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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, the focus was on testing additional participants for both aims. Because of recruitment challenges in our local area, we conducted many of the tests at remote sites (East Coast, Midwest) at clinics we recruited as collaborators. Results from studies to date suggest that limb fluid volume changes over the course of the test sessions are larger pre-modification than post-modification, and that participants increase daily prosthesis wear and walk times post-modification compared with pre-modification. Individual participant reports are helpful towards characterization of how modifications affected limb fluid volume and user activity. Participant self-report scores appear to be slightly higher for the treatment than control group. Practitioners felt the data presentation improved understanding of their patient's limb fluid volume management issues. Additional participants need to be tested for statistical comparisons to be made.

15. SUBJECT TERMS

none provided

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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 2?

Aim #1.

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

A minor modification was made to the IRB as summarized in TABLE 1 below.

TABLE 1. IRB modifications in Year 2.

Version	Date Approved	Description
5	2/6/2018	Added Scheck & Siress Prosthetics (Chicago, Illinois) as an engaged institution

Task 1.2. Recruit practitioners

In Year 2, we enhanced practitioner recruitment efforts to hand out flyers and give presentations at local chapter meetings (NWAAOP). We also gave presentations to several local northwest clinics at their private offices. These efforts were somewhat effective. We have to some extent, however, exhausted the local region for recruitment for Aim #1 because Aim #2 is more interesting to practitioners. They prefer to participate in that aim instead.

Task 1.3. Fabricate additional bioimpedance units

In Year 2 minor fixes to the board layout were made, and brightness of one of the LEDs was reduced since it made it hard to tell if other LEDs were on. An additional run of boards was executed, and two of those units were brought up.

Task 1.4. Automate electrode assembly/fabrication

No changes were made to the electrode assembly/fabrication process from Year 1 procedures.

Task 1.5. Recruit subjects

In Year 2, locally we continued to post flyers in prosthetist offices, and attended local amputee events and support group meetings. For off-site testing clinics outside Washington State, we provided recruitment material for clinic staff to place in their offices, which proved effective.

Task 1.6. Conduct pre-implementation testing

Pre-implementation testing as described in the Year 1 report was continued. A total of 14 participants started the Aim #1 protocol, and 6 have completed testing.

Task 1.7. Monitor activity during interim 2-4 weeks

Activity during the interim 2-4 weeks was conducted using procedures described in the Year 1 report.

Task 1.8. Conduct post-implementation testing

Post-implementation as described in the Year 1 report was continued.

Task 1.9. Process collected data

Data was processed as described in the Year 1 report.

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

TABLE 2. 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
9	1/17/2018	X	N	Participant skipped clinic appointment, still ignoring contact
10	2/22/2018	5/9/2018	Y	
11	3/17/2018	6/3/2018	Y	
12	8/23/2018		ongoing	
13	7/27/2018		ongoing	
14	9/14/2018		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**	**5**	**2**	**0**	**0**	**3**	**0**	**3**					

Task 1.10. Address hypotheses

In addition to the modifications listed previously (tibial crest relief, fibular head relief, large posterior pad, and a posterior trim line reduction), another modification executed was fabrication of a new socket with multiple ply reduction.

In general, limb fluid volume changes over the course of the test sessions are larger pre-modification than post-modification, suggesting practitioner modifications improve daily limb fluid volume stability. Results for both posterior and anterior regions are shown below in Figures 1 and 2. In general, the first of each pair of bars is taller than the second pair.

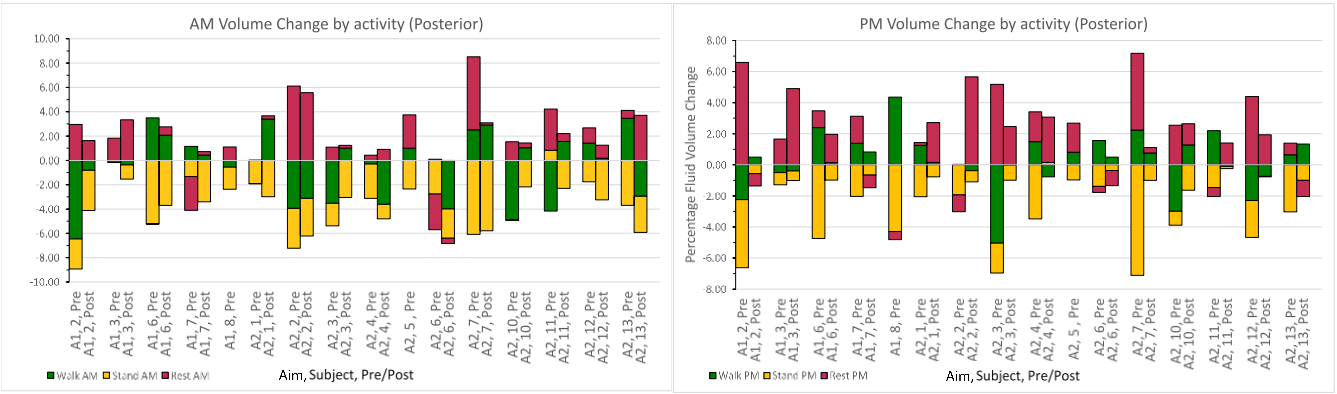


Figure 1. Posterior channel limb fluid volume results for a sample of Aim 1 and Aim 2 participants. Overall, greater losses occurred during the AM session than the PM session. Also, pre-modification sessions often demonstrated higher volume volatility, i.e. greater fluctuations throughout the day as shown by the larger pre-modification bars than post-modification bars.

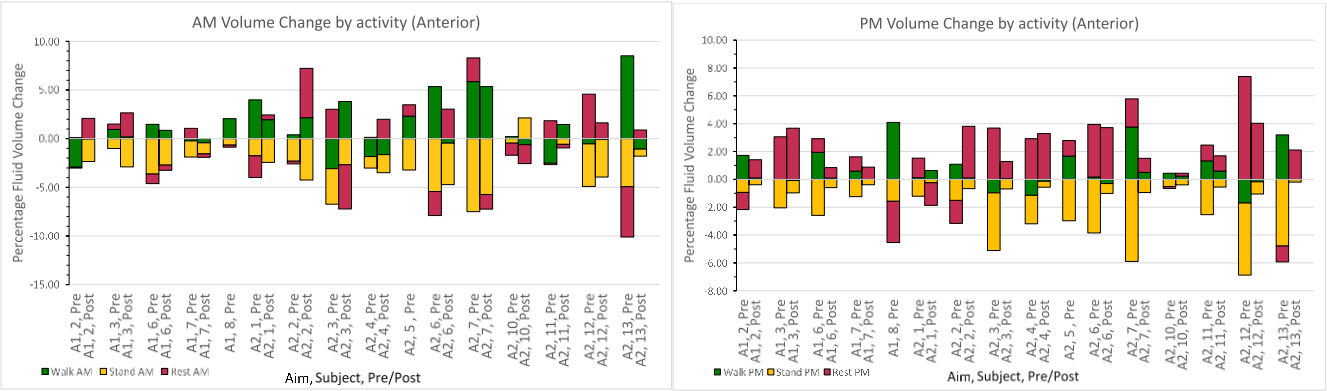


Figure 2. Anterior channel limb fluid volume results for a sample of Aim 1 and Aim 2 participants. Overall, greater losses occurred during the AM session than the PM session. Also, pre-modification sessions often demonstrated higher volume volatility, i.e. greater fluctuations throughout the day as shown by the larger pre-modification bars than post-modification bars.

Aim #1 participant activity monitor data to date demonstrated small increases in average daily prosthesis wear time (increased don time, decreased doff time) and walk time. Although these differences were not statistically significant (paired *t*-test, alpha = 0.05, Table 3), this analysis was performed with a relatively small sample size and needs to be revisited once more participants are tested. We expect to see an overall increase in don and walk time for participants post-modification compared with pre-modification.

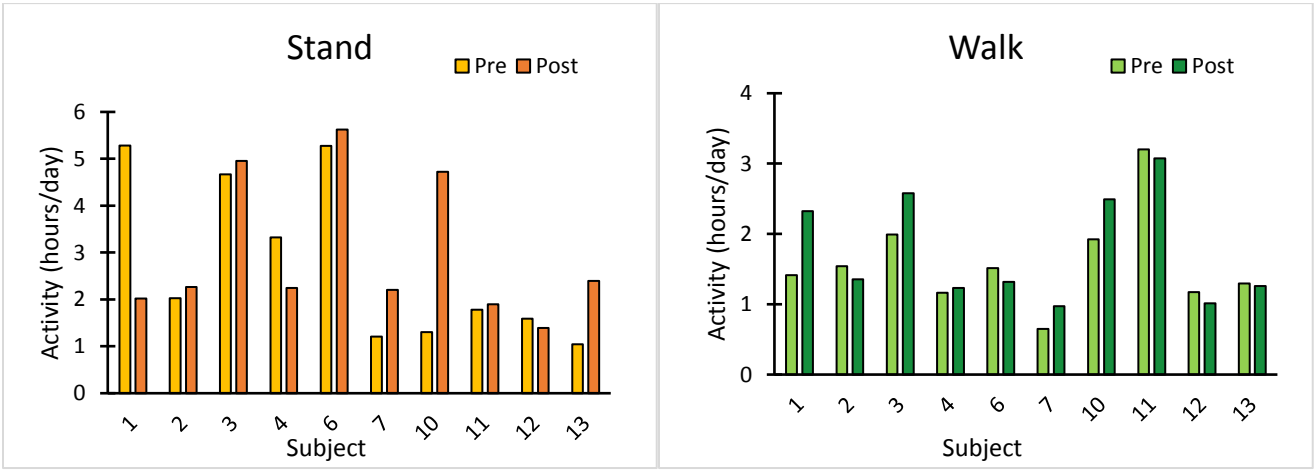


Figure 3. Sample of participant activity data demonstrating pre and post-modification differences.

Table 3. Paired *t*-test results from activity monitor data.

Daily Metric (hours)	Mean Difference	p-value
Doff	-1.00	0.11*
Don	0.89	0.13*
Sit	0.49	0.39
Stand	0.22	0.69
Walk	0.18	0.19*

*indicating metrics nearing significance

Participant recruitment and completion of the study within the allowed time frame have proven challenging in Aim #1. Often times, a participant and prosthetist start a modification process, but it takes months to complete, outside the time frame of our study protocol. This result points to the limitations of current treatment strategies and the need for objective tools to better identify participant socket fit issues. Further, because practitioners see the collected data and may incorporate it into their treatment plan in Aim #2 but not in Aim #1, there is far more interest in our local population in Aim #2 participation than in Aim #1 participation.

Aim #2.

Minor modifications to the Aim #2 protocol described in the Year 1 report were executed (Figure 4). We no require prosthetists transfer activity monitors in between the modification and post-modification sessions, because experience in Year 2 demonstrated that those monitors were not necessarily properly attached or

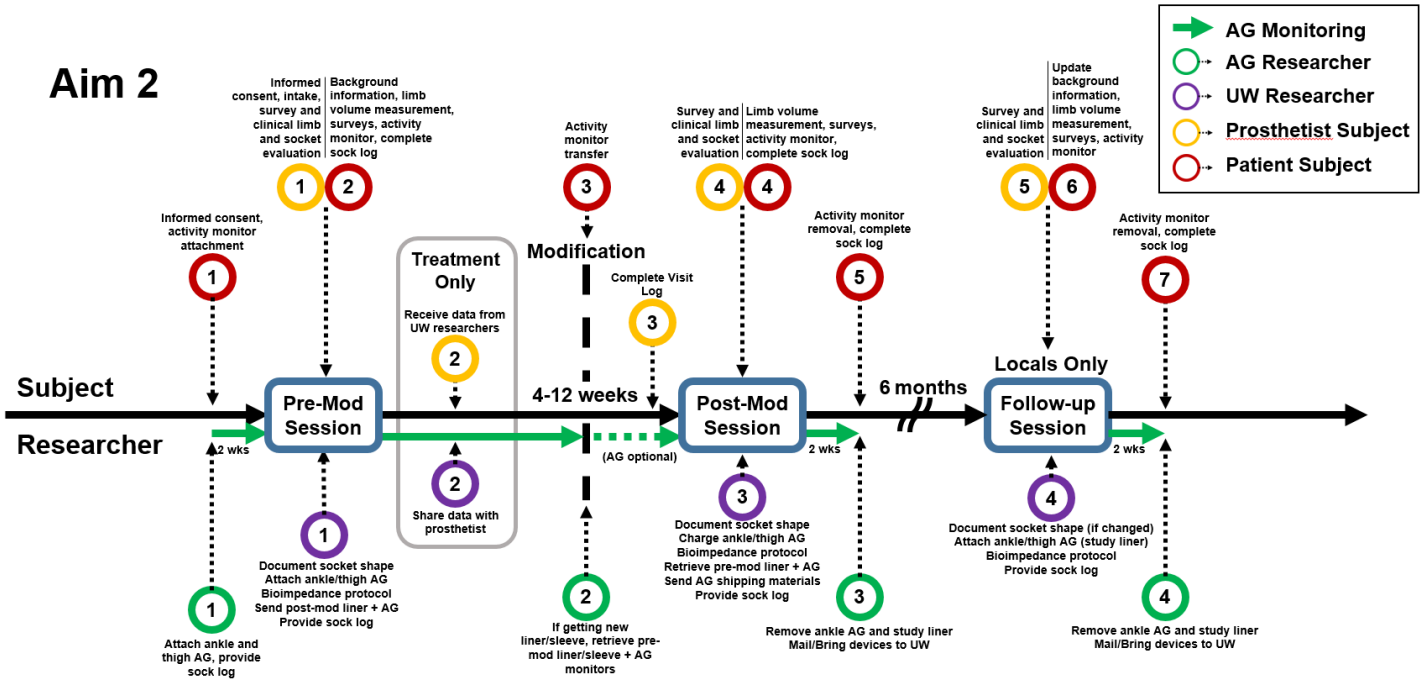


Figure 4. Aim 2 modified protocol.

aligned, producing erroneous data. The updated study flow chart now indicates “AG optional” at this time point, and has a dotted green line right before the post-modification session. We have the practitioner remove the AG monitors that UW researchers applied (before the pre-modification session) if the amputee participant receives a new ankle, liner, or sleeve. Otherwise, the AG monitors are left on.

Task 2.1. Recruit practitioners

Another remote site clinic in the Midwest was added: Scheck and Siress in Chicago, Illinois. We continued studies at Ability Clinics in the mid-Atlantic states. We continue to recruit locally as well.

Task 2.2. Recruit subjects

Participants were recruited locally and through our three remote site clinics using recruitment flyers and website postings.

Task 2.3. Randomization and blinding

Randomization and blinding was conducted as described in the Year 1 report.

Task 2.4-2.8

All test procedures (Tasks 2.4 – 2.8) were conducted as described in the Year 1 report.

Amputee participants tested in Aim #2 are summarized in Table 4. Practitioner participants tested are summarized in Table 5.

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	r	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	11	C	2/21/18	3/7/18	4/12/18	Y	
18	Y	13	C	2/27/18	3/13/18		N	Skin breakdown before post-mod session
19	Y	12	C	3/1/18	3/12/18	6/4/18	Y	
20	Y	12	T	2/28/18	3/16/18	6/1/18	Y	
21	Y	13	C	3/1/18	3/14/18		N	Skin breakdown before post-mod session
22	Y	13	C	3/1/18	3/15/18		N	Subject ignoring contact from researchers and clinician
23	Y	10	T	X	3/8/18		N	Modification delayed; contralateral surgery
24	Y	15	C	6/6/18	6/22/18		ongoing	delayed; death in family and could not attend session
25	Y	15	T	6/7/18	6/25/18	8/8/18	N	waiting for activity monitor return shipment
26	Y	15	T	6/7/18	6/26/18	8/7/18	N	waiting for activity monitor return shipment
27	Y	14	C	6/8/18	6/21/18	8/6/18	Y	

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**	**7**	**4**	**0**					

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	.	
	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	8	X	X	N	Patient missed session, proceeded with modification
X	X	9	X	X	N	No modification made
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	23	03/08/18		ongoing	Modification delayed; then subject got surgery on contralateral
11	C	17	03/07/18	03/29/18	Y	
12	C	19	03/12/18	06/04/18	Y	
	T	20	03/16/18	06/01/18	Y	
13	C	18	03/13/18	X	N	Patient skin breakdown before post-mod session
	C	21	03/14/18	X	N	Patient skin breakdown before post-mod session
	C	22	03/15/18	X	N	Patient ignoring contact from researchers and prosthetist
14	C	27	06/21/18	08/06/18	Y	
15	C	24	06/22/18		ongoing	delayed; death in family and could not attend session
	T	25	06/25/18	08/07/18	Y	
	T	26	06/26/18	08/08/18	Y	

Prost. = prosthetist, T/C = treatment/control

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					

Task 2.9. Address hypotheses

Aim #2 results to date are summarized below. Formal statistical analysis is not presented because not enough participants have yet been tested. Prostheses and modifications tested are summarized in Appendix 1.

Example daily activity data for four different participants from Aim 2 are shown in Figure 5 below. To date, most participants demonstrate little or minor increases in activity when comparing post-modification data to pre-modification data. For active individuals (K-3 or higher), daily activity may be dictated by occupation, behavior, and individuals' established lifestyle. For some low-level participants (sick, low activity K-2), we have seen increases in activity post-modification vs. pre-modification, but this is anecdotal thus far.

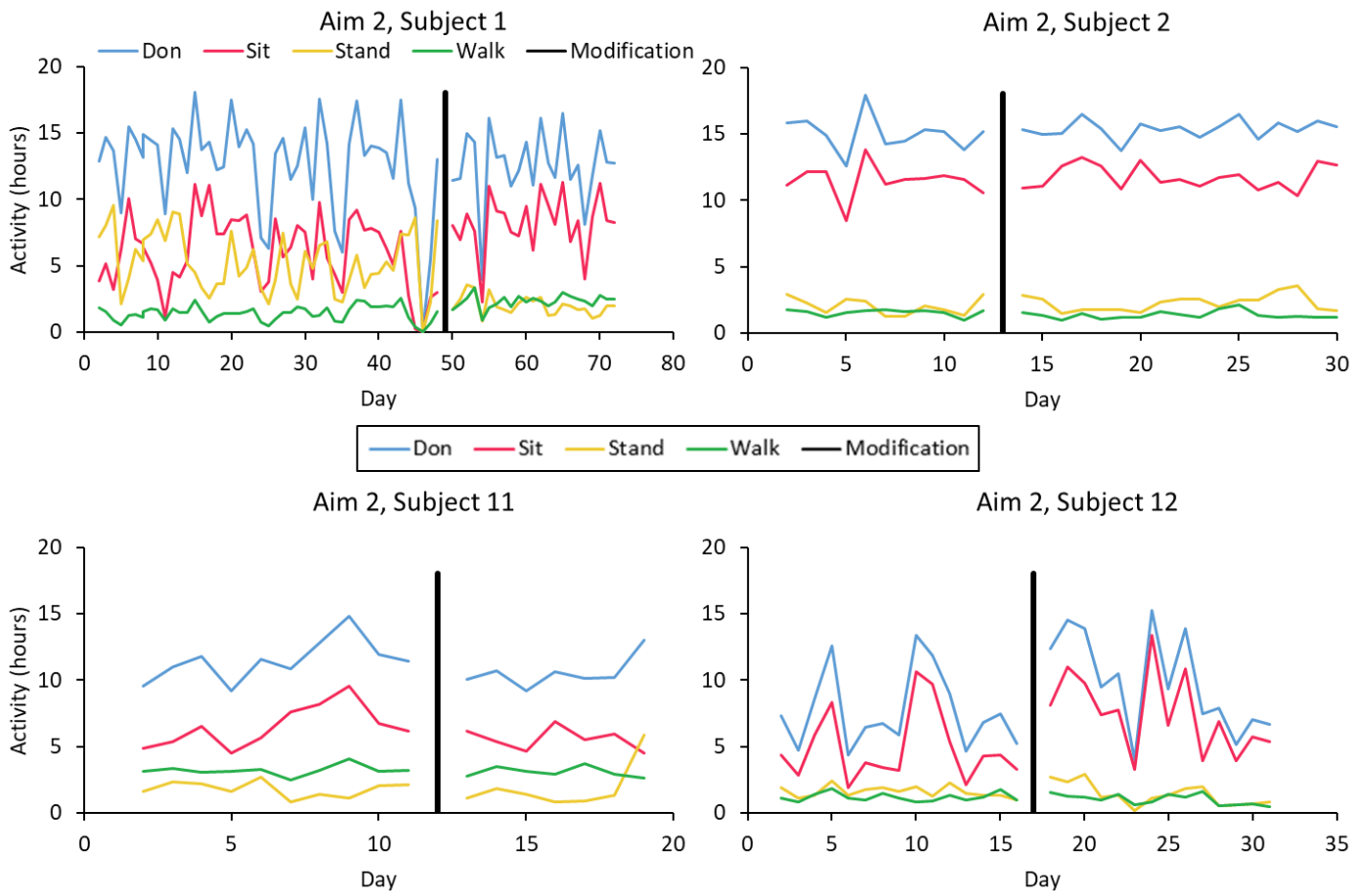


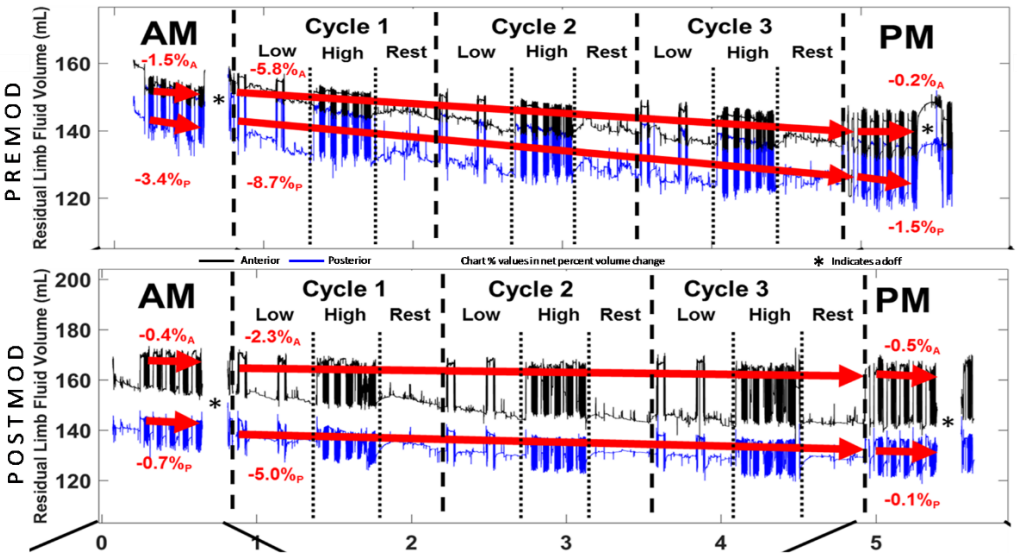
Figure 5. Example results: activity data from four participants. Black vertical bar indicates time of prosthesis modification.

An example completed case study for a participant (#10) is discussed below. This participant was wearing an extremely oversized socket (10+ply) at the outset of the study, so the prosthesist determined it was necessary to place him in a check socket immediately - before the first 6-hour test session. Between the two 6-hour sessions, slight shape adjustments were made to the check socket, and then a Limb Logic vacuum system was added to the prosthesis, mounted on the side of the socket in the carbon fiber. Due to relatively similar socket shape/size, little change was seen in the participants' SCS and PEQ values recorded. However, the individual lost 15 pounds between his pre-modification and post-modification sessions, likely accounting for the slight increase in sock ply necessary between the pre-modification session test socket and the post-modification definitive socket. This individual's limb fluid volume results may demonstrate that the vacuum system aided limb fluid volume management. After addition of the elevated vacuum, this participant retained and at times gained fluid volume when walking, in comparison to the pre-modification socket with passive suction where fluid volume losses were seen during walking. This is apparent in the limb fluid volume data split by activity (2nd page of case study report). Overall, this individual is much more volume stable throughout the 6-hour test session. Finally, we see an increase in the time this participant spends walking after his socket modification.

Aim	Subject	ScktAge(mo.)	Pre/Post	Socket	Suspension	Liner	Foot/Component	Socks?	Accomodation	Notes
2	10	1	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 ;
		(new)	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)	0	0

Participant:
10

Aim	2
Subject	10
Age (years)	52.5
PostAmp(yrs)	12.8
Mass (kg)	137.4
Height (cm)	195.6
BMI (AC)	35.9
RL length(cm)	15.1
Limb Shape	Cyl
Side	R
Group	C
MCFL	K-3
Gender	M
Amp Cause	T
DM	0
HBP	X
TOBAC	0
VASC	0
Amp Date	9/18/2004
Pre-Mod	7/20/2017
ScktAge(mo.)	1
DOB	1/4/1965
Weight (lbs)	303
Height (in)	77
Feet	6
Inches	5
Pweight (lb)	10
Notes	Cholesterol, heart attack



Volume Change (%/h)		
Cycle	Post	Ant
AM	-10.0	-5.1
PM	-4.0	-0.1
L1	-4.6	-4.2
H1	-4.5	-2.4
R1	-0.5	-2.3
L2	-4.6	-3.5
H2	-4.2	-1.5
R2	4.7	-0.8
L3	-4.7	-3.0
H3	-5.4	-1.7
R3	1.1	-1.0

Volume Change (%/h)		
Cycle	Post	Ant
AM	-3.3	-0.1
PM	-3.2	-3.1
L1	-5.3	-3.6
H1	-5.1	-4.6
R1	-5.2	-4.9
L2	-1.9	0.5
H2	-0.7	2.4
R2	2.7	0.3
L3	-3.4	-2.1
H3	-1.3	0.2
R3	-1.7	0.4

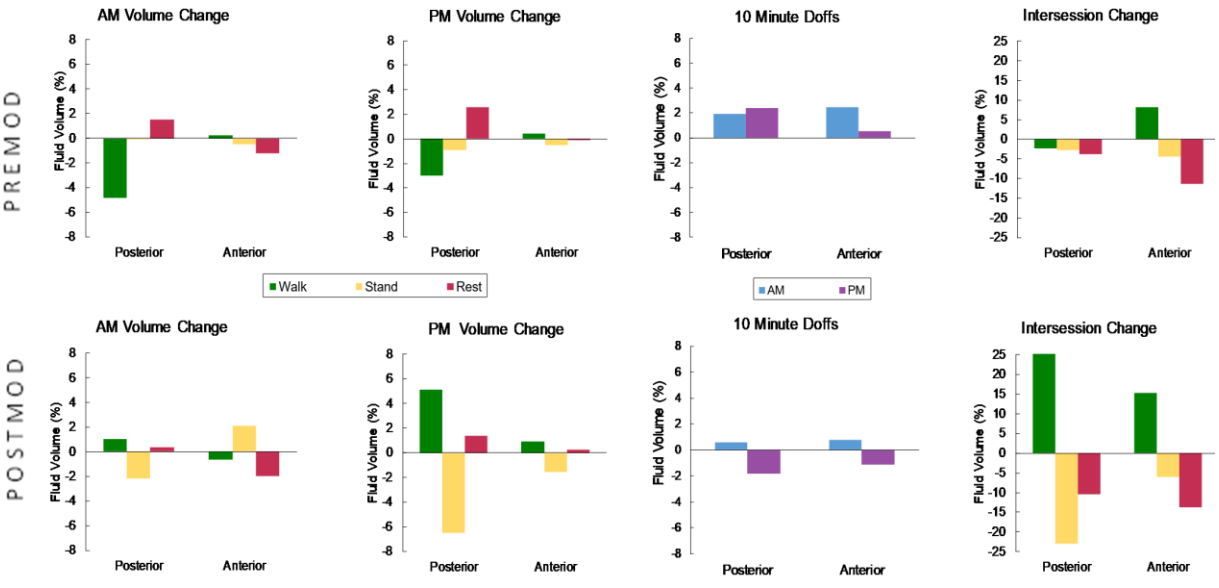
Subject	Group	Session	Date	SCS (now)	SCS (avg)	SCS (best)	SCS (worst)	Satisfaction	Ambulation	RL Health	Utility	Well Being
10	C	Pre	7/20/2017	10	10	10	10	99	81	71	95	96
		Post	9/22/2017	9	9	9	1	96	96	80	86	86

Case Study Page 1: 6-hour session limb fluid volume results, fluid volume changes at various times of day, and Socket Comfort Score self-report results.

Aim	Subject	ScktAge(mo.)	Pre/Post	Socket	Suspension	Liner	Foot/Component	Socks?	Accomodation	Notes
2	10	1	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 ;
		(new)	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)	0	0

Participant:
10

Aim	2
Subject	10
Age (years)	52.5
PostAmp(yrs)	12.8
Mass (kg)	137.4
Height (cm)	195.6
BMI (AC)	35.9
RL Length (cm)	15.1
Limb Shape	Cyl
Side	R
Group	C
MCFL	K-3
Gender	M
Amp Cause	T
DM	0
HBP	X
TOBAC	0
VASC	0
Amp Date	9/18/2004
Pre-Mod	7/20/2017
ScktAge(mo.)	1
DOB	1/4/1965
Weight (lbs)	303
Height (in)	77
Feet	6
Inches	5
Pweight (lb)	10
Notes	Cholesterol, heart attack



Case Study Page 2: Fluid volume changes by activity, including sitting, standing, walking, and doffing.

Case Study Page 3: Activity data for participant, prosthetist comments, and prosthesis and limb photos.

TABLE 6. Changes from pre-modification to post-modification.

Subject Number	Group	Activity	Survey	Limb Fluid Volume	Prosthetic Fit	Clinical Visits between pre- and post-mod
1	Control	Slight increase	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
4	Treatment	Little to no change	Small decrease in SCS (worst), PEQ satisfaction, ambulation	Significantly less loss throughout day, more recovery from doff	No change in sock ply	4
5	Treatment	(unenrolled; subject incarcerated)				
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 standing, increased gain during walking	No change in sock ply, no longer changes during day	3
8	(unenrolled prior to premod; did not go through with modification)					
9	(unenrolled went through modification after missing premod)					

8	(unenrolled prior to premod; did not go through with modification)					
9	(unenrolled went through modification after missing premod)					
10	Control	Slight increase	Generally unchanged, large decrease in SCS (worst)	slightly less loss throughout day, more fluid gains during walks	6 ply in final socket; was in check socket for premod	5
11	Treatment	Little to no change	Some improvement, still poor SCS/PEQ scores overall	lincreased gains from walks, less gain from sits, net volume change similar throughout day	same fit (1 ply worn) but subject doffing for relief less	6
12	Treatment	Little to no change	Improvements in everything, from moderate to good	little difference in overall; more loss duringa ctivity but increased recovery from doffing	great reduction in socks (13 pre to 3 to 5 post)	5
13	Treatment	Little to no change	Little change, small decrease in SCS	increased losses throughout the day; increased relief from doffing	from 20+ sock ply to no socks	4
14	(unenrolled; sores at premod)					
15	Control	(summary not created yet)	Little change, big increase in SCS (worst)	similar overall loss, increased losses during prolonged rest with increased recover during walk	subject reported tighter socket but no socks in either	4
16	Control	(summary not created yet)	Large increases in comfort and PEQ	less recovery during walking/doffing leading to increasd overall loss	13 ply to 3 ply; less reliant on cane	4
17	Control	(summary not created yet)	Largely unchanged, slight increases in PEQ-Utility, -Residual Limb Health, and SCS	very stable pre and post-mod; decreased losses from standing with less recovery from doffs post mod	no socks pre or post; subject is comfortable walking without cane now	(prosthetist did not complete second visit)
18	Control	(skin breakdown before post mod session; incomplete)				
19	Control	(summary not created yet)	Slight increases overall, small decrease in SCS (worst)	slight reduction in overall losses;now consistently recovers/maintains during walks	reduction in 10 to 15 ply; reports doffing less for relief	5
20	Treatment	(summary not created yet)	Large decreases in comfort, PEQ decreases in satisfaction, ambulation, utility	slight reduction in overall losses; now benefits from doffing	3-5 ply tighter but subject over uses socks	4
21	Control	(sores developed prior to post mod; had surgery)				
22	Control	(stopped communicating with prosthetist; has not picked up new socket)				
23	Treatment	(had surgery on contralateral foot)				
24	Control	(death in family; missed post mod session)				
25	Treatment	(waiting for sensor return shipment)	SCS relatively unchanged, PEQ small increases with large increase in RL health	modest reduction in overall losses; gains fluid from doffign now	reduction in size by 1 to 3 ply	5
26	Treatment	(waiting for sensor return shipment)	Large icnreases across SCS, PEQ satisfaction, Ambulation, and Utility	less loss throughout the day; more consistent recovery from walking	reduction in size by 8 or 9 ply	2
27	Control	(waiting for sensor return shipment)	Slight increases in SCS, increases in PEQ except for RL Health	little to no change in volume profile; similar modest losses throughout the day	no size changes; new sleeve (no hole in it) + new foot	1

Comparison of Socket Comfort Score and Prosthesis Evaluation Questionnaire results for treatment and control groups is inconclusive at this point due to the low participant numbers. Data are presented in Figure 6.

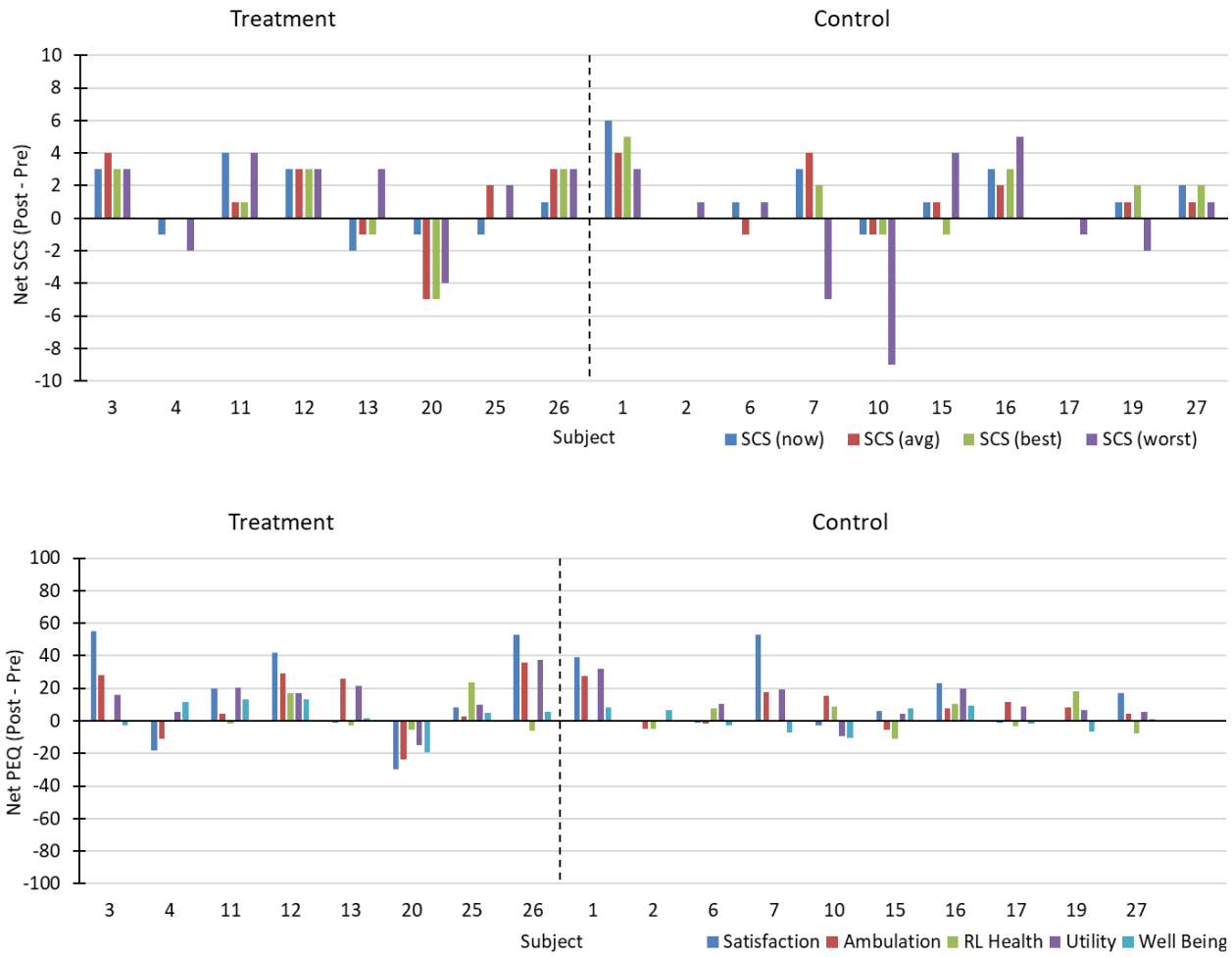


Figure 6. Socket Comfort Score (SCS) and Prosthesis Evaluation Questionnaire (PEQ) results from all Aim 2 participants.

Prosthetist survey results from Aim 2 are inconclusive at this point because not enough participants have been tested. Questions related to limb fluid volume data were only asked of treatment group prosthetists, as the control group prosthetists were not presented limb fluid volume results. Full questions are listed below, columns left to right in table listed in order of first to last.

Subject	Prosthet	Group	Date	Session	RL Health	Current Fit	Comm w patient	Mod Success	Strategy Success	Change Satisfaction	BIOZ for design	BIOZ for strategy	BIOZ for issues	Improve comm	Improve outcomes	Request for others	Presentation improve understanding
1	1	C	5/14/2017	Pre	8	3	7										
			7/17/2017	Post	9	9	8	9	X	10							
2	1	C	5/15/2017	Pre	8	5	10										
			7/17/2017	Post	8	9	9	10	X	10							
6	2	C	5/16/2017	Pre	6	7	8										
			7/13/2017	Post	7	7	8	5	5	5							
5	2	T	5/12/2018	Pre	9	7	9										
				Post				(prosthetists subject incarcerated)									
3	3	T	5/17/2017	Pre	8	4	8										
			7/18/2017	Post	8	9	10	9	0	9	0	5	0	7	2	5	9
4	4	T	5/17/2017	Pre	10	8	10										
			5/26/2017	Post	10	10	6	10	8	9	10	10	10	10	8	9	10
7	5	C	5/26/2017	Pre	3	5	8										
			6/22/2017	Post	4	7	10	8	7	8							
11	6	T	7/19/2017	Pre	7	4	8										
			9/26/2017	Post	7	8	8	8	8	8	8	8	8	8	6	8	8
13	7	T	7/18/2017	Pre	10	3	10										
			9/25/2017	Post	8	9	10	10	8	10	7	8	1	6	5	6	8

10	8	C	7/20/2017	Pre	10	9	10													
			9/22/2017	Post	9	8	10	9	7	9										
12	8	T	7/21/2017	Pre	8	6	10													
			9/27/2017	Post	8	9	9	9	7	8	9	8	8	8	8	10	9			
15	9	C	12/13/2017	Pre	8	6	9													
			3/28/2018	Post	9	9	10	9	9	9										
16	10	C	1/18/2018	Pre	10	5	10													
			5/16/2018	Post	8	9	10	10	6	7										
23	10	T	3/8/2018	Pre	8	7	10													
				Post																
17	11	C	3/7/2018	Pre	9	6	6													
			3/29/2018	Post				(prosthetist did not show up to post-mod session and did not complete emailed survey)												
19	12	C	3/12/2018	Pre	9	3	9													
			6/4/2018	Post	9	9	9	9	8	8										
20	12	T	3/16/2018	Pre	8	4	9													
			6/1/2018	Post	7	8	7	3	4	7	4	7	2	7	7	5	6			
18	13	C	3/13/2018	Pre	5	2	8													
				Post																
21	13	C	3/14/2018	Pre	7	3	9													
				Post																
22	13	C	3/15/2018	Pre	6	6	8													
				Post																
27	14	C	6/21/2018	Pre	7	6	8													
			8/6/2018	Post	7	7	8	8	5	5										
24	15	C	6/22/2018	Pre	8	3	5													
				Post																
25	15	T	6/25/2018	Pre	6	6	9													
			8/8/2018	Post	6	7	8	9	8	8	9	10	10	10	9	10	9			
26	15	T	6/26/2018	Pre	7	4	8													
			8/7/2018	Post	6	8	8	8	7	8	8	10	8	9	8	9	9			

Questions asked:

- Overall how would you rate your patient's present **limb health**?
- Overall, how would you rate the **current fit** of your patient's prosthetic socket?
- Overall, how would you rate your ability to **communicate effectively with this patient**?
- How would you rate the **success these modifications** had on improving patient outcomes?
- How would you rate the **success these strategies** had on improving patient outcomes?
- Overall, how would you rate your **satisfaction** with the changes you made to the patient's socket and/or volume management practices?
- 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**?
- To what extent did the presentation and discussion of bioimpedance information **improve your understanding** of the information?

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

No additional opportunities beyond those listed in Year 1 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:

- Recruitment of an additional remote clinic so as to enhance participant recruitment for Aim #2
- Disseminate findings at conference and meeting presentations
- Extend analysis in Aims #1 and #2

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 were made to activity monitoring (interim monitoring between pre-modification and post-modification was optional) because practitioners did not apply the monitors correctly when the ankle, liner, or sleeve were changed. We modified the protocol so that only data from monitors applied by UW researchers was used to determine participant activity level. Thus the impact of this change on study design was minimal.

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

Our most important challenges are participant recruitment and dropout. We undertook efforts to overcome these problems, including enhancing recruitment efforts, and re-emphasizing to practitioners and participants the need to participate in the study to the end.

To enhance recruitment, we recruited an additional remote site – Scheck and Siress in the Chicago area. The trips for remote data collection allow us to collect much data in a short period of time, which moves the project forward quickly. We plan to add one additional remote site next year.

Identification and recruitment of remote sites takes considerable effort and organization, which has drawn us away from other aspects of the study. We are focusing on Aim #2 since we view it as the more clinically relevant study.

- **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 2?**

Name:	Joan E Sanders PhD
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-8850-243X
Nearest person month worked:	1.5
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):	N/A
Nearest person month worked:	1.2
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:	9.0
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:	4.7
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:	2.7
Contribution to Project:	Mechanical design; data collection
Funding Support:	

Name:	Ethan Weathersby
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.7
Contribution to Project:	Mechanical design; data collection
Funding Support:	

Name:	Jacob Brzostowski
Project Role:	Research Scientist

Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.6
Contribution to Project:	Mechanical design; 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	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 Names, Locations: Ability Prosthetics and Orthotics, Exton, Pennsylvania; Scheck and Siress, Chicago, Illinois

- **Partner's contribution to the project**

  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.

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)	**$410**	**$493**	**$687**

Updated: October 1, 2018

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 Goal –

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

Comments/Challenges/Issues/Concerns

- Not applicable

Budget Expenditure to Date

Projected Expenditure: $1,040,443
Actual Expenditure: $903,849

Appendix 1. Prostheses and modifications

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

Aim	Subject	Pre/Post	Socket	Suspension	Liner	Foot/Components	Socks	Accommodation	Notes
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)		
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 w/ inner flexible	suction/sleeve, ottobock dermoflex sleeve	Ossur Iceross Dermo	Ability RUSH dynamic foot	3x 5 ply, 2x 3 ply	frequently adds a 3 ply in the middle of the day	first definitive socket; way oversized due to atrophy in first year since amputation
		Post	definitive CF incomplete; in thermoplastic check socket for post mod session; no flexible inner liner	pin/lock	Ossur Iceross dermo	same	no socks	no socks, no changes needed	first tried Seal-In V liner; was not working, so switched to pin/lock
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 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	18	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)							

Aim	Subject	Pre/Post	Socket	Suspension	Liner	Foot/Components	Socks	Accommodation	Notes
2	19	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
2	20	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	21	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	22	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	23	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; will attempt to resume afterwards
2	24	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	25	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	26	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	27	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