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TITLE: The Effect of a Powered Ankle Foot Orthosis (PAFO) on Function, Safety, and Quality of Life in Military Service Members and Veterans Who Wear a Prescribed Orthosis

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14. ABSTRACT This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a powered ankle foot orthosis (PAFO), that assists with toe clearance and provides push-off power when taking a step, will translate into enhanced function in individuals who walks with a prescribed AFO. We will assess these outcomes in veterans who walk with a prescribed AFO by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. Participants in both groups will receive new shoes to be worn with their orthosis to eliminate any confounding variables presented by worn or inadequate shoes. Participants in the intervention group will be provided enhanced training opportunities to use a PAFO while the comparison group will continue with their currently prescribed orthosis. All participants will be followed with weekly contact over a 7-month period of time and receive physical therapy training. All outcome measures will be evaluated three times during the 7-month study period. Recruitment resources via Partner Orthotic clinics, Regional DAV, Memphis VAMC, local area health care agencies and physician practices have been identified and approval to contact potential study volunteers is currently in progress. Recruitment, enrollment/randomization, intervention is in progress and follow-up assessments will take place during in the coming quarters/year.					
15. SUBJECT TERMS Ankle foot orthosis (AFO), powered ankle foot orthosis (PAFO), randomized clinical trial, functional performance, ambulatory safety, falls, quality of life, gait symmetry, foot drop, stroke, spinal cord injury (SCI), traumatic brain injury (TBI), peripheral injury.					
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1. INTRODUCTION:

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to quantify functional performance, gait symmetry, ambulatory safety, and quality of life in veterans who walk with a prescribed AFO. The cohort will be randomized in a 1:1 ratio into an intervention or 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 both groups will receive new shoes to be worn with their orthosis to eliminate any confounding variables presented by worn or inadequate shoes. Participants in the intervention group will receive enhanced training opportunities with the PAFO while the comparison group will continue with their currently prescribed orthosis. All participants will be followed with weekly contact over a 7-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 currently prescribed AFO, strengthening and stretching based on published guidelines, balance training and training on traversing environmental barriers. All outcome measures will be evaluated three times during the 7-month study period: At baseline, at the 4-month follow up visit and at the 7-month follow up visit. We believe the immediate benefit of this project will determine if an innovative PAFO, designed to assist with toe clearance and provide push off power when taking a step, will improve functional performance, gait symmetry, ambulatory safety (risk of falls), and quality of life in the typical veteran with lower extremity impairment. We will also study whether the same variables/constructs show evidence of any carry over effect of the PAFO when the patients are not wearing an AFO. This study will have significant long-term benefit for all people who depend on an AFO to walk, 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:

Ankle foot orthosis (AFO)
Powered ankle foot orthosis (PAFO)
Randomized clinical trial
Functional performance
Ambulatory safety
Falls
Quality of life
Gait symmetry
Foot drop
Stroke
Spinal cord injury (SCI)
Traumatic brain injury (TBI)
Peripheral injury.

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, Screening Eligibility and Baseline Evaluations (Months 7-24)
4. Participant Randomization (Months 7-24)
5. Participant Fit with Powered Ankle Foot Orthosis (PAFO); Intervention Group (N=32; Months 7-24)
6. Physical Therapy Sessions and Orthosis Accommodation Period (N=64; Months 7-25)
7. 4-Month Follow Up Visit and Prosthesis Accommodation Period (N=64; Months 10-30)
8. 7-Month Follow Up Visit and subject closure (N=64; Months 13-30)
9. Assess Secondary Aims (N=64; Months 7-36)
10. Data Analysis/Dissemination of Findings (Months 28-36)

What was accomplished under these goals?

1. Perform Preliminary Study Requirements (Months 1-6)
 - a. Prepare study documents and apply for Local IRB (UTHSC) and USAMRM Human Research Protection Office (HRPO) approval – **Completed (September 28, 2018)**
 - The University of Tennessee Health Science Center IRB – **Completed (08/06/2018)**
 - USAMRM Human Research Protection Office Approval – **Completed (September 28, 2018)**
 - b. Refine eligibility criteria, exclusion criteria, screening protocol – **Completed**
 - Refine eligibility criteria and exclusion criteria - **Completed**
 - Develop screening protocol – **Completed**
 - Finalize consent form and human subjects' protocol - **Completed**
 - Finalize and submit human subjects' protocol and consent form to UTHSC IRB - **Completed, (08/06/2018)**
 - c. Submit human subjects' protocol and consent form to HRPO – **Completed (September 28, 2018)**
 - d. Create Manual of Operations - **Completed**
 - Finalize procedure to coordinate evaluation, orthosis and physical therapy services - **Completed**
 - Develop flow chart for all study steps, data collection, and database requirements- **Completed**
 - Development of adverse event and data safety monitoring plan sections- **Completed**
 - e. Selection and recruitment of members for the Data Safety Monitoring Panel - **Completed**
 - f. Develop database management system - **Completed**
 - g. Develop and finalize all study data collection forms - **Completed**
 - h. Submit amendments, adverse events and protocol deviations – **As needed. None to report this year.**
 - a. Maintain, update and perform data integrity test on study DBMS – **Completed**
2. Recruit, Coordinate and Train Study Personnel for Clinical Trial – **Complete**
 - b. Advertise, Interview and recruit Physical Therapist to perform evaluation – **Completed**
 - c. Coordinate and train staff, evaluation physical therapist, treating physical therapist and orthotists for project - **Completed**
 - c. Develop recruitment materials. – **Completed**
3. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit – **Completed August 31, 2023.**

- a. Participant recruitment – Completed. Performed initial targeted recruitment via community orthotic clinics, Regional DAV local area physician practices.
 - Identify prospective participants for targeted recruitment
 - Perform phone (pre-) screening, schedule qualifying participants to baseline session.
 - b. Participant Screening Eligibility Visit - Completed August 31, 2023.
 - Confirm Pre-Screening in person
 - Sign informed consent
 - Evaluate current orthosis fit
 - c. Baseline Evaluation/Randomization Visit – Completed August 31, 2023.
 - Evaluate participant function
4. Participant randomization – Completed August 31, 2023.
 - a. Randomize and orient participants to group assignment, schedule follow-up visit
 - b. Complete data entry for participant enrollment, evaluation, and randomization
 - c. Perform data monitoring and quality assurance as needed
 5. Fit with Powered Ankle Foot Orthosis (PAFO) – Completed August 31, 2023.
 - a. Fit participants randomized to Intervention with PAFO and train to use
 6. Physical Therapy Sessions and Orthosis Accommodation Period– Completed August 31, 2023.
 - a. Provide all participants (intervention and comparison group) once weekly physical therapy for 4 weeks.
 - b. Provide weekly phone visits during 8-week accommodation period 1 to all participants in both groups
 7. Follow Up Visits and Orthosis Accommodation Periods– Completed August 31, 2023.
 - a. Perform Follow Up Evaluations

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

During this reporting period, Dr. Karen Johnson, MD, MPH, study Co-Investigator and study medical safety officer, provided the annual refresher training on Adverse Event Reporting for all study personnel at the University of Tennessee Health Science Center (UTHSC).

How were the results disseminated to communities of interest?

During this final reporting period, through the UTHSC Graduate Medical Education program, we informed physicians physical therapists and primary care orthotic providers of the publication opportunities now available with the dataset.

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

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

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

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

Although the findings presented below are limited by the small sample size they indicate that training with a Powered Ankle-Foot Orthosis (PAFO) therapeutic device, which provides assistance with toe clearance and provides push off power when a step is taken, may be successfully translated to patients with lower extremity impairment from neurologic injury who require a prescribed AFO to walk.

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, although limited by small sample size, indicate that training with a Powered Ankle-Foot Orthosis (PAFO) therapeutic device, which aids with toe clearance and provides push off power when a step is taken, may be successfully translated to patients suffering from drop foot resulting from a lower extremity neurological injury. Specifically, results showed that participants improved their dynamic standing balance and mobility as well as reported improved functional status and health-related quality of life.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

This project was plagued with what proved to be insurmountable problems from its inception although extraordinary steps were repeatedly taken throughout, with the support and guidance of the PO, to overcome each as it arose. Additionally, the project was impacted by the extended shutdown from the COVID-19 Pandemic resulting in a loss of several participants to follow-up, reluctance to volunteer for and participate in the study which involved high burden on time and physical tolerance to wear the uncomfortable study device.

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

Although no problem was anticipated the actual problems and delays began immediately following award with the discontinuation of the proposed study device by the manufacturer. With the support of the PO we undertook a search for an adequate replacement device which would not change the aims of the project and identified one late during the initial year. Unfortunately, a replacement device was unavailable for use until a "beta" prototype was available for distribution, which occurred late in year two, and also required alteration of the intervention protocol since it was restricted to use in a therapeutic environment. Once the beta device, intervention protocol and staff training were secured

and recruitment and enrollment initiated, the project was paused again by the extended COVID-19 Pandemic. Once the project was finally allowed to open up to enrollment again the device manufacturer recalled the beta device prototype devices requiring an additional delay until the “commercial” device was manufactured and on-site training and certification were completed. Once recruitment, enrollment and intervention were finally in full swing participant eligibility became challenging due to the higher physical requirements of the device on the participant. The device was heavier and more restricting than the originally proposed study device which was discontinued and required a higher functional status for participants to qualify and therefore the recruitment pool became extremely limited. Of the participants that did qualify for the study, retention became difficult due to apprehension of participant’s COVID-related concerns and apprehension of complying with the time burden of the intervention protocol and physical burden of wearing the study device.

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

Not Applicable

Significant changes in use or care of human subjects

None to report

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 may 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 fulfilling the role of co-Principal Investigator as outlined in the SOW.

Name: Matt Hood
Project Role: Study Coordinator/Informatics
Research Identifier: 3
Nearest person month worked: 12
Contribution to Project: Mr. Hood has worked with IRB submissions, HRPO submissions, database development, data collection form design, staff development and training

Name: Elizabeth Seewer, DPT
Project Role: Physical Therapist
Research Identifier: 5
Nearest person month worked: 12
Contribution to Project: Ms. Seewer is fulfilling the role of Evaluation PT as outlined in the SOW

Name: LaToya Green, PT, DPT, EdD, CDNT
Project Role: Physical Therapist
Research Identifier: 6
Nearest person month worked: 12
Contribution to Project: Dr. Green is providing additional support as an Evaluation PT, as outlined in the SOW, to provide additional expanded opportunities to accommodate participant's availability.

Name: Karen Johnson, MD, MPH
Project Role: Co- Investigator
Research Identifier: 7
Nearest person month worked: 12
Contribution to Project: Dr. Johnson is fulfilling the role of co-Investigator as outlined in the SOW

Name: William Mihalko, MD, PhD
Project Role: Co- Investigator
Research Identifier: 8

Nearest person month worked: 12
 Contribution to Project: Dr. Mihalko is fulfilling the role of co-Investigator as outlined in the SOW

Name: Jim Wan, PhD
 Project Role: Co- Investigator
 Research Identifier: 9
 Nearest person month worked: 12
 Contribution to Project: Dr. Wan is fulfilling the role of co-Investigator biostatistician as 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:	Human Technology Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Orthotic Clinic
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
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:	Memphis Veterans Administration Medical Center
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

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

Not Applicable

QUAD CHARTS:

Attached

9. APPENDICES:

Attached

Appendix A - Baseline Characteristics of Participants by Tx Group

	All	Intervention	Comparison	P-value
Treatment Assignment, No. (%)		13 (61.9%)	8 (38.1%)	
Demographic measures				1.000
Age, mean \pm SD, years	57.45 \pm 9.97	57.71 \pm 11.22	57.00 \pm 8.91	
Gender, No. (%)				0.776
Male	15 (71.4)	9 (69.2)	6 (75.0)	
Female	6 (28.6)	4 (30.8)	2 (25.0)	
Race, No. (%)				0.005
African American / Black (not Hispanic)	13 (61.9)	5 (42.9)	8 (100.0)	
White	8 (38.1)	8 (57.1)	0 (0.0)	
Other race	0 (0.0)	0 (0.0)	0 (0.0)	
Military Status, No. (%)				0.421
Veteran	1 (4.8)	1 (14.3)	0 (0.0)	
Non-veteran	20 (95.2)	12 (85.7)	8 (100.0)	
Military beneficiary	0 (0)	0 (0)	0 (0)	
Anthropometric				0.927
Body Mass Index, mean \pm SD, kg/m ²	29.15 \pm 3.07	29.17 \pm 2.53	29.10 \pm 4.32	
Physical Function measures				
Dynamic Gait Index, mean \pm SD				
With AFO Score	12.92 \pm 8.88	21.80 \pm 3.19	6.57 \pm 5.00	0.005
Without AFO Score	16.12 \pm 8.10	21.00 \pm 3.08	8.00 \pm 7.21	0.036
Powered AFO Score	---	21.80 \pm 3.35	---	
Four Square Step Test, mean \pm SD				
With AFO Time	22.59 \pm 14.82	17.79 \pm 15.50	31.01 \pm 10.15	0.073
Without WITH AFO Time	16.98 \pm 10.37	12.31 \pm 4.13	31.00 \pm 11.98	0.071
Powered AFO Time	---	11.26 \pm 3.17	---	
Six Minute Walk, mean \pm SD				
Distance (ft)	871.93 \pm 508.90	1142.01 \pm 433.62	399.31 \pm 139.46	0.042
Quality of Life/Psychosocial measures				
CESD-R, mean \pm SD				
Score	9.27 \pm 6.54	8.86 \pm 7.43	10.00 \pm 5.60	0.776
Orthotic /Prosthetic User Survey, mean \pm SD				
Functional Status Measure	55.70 \pm 12.31	60.00 \pm 13.19	49.25 \pm 8.50	0.391
Health / Quality of Life Index	53.50 \pm 6.77	56.00 \pm 6.26	49.75 \pm 6.40	0.237
Psychosocial Impact of Assistive Devices Scale, mean \pm SD				
Score (PIADS)	25.55 \pm 28.32	37.57 \pm 24.95	4.50 \pm 22.40	0.109

Appendix B - Differences in Outcome Measures at Follow-up between Tx Groups

I. 3-month Follow-up

Outcome Measurement	3-Month Follow-up Visit			P-value
	All Mean ± SD	Intervention	Comparison	
DGI-Score With AFO	15.42 ± 7.08	21.17 ± 3.49	9.67 ± 4.32	0.005
DGI-Score Without AFO	15.67 ± 7.08	18.83 ± 4.17	9.33 ± 5.69	0.04
DGI-Score Powered AFO	---	20.50 ± 3.56	---	
FSST-Time With AFO	17.52 ± 9.92	11.53 ± 3.83	26.51 ± 9.55	0.010
FSST-Time Without AFO	14.20 ± 6.83	11.15 ± 3.21	24.90 ± 4.21	0.056
FSST-Time Powered AFO	---	12.22 ± 4.65	---	
Six Minute Walk- Distance	984.18 ± 476.21	1263.73 ± 259.56	425.08 ± 187.99	0.024
CESDR-Score	8.75 ± 10.31	10.67 ± 11.45	3.00 ± 0.00	0.241
OPUS-FSM (Functional Status Measurement)	53.89 ± 15.22	60.50 ± 12.47	40.67 ± 12.01	0.048
OPUS-HQLI (QOL)	53.22 ± 7.69	56.33 ± 6.35	47.00 ± 7.00	0.167
PIADS-Score	27.25 ± 30.41	25.00 ± 39.19	31.00 ± 11.53	1.000

II. 6-month Follow-up

Outcome Measurement	6-Month Follow-up Visit			P-value
	All Mean ± SD	Intervention	Comparison	
DGI-Score With AFO	14.58 ± 7.60	20.50 ± 4.18	8.67 ± 5.05	0.005
DGI-Score Without AFO	14.78 ± 7.69	18.83 ± 3.97	6.67 ± 7.02	0.037
DGI-Score Powered AFO	---	20.17 ± 3.87	---	
FSST-Time With AFO	16.09 ± 9.96	11.16 ± 3.99	25.94 ± 11.79	0.024
FSST-Time Without AFO	12.30 ± 4.20	11.60 ± 4.12	16.52 ± NA	0.571
FSST-Time Powered AFO	---	10.94 ± 3.03	---	
Six Minute Walk- Distance	1028.73 ± 520.40	1336.39 ± 290.29	413.41 ± 143.79	0.024
CESDR-Score	6.71 ± 4.64	7.25 ± 6.13	6.00 ± 2.65	0.858
OPUS-FSM	53.62 ± 14.05	58.00 ± 14.68	46.33 ± 11.50	0.230
OPUS-HQLI	52.75 ± 8.50	57.60 ± 2.30	44.67 ± 9.24	0.036
PIADS-Score	22.25 ± 30.66	21.60 ± 38.36	23.33 ± 18.56	1.000

Appendix C - Changes in Outcome Measures over time within Treatment Groups

I. Intervention Group

Outcome Measurement	Intervention Baseline to 3-Month Change		P-value
	Baseline Visit Mean \pm SD	3-Month Visit Mean \pm SD	
DGI-Score With AFO	21.80 \pm 3.19	21.17 \pm 3.49	1.00
DGI-Score Without AFO	21.00 \pm 3.08	18.83 \pm 4.17	1.00
DGI-Score Powered AFO	21.80 \pm 3.35	20.50 \pm 3.56	0.912
FSST-Time With AFO	17.79 \pm 15.50	11.53 \pm 3.83	1.00
FSST-Time Without AFO	12.31 \pm 4.13	11.15 \pm 3.21	1.00
FSST-Time Powered AFO	11.26 \pm 3.17	12.22 \pm 4.65	1.00
Six Minute Walk- Distance	1142.01 \pm 433.62	1263.73 \pm 259.56	0.867
CESDR-Score	8.86 \pm 7.43	10.67 \pm 11.45	0.84
OPUS-FSM	60.00 \pm 13.19	60.50 \pm 12.47	0.909
OPUS-HQLI	56.00 \pm 6.26	56.33 \pm 6.35	0.909
PIADS-Score	37.57 \pm 24.95	25.00 \pm 39.19	0.688
Outcome Measurement	Intervention 3-Month to 6-Month Change		P-value
	3-Month Visit Mean \pm SD	6-Month Visit Mean \pm SD	
DGI-Score With AFO	21.17 \pm 3.49	20.50 \pm 4.18	1.00
DGI-Score Without AFO	18.83 \pm 4.17	18.83 \pm 3.97	0.957
DGI-Score Powered AFO	20.50 \pm 3.56	20.17 \pm 3.87	1.00
FSST-Time With AFO	11.53 \pm 3.83	11.16 \pm 3.99	0.817
FSST-Time Without AFO	11.15 \pm 3.21	11.60 \pm 4.12	0.970
FSST-Time Powered AFO	12.22 \pm 4.65	10.94 \pm 3.03	1.00
Six Minute Walk- Distance	1263.73 \pm 259.56	1336.39 \pm 290.29	1.00
CESDR-Score	10.67 \pm 11.45	7.25 \pm 6.13	1.00
OPUS-FSM	60.50 \pm 12.47	58.00 \pm 14.68	1.00
OPUS-HQLI	56.33 \pm 6.35	57.60 \pm 2.30	1.00
PIADS-Score	25.00 \pm 39.19	21.60 \pm 38.36	1.00
Outcome Measurement	Intervention Baseline to 6-Month Change		P-value
	Baseline Visit Mean \pm SD	6-Month Visit Mean \pm SD	
DGI-Score With AFO	21.80 \pm 3.19	20.50 \pm 4.18	0.812
DGI-Score Without AFO	21.00 \pm 3.08	18.83 \pm 3.97	1.00
DGI-Score Powered AFO	21.80 \pm 3.35	20.17 \pm 3.87	1.00
FSST-Time With AFO	17.79 \pm 15.50	11.16 \pm 3.99	1.00
FSST-Time Without AFO	12.31 \pm 4.13	11.60 \pm 4.12	1.00
FSST-Time Powered AFO	11.26 \pm 3.17	10.94 \pm 3.03	0.909
Six Minute Walk- Distance	1142.01 \pm 433.62	1336.39 \pm 290.29	1.00
CESDR-Score	8.86 \pm 7.43	7.25 \pm 6.13	1.00
OPUS-FSM	60.00 \pm 13.19	58.00 \pm 14.68	1.00
OPUS-HQLI	56.00 \pm 6.26	57.60 \pm 2.30	1.00
PIADS-Score	37.57 \pm 24.95	21.60 \pm 38.36	0.843

p-values calculated using Kruskal-Wallis multiple comparison adjust with the Holm method.

II. Comparison Group

Outcome Measurement	Comparison Baseline to 3-Month Change		P-value
	Baseline Visit Mean ± SD	3-Month Visit Mean ± SD	
DGI-Score With AFO	6.57 ± 5.00	9.67 ± 4.32	0.559
DGI-Score Without AFO	8.00 ± 7.21	9.33 ± 5.69	1.00
DGI-Score Powered AFO	---	---	--
FSST-Time With AFO	31.01 ± 10.15	26.51 ± 9.55	0.911
FSST-Time Without AFO	31.00 ± 11.98	24.90 ± 4.21	0.527
FSST-Time Powered AFO	---	---	--
Six Minute Walk- Distance	399.31 ± 139.46	425.08 ± 187.99	1.00
CESDR-Score	10.00 ± 5.60	3.00 ± 0.00	0.205
OPUS-FSM	49.25 ± 8.50	40.67 ± 12.01	0.835
OPUS-HQLI	49.75 ± 6.40	47.00 ± 7.00	1.00
PIADS-Score	4.50 ± 22.40	31.00 ± 11.53	0.215
Outcome Measurement	Comparison 3-Month to 6-Month Change		P-value
	3-Month Visit Mean ± SD	6-Month Visit Mean ± SD	
DGI-Score With AFO	9.67 ± 4.32	8.67 ± 5.05	0.818
DGI-Score Without AFO	9.33 ± 5.69	6.67 ± 7.02	1.00
DGI-Score Powered AFO	---	---	--
FSST-Time With AFO	26.51 ± 9.55	25.94 ± 11.79	0.844
FSST-Time Without AFO	24.90 ± 4.21	16.52 ± NA	0.603
FSST-Time Powered AFO	---	---	--
Six Minute Walk- Distance	425.08 ± 187.99	413.41 ± 143.79	0.893
CESDR-Score	3.00 ± 0.00	6.00 ± 2.65	0.350
OPUS-FSM	40.67 ± 12.01	46.33 ± 11.50	0.998
OPUS-HQLI	47.00 ± 7.00	44.67 ± 9.24	0.682
PIADS-Score	31.00 ± 11.53	23.33 ± 18.56	0.500
Outcome Measurement	Comparison Baseline to 6-Month Change		P-value
	Baseline Visit Mean ± SD	6-Month Visit Mean ± SD	
DGI-Score With AFO	6.57 ± 5.00	8.67 ± 5.05	0.541
DGI-Score Without AFO	8.00 ± 7.21	6.67 ± 7.02	0.985
DGI-Score Powered AFO	---	---	--
FSST-Time With AFO	31.01 ± 10.15	25.94 ± 11.79	1.00
FSST-Time Without AFO	31.00 ± 11.98	16.52 ± NA	0.364
FSST-Time Powered AFO	---	---	--
Six Minute Walk- Distance	399.31 ± 139.46	413.41 ± 143.79	1.00
CESDR-Score	10.00 ± 5.60	6.00 ± 2.65	0.656
OPUS-FSM	49.25 ± 8.50	46.33 ± 11.50	0.718
OPUS-HQLI	49.75 ± 6.40	44.67 ± 9.24	1.00
PIADS-Score	4.50 ± 22.40	23.33 ± 18.56	0.560

p-values calculated using Kruskal-Wallis multiple comparison adjust with the Holm method.