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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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CONTRACTING ORGANIZATION: UNIVERSITY OF TENNESSEE
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6. AUTHOR(S)

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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
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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 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 (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.***
   i. Maintain, update and perform data integrity test on study DBMS – ***As needed***

2. Recruit, Coordinate and Train Study Personnel for Clinical Trial – ***Complete***
   a. Advertise, Interview and recruit Physical Therapist to perform evaluation – ***Complete***

b. 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– ***In progress***
   a. Participant recruitment – In progress. We are preforming 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
      - Confirm Pre-Screening in person
      - Sign informed consent
      - Evaluate current orthosis fit
   c. Baseline Evaluation/Randomization Visit
      - Evaluate participant function

4. Participant randomization– ***In progress***
   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)– ***In progress***
a. Fit participants randomized to Intervention with PAFO and train to use

6. Physical Therapy Sessions and Orthosis Accommodation Period– ***In progress***
   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– ***In progress***
   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 a refresher training on Adverse Event Reporting for all study personnel at the University of Tennessee Health Science Center (UTHSC). Additionally, ReWalk Robotics provided professional training refresher for study personnel on the use of the RESTORE study device.

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 through Memphis area hospitals, orthopedic and primary care practices in addition to continuing recruitment efforts 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 visits

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

The impact of the COVID-19 pandemic and subsequent variants has dramatically hampered the ability to recruit, evaluate and collect follow-up assessments on participants. Hesitation of potential and current participants to engage in the in-person study contacts continues to slow study progress tremendously.

To address these unanticipated problems, we continue to press forward with our modified clinical assessment visits minimizing in-person contact, all study personnel have been vaccinated and have received one or more booster and every precaution to protect study staff and participants is exercised. Additionally, we have expanded our recruitment strategy to include local area primary care, regional medical centers and orthopedic practices in addition to continued recruitment efforts through 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.

Changes that had a significant impact on expenditures

None to report

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**
  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:	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:	Kip Handwerker
Project Role:	Study Coordinator
Research Identifier:	4
Nearest person month worked:	12
Contribution to Project:	Mr. Handwerker is assisting with IRB and HRPO submissions, data collection form development. He is leading the maintenance of all recruitment materials and facilitating coordination for recruitment with all local area orthotic, physician clinics and hospitals from which the study recruitment pool will be derived.
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 avalibility.
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:
Not Applicable