AWARD NUMBER: W81XWH-17-1-0451

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

PRINCIPAL INVESTIGATORS: Phyllis A. Richey, PhD

CONTRACTING ORGANIZATION: UNIVERSITY OF TENNESSEE
DR. DEBORAH SMITH
62 S DUNLAP STREET STE 103
MEMPHIS TN 38103-4903

REPORT DATE: Sept 2020

REPORT TYPE: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
Sept 2020	Annual	01 Sep 2019 - 31 Aug 2020

4. TITLE AND SUBTITLE
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

5a. CONTRACT NUMBER
W81XWH-17-1-0451

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Phyllis A. Richey,PhD.
E-Mail: prichey@uthsc.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

UNIVERSITY OF TENNESSEE
62 S DUNLAP STREET RM 300
MEMPHIS TN 38103-4903

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

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 64 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.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	11	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

Page No.

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 64 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
   a. Prepare study documents and apply for Local IRB (UTHSC) – Approved 08/06/2018
   b. Apply for USAMRM Human Research Protection Office (HRPO) Approved 09/28/2018
   c. Complete Manual of Operations finalizing procedures sections and forms for recruiting and reporting – Completed
   d. Develop database management system – Completed
   e. Develop and finalize all study data collection forms – Completed
   f. Submit amendments, adverse events and protocol deviations – None to report.
   g. Maintain, update and perform data integrity test on study DBMS – None to report

2. Train Study Personnel for Clinical Trial
   a. Train staff, evaluation physical therapist, treating physical therapist for project – Completed
   b. Trial run through of Screening and Baseline visits for the study – Completed
   c. Eligibility and Randomization training – In Progress
   d. Adverse Events Training with Dr. Johnson, MD – Completed
   e. Develop participant recruitment materials – Completed

3. Participant Recruitment
   a. Establish participant recruitment resources with partner Orthotic Clinics, healthcare agencies, physician practices and Regional DAV – Completed
   b. Identify targeted mailings to prospective participants – Completed

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

During this reporting period an additional annual professional development seminar for all study personnel and physical therapists was conducted by ReWalk Restore engineer trainers at our study facility at the University of Tennessee Health Science Center (UTHSC) on the Restore PAFO.

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?

During the next reporting period we will continue to perform the following actions to accomplish the goals and objectives listed:

1. Continue to identify prospective participants for targeted recruitment- specifically at the Memphis VA Medical Center and via the TriNetX electronic data warehouse network

2. Participant Recruitment and enrollment, phone (pre-) screening, schedule in-person screening eligibility visit

3. Confirm pre-screening information at in-person Screening Eligibility Visit
    a. Sign Informed Consent
    b. Confirm pre-screening information
    c. Perform screening evaluation including evaluation of functional level of participant
    d. Evaluate orthotic fit

6. Participant Randomization
    a. Randomize participants into Intervention (N=32) or Comparison (N=32) Groups
    b. Schedule physical therapy visits
    c. Provide all participants new pair of shoes

7. Participant Fit with PAFO
    a. Conduct physical therapy sessions
    b. Provide all participants 2 sessions per week of physical therapy for 4 weeks
    c. Provide weekly phone visits during 8-week following completion of PT sessions to all participants in both groups

8. Perform 3-month evaluation
    a. Perform repeat of all baseline evaluation measures
    d. Provide weekly phone visits during 12-week following completion of 3-month follow-up visit to all participants in both groups

9. Perform 6-month evaluation and subject closure
    a. Perform repeat of all baseline evaluation measures

10. Continue to perform ongoing study requirements
    a. Submit amendments, adverse events and protocol deviations as necessary
    b. Maintain, update and perform data integrity test on study DBMS

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?

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:** 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

None

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

As is a wide-spread problem with many grant awards, this one has been greatly hindered by the COVID-19 pandemic impacting the ability to recruit, evaluate and collect follow-up assessments on participants as the clinical trial was shut down for over four months. Since February 2020, we have also incurred the loss of two key study staff, which we were not allowed to replace until recently. We have pushed forward with study activities using temporary personnel as much as possible. We have experienced a loss of participants to follow-up as well. Finally, delays continue to persist in receiving support from the device manufacturer ReWalk and acquiring adequate number of device units to carry out all study activities in a timely manner, as they too have been hindered by device production delays and the pandemic.

To address these unanticipated problems we have modified our clinical assessment visits to minimize in-person contact and expanded our recruitment strategy to include utilization of the TriNetX electronic data warehouse network for targeted recruitment within local area hospitals in addition to our continued pursuit of participants within the VA Medical Center. In September 2020 we were allowed to open a search for new research study staff which resulted in the

replacement of one of our research coordinators. We are also working with ReWalk to conduct an additional training with the new staff and acquisition of additional study devices.

Changes that had a significant impact on expenditures

As mentioned above, during the COVID-19 shut down we have had significant loss of funds in the personnel category during the months that the clinical trial was shut down and not allowed to recruit or see participants. During this time we continued support the salaries our key personnel rather than lose them to layoff. Therefore, this unanticipated extra expense has created a significant negative impact on expenditures.

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**
  Nothing to Report

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:	Kristen Leone
Project Role:	Study Coordinator
Research Identifier:	3
Nearest person month worked:	7
Contribution to Project:	Ms. Leone has worked with IRB submissions, HRPO submissions, recruitment materials, participant recruitment, retention, screening, conducting evaluation visits, performing phone visits, and scheduling, as well as PT visit scheduling and intervention group enhanced PAFO training session scheduling

Name:	Matt Hood
Project Role:	Study Coordinator/Informatics
Research Identifier:	4
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:	Lindsey Siegfried
Project Role:	Study Coordinator
Research Identifier:	5
Nearest person month worked:	6

Contribution to Project: Ms. Siegfried has assisted Ms. Leone with data collection, participant recruitment, retention, screening, conducting evaluation visits and performing phone visits, measurement visit scheduling, as well as PT visit scheduling and intervention group enhanced PAFO training session scheduling.

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 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:	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:	Spears 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:
Not Applicable