

AWARD NUMBER: W81XWH-15-1-0470

TITLE: The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited Community Ambulators

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14. ABSTRACT This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6-month period of time in addition to receiving physical therapy training. All outcome measures will be evaluated three times during the 6-month study period. Once HRPO approval for the project was received in April 2016, recruitment efforts via Partner Prosthetic clinics was undertaken to identify over 700 potentially eligible individuals, 40 of whom were veterans. Similar efforts with the Regional DAV, local area hospitals, and additional prosthetic clinics in the mid-south region have also been undertaken yielding over 2300 additional potentially eligible individuals. Active recruitment began in July 2016 and has yielded 373 individuals responding to recruitment efforts to date, 251 of whom have been screened for eligibility. Of those, 91 (36%) met eligibility criteria to qualify for evaluation. Forty-two (46.2%) of those individuals (who comprised 11.3% of the total 373 screened) met the K-Level 2-3 classification as a "community ambulator" and were eligible for randomization to group assignment. Completion of the study recruitment, enrollment/randomization, intervention and follow-up assessments will be accomplished in the coming quarter/year.						
15. SUBJECT TERMS Trans-tibial amputee (TTA), microprocessor controlled prosthetic foot (MPF), randomized clinical trial, functional performance, ambulatory safety, falls, quality of life, community ambulator						
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1. INTRODUCTION:

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. The blocked randomization schedule will be generated by a computer program with a block size of 4; this will guarantee that we have approximately the same number of participants in each treatment group throughout the trial. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6-month period of time and receive physical therapy training to minimize deviations resulting from habit or lack of training, education to maximize use of the mechanical properties of their current foot, strengthening and stretching based on published guidelines for TTA, balance training and training on traversing environmental barriers. All outcome measures will be evaluated three times during the 6-month study period: At baseline, at the 3-month follow up visit and at the 6-month follow up visit. We believe the immediate benefit of this project will determine if an innovative MPF, designed to facilitate toe clearance by optimizing ankle angle and foot position, will improve functional performance, ambulatory safety (risk of falls), and quality of life in the typical veteran amputee. This study will also have significant long-term benefit for all typical amputees, both veterans and the general public, as they face medical, social and psychological complications associated with falling (broken bones, head trauma, depression, social isolation and death), decreased function and poor quality of life that directly impacting their families and caregivers.

2. KEYWORDS:

Trans-tibial amputee (TTA)
Microprocessor controlled prosthetic foot (MPF)
Randomized clinical trial
Functional performance
Ambulatory safety
Falls
Quality of life
Community ambulator

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of this project as stated in the approved SOW are as follows:

1. Perform Preliminary Study Requirements (Months 1-6)
2. Recruit, Coordinate and Train Study Personnel for Clinical Trial (Months 3-6)
3. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Baseline Randomization Evaluations (Months 7-24)
4. Participant Randomization (Months 7-24)
5. Participant Fit with Microprocessor Foot; Intervention Group (N=27; Months 7-24)
6. Physical Therapy Sessions and Prosthesis Accommodation Period (N=54; Months 7-24)
7. 3-Month Follow Up Visit and Prosthesis Accommodation Period (N=54; Months 10-27)
8. 6-Month Follow Up Visit and subject closure (N=54; Months 10-30)
9. Data Analysis/Dissemination of Findings (Months 28-36)
10. Assess Prosthesis related quality of life (N=54; Months 7-36)

What was accomplished under these goals?

1. Perform Preliminary Study Requirements
 - a. Prepare study documents and apply for Local IRB (UTHSC) and USAMRM Human Research Protection Office (HRPO) approval- Complete, HRPO approval received Apr 5, 2016.
 - Updated consent form submitted Apr 26, 2016- Approved May 5, 2016
 - b. Complete Manual of Operations finalizing procedures sections and forms for recruiting and reporting – completed May 2, 2016
 - e. Develop database management system – completed May 26, 2016
 - f. Develop and finalize all study data collection forms – completed May 2, 2016
 - g. Submit amendments, adverse events and protocol deviations Completed August 31, 2020
 - h. Maintain, update and perform data integrity test on study DBMS – Completed August 31, 2020.

2. Train Study Personnel for Clinical Trial
 - a. Train staff, evaluation physical therapist, treating physical therapist and prosthetists for project – completed May 27, 2016
 - Trial run through of Screening and Baseline visits for the study
 - Eligibility and Randomization training – Completed March 31, 2016
 - Adverse Events Training with Dr. Mihalko, MD – Completed April 1, 2016
 - b. Develop participant recruitment materials – completed May 13, 2016
 - Participant Flyer - Completed Mar 16, 2016
 - Participant Flyer with Tear-offs – Completed Mar 16, 2016
 - Business Card – Completed Mar 16, 2016
3. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit– Completed February 28, 2020
 - a. Participant recruitment – Completed. Performed initial targeted recruitment via Partner Prosthetic clinics, Regional DAV, VA and local area hospitals and physician practices, to identify targeted mailings to prospective participants.
 - Identify prospective participants for targeted recruitment
 - Perform phone (pre-) screening, schedule qualifying participants to baseline session – Completed February 28, 2020
 - b. Confirm pre-screening at in person Screening Eligibility Visit – Completed February 28, 2020
 - Sign informed consent
 - Evaluate functional level of participant
 - Evaluate fit of current prosthesis
 - c. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Evaluations – Completed February 28, 2020
 - d. Baseline Randomization Evaluations – Completed February 28, 2020
4. Participant Randomization – Completed February 28, 2020
5. Participant Fit with Microprocessor Foot; Intervention Group – Completed February 28, 2020
6. Physical Therapy Sessions and Prosthesis Accommodation Period– Completed March 7, 2020
7. 3-Month Follow Up Visit and Prosthesis Accommodation Period- Completed- missed evaluation due to COVID-19 shutdown
8. 6-Month Follow Up Visit and subject closure Completed August 31, 2020.
9. Assess Prosthesis-related quality of life– Completed August 31, 2020
10. Data Analysis and dissemination of findings– Completed October 31, 2020

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

During the final reporting period we had to cancel a planned annual CEU professional development seminar for physical therapists and prosthetists in the Memphis area conducted by Ossur trainers due to the COVID-19 shutdown.

How were the results disseminated to communities of interest?

During this final reporting period we reached out to the UTHSC Graduate Medical Education program to inform physicians and primary care prosthetic providers of the publication opportunities now available with the VALOR dataset.

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

Nothing to Report – We will continue to pursue dissemination of the study results beyond the closure of this project.

4. IMPACT:

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

The findings presented below demonstrate that the use of a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, was successfully translated to the trans-tibial amputees (TTA) who function as limited community ambulators.

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?

The findings presented below demonstrate that the use of a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, was successfully translated to the trans-tibial amputees (TTA) who function as limited community ambulators. Additionally, results showed that participants reported improved satisfaction with their prosthesis and improved quality of life.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

During this reporting period the project was impacted by the COVID-19 Pandemic, shutting down the trial which resulted in a loss of several participants to follow-up.

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

COVID-19 shutdown resulted in a loss of participant follow-up evaluation

Changes that had a significant impact on expenditures

None

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

None

Significant changes in use or care of vertebrate animals.

Not Applicable

Significant changes in use of biohazards and/or select agents

Not Applicable

6. PRODUCTS:

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

Nothing to Report

- **Journal publications.**
Nothing to Report
- **Books or other non-periodical, one-time publications.**
Nothing to Report
- **Other publications, conference papers, and presentations.**
Nothing to Report

- **Website(s) or other Internet site(s)**
Nothing to Report
- **Technologies or techniques**
Nothing to Report
- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

During this final reporting period study data collection was completed and data analysis performed. Results from data analyses are presented in the appendix of this report. These results be shared via dissemination at professional conferences and through publication.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Phyllis Richey, PhD
Project Role:	Joint-Principal Investigator
Research Identifier:	1
Nearest person month worked:	12
Contribution to Project:	Dr. Richey is fulfilling the role of co-Principal Investigator as outlined in the SOW.
Name:	Kunal Singhal, PhD, PT
Project Role:	Co-Investigator
Research Identifier:	2
Nearest person month worked:	12
Contribution to Project:	Dr. Singhal is continuing to fulfill the role providing the physical therapy intervention for participants and insuring consistency in delivery of the intervention protocol as

outlined in the SOW. Additionally, as described in the change of PI request and revised SOW (Apr, 10, 2018), Dr. Singhal has been performing the Joint-PI duties as the acting “Intervention PI,” previously assigned to Dr. Zucker-Levin, following her departure from the University as a full-time employee.

Name: Kristen Leone
Project Role: Study Coordinator
Research Identifier: 3
Nearest person month worked: 5
Contribution to Project: Ms. Leone has worked with IRB submissions, data collection, participant recruitment, retention, screening, conducting evaluation visits, performing phone visits, and scheduling, as well as PT visit scheduling and prosthetic clinic communication and scheduling.

Name: Lindsey Siegfried
Project Role: Study Coordinator
Research Identifier: 4
Nearest person month worked: 5
Contribution to Project: Ms. Siegfried has assisted Ms. Leone with data collection, participant recruitment, retention, screening, conducting evaluation visits and performing phone visits.

Name: Matt Hood
Project Role: Study Coordinator/Informatics
Research Identifier: 5
Nearest person month worked: 12
Contribution to Project: Mr. Hood has worked with IRB submissions, HRPO submissions, database development/maintenance, participant recruitment, screening, conducting evaluation visits, retention, and scheduling, prosthetic clinic communication and scheduling.

Name: William Mihalko, MD, PhD
Project Role: Co-Investigator
Research Identifier: 6
Nearest person month worked: 12
Contribution to Project: Dr. Mihalko is fulfilling the role of co-investigator overseeing intervention safety and adverse event reporting as outlined in the SOW.

Name: Catherine Womack, MD
Project Role: Co-Investigator
Research Identifier: 7
Nearest person month worked: 12
Contribution to Project: Dr. Womack is fulfilling the role of co-investigator adjudicating any participant eligibility determinations in which medical history and/or current health habits (e.g. medication and/or substance abuse, depression status, etc) are in question.

Name: Richard Kasser, PhD, PT
Project Role: Staff Evaluation PT
Research Identifier: 8
Nearest person month worked: 12
Contribution to Project: Dr. Kasser is fulfilling the role of staff evaluation PT needed for the expanded screening physical therapy evaluations and other primary outcome measurements during the in-person evaluation visits (baseline, 3-month and 6-month) the as outlined in the SOW.

Name: Kip Handwerker
Project Role: Study Coordinator
Research Identifier: 9
Nearest person month worked: 5
Contribution to Project: Mr. Handwerker worked with IRB submissions, data collection, participant recruitment, retention, screening, conducting evaluation visits, performing phone visits, and scheduling, as well as PT visit scheduling and prosthetic clinic communication and scheduling.

Name: Jim Wan, PhD
Project Role: Co-Investigator
Research Identifier: 10
Nearest person month worked: 12
Contribution to Project: Dr. Wan is fulfilling the co-investigator role as Statistician outlined in the SOW.

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

Nothing to Report

What other organizations were involved as partners?

Organization Name:	CFI Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Human Technology Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures

Personnel exchanges:	None
Other:	None
Organization Name:	Precision Prosthetics, Inc.
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Spears Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Hanger Prosthetics Inc
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Memphis Prosthetics Inc
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Disabled American Veterans (DAV)
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None

Other:	None
Organization Name:	Methodist Healthcare
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Region One Healthcare
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Baptist Memorial Healthcare
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Arkansas State University, Department of Physical Therapy
Location of Organization:	Jonesboro, AR
Partner's contribution to the project:	Partner Physical Therapy site
Financial support:	None
In-kind support:	None
Facilities:	Physical therapy intervention group participants
Collaboration:	Physical Therapists providing physical therapy sessions for study participants living in the north-east Arkansas area
Personnel exchanges:	None
Other:	None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

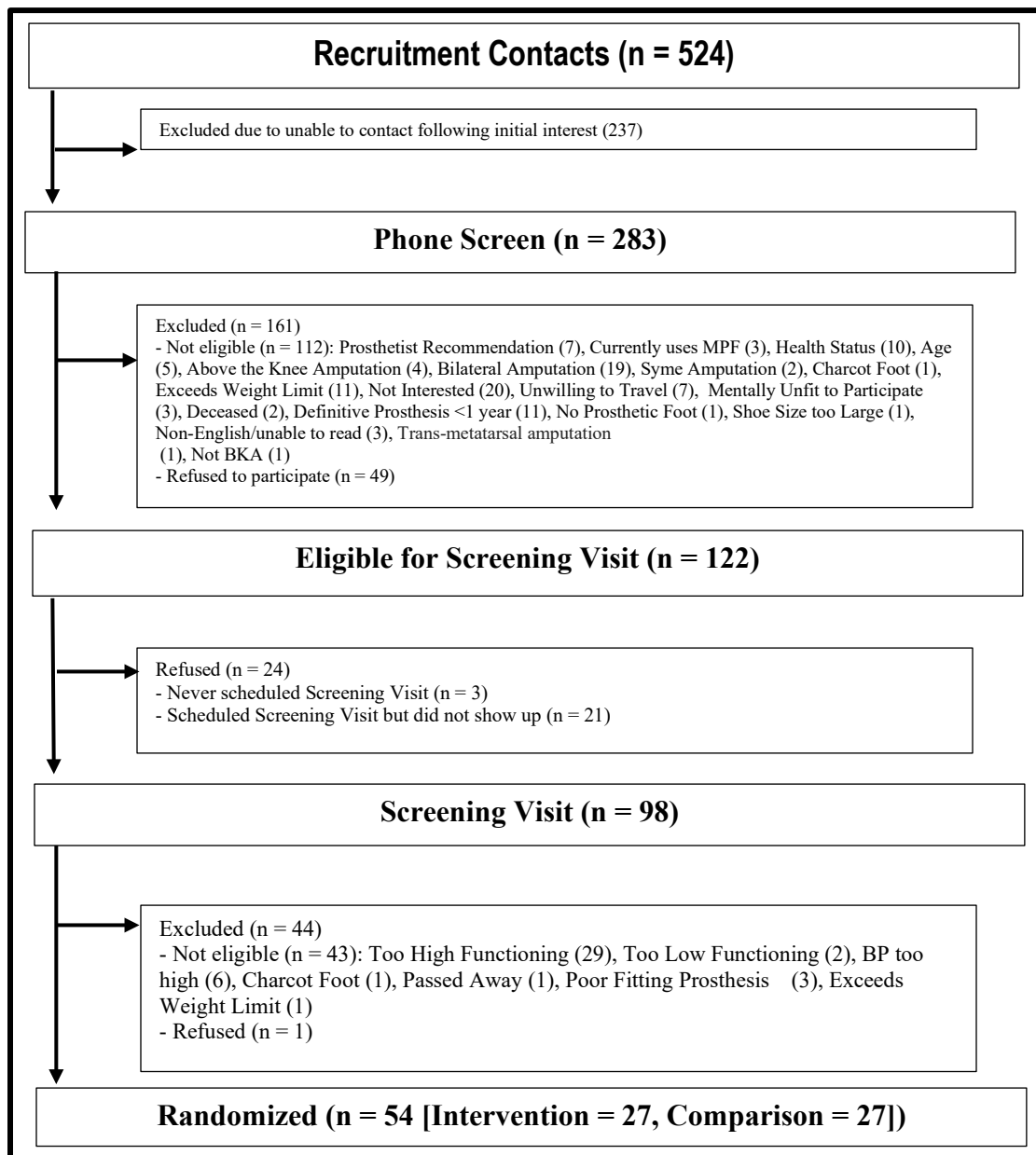
Not Applicable

QUAD CHARTS:

Attached

9. APPENDICES:

Appendix A: *Consort Diagram*



Appendix B: Baseline Characteristics of Participants by Tx Group

	All (n=54)	Intervention (n=27)	Comparison (n=27)	P-value
Treatment Assignment, No. (%)		27 (50.0%)	27 (50%)	
Demographic measures				0.4845
Age, mean \pm SD, years	57.3 \pm 9.85	58.2 \pm 9.62	56.3 \pm 10.17	
Age Category, No. (%), years				
>40	31.5 (0.04)	34 (0.04)	29 (0.04)	
40 – 49	45.1(0.16)	45 (0.15)	45.2 (0.18)	
50 – 59	55.4 (0.39)	55.7(0.33)	55.2 (0.44)	
60 – 69	64.4 (0.30)	64.7 (0.41)	64.0(0.19)	
70 +	71.5 (0.11)	72.5(0.07)	71.0 (0.15)	
Gender, No. (%)				0.5346
Male	40 (0.74)	21 (0.78)	19 (0.74)	
Female	14 (0.26)	6 (0.22)	8 (0.26)	
Race, No. (%)				0.5954
African American / Black (not Hispanic)	26 (0.48)	13 (0.48)	13(0.48)	
White	27 (0.5)	13 (0.48)	14 (0.52)	
Other race	1 (0.02)	1 (0.04)	0 (0.0)	
Military Status, No. (%)				
Veteran	18 (0.33)	11 (0.61)	7 (0.39)	
Non-veteran	36 (0.67)	16 (0.44)	20 (0.56)	
Military beneficiary				
Anthropometric measures				0.3719
Body Mass Index, mean \pm SD, kg/m ²	29.79 \pm 5.29	29.66 \pm 4.67	29.91 \pm 5.93	
Body Mass Index Category, No. (%), kg/m ²				
Normal	8 (0.148)	3 (0.11)	5 (0.19)	
Overweight	23 (0.426)	14 (0.52)	9 (0.33)	
Obesity	23 (0.426)	10 (0.37)	13 (0.48)	
Amputation Etiology				0.7757
Non-Traumatic	35 (0.65)	18 (0.67)	17 (0.63)	
Traumatic	19 (0.35)	9 (0.33)	10 (0.37)	

	All (n=54)	Intervention (n=27)	Comparison (n=27)	P-value
K-Level Classification				0.3108
Pre-Study (Prosthetist) K-Level				
K2	11 (0.20)	4 (0.15)	7 (0.26)	
K3	43 (0.80)	23 (0.85)	20 (0.74)	
Physical Function measures				
AmpPRO (with prosthesis)				
Score	36.18 ± 6.54	37.04 ± 5.91	35.25 ± 7.18	0.3439
K-Level				0.7027
K2	16 (0.32)	9 (0.35)	7 (0.29)	
K3	25 (0.50)	13 (0.50)	12 (0.50)	
Berg Balance Scale				
Score	46.61 ± 9.00	47.56 ± 7.91	45.67 ± 10.03	0.2336
Dynamic Gait Index				
Score	18.44 ± 4.63	19.16 ± 3.87	17.70 ± 5.25	0.1226
Four Square Step Test				
Time	17.49 ± 14.81	14.13 ± 5.81	20.85 ± 19.75	0.0957
Uneven Terrain				
Trips (#)	0.56 ± 1.19	0.385 ± 0.697	0.731 ± 1.54	0.3009
Falls (#)	0.04 ± 0.19	0.039 ± 0.196	0.039 ± 0.196	1.000
Time (sec)	13.68 ± 12.77	10.69 ± 3.52	16.56 ± 17.23	0.0951
GaitRite				
Velocity (cm/sec)	93.33 ± 23.25	91.42 ± 21.32	95.31 ± 25.39	0.5560
Step Length (R)	56.02 ± 11.06	54.57 ± 10.69	57.54 ± 11.44	0.3428
Step Length (L)	56.36 ± 11.41	55.79 ± 10.72	56.95 ± 12.28	0.7219
Six Minute Walk				
Distance (ft)	1034.36 ± 340.07	1086 ± 343.1	982.7 ± 335.4	0.2687

	All (n=54)	Intervention (n=27)	Comparison (n=27)	P-value
Quality of Life/Psychosocial measures				
CESD-R				
Score	8.85 ± 7.04	10.31 ± 7.73	7.44 ± 6.12	0.1405
Orthotic /Prosthetic User Survey				
Functional Status Measure	46.51 ± 11.17	45.84 ± 11.15	47.27 ± 11.41	0.6657
Health / Quality of Life Index	49.24 ± 11.14	49.84 ± 45.54	48.52 ± 43.98	0.6659
Satisfaction with Devices and Services	39.00 ± 7.37	38.36 ± 34.93	39.76 ± 36.95	0.5265
Prosthetic Evaluation Questionnaire				
Ambulation	8.76 ± 4.64	7.51 ± 2.73	9.96 ± 5.74	0.0646
Appearance	15.08 ± 5.39	13.46 ± 5.53	16.50 ± 4.93	0.0525
Frustration	39.29 ± 17.12	37.33 ± 13.66	41.09 ± 19.89	0.4526
Perceived Response	19.88 ± 13.17	17.06 ± 5.83	22.37 ± 17.00	0.1709
Residual Limb Health	14.76 ± 11.38	15.40 ± 15.42	14.12 ± 5.08	0.7015
Social Burden	27.61 ± 17.54	24.99 ± 8.69	30.12 ± 23.02	0.3115
Sounds	38.19 ± 38.22	28.98 ± 21.42	47.01 ± 26.05	0.1066
Utility	10.62 ± 13.21	8.36 ± 2.40	12.79 ± 18.27	0.2455
Well Being	36.66 ± 10.75	35.24 ± 10.87	38.03 ± 10.68	0.3694

Appendix C: Overall Changes in Outcome Measures from Baseline to 3-month and 6-month Follow-up by Tx Group

Outcome Measurement	Change at 3 Months			Change at 6 Months			P-value
	All Mean \pm SD (N)	Intervention	Comparison	All Mean \pm SD (N)	Intervention	Comparison	
AmpPRO-Score	1.40 \pm 3.33	1.79 \pm 2.53	0.94 \pm 4.12	1.63 \pm 4.49	2.48 \pm 3.03	0.357 \pm 5.97	0.1746
Berg-Score	1.14 \pm 4.97	0.900 \pm 4.48	1.41 \pm 5.71	2.23 \pm 4.41	2.59 \pm 5.28	1.94 \pm 2.96	0.6584
DGI-Score	0.19 \pm 3.16	1.40 \pm 3.02	-1.24 \pm 2.77	0.08 \pm 2.84	0.61 \pm 2.93	-0.69 \pm 2.65	0.1640
FSST-Time	-0.14 \pm 3.20	0.026 \pm 1.52	-0.33 \pm 3.16	-1.21 \pm 3.79	-1.16 \pm 4.12	-1.29 \pm 3.36	0.9211
Uneven Terrain-Trips	-0.38 \pm 1.39	-0.56 \pm 0.64	-0.79 \pm 1.93	-0.20 \pm 0.47	-0.091 \pm 0.294	-0.385 \pm 0.65	0.0753
Uneven Terrain-Falls	0.00 \pm 0.00	0	0	0.00 \pm 0.00	0	0	.
Uneven Terrain-Time	-0.27 \pm 3.26	-0.67 \pm 2.93	0.200 \pm 3.67	10.03 \pm 68.82	17.09 \pm 88.05	-1.07 \pm 2.97	0.4481
GaitRite-Velocity	2.09 \pm 15.70	4.89 \pm 15.13	-0.71 \pm 16.21	1.43 \pm 15.23	5.94 \pm 15.75	-3.98 \pm 13.09	0.0612
GaitRite-Step Length (R)	0.82 \pm 7.80	2.46 \pm 8.54	-0.82 \pm 6.85	-0.22 \pm 7.22	2.058 \pm 7.986	-2.943 \pm 6.645	0.0628
GaitRite-Step Length (L)	1.04 \pm 7.23	2.50 \pm 7.41	-0.41 \pm 6.96	0.03 \pm 6.69	1.12 \pm 7.52	-1.28 \pm 5.52	0.3143
Six Minute Walk-Distance	-31.64 \pm 140.05	-27.65 \pm 132.9	-36.11 \pm 151.6	-17.80 \pm 217.0	-19.59 \pm 269.1	-14.99 \pm 99.60	0.9517
CESDR-Score	1.03 \pm 6.07	-1.58 \pm 6.37	3.94 \pm 4.22	1.33 \pm 7.08	-1.476 \pm 6.306	5.267 \pm 6.319	0.0033
OPUS-FSM	2.28 \pm 9.88	3.11 \pm 9.95	1.21 \pm 10.06	3.58 \pm 16.01	4.89 \pm 15.94	1.79 \pm 16.54	0.5896
OPUS-HQLI	2.06 \pm 9.52	1.78 \pm 11.21	2.46 \pm 6.96	-0.63 \pm 14.75	0.737 \pm 17.505	-2.615 \pm 9.76	0.5366
OPUS-SDS	0.26 \pm 8.62	1.00 \pm 8.87	-0.77 \pm 8.50	0.00 \pm 5.89	-0.053 \pm 3.03	0.077 \pm -3.35	0.9524
PEQ-Ambulation	0.42 \pm 3.18	1.97 \pm 2.22	-1.44 \pm 3.22	0.17 \pm 3.00	1.15 \pm 2.51	-1.11 \pm 3.20	0.0386
PEQ-Appearance	2.41 \pm 6.90	1.79 \pm 2.50	3.06 \pm 9.70	1.49 \pm 4.09	2.656 \pm 4.96	0.229 \pm 2.509	0.1257

PEQ-Frustration	-0.38 ± 14.77	0.25 ± 15.77	-0.05 ± 14.12	18.17 ± 61.30	30.62 ± 80.64	2.856 ± 13.33	0.2317
PEQ-Perceived Response	-0.19 ± 7.68	0.977 ± 4.86	-1.44 ± 9.87	3.47 ± 11.95	6.013 ± 15.946	0.722 ± 4.639	0.2581
PEQ-Residual Limb Health	1.45 ± 10.16	-0.16 ± 2.59	3.37 ± 14.85	7.75 ± 23.61	13.494 ± 30.405	0.237 ± 2.625	0.1297
PEQ-Social Burden	-0.03 ± 7.11	0.66 ± 9.18	-0.81 ± 3.82	5.07 ± 20.65	7.576 ± 26.63	1.787 ± 8.023	0.4563
PEQ-Sounds	9.87 ± 43.28	3.94 ± 17.35	16.53 ± 60.75	16.02 ± 45.36	25.617 ± 59.99	4.942 ± 13.511	0.2359
PEQ-Utility	0.04 ± 1.90	0.18 ± 2.27	-0.115 ± 1.42	0.05 ± 1.21	-0.060 ± 1.154	0.193 ± 1.307	0.5781
PEQ-Well Being	-0.79 ± 11.23	2.01 ± 10.26	-3.94 ± 11.76	0.94 ± 9.08	0.772 ± 8.354	1.154 ± 10.29	0.9115