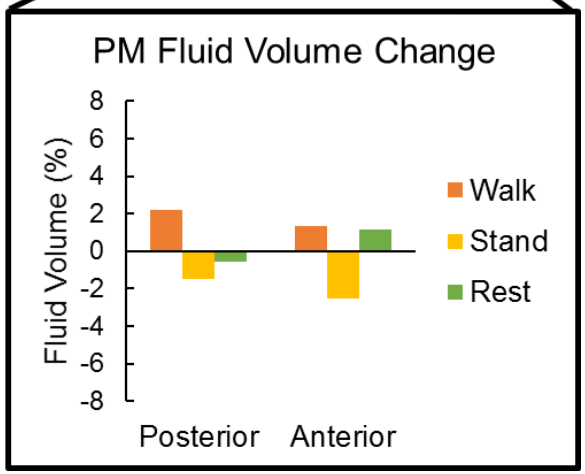
UNIVERSITY of WASHINGTON

BIOIMPEDANCE RESULTS









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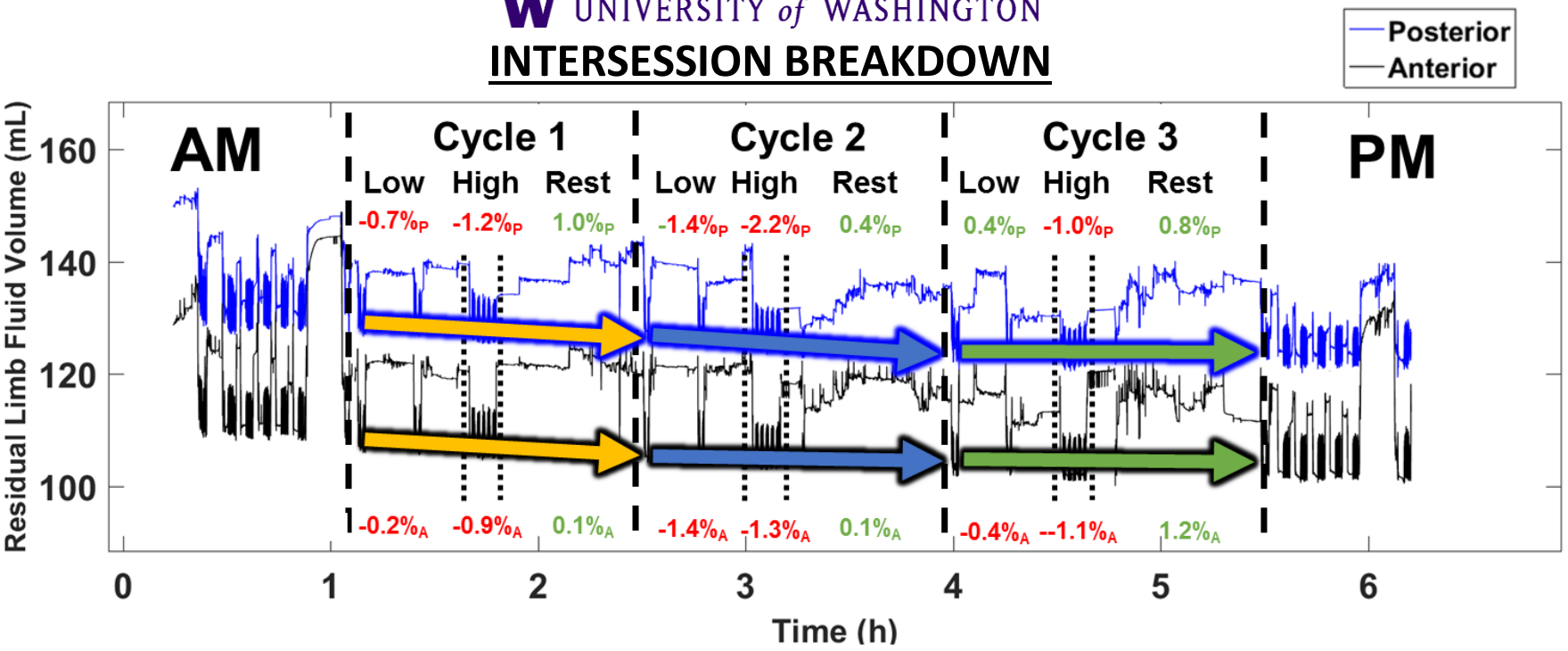
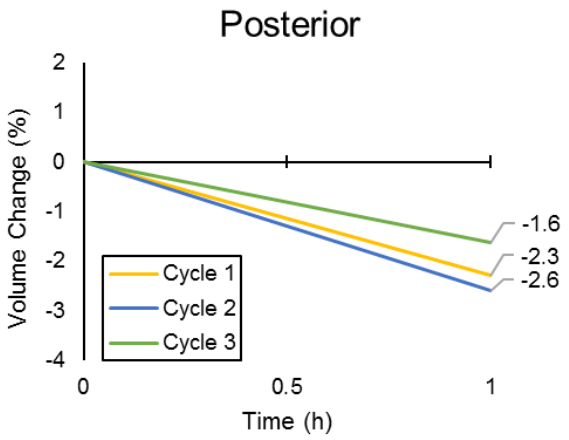
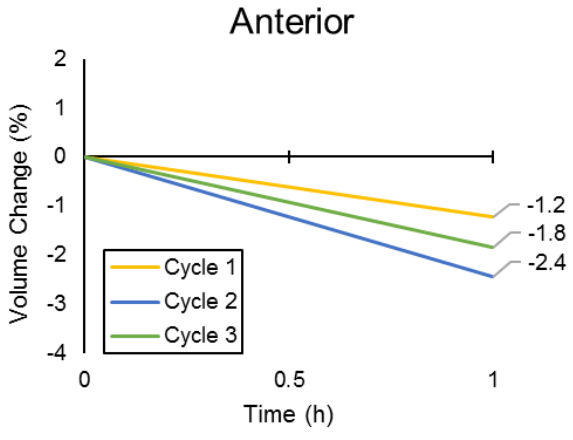
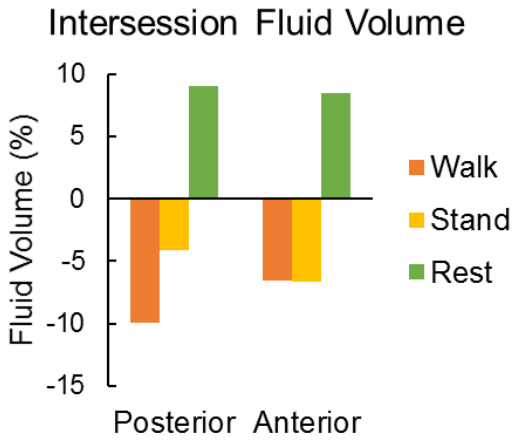
INTERSESSION BREAKDOWN









Clinical Summary

- Periods of rest resulted in less fluid volume loss and led to fluid volume recovery in most cases for this participant
    - High activity showing higher loss than low activity portion
    - Maintaining periods of rest during the day and breaking up longer periods of weight bearing will help the participant limit fluid volume loss
    - The planned larger socket may help to improve recovery during rest – this will be something to watch for in the follow-up session
    - Determining appropriate sock thickness may be difficult due to the participant's limited sensation, increased rests or doffs (not only when the limb hurts) may be a better volume management strategy

- The participant experiences stable fluid volume when breaking up activity as in AM and PM 5-cycles
    - Some fluid volume benefit while walking during PM session but limited elsewhere
    - No major differences between anterior and posterior volume loss over the whole day

- The participant showed limited to no fluid volume benefit from releasing socket pressures by doffing, exhibited fluid volume loss or minimal gain
    - Suggests the participant may be experiencing venous occlusion immediately prior to doffing
    - This will be further examined in the follow-up visit when the participant is in a larger socket

Consolidated Summary

- Participant may benefit from incorporating more rests during his active day to help with fluid volume recovery

Prosthetist Survey 2

Overall, how would you rate your ability to communicate effectively with this patient?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

VERY POOR VERY GOOD

Describe your most recent interaction with the patient:

What <u>socket modifications</u> did you implement *(check all that apply, add details as needed)*?

- ☐ New socket _____
- ☐ Socket pad/insert _____
- ☐ Socket relief _____
- ☐ Suspension change _____
- ☐ Other _____
- ☐ None _____

How would you rate the success these <u>modifications</u> had on improving patient outcomes?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

NOT AT ALL SUCCESSFUL VERY SUCCESSFUL

Why do you think these <u>socket modifications</u> affected clinical outcomes? What worked? What did not?

Prosthetist Survey 2

What changes to volume management strategies did you recommended to this patient?

- ☐ New sock regimen _____
- ☐ Periodic doffing _____
- ☐ New activity regimen _____
- ☐ New self-care regimen _____
- ☐ Other: _____
- ☐ None _____

How would you rate the success these strategies had on improving patient outcomes?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT AT ALL SUCCESSFUL VERY SUCCESSFUL

Why do you think these volume management strategies affected clinical outcomes? What worked? What did not?

Overall, how would you rate your satisfaction with the changes you made to the patient's socket and/or volume management practices?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT AT ALL SATISFIED COMPLETELY SATISFIED

What would you change about your approach or methodology?

Prosthetist Survey 2

Overall, how would you rate your ability to communicate effectively with this patient?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

VERY POOR VERY GOOD

Describe your most recent interaction with the patient:

What <u>socket modifications</u> did you implement *(check all that apply, add details as needed)*?

- ☐ New socket _____
- ☐ Socket pad/insert _____
- ☐ Socket relief _____
- ☐ Suspension change _____
- ☐ Other _____
- ☐ None _____

How would you rate the success these <u>modifications</u> had on improving patient outcomes?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

NOT AT ALL SUCCESSFUL VERY SUCCESSFUL

Why do you think these <u>socket modifications</u> affected clinical outcomes? What worked? What did not?

Prosthetist Survey 2

What changes to volume management strategies did you recommended to this patient?

- ☐ New sock regimen _____
- ☐ Periodic doffing _____
- ☐ New activity regimen _____
- ☐ New self-care regimen _____
- ☐ Other: _____
- ☐ None _____

How would you rate the success these strategies had on improving patient outcomes?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT AT ALL SUCCESSFUL VERY SUCCESSFUL

Why do you think these volume management strategies affected clinical outcomes? What worked? What did not?

Overall, how would you rate your satisfaction with the changes you made to the patient's socket and/or volume management practices?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT AT ALL SATISFIED COMPLETELY SATISFIED

What would you change about your approach or methodology?

Prosthetist Survey 2

Describe your impression of the bioimpedance results

Describe how you used the results to inform your clinical decisions

How would you rate the utility of the bioimpedance results in <u>designing the socket</u> for your patient?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT USEFUL VERY USEFUL

How would you rate the utility of the bioimpedance results in <u>choosing volume management strategies</u> for your patient?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT USEFUL VERY USEFUL

Overall, to what extent did the bioimpedance results affect how you addressed the patient's issues?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT AT ALL VERY MUCH

To what extent did bioimpedance results improve your ability to communicate with your patient?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

NOT AT ALL VERY MUCH

Prosthetist Survey 2

To what extent did bioimpedance results improve your patient's clinical outcomes?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

NOT AT ALL VERY MUCH

How likely would you be to request bioimpedance results for each of your patients?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

NOT LIKELY AT ALL VERY LIKELY

Which bioimpedance information was most useful to you?

- ☐ Percent fluid volume change over the whole day
- ☐ Percent fluid volume change by regions of the limb
- ☐ Percent fluid volume change by activity (e.g. sitting, standing, walking)
- ☐ Rate of fluid volume change over the whole day
- ☐ Rate of fluid volume change by activity intensity (e.g. low, high activity)
- ☐ Other: _____

What additional volume information would you find useful towards assessing socket fit, improving socket design, or recommending volume management strategies?

To what extent did the presentation and discussion of bioimpedance information improve your understanding of the information?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

NOT AT ALL VERY MUCH

How would you recommend improving the presentation and discussion of bioimpedance information?