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TITLE: Preliminary Evaluation of a Diagnostic Tool for Prosthetics

PRINCIPAL INVESTIGATOR: Joan E Sanders PhD

RECIPIENT: University of Washington

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University of Washington
Seattle WA 98195

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this research is to integrate a novel limb fluid volume measurement instrument into clinical care, 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, the focus was on recruitment of additional participants and test sites, and enhancement of the data processing and analysis techniques. Enhancement of recruitment efforts was modestly successful locally but not nationally. Data analysis conducted to date using limb fluid volume data collected during standing demonstrated variability and noise, possibly explaining the lack of statistical significance in study results to date. The analysis is now being conducted using stance phase minima during walking, which based from experience, should reduce variability and noise. The analysis variables have been expanded to include rate of limb fluid volume change during the AM 5-cycle test, PM 5-cycle test, intersession, as well as during each type of activity (walk, stand, sit). Relationships between these variables, self-report outcomes, field-measured activity, participant characteristics, and prosthetic componentry and design are being investigated.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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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 are the major goals of the project?

The major goals of the project are 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 in Year 3?

Aim #1.

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

Modifications were made to the IRB to enhance participant recruitment and retention. They are summarized in TABLE 1 below.

TABLE 1. IRB modifications in Year 3.

Version	Date Approved	Description
Versions 6,7	10/25/2018	• Modified prosthetist consent form to allow for remote completion of surveys (i.e. via email, researcher not present) with the payment now being $50 per survey; intended to facilitate prosthetist involvement in Aim 2 • Modified language for both Aim 1 and Aim 2 so it is clear that the time between visits may extend past the desired 12-week timeline due to delays in clinical care • Added a $150 completion bonus for amputee participants to reduce attrition

Task 1.2. Recruit practitioners

In Year 3, multiple efforts were made to recruit additional clinicians through our contact network. Some success was made in recruiting more local practitioners.

Task 1.3. Fabricate additional bioimpedance units

No additional bioimpedance units were fabricated in Year 3. All previously fabricated units from Year 1 and 2 are still functioning and are in use.

Task 1.4. Automate electrode assembly/fabrication

No changes were made to the electrode assembly/fabrication process from Year 2 procedures.

Task 1.5. Recruit subjects

We continued to distribute and post flyers in local prosthetic offices as well attend local amputee events and support group meetings.

Task 1.6. Conduct pre-implementation testing

Pre-implementation testing as described in previous reports was continued. Additionally, when we are unable to get prosthetists involved for Aim 2, Aim 1 allows us to still enroll and complete testing with amputee participants. A total of 19 participants have enrolled in the Aim 1 protocol, and 12 have completed testing.

Task 1.7. Monitor activity during interim 2-4 weeks

We have continued to monitor participants' activity during the socket modification process as described in previous reports. Due to the iterative nature of the socket modification process, activity data collected before or after the interim modification period is less prone to interference by changes to their liner/sleeve, prosthesis, or limb health. We have made more efforts to collect activity data outside of this window before and after the clinical process as it is more representative of their habitual routine.

Task 1.8. Conduct post-implementation testing

Post-implementation was continued as described in previous reports.

Task 1.9. Process collected data

Aim 1 - Participants

#	Pre-Mod Session	Post-Mod Session	Completed?	Notes
1	11/9/2016	X	N	Delayed 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	4/17/2017	Y	
7	4/10/2017	5/4/2017	Y	
8	4/11/2017	X	N	Withdrew due to activity monitors
9	X	4/20/2017	Y	Repeated post mod session (subject 6) due to bad dataset
10	1/17/2018	X	N	Subject ignoring contact
11	2/22/2018	5/9/2018	Y	
12	3/17/2018	6/3/2018	Y	
13	8/23/2018	10/25/2018	Y	
14	7/27/2018	1/25/2019	Y	
15	9/14/2018	1/29/2019	Y	
16	3/26/2019	6/21/2019	Y	
17	4/3/2019	6/18/2019	Y	
18	9/27/2019		ongoing	
19	10/14/2019		ongoing	

Aim #1- recruited	**Year 1**				**Year 2**				**Year 3**				**Total**
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
Amputee participants	**1**	**4**	**4**	**0**	**0**	**2**	**1**	**3**	**0**	**0**	**2**	**2**	**19**

Task 1.10. Address hypotheses

Self-report scores for the participants tested in Aim #1 demonstrated, in general, more favorable results after the prosthesis was modified than before, consistent with expectation. Interestingly, three participants demonstrated less favorable "best" scores after modification, though average and worst scores were more favorable for the modified socket. Figure 1 below summarizes the differences in SCS scores (after modification minus before modification).

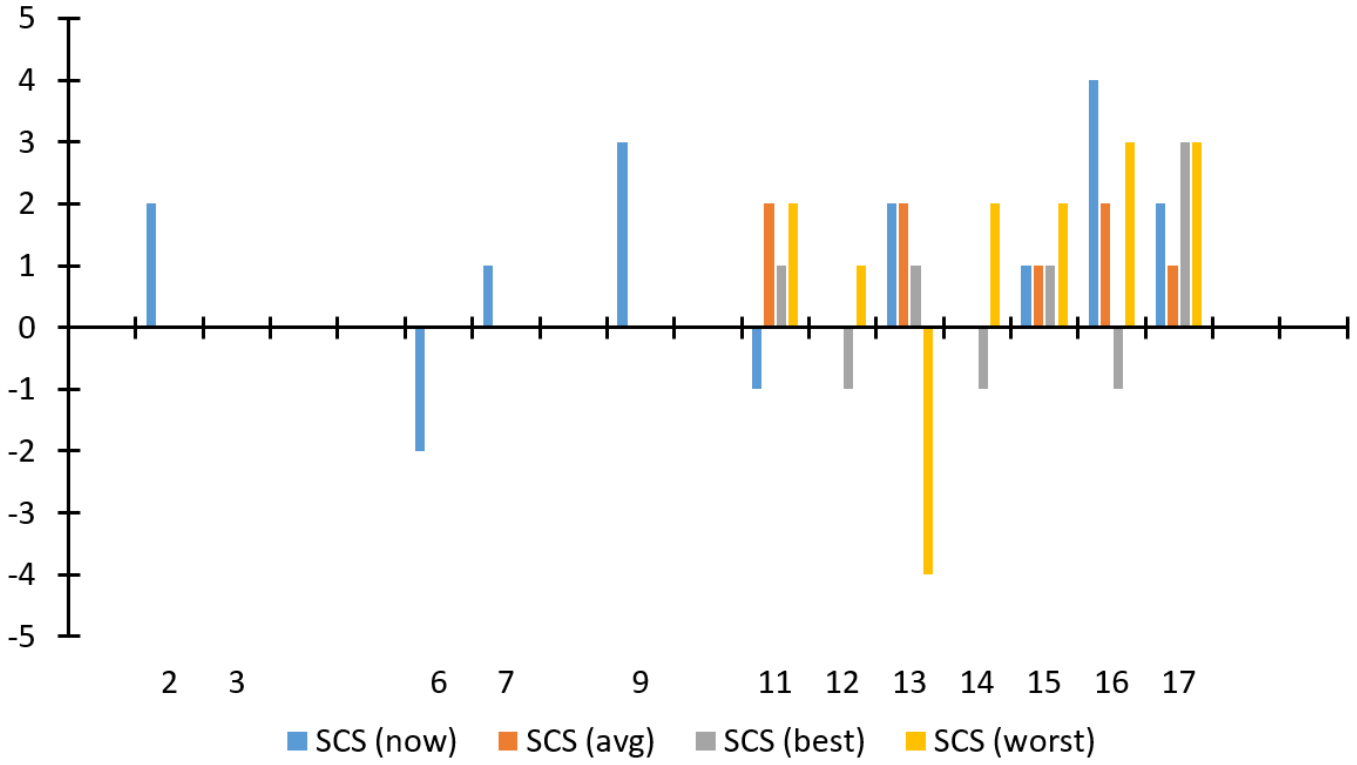


Figure 1. Aim #1 Net SCS Scores. Differences in SCS scores, after modification minus before modification, are shown. Absent data indicates incomplete datasets most often a result of an inability to collect the post-modification data within the time frame specified in the protocol. Participants 1-9 were completed with the traditional SCS prompt, "What is your socket comfort score at this moment?" Participants 11 and onwards were asked to score their comfort at the moment (now), on average, at best, and at worst over the past week.

In general, PEQ results also showed more positive results post-modification than before modification. Data are summarized in Figure 2.

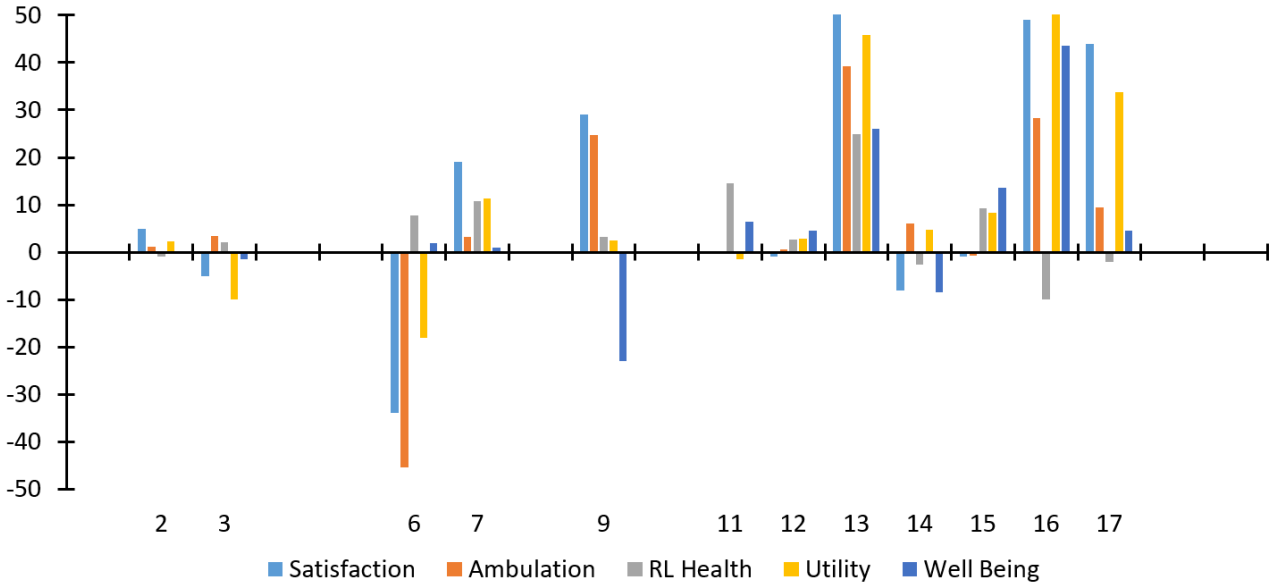


Figure 2. Aim #1 Net PEQ Scores. Differences in PEQ scores, after modification minus before modification, are shown. Absent data indicates incomplete datasets most often a result of an inability to collect the post-modification data within the time frame specified in the protocol.

A next step in this effort is to investigate relationships between limb fluid volume results (bioimpedance data) and self-report scores to determine if bioimpedance data predict outcomes. Our efforts using standing data points collected over the course of the protocol for analysis was not successful. While the computational algorithms we created did effectively identify standing data in each trial, there was much noise in the data, presumably because differences in posture from one stand to the next. We have seen this issue in other bioimpedance projects in our lab. To overcome this challenge, we analyze data collected during walking instead, using the minimum fluid volume during stance phase of each step. Given the success of this strategy in other projects, we are hopeful this effort is also successful here. It is, however, requiring a revision to our processing code and analysis. The new processing method is discussed in more detail in the hypotheses section of Aim #2 below.

Aim #2.

Task 2.1. Recruit practitioners

Efforts to enhance participant were attempted locally as well as at our prior locations (Ability Clinics in the mid-Atlantic states, Scheck and Siress in Chicago, Illinois). We also arranged trips to Edmonton and to the Bay Area. However, employee attrition and participant dropout problems before the first visit required us to cancel these trips.

Task 2.2. Recruit subjects

Recruitment of local and remote site participants continued with flyers and website postings.

Task 2.3. Randomization and blinding

All Aim 2 subjects were randomly placed in the treatment or control groups after pre-implementation according to our previously reported randomization scheme.

Task 2.4-2.8

TABLE 4. Participants tested in Aim #2.

#	Prost. Enrolled?	Prost. #	Group	AG Placement	Pre-Mod Session	Post-Mod Session	Complete?	Notes
1	Y	1	C	5/2/17	5/15/17	7/17/17	Y	
2	Y	1	C	5/2/17	5/14/17	7/14/17	Y	
3	Y	3	T	5/2/17	5/17/17	7/19/17	Y	
4	Y	4	T	5/2/17	5/13/17	9/23/17	Y	
5	Y	2	T	5/3/17	5/12/17	X	N	Suspended, subject incarcerated
6	Y	2	C	5/3/17	5/16/17	7/13/17	Y	
7	Y	5	C	5/22/17	5/22/17	6/16/17	Y	Activity determined previously
8	N	X	X	5/25/17	X	X	N	No modification made
9	N	X	X	6/14/17	X	X	N	Missed session, proceeded with mod
10	Y	8	C	7/11/17	7/20/17	9/22/17	Y	
11	Y	6	T	7/5/17	7/16/17	9/24/17	Y	
12	Y	8	T	7/7/17	7/21/17	9/27/17	Y	
13	Y	7	T	7/11/17	7/18/17	9/28/17	Y	
14	N	X	X	7/25/17	X	X	N	Skin breakdown before pre-mod session
15	Y	9	C	11/29/17	12/13/17	3/28/18	Y	Delayed modification process
16	Y	10	C	12/12/17	1/18/18	5/16/18	Y	Delayed modification process
17	Y	X	X	1/4/18	X	X	N	Prosthetist did not enroll; completed study with aim 1 consent
18	Y	11	C	2/21/18	3/7/18	4/12/18	Y	
19	Y	13	C	2/27/18	3/13/18		N	Skin breakdown before post-mod session
20	Y	12	C	3/1/18	3/12/18	6/4/18	Y	
21	Y	12	T	2/28/18	3/16/18	6/1/18	Y	
22	Y	13	C	3/1/18	3/14/18		N	Skin breakdown before post-mod session
23	Y	13	C	3/1/18	3/15/18		N	Subject ignoring contact from researchers and clinician
24	Y	10	T	X	3/8/18		N	Modification delayed; contralateral surgery; definitive socket finally in August 2019; unenrolled
25	Y	15	C	6/6/18	6/22/18		N	missed session; death in family; unenrolled (NC participant)
26	Y	15	T	6/7/18	6/25/18	8/8/18	Y	
27	Y	15	T	6/7/18	6/26/18	8/7/18	Y	
28	Y	14	C	6/8/18	6/21/18	8/6/18	Y	
29	N	X	X	X	7/27/18		N	Prosthetist did not enroll; completed study with aim 1 consent
30	Y	Y	C	X	10/19/18	1/24/19	Y	
31	Y	Y	T	1/28/19	2/1/18	3/29/19	Y	
32	N	X	X	9/17/19			ongoing	

Aim #2 - recruited	Year 1				Year 2				Year 3				Total
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Amputee participants	0	0	9	5	2	8	4	1	1	1	0	1	32

TABLE 5. Participant practitioners tested in Aim #2.

Prost. #	Group	Participant #	Pre-Mod Session	Post-Mod Session	Completed?	Notes
1	C	2	05/14/17	07/14/17	Y	
	C	1	05/15/17	07/17/17	Y	
2	T	5	05/12/17	X	N	Suspended, prosthetist's patient incarcerated
	C	6	05/16/17	07/13/17	Y	
3	T	3	05/17/17	07/19/17	Y	
4	T	4	05/13/17	09/26/17	Y	
5	C	7	05/26/17	06/22/17	Y	
X	X	9	X	X	N	No modification made
X	X	8	X	X	N	Patient missed session, proceeded with modification
6	T	11	07/19/17	09/26/17	Y	
7	T	13	07/18/17	09/25/17	Y	
8	C	10	07/20/17	09/22/17	Y	
	T	12	07/21/17	09/27/17	Y	
X	X	14	X	X		
9	C	15	12/13/17	03/28/18	Y	
10	C	16	01/18/18	05/16/18	Y	
	T	24	03/08/18		ongoing	Modification delayed; then subject got surgery on contralateral
11	C	18	03/07/18	03/29/18	Y	
12	C	20	03/12/18	06/04/18	Y	
	T	21	03/16/18	06/01/18	Y	
13	C	19	03/13/18	X	N	Patient skin breakdown before post-mod session
	C	22	03/14/18	X	N	Patient skin breakdown before post-mod session
	C	23	03/15/18	X	N	Patient ignoring contact from researchers and prosthetist
14	C	28	06/21/18	08/06/18	Y	
15	C	25	06/22/18		ongoing	delayed; death in family and could not attend session
	T	26	06/25/18	08/07/18	Y	waiting for activity sensor shipment; delayed due to hurricane
	T	27	06/26/18	08/08/18	Y	waiting for activity sensor shipment; delayed due to hurricane
16	C	30	10/19/18	01/24/19	Y	
17	T	31	02/01/18	03/29/19	Y	

Aim #2 - recruited	Year 1				Year 2				Year 3				Total
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Practitioner participants	0	0	5	3	1	4	2	0	1	1	0	0	17

Task 2.9. Address hypotheses

In general, self-report results were more favorable than pre-modification. SCS results are shown in Figure 3, and PEQ results are shown in Figure 4.

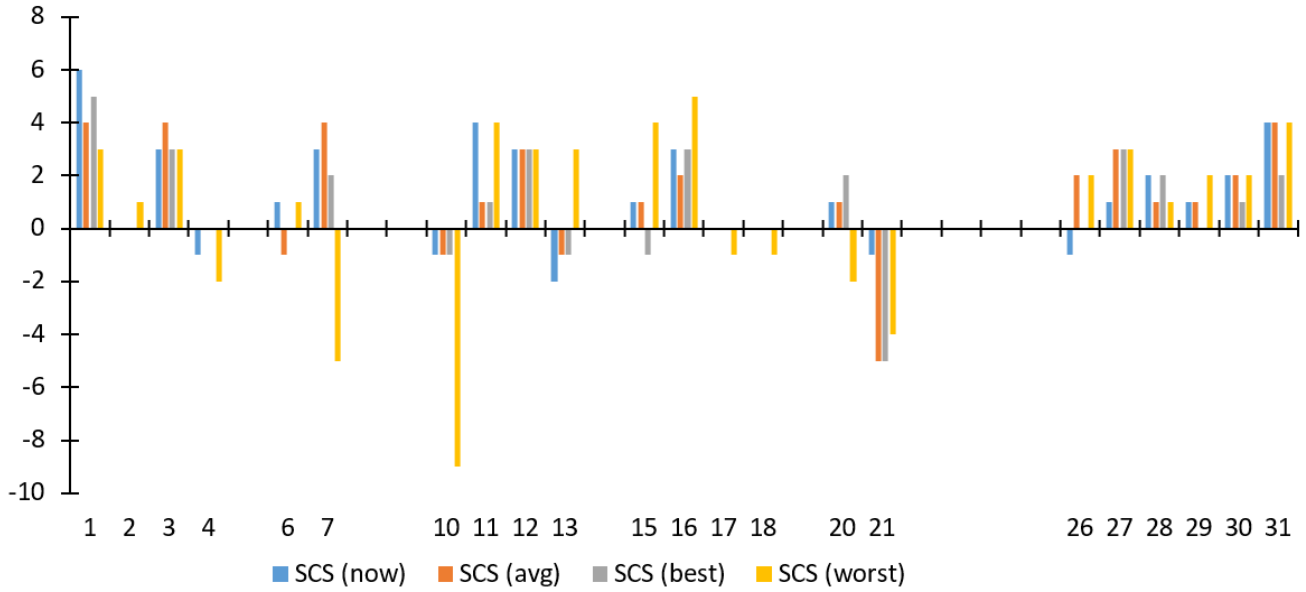


Figure 3. Aim 2 Net SCS Scores. Differences in SCS scores, after modification minus before modification, are shown. Absent data indicates incomplete datasets most often a result of an inability to collect the post-modification data within the time frame specified in the protocol.

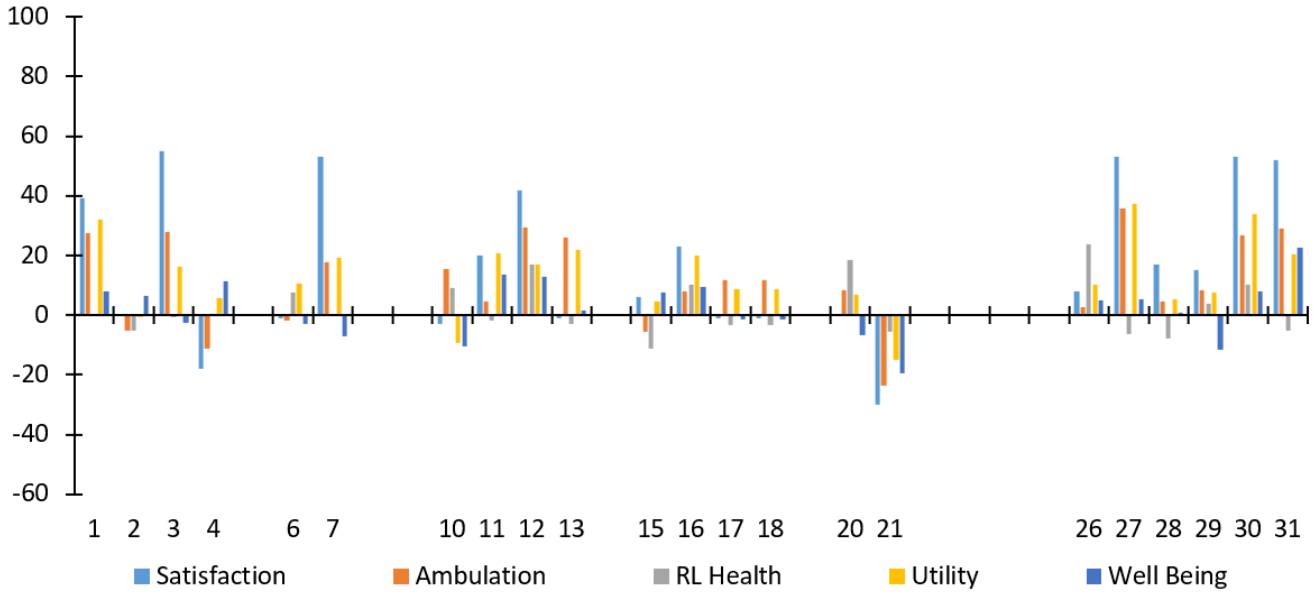


Figure 4. Aim #2 Net PEQ Scores. Differences in PEQ scores, after modification minus before modification, are shown. Absent data indicates incomplete datasets most often a result of an inability to collect the post-modification data within the time frame specified in the protocol.

As discussed above in Aim #1, a next step in this effort is to investigate relationships between limb fluid volume results (bioimpedance data) and self-report scores to determine if bioimpedance data predict outcomes. Our efforts using standing data points collected over the course of the protocol for analysis was not successful. While the computational algorithms we created did effectively identify standing data in each trial, there was much noise in the data, presumably because differences in posture from one stand to the next. Many of our participants for this study are less-capable K-3 and even K-2 individuals. This is demonstrated in Figure 5 below. This participant struggled to maintain steady equal weight bearing but still has relatively consistent gait.

In our work for projects separate from the current study, we have had success calculating bioimpedance metrics using the stance phase minima of each step. A peak detection algorithm finds the beginning and end of a cycle, and then the minima between the points determined. We use the volume at each stance phase minima to characterize participant residual limb fluid volume change over the course of the bout. Our efforts on other projects have refined this walking detection algorithm to identify and eliminate outliers from stumbles, short stops in walking, and other events that affect analysis. We are now using it to analyze all of the bioimpedance data that has been collected for the current study. This walking data analysis may provide a more representative summary of participants' residual limb fluid volume fluctuations both within each bout and over the course of the testing session. The consistent structured nature of bioimpedance measurement during walking also allows for more accurate automated post processing in comparison to the standing data.

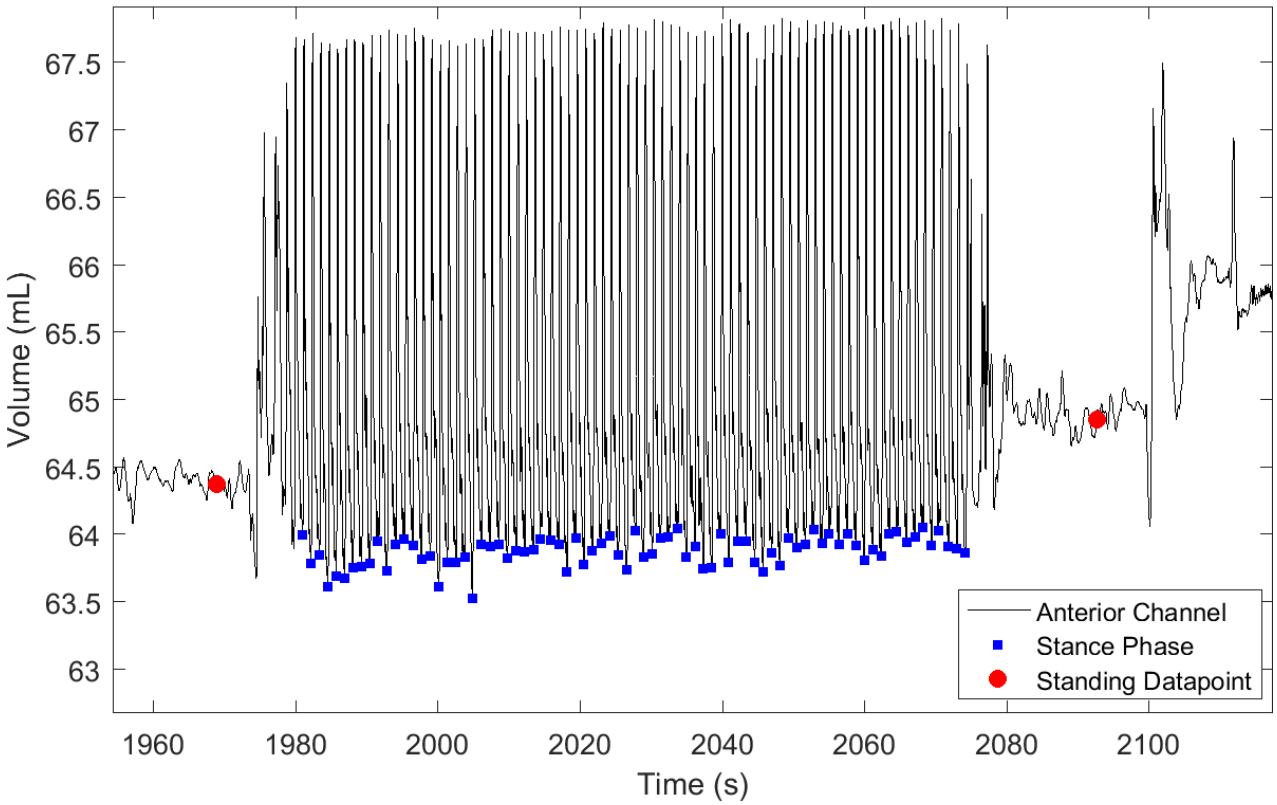


Figure 5. Example Data from a Participant Demonstrating Noisy Standing Data and Relatively Consistent Stance Phase Minima Data. Detected stance phase minima are in blue. Relatively noisy standing data before and after walking (1960-1975s, 2080-2100s) poorly characterize limb fluid volume changes. Stance phase minima during steady walking may provide may better characterize participants' pre and post-modification activity fluid-volume profiles.

There are several key variables of interest to calculate from this data, and then subsequently investigate correlations with outcomes (SCS, PEQ, number of clinic visits for care, and activity data collected in the field between sessions). Bioimpedance data metrics are illustrated in Figure 6. The objective is to establish patterns between the in-clinic test (bioimpedance data) and well-fitting comfortable sockets, evaluating the

utility of the biompedance system and a diagnostic tool for patient care. We will also investigate correlations with categorical data – participant characteristics, limb shape, and prosthesis design variables.

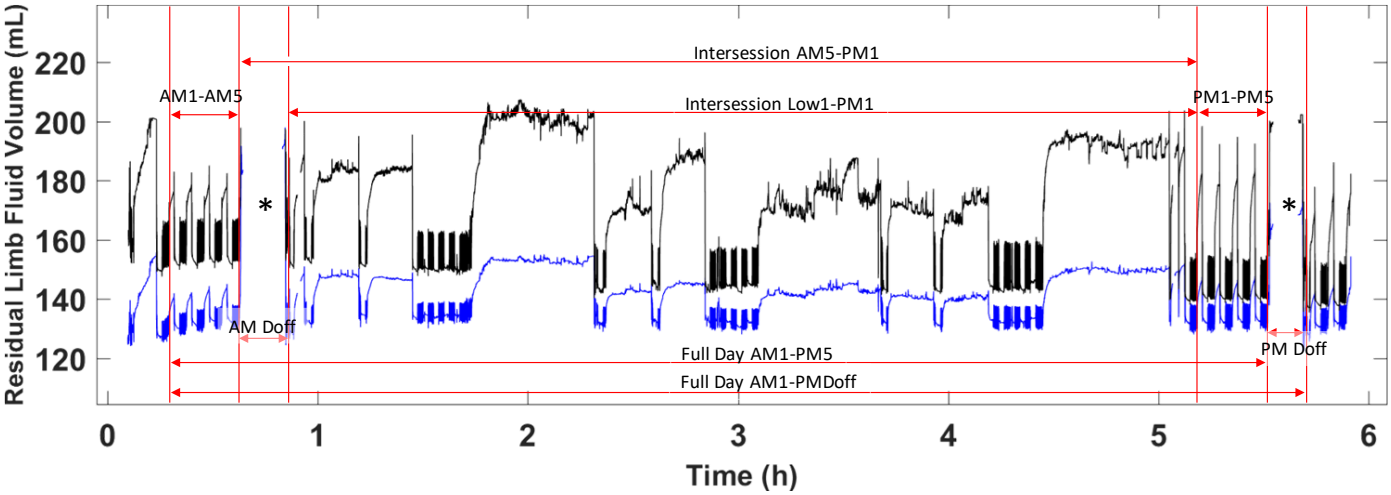


Figure 6. Bioimpedance Analysis – Variables under Investigation. Variables AM1-AM5 and PM1-PM5 are those historically used for bioimpedance analysis, characterizing limb fluid volume response to activity early in the day and late in the day. Doff segments AM Doff and PM Doff assess fluid volume response to socket release (10 minutes). Effects of fluid volume of multiple Intersession and Full Day session activities are investigated are considered to characterize how activity without doffing affects limb fluid volume.

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

No additional opportunities beyond those listed in prior reports were carried out.

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:

- Complete data collection and processing on current and new participants
- Extend analysis in Aims #1 and #2 to include analysis of stance phase walking data in limb fluid volume characterization
- Investigate correlations to determine if the bioimpedance analysis instrument is an effective diagnostic tool for patient care

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**

Changes were made in the analysis to include stance phase walking data as a measured variable. This was done because investigations in other projects suggests this data has lower variability (less noise) than standing data used to date.

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

Our most important challenges are participant recruitment and dropout. We adjusted the participant pay level to include a finishing bonus to improve retention. We also pursued studies in Edmonton, Canada and the San Francisco Bay Area in California, though participant dropout problems required those trips to be cancelled.

- **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**
- **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 in Year 3?**

Name:	Joan E Sanders PhD
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-8850-243X
Nearest person month worked:	1.0
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:	0.6
Contribution to Project:	Study design, data interpretation
Funding Support:	

Name:	Katheryn J Allyn CPO
Project Role:	Research Prosthetist
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.6
Contribution to Project:	Clinical support; participant recruitment and management
Funding Support:	

Name:	Andrew Vamos
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	10.7
Contribution to Project:	Instrumentation development; data processing, analysis and visualization
Funding Support:	

Name:	Robert T Youngblood
Project Role:	Research Scientist

Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.8
Contribution to Project:	Instrumentation development; data processing, analysis and visualization
Funding Support:	

Name:	Eric C Swanson
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.0
Contribution to Project:	Instrumentation development; data processing, analysis and visualization
Funding Support:	

Name:	Clement Gurrey
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	0.9
Contribution to Project:	Mechanical design; data collection
Funding Support:	

Name:	Ryan Carter
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.0
Contribution to Project:	Mechanical design; data collection
Funding Support:	

Name:	Horace Wang
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.7
Contribution to Project:	Instrumentation preparation; data collection
Funding Support:	

Name:	Brian Larsen MS
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.5
Contribution to Project:	Data analysis
Funding Support:	

Name:	Daniel Ballesteros
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.1
Contribution to Project:	Instrumentation preparation; data collection
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	closed	$384k/year direct	-
	A112491 (Sanders) 07/01/2016-06/30/2018 Sandia National Laboratories	closed	$166k/year direct	-
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020	no change	$960k/year direct	3.60
	W81XWH-16-1-0585 (Sanders) 09/15/2016-09/14/2020 (including 1-year NCE)	no change	$324k/year direct	1.60
	W81XWH-18-1-0595 (Sanders) 09/01/2018-08/30/2022	added	$288k/year direct	1.80
	R01HD060585-08 (Sanders) 09/15/2019-09/14/2024 NIH/NICHD	added	$394/year direct	2.40
	Total Effort (months per year)			9.40

HAFNER, BRIAN J				
	R01HD060585-03 (Sanders) 12/01/12-05/30/18 NIH/NICHD	closed	$383,756/year direct	-
	W81XWH-15-1-0458 (Hafner) 9/01/2015-08/31/2018	closed	$162,249/year direct	-
	W81XWH-16-1-0585 (Sanders) 09/15/2016-09/14/2020 (including 1-year NCE)	no change	$324,000/year direct	0.30
	2R01HD065340 (Hafner) 02/13/2017-01/31/2022 NIH/NICHD	no change	$377,480/year direct	3.00
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020	no change	$960,000/year direct	1.20
	W81XWH-16-1-0569 (Morgenroth) 10/01/2016-09/30/2020 (including 1-year NCE)	no change	$24,386/year direct	0.60
	W81XWH-17-1-0617 (Morgan) 10/01/2017-09/30/2020 (including 1-year NCE)	no change	$99,231/year direct	0.48
	W81XWH-17-1-0547 (Sawers) 09/30/2917-09/29/2020 (including 1-year NCE)	no change	$60,645/year direct	2.40
	W81XWH-17-1-0551 (Hafner) 09/01/2016-08/31/2020	no change	$132,165/year direct	1.80
	W81XWH-18-1-0595 (Sanders) 09/01/2018-08/30/2022	added	$288,260/year direct	1.20
	A138692 (Morgan) 12/07/2018-3/14/2021 Industry	added	$30,073/year direct	0.12
	Total Effort (months per year)			11.10

FRIEDLY, JANNA L.				
	CE-12-11-4469 (Friedly) 7/1/2013-2/28/2018 PCORI	closed	$536,221 direct total	-
	4UH3AR066795 - 02 (Jarvik) 1/1/2014-12/31/2017 NIH	closed	$1,298,074 direct total	-
	Evidence Based Practice Center (Devine) 10/01/16-09/20/2017 AHRQ	closed		-
	W81XWH-15-1-0291 (Mourad) 09/15/15 – 09/14/18	closed		-
	W81XWH-16-1-0585 (Sanders) 09/15/2016-10/31/2019	no change	$324,000/year direct	0.60
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020	no change	$960,000/year direct	0.39
	W81XWH-17-1-0617 (Morgan) 10/01/2017 – 09/14/2020	added	$101,327/year direct	0.06
	R01HD060585-08 (Sanders) 09/15/2019-09/14/2024 NIH/NICHD	added	$394/year direct	0.60
	W81XWH-18-1-0595 (Sanders) 09/01/2018-08/30/2022	added	$288,260/year direct	0.60
	P30 (Jarvik) 9/1/2017-8/31/2022 NIAMS	added	$519,122/year direct	1.20
	OP160059 W81XWH-17-1-0617 (Morgan) 10/01/2017 – 09/14/20	added	$101,327/year direct	0.06
	5 R01 AT 008559-03 (Jensen) 08/15/2017 - 07/31/2022 NIH	added	$579,375/year direct	1.20
	ZZ636607 (Morgan) 12/07/2018 - 03/14/2021 Industry	added	$30,073/year direct	0.06
	Total Effort (months per year)			4.77

CIOL, MARCIA A		status	annual direct cost	person mon
	R01 AF 059102 (Turk) 09/01/11– 07/31/18 NIH/DHHS	closed	$ 768,194	-
	R01HD060585-03 (Sanders) 12/01/12-05/30/18 NIH/NICHD	closed	$ 383,756	-
	P30 AG034592 (Matsuda) 06/01/16 – 05/31/18 Roybal	closed	$ 74,285	-
	A121025 (Maitland) 10/02/17 – 04/02/18 NCMRR	closed	$ 62,279	-
	R01AT008336 (Jensen) 09/01/14 – 06/30/19	closed	$ 534,591	-
	PCS-1604-35115 (Hoffman) 08/01/17 – 04/30/23 PCORI	no change		2.40
	R01AT008336 (Jensen & Williams) 10/01/14 – 09/30/19 NIH	no change	$ 421,499	0.60
	W81XWH-16-1-0585 (Sanders) 09/15/2016-10/30/2019 (including 1-year extension)	no change	$ 324,000	0.30
	W81XWH-16-C-0020 (Sanders) 06/07/2016-06/06/2020	no change	$ 960,000	0.60
	PCS-1604-35115 (Hoffman) 08/01/17 – 04/30/23 PCORI	no change	$ 377,731	2.40
	5 R01 AT 008559-03 (Jensen&Williams) 10/01/14-09/30/19	no change		0.60
	A117990 (Ladiges) 04/01/18-05/31/22	no change		1.20
	RG-1707-28401 (Ehde) MNSS 04/01/18-03/31/22	no change		0.60
	R01 NR 016942 (Molton) NIH 06/08/18-03/31/23	no change		0.60
	Total Effort (months per year)			9.30

- **What other organizations were involved as partners?**

  Organization Names, Locations: Ability Prosthetics and Orthotics, Exton, Pennsylvania; Scheck and Siress, Chicago, Illinois

- **Partner's contribution to the projec**t

  Collaboration. Participating prosthetists facilitated practitioner recruitment and helped coordinate study visits. They 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

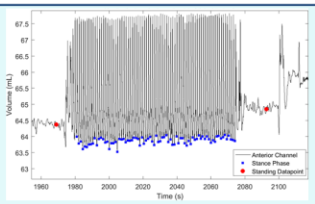
Study/Product Aim(s)

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.



Example collected data showing improvement in signal consistency using stance phase minima data (blue) compared with standing data (red).

Timeline and Cost

Activities / CY	17	18	19	20
Conduct observational study				
Relate data to clinical outcomes				
Conduct randomized control trial				
Assess monitor effectiveness				
Estimated Budget (total) ($K)	**$411**	**$493**	**$410**	**$274**

Updated: October 14, 2019

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 –

- ☐ Conduct observational cohort study
- ☐ Establish how measured variables relate to clinical outcomes
- ☐ Continue randomized control trial

CY19 and CY20 Goals –

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

Comments/Challenges/Issues/Concerns

- Not applicable

Budget Expenditure to Date

Projected Expenditure: $1,588,038
Actual Expenditure: $1,313,651

Appendix 1. Prostheses and modifications

Aim	Subject	Pre/Post	Socket	Suspension	Liner	Foot/Components	Socks	Accommodation	Notes
1	1	Pre	CF Laminate PTB	pin/lock	WW alpha	veraflex low profile	1x 3 ply, sometimes 5+1 ply		getting smaller socket + new foot
		(incomplete)							
1	2	Pre	CF Laminate PTB	pin/lock	WW alpha hybrid	veraflex low profile	2X 3 ply, sometimes 5+1 ply	few sock changes; rarely doffs	getting smaller socket + new foot of same type
		Post	CF hybrid	pin/lock	WW alpha classic M+	veraflex low profile	1x 5 ply sock		did not end up getting new foot; used old one for new socket
1	3	Pre	CF PTB, post brim irritates hamstring, loose	pin/lock	WW alpha classic	Freedom Inv Renegade	3 ply everyday, 2 ply halfsock sometimes	additions of 1/2 ply distal sock on occasion	
		Post	same, but reduced brim height and added more padding	pin/lock	WW alpha classic	Freedom Inv Renegade	2 ply consistently		ground out: crest of tibia, fibula head, new pads in distal end
1	4	Pre	CF endoskeletal PTB	pin/lock	WW alpha classic L	dyanamic response foot	18 ply (L) (3x5+ 3ply)	usually doesn't change during the day	subject is bilateral bk; getting left socket replaced
		Post	(participant did not get socket; premod was repeated under new consent form						
1	5	Pre	CF Laminate TSB	1 way valve; Ottobock sleeve	Ottobock custom liner	Rush	1 ply minimum; 6 ply max	Generally adds a 3ply in the afternoon	gained 30 lbs in past year
		Post	(did not end up getting a new socket)						
1	6	Pre	CF Laminate PTB (red socket)	pin/lock	WW alpha classic (L)	Dynamic Response (seattle/renegade)	2x 5 ply	usually doesn't change during the day	subject is bilateral bk; getting left socket replaced
		Post	CF tsb	pin/lock	WW alpha classic L (new)	dynamic response foot	0 socks	doffs for few minutes of relief 5-6 times a day w/ new socket	pylons lengthened by 6cm in both prostheses; having issues with right socket now
1	7	Pre	CF TSB	pin/lock	WW Alpha Hybrid	college park foot	1x 2 ply sock		poor fit/large posterior pad
		Post	CF TSB	pin/lock	WW Alpha hybrid	college park foot (new)	1x 1 ply half sock		
1	8	Pre	CF Laminate TSB w/ pigment	pin/lock + sleeve	Ossur Iceross Comfort (M)	Rush dynamic response	2x 1 ply	sometimes adds a 2 or 3 ply half sock if active	
		Post	(participant did not want to continue with study and was unenrolled)						
1	9	Pre	(re-enrolled only for postmod)						
		Post	CF TSB	pin/lock	WW alpha classic L (new)	dynamic response foot	0 socks	doffs for few minutes of relief 5-6 times a day w/ new socket	pylons lengthened by 6cm in both prostheses; having issues with right socket now
1	10	Pre	CF PTB Adjustable RevoFit socket	Seal-in liner	Ossur Sealin X	Freedom Innovations (dynamic response)	1x 1 ply	rarely doffs during the day	seal in liner too short so no thigh AG
		Post							
1	11	Pre	CF PTB, flexible inner liner	pin/lock	WW alpha classic	endolite eschelon	1x 1 ply, 1x 3 ply	doff while watching TV or after a lot of walking	
		Post	CF TSB?	1-way valve + Ottobock Proflex sleeve	WW alpha hybrid cushion M	Rush foot	1x 3 ply	has adds an additional 1 ply to the 3 ply occasionally	
1	12	Pre	CF TSB	Seal in v	Ossur Seal In V suspension	fillauer wavesport pro modified cheetah	none	rarely doffs during the day	rubbing/discomfort on posterior skin fold; on feet alld a for work;
		Post	CF TSB acryllic ultralight, recast for shape	1-way valve + Iceross Seal in V	new Ossur Seal in V	dynamic, multiaxis Aeris Performance 2	none		
1	13	Pre	CF TSB + PTB hybrid w/ horse pattern	Suction (Ossur proflex foot + mechanical vacuum)	Ossur Seal in X	Ossur Proflex pump foot (dynamic response)	none	will doff after higher activity	
		Post	CF TSB w/ flexible inner liner	Suction (Ossur iceross seal in)	Ossur Seal in X	Ossur Proflex pump foot (dynamic response)	2ply under liner	will wear 1 to 3 ply under-liner socket as needed	
1	14	Pre	CF	pin/lock	Ossur Iceross Comfort	Ossur Reflex Evo	2x 5 ply		
		Post	CF laminate; flexible inner liner	pin/lock	Ossur Iceross Comfort	Ossur Reflex Evo	2x 1 ply	occasionally removes a 1 ply sock	
1	15	Pre	CF TSB	1-way valve + sleeve (alps)	WW smart Temp Liner (cut short)	Rush size 11	1x 1 ply sock	0-2ply socks generally	
		Post	CF TSB	1-way valve + sleeve (alps)	WW Alpha	Rush size 11	1x 1 or 2 ply sock		
1	16	Pre	CF TSB w/ flexible inner liner	Suction (Ossur iceross seal in) + Alps sleeve	Ossur Seal in X	Ossur Proflex pump foot (dynamic response)	2ply under liner	will wear 1 to 3 ply under-liner socket as needed	
		Post	CF TSB w/ foam inner (supracondylar sspnsn)	supracondylar suspension	(no liner)	Ossur Proflex (getting new foot though)	1 to 3ply sock as needed		
1	17	Pre	CF	pin/lock	WW Express Original L	WW Express Original L	2x 3 ply		
		Post	CF TSB	pin/lock	WW Express Original L	Renegade Freedom Innovations	1x 3 ply sock or an old 5 ply sock		medial brim irritation; may get it trimmed
1	18	Pre	Clear check socket at very start of modificaiton process;	1-way valve + sleeve (he usually has a pin/lock)	Ossur Iceross Comfort 30	Endolite Javelin	1x3 ply, 1x 5 ply	ususally starts with 3 ply, adds 5 ply in afternoon	removes prosthesis for long car rides
		Post							
1	19	Pre	CF PTB flexible inner	sleeve (locking pin present but not in use; usually use both)	Alps Cushion	Endolite Eschelon	1x 3 ply		
		Post							

Aim	Subject	Pre/Post	Socket	Suspension	Liner	Foot/Components	Socks	Accommodation	Notes
2	1	Pre	CF Laminate TSB	Seal-in suction, expulsion plate	Ossur Seal-In V	Freedom renegade foot w/ adapter	5 ply, then gel sock under liner	doesn't take it off during his waking hours	
		Post	CF Laminate TSB (smaller - wt loss)	New expulsion plate (Unity Elevated Vacuum, mech pump)	Ossur Seal-In V (newer/smaller)	Ossur Unity low profile veriflex	no socks, no changes during day	doesn't take it off during his waking hours	new alignment w/ new prosthesis/foot
2	2	Pre	CF Laminate TSB (3 yrs old, many pads)	Ottobock P3 vacuum pump (fails sometimes) w/ Proflex sleeve	Ottobock custom urethane uncovered liner	College Park Odyssey, dynamic response	Sheath, 1 or 2 ply sock use	Doffs for naps, uses sheat and 1 to 2 plys to manage volume and irritation	
		Post	CF Laminate TSB (shape change due to weight gain and distal tibia prominince + adding pretibial pads under lamination	Ottobock P3 vacuum pump (new)	Ottobock custom urethane unovered liner (new scan)	College Park Odyssey, dynamic response (new)	Sheath 1x2 ply sock use, no changes during day	no new strategies - "this is the most comfortable socket he has ever had"	
2	3	Pre	TSB cushion inner liner, foam inner socket, 6 yrs old	Sleeve	WW Alpha Original	Hydraulic ankle, dynamic foot	1x3 ply, no changes	pulls sleeve tighter to adjust socket	**wearing even older socket, not his current daily socket. Liner wore out for his current socket. Modification socket modeled after the newer socket
		Post	New socket lamination + inner flexible socket	Sleeve + expulsion valve/plate	Ossur Iceross Dermo	Same foot, new pylon components	1x 3 ply, no changes		
2	4	Pre	CF Laminate TSB	Sleeve: Alphs Superior suspension HD gel	WW Alpha Hybrid Cushion	College Park elsus - multiaxis dynamic response	2x 1 ply cotton	6:30a-8:30p, does not generally doff	prosthestist very enthusiastic during conference call, talked through a modification with us based on bioimpedance results
		Post	CF Laminate TSB; flexible inner liner; posterior trimline cut to releave popliteal irritation	Suction w/ 1-way valve on flexible inner liner; sleeve (over flexible, under CF); flexible inner liner held in w/ lock & pin; (sleeve is same type)	WW Alpha sybrid Cushion	Ossur Proflex XC	2x 1 ply cotton	no changes needed during day	
2	5	Pre	modified CF Laminate PTB; proflex inner socket; 6-7 months in this temporary socket	Expulsion valve + sleeve	Ossur Dermo 3mm silicone liner	Dynamic foot, hydraulic ankle		Sock ply changes, periodic doffing to manage limb volume	"Doffs socket to let his limb relax when sitting for long periods of time, such as watching tv" Prominent anterior distal tibia sore/callus; switching to Pin/lock, reducing size and changing shape; 6-7 months in current temporary socket
		(incomplete)							
2	6	Pre	PTB test socket (thermoplastic)	Suspension w/ valve, Ottobock proflexe sleeve	Encore V	Endolite Elan multi axis dynamic foot	1x 5ply, 1x 3-ply, 1x 1-ply (9 ply total) cotton socks *7 ply on test day	Adds 1ply sock 2-3 times a day, max is 20 ply though	Rare usage of cane or walker, wheelchair late night for bathroom
		Post	CF Laminate TSB, flexible inner socket, 3 ply between inner socket and outer socket in bottom half	Suction and sleeve	Encore V	Endolite Elan multi axis dynamic foot; new pylon of same style	New gel sock; still 9 pyl on top of it; adds 1x or 2x 1 ply mid day		
2	7	Pre	CF Laminate TSB	Harmony EV ("automatic setting); Ottobock sleeve	Ottobock custom liner	Rush	Sheath	Generally adds a 3ply in the afternoon	Generally doffs at least once around mid day to check limb/wipe down; *Caffeine on test day (12oz iced tea)
		Post	CF Laminate TSB (new)	Willowood One system w/ Limb Logic set to "adaptive", WW One sleeve	WW Alpha Duo	Fillauer AllPro	WW One Gel Sock	No traditional socks, removes prosthesis about once a day	Also changed shoes; no caffeine on test day
2	8	Pre	CF endoskeletal suprapatella, supracondylar	suspension strap with velcro	Ossur Iceross Synergy	undocumented	1x 1 ply + 1/2 sock 1 ply	Sometimes adds 2 ply or 3 ply in afternoon; uses cane when out and about	participant never received modificationafter several months; unenrolled
2	9	Pre	CF endoskeletal SC SP	suprapatella, supracondylar	WW Alpha Classic M+ 3mm	Fillauer Aeris Perf 2	1x 3ply, 2 ply, 1 ply	keeps 6 ply all day; also frequently uses 5 ply + 1 ply	subject did not show up to 6 hour session; proceded with modification prior to rescheduling; subsequently unenrolled
2	10	Pre	TSB (in 2nd test socket for premod session)	Ottobock sleeve; expulsion plate (evolution industries)	Ossur Iceross Dermo Seal in V	BionX emPower bionic foot, torsional adapter in pylon	5 ply	no sock changes; occasional temporary doff to recover	infection last november + revision surgery; current socket way too big and not wearing for test (TSB limb logic w/ renegade foot, pressure points led to pads being added); test socket described ; cane for rough terrain/high activity
		Post	CF Laminate TSB (smaller, approx 2 ply reduction)	Sleeve + expulsion plate + side mount Limb Logic	Ossur Iceross Dermo Seal in V	BionX emPower bionic foot, torsional adapter in pylon	6 ply (1 + 5)		

Aim	Subject	Pre/Post	Socket	Suspension	Liner	Foot/Components	Socks	Accommodation	Notes
2	11	Pre	CF Laminate PTB (socket too tight, overcorrection from previous socket that was 25 ply)	Sleeve - Ottobock Profles Plus	WW Alpha Hybrid	2 separate feet, swaps them outon his own (is a "tinkerer")	1x 1ply cotton	subject will change out socket components on his own; switch between feet, old, and older socket	
		Post	CF Laminate PTB (larger CF, flexible inner socket added + distal gel pad)	Sleeve - Ottobock Proflex plus	WW Alpha Hybrid (new); also has thicker version he switches to in late morning	same foot from previous session	1x 1 ply added mid day, taking off socket less during day	Will switch to "thick" liner (WW Alpha Hybrid) @ 10 or 11 am and wear rest of the day; Adds sock after lunch; Says limb shrinks during day; Socket squeaks when walking; Participant adjusts foot periodically on his own	will switch sockets to old socket (same pylon, new sleeve) every few days and wear for a day or two Only in new socket for 2-3 days at a time, switching back and forth w/ old Cut his own flexible inner flap
2	12	Pre	CF Laminate TSB	Pin/Lock	Ossur iceross synergy silicone	Freedom Innovations Kinterra single axis dyamic repsonse	2x5ply wool start, add 1x3ply wool~ noon, half sock 1 ply on distal end	some sock additions	
		Post	CF Laminate TSB (approx 7 plys smaller, same style)	Pin/Lock	Ossur iceross synergy silicone (new)	Freedom Innovations Kinterra single axis dyamic repsonse	start with 3 ply, up to 5 ply	some (less) sock additions	test socket starting on 8/2, modified on 8/16, 8/30
2	13	Pre	CF Laminate TSB Flexible inner socket	Ottobock sleeve w/ expulsion port	Ossur Iceross Dermo	Ability RUSH foot; solid ankle w/ dynamic response	3x5 ply, 1x 2 ply, adds another 2 ply mid day; (all synthetic; acrylic/lycra)	Adds 2 ply around mid day, uses socket ~5:30am-9pm, doffs to change socks	newer amputee
		Post	Hybrid PTB/TSB Test socket	Pin/Lock	Ossur Iceross Dermo (tried seal in V, didn't work)	Ability RUSH foot; solid ankle w/ dynamic response	No socks	no changes needed during day	this will be final socket, laminate CF in beginning of October if things stay good
2	14	Pre	CF laminate w/ pattern	Seal in suction	Ossur Iceross Seal in X with removal band	Ossur Proflex	1x 1 ply	may add up to 3 ply, depends on the day	subject develop open sores between activity monitor attachment and day of 6 hour session; did not proceed with activity protocol; unenrolled
2	15	Pre	CF TSB flexible inner liner	vacuum; WW Limb Logic	Ossur Iceross cushion dermo	modified cheetah	no socks	none reported	vacuum on high, generally does not doff; some swelling in contralateral limb (wears compression sleeve)
		Post	CF TSB flexible inner liner, slight size reduction (tighter)	WW Limb logic, 18-20	Ossur Iceross Dermo	Fillauer Formula, allows greater heel movement and improves loading response	no socks used	none reported	
2	16	Pre	CF PTB flexible inner	Pin/Lock	WW Alpha hybrid	ossur veriflex foot w/ gray ball rotation unit	13 ply; small grey half sock (sheat) under liner on limb	uses cane, doffs a lot for power chair	generally gets around house in wheelchair and will doff prosthesis for this
		Post	CF PTB flexible inner with cushioning	Pin/Lock	WW Alpha hybrid uniform (new)	Fillauer Formula	1x 3 ply, same small grey half sock/sheat under liner on limb	uses cane doffs a lot for power chair	did not use cane for all walks, see session notes
2	17	Pre	CF PTB Adjustable RevoFit socket	Seal-in liner	Ossur Sealin X	Freedom Innovations (dynamic response)	1x 1 ply	rarely doffs during the day	seal in liner too short so no thigh AG
2	18	Pre	CF PTB with pigment	Pin/Lock	Ossur Iceross Comfort 6mm	College Park	no socks	uses cane, doffs at computer desk, for lunch, dinner	used cane for premod test
		Post	CF PTB with pigment, pelite inner liner	Pin/Lock	Ossur Iceross Comfort	Ossur Proflex Low profile, split toe/arched foot plate	no socks	uses cane less, subject now exhibiting characteristics of K-3 level ambulator	did not use cane for post mod session
2	19	Pre	CF pigment, hybrid PTB, w/ pelite inner liner	Ottobock Harmony	gel sheath on test day? But iceross dermo new liner usually	SACH foot	13 ply but didn't wear any on test day	doffs on couch, uses cane, walker, wheelchair	subject wore a single gel sheath on test day when socket was in fact ~13 ply too large. Subject thought that the single gel sheath felt better to prosthetists dismay
		(incomplete)							
2	20	Pre	CF TSB, flexible inner liner, first definitive socket	suction valve + Ottobock proflex sleeve	Ossur Iceross Dermo, Ottobox Proflex	Ossur Balance Foot J category 5	15 ply	adds 1 ply to fit better; doffs to wipe away sweat/adjust bunching; 4-5 times per day	
		Post	CF socket not delivered yet (insurance) so performed session in thermoplastic check socket	suction valve + Ottobock Proflex sleeve	Ossur Comfort Cushion 34	(same)	0 to 5 ply	ususally starts 0, up to 3 or 5 ply by end of the day; no socks worn for test	subject noted he would have added a 3 ply sock ~3 hours into the session

Aim	Subject	Pre/Post	Socket	Suspension	Liner	Foot/Components	Socks	Accommodation	Notes
2	21	Pre	CF + pigment, flexible inner liner	sleeve + valve (Ottobock proflex)	Ottobock Custom Liner (rubber, no backing);	College Park Tribute	7 ply	uses walker in morning/evening when leg is not on	
		Post	CF TSB Sleeve	sleeve + valve (Ottobock proflex)	Ottobock Uneo Unique custom liner (new, black backing)	College Park Tribute	3 ply during test after adjustment	heavy sock user still; subject had been wearing too many for his new socket and needed more time to break it in	subject routinely wears too many socks; wore too many during session and had to stop protocol temporarily to doff and change socks; consulted with PT and remvoal of socks helped subject
2	22	Pre	CF TSB outer pigment	sleeve	ottobock custom liner; proflex sleeve	Ottobock	2x full length cotton, 1 half sock outer layer		part time maintenance man in his community' bilateral ak/bk
		(incomplete)							
2	23	Pre	CF TSB	Vacuum, harmony P2	Otobock Eurethane Custom Liner; Ottobock Proflex sleeve	Freedom Agilex	3x 2 ply, 1x ply	doff for pain/comfort; infrequently when sitting for extended periods	bilateral bk
		(incomplete)							
2	24	Pre	CF PTB "chrome" lamination	pin/lock	WW Alpha hybrid custom large	modified Cheetah foot direct lamination	3 ply sock	little change, usually 3 ply all day	Dx3 activity protocol proved too much, did Dx3 for cycle 1 and 2, Dx1 for cycle 3. will repeat this for post mod for concistency
		(incomplete)							subject had surgery on contralateral foot; over a year elapsed between premod and socket delivery and subject was unenrolled
2	25	Pre	CF PTB with pigment; 3rd socket so far	pin/lock	Ossur Iceross comfort has thin and thick type	College park	3x 3 ply, 1x 1 ply	uses either thin or thick liner depending on the day and how limb feels; occasionally doffs and elevates limb; uses wheelchair at night around house	
		(incomplete)							
2	26	Pre	CF TSB with relief areas in atnerior and postierior regions of CF, flexible inner liner	pin/lock	Alps Superior Perform HD Gel (6mm)	dynamic foot, single axis	0 to 1 or 3 ply by mid day	patient practices sock management as needed	posterior/lateral callus on knee
		Post	CF TSB, mild ptb bar, rigid outer w/ proflex inner	pin/lock	Alps Superior Perform HD Gel (6mm)	Microprocessor hy draulic ankle	no socks	has not had to use socks since receviing now socket	
2	27	Pre	polypropylene PTB socket	pin/lock note: locking mechanism damaged and not functioning fully	Ossur Iceross Dermo	dynamic response foot	2x 5 ply	doffs for lunch at work, sometimes during short work breaks	crutches at home w/ leg off early in morning/ late at night
		Post	CF TSB w/ proflex flexible inner for relief on bony prominences	pin/lock, w/ auxillary suction suspension due to high activity lifestyle	Ossur Iceross Dermo	dynamic response foot w/ torsiona dapter	1x 1 ply, 1x 2 ply	New 1,2,3, and 5 ply socks for management;	participant appeared extremely satisfied with new socket;
2	28	Pre	CF TSB with Keasy Cone inner padding	Sleeve w/ hole in it - valve in socket but subject would let it get clogged, PT opened it up and suction isn't used	Willowood alpha smart temp	Freedom Kinterra	no socks	power chair or wheel chair if sore develops	subject had small sore at initial screening, were healed nicely 2 weeks later for premod session
		Post	CF TSB with Keasy cone inner padding	new sleeve, same inactive valve (no suction)	same	Ossur pro-flex pivot	no socks		crutches at home w/ leg off early in morning/ late at night
2	29	Pre	CF	pin/lock	Ossur Iceross Comfort	Ossur Reflex Evo	2x 5 ply		
		Post							
2	30	Pre	CF laminate w/ pigment	pin/lock	WW Alpha Silicone L progressive	Flexfoot split toe	1x 5 ply	rarely changes socks; doffs frequently throughout day when seated	
		Post	CF laminate w/ pigment	pin/lock	WW Alpha Hybrid Select L Progressive	Fillauer All Pro (more dynamic + rotation)	1x 5 ply	no sock changes	
2	31	Pre	CF w/ flexible inner liner w/ additional pading	pin/lock	Ossur Iceross Dermo 6mm	Ossur Proflex XC	1x 5 ply	no changes; 5 ply all day everyday	
		Post	CF RevoFit w/ flexible inner liner	pin/lock	Uniprox Softskin porous liner	Ossur Proflex XC	5 ply sock	usually finds a size he is comfortable with at start of day and keeps it	
2	32	Pre	CF laminate PTB	pin/lock	Alps 20	Eschelon	1x 3 ply + 3/4 length 1 ply sock	constant for past 3 weeks	
		Post							