AWARD NUMBER: W81XWH-17-1-0568

TITLE: Effects of a Powered Ankle-Foot Prosthesis and Device-Specific Physical Therapy on Function and Pain for Individuals Living with Transfemoral Limb Loss

PRINCIPAL INVESTIGATOR: Jason Maikos, PhD

CONTRACTING ORGANIZATION: Narrows Institute for Biomedical Research

REPORT DATE: OCTOBER 2023

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2023	Annual	15 Sept 2022- 14 Sept 2023

4. TITLE AND SUBTITLE

Effects of a Powered Ankle-Foot Prosthesis and Device-Specific Physical Therapy on Function and Pain for Individuals Living with Transfemoral Limb Loss

5a. CONTRACT NUMBER
W81XWH-17-1-0568

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Jason Maikos, PhD and Bradford Hendershot, PhD (WRNMMC Site PI)

E-Mail: jason.maikos@va.gov and bradford.d.hendershot2.civ@health.mil

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

NARROWS INSTITUTE FOR
BIOMEDICAL RESEARCH
800 POLY PL 151BROOKLYN NY
11209-7104

8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Medical Research and Development 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

Lower limb prosthetic technology has evolved into advanced powered devices that can better replicate the gastroc-soleus complex for individuals with lower limb loss. However, the current state of prosthetic research appears to favor the evaluation of prosthetic componentry on gait mechanics and rarely incorporates any device-specific physical therapy (PT) program. This study proposes to measure the biomechanical and functional response of participants with transfemoral limb loss to an advanced prosthetic and rehabilitative intervention. This investigation is a multi-site, 8-week, randomized, clinical trial. Individuals with transfemoral limb loss are fit with a powered ankle-foot prosthesis and randomized to receive either device-specific PT or the current standard of care. At baseline (utilizing their current passive prosthesis), and again 4- and 8-weeks later utilizing the powered device, all participants undergo a full gait analysis, as well as functional, neurocognitive, cognitive, and pain assessments. Results from this investigation will drive prosthetic and PT prescriptions for use of powered devices in this population.

15. SUBJECT TERMS
Amputation, Powered Prosthesis, Transfemoral Amputation, Physical Therapy, Rehabilitation

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
U	U	U	UU	21	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION:

Individuals with transfemoral limb loss who are prescribed energy storing and returning (ESR) feet encounter an asymmetrical distribution of lower limb load that results in a series of gait anomalies, which can lead to higher incidences of comorbidities. In recent years, lower limb prosthetic technology has evolved, including the development of powered ankle-foot devices that can better replicate the gastroc-soleus complex for individuals with a lower limb loss, potentially reducing kinetic and kinematic asymmetries associated with the development of musculoskeletal imbalances. However, the current state of prosthetic research and clinical efforts appear to favor the evaluation of prosthetic componentry on gait mechanics, often in the absence of any device-specific physical therapy (PT) program. Given the accelerated rate of technological innovation in the field of prosthetic devices, there is a fundamental knowledge gap concerning how individuals with lower limb loss should learn to correctly use this advanced technology for maximum benefit. This study proposes to measure the biomechanical and functional response of, and cognitive and neurocognitive impact to, participants with transfemoral limb loss to an advanced prosthetic and rehabilitative intervention. The objectives of this study are to: (1) determine the effects of a powered prosthetic ankle-foot device, as well as a PT intervention on (a) lower extremity kinematic and kinetic patterns, (b) functional efficacy, and (c) pain for individuals with transfemoral limb loss, and (2) develop preliminary rehabilitation guidelines for advanced lower extremity powered devices to minimize gait imbalances and maximize function, as well as establish preliminary guidelines for powered ankle-foot prosthetic prescription. The central hypothesis is that the addition of powered plantarflexion, coupled with an evidenced-based, device-specific PT intervention, will result in improved biomechanical gait kinematics and kinetics, which will correlate with a decrease in pain and improved functional performance.

2. KEYWORDS:

Amputation, Transfemoral limb loss, Biomimetic, Prosthesis, Powered, Prosthetic Prescription, Physical Therapy, Device-Specific Physical Therapy

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The overarching goal for investigation OP160073 is to examine the mechanisms of action and the effectiveness of a powered ankle-foot prosthesis on gait biomechanics, performance, and pain, as well as the role of a rehabilitative intervention in conjunction with advanced technology on mitigating gait abnormalities for individuals with transfemoral limb loss.

The specific goals for this investigation include:

1. To examine the effect of a device-specific PT intervention on kinematic, kinetic, and functional efficacy of powered ankle-foot prostheses for individuals with transfemoral limb loss compared to the current standard of practice, which does not include a standardized device-specific PT intervention.
2. To correlate the contribution of a powered prosthetic ankle-foot device and device-specific physical therapy with changes in pain.
3. To determine if neurocognitive function is a limiting factor in improvement in functional outcomes, gait symmetry, and pain achieved through powered prosthetic devices and/or physical therapy.

The major goals and tasks as stated in the approved SOW for Project OP160073 are listed in the table below. The table includes % completion of each task and, where appropriate, completion dates.

Major Task 1: IRB Submission	% Completion	Completion Date	Expected completion
Coordinate with Sites for CRADA/Subaward Submission	100%	12/8/2017	-
Refine eligibility criteria, exclusion criteria, screening protocol	100%	10/17/17	-
Finalize consent form & human subjects protocol	100%	10/17/17	-
Coordinate with Sites for IRB protocol approval	100%	NYHHS: 10/17/2017 WRNMMC: 09/25/2018 JAHVH: 06/30/2020	-
Coordinate with Sites for Military 2nd level IRB** approval (ORP/HRPO)	100%	NYHHS: 06/27/2018 WRNMMC: 10/30/2018 JAHVH: 03/29/2021	-
Milestone Achieved: Local IRB approval at each site	100%	VA NYHHS: 10/17/2017 WRNMMC: 09/25/2018 JAHVH: 02/16/2021	-
Milestone Achieved: HRPO approval for all protocols	100%	VA NYHHS: 06/27/2018 WRNNMC: 10/30/2018 JAHVH: 04/08/2021	-
Major Task 2: Coordinate Study Staff for Clinical Trials			
Subtask1: Hiring and Training of Study Staff	-		
Coordinate with Sites for job descriptions design	100%	10/01/17	-
Advertise and interview for project related staff	100%	12/18/17	-
Coordinate with Sites for hiring, training, supervision and fidelity checks as needed for attrition.	100%	2/28/18	-
Train project physical therapist on protocol.	100%	4/2018	-
Milestone Achieved: Project Research staff hired and trained	100%	4/2018	-
Major Task 3: Participant Recruitment			
Subtask 1: Subject recruitment			
Coordinate with Prosthetics and Rehabilitation Clinic for Subject Recruitment	ongoing-		
Assign participants to one of the two randomized groups	NYHHS: 86% WRNMMC: 20% JAHVH: 53%	ongoing	-
Milestone Achieved: Study begins	100%	9/2018	
Milestone Achieved: First subject consented, screened, and enrolled	100%	10/2018	
Major Task 4: Data Collection			
Subtask 1: Prosthetic Setup			
Alignment and fit of current prosthesis	NYHHS:60% WRNNMC:20% JAHVH: 53%	ongoing	-
Fitting of powered prosthesis	NYHHS: 47% WRNMMC: 20% JAHVH: 40%	ongoing	-
Subtask 2: Conduct Study	-		
Collect biomechanical, functional, pain, and neurocognitive data according to the project timeline	NYHHS: 60% WRNMMC: 20% JAHVH: 27%	ongoing	-

Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled	Overall: 73%	Ongoing	4/2024
Milestone Achieved: 50% of participants have completed the 8-week physical therapy program and data has been collected.	Overall: 40%	Ongoing	12/2023
Milestone Achieved: All subjects have completed the research protocol	Overall: 30%	Ongoing	8/2024
Major Task 5: Data Analysis			
Subtask 1: Analyze, measure and determine all parameters in the 2 randomized groups			
Perform all analyses according to specifications, share output and finding with all investigators	Overall: 33%	Ongoing	10/2024
Annual Meetings will be held at NYHHS to discuss the current progress of the study and data analysis related to Aims 1-3.	100%	Ongoing	-

What was accomplished under these goals?

Major Activities and specific objectives for Year 4 include:

Administrative

A one-year extension without funds was granted on 9/28/2022. Advanced funding was requested and received.

Recruitment and Enrollment

Table 1 outlines current enrollment at each site.

NYHHS: 18 participants have been screened. There were 5 screen fails, and 13 participants have been consented. Seven participants have completed all protocol activities and 1 has withdrawn. Two participants are ongoing.

WRNNMC: WRNMMC has modified their local protocol to enroll participants with osseointegration. One participant with osseointegration has completed all protocol activities.

JAHVH: Eleven participants have been screened. There were 3 screen fails and 8 participants have been enrolled. Two participants have completed all protocol activities and 2 participants are ongoing. Three participants were withdrawn prior to the end of data collection, but data was collected for at least 1 out of 3 visits for each of them. The team will work with the study statistician to account for missing data for the visits not completed.

TABLE 1: Recruitment and Enrollment

Site	Screened	Screen Failure	Enrolled	Withdrawn	Completed	In Protocol
NYHHS	18	5	13	1	7	2
WRNMMC	2	1	1	0	1	0
JAHVH	11	3	8	4	2	2
Total	**31**	**9**	**22**	**5**	**10**	**4**

Significant Results and Key Outcomes for Year 6

Research Design and Project Timeline:

This research investigation proposes a multi-center, 8-week investigation, outlined in Figure 1. Briefly, 30 individuals with transfemoral limb loss, enrolled at VANYHHS, WRNMMC, and JAHVH are fit with a powered ankle-foot prosthesis and evaluated for safe use prior to completing the fitting. Currently, the only commercially available powered prosthetic foot is the emPOWER (formally BiOM).

For all participants, a full gait analysis, functional measures, cognitive load, neurocognitive battery, and pain assessment is captured at baseline on their current passive prosthesis. Participants are then randomly assigned into 2 equal groups: Powered device with an 8-session intensive device-specific PT intervention (Group A); or powered device with current standard of practice (Group B), which includes basic device education and training, but no PT intervention. Baseline testing measures will again be completed in the powered device at 4- and 8-weeks post fitting, as outlined in Figure 1. Participants then undergo the biomechanical, functional, pain, cognitive load, and neurocognitive assessments according to the schedule outlined in Figure 1.

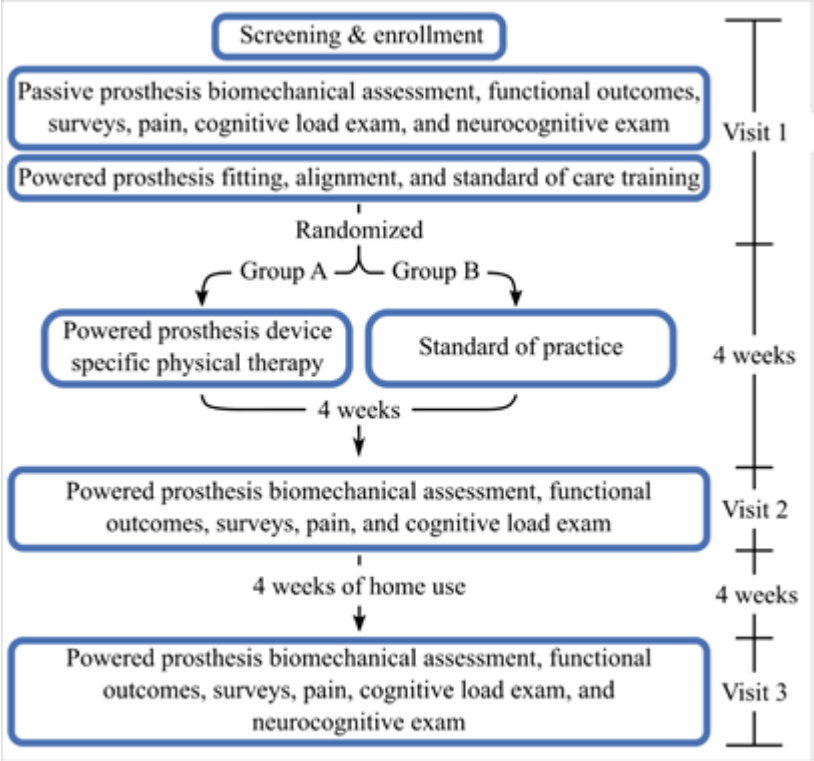

Figure 1: Participant timeline of activities

Preliminary Data Analysis

Data presented below is from completed participants to date. The intent of the preliminary data analysis is for the purposes of data quality. As such, no formal stats or other analyses were performed to test study hypotheses at this time.

Functional Outcome Measures

Participants are evaluated with the 6-minute walk and Amputee Mobility Predictor (AmpPro) (Figure 2) at baseline utilizing the ESR foot and again 4- and 8-weeks later using the emPOWER. Figure 2 illustrates average scores for subjects who were randomized to the PT and non-PT groups.

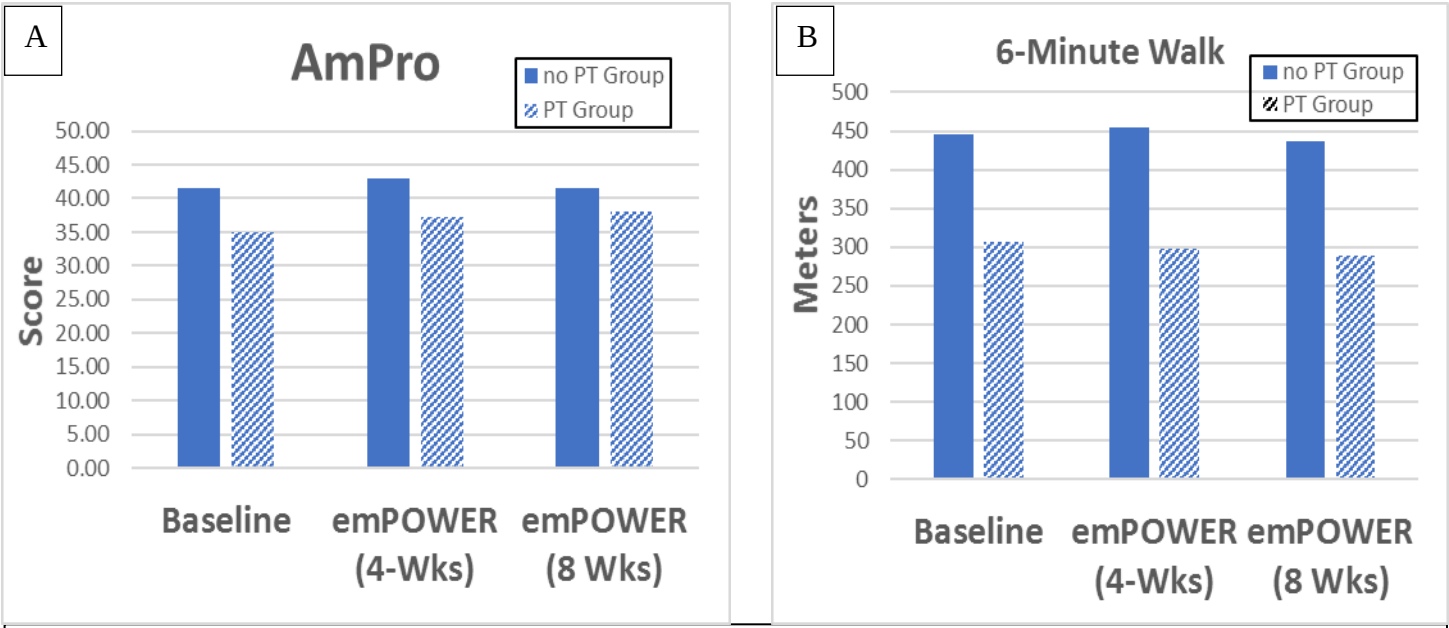

Figure 2: A) AmpPro scores comparing ESR versus emPOWER at 4- and 8-weeks for subjects randomized to PT or non-PT groups. B) 6-min walk distances at baseline (ESR foot) and 4- and 8-weeks later using the emPOWER device for subjects randomized to the PT and non-PT groups. Higher values indicate greater functional abilities.

Neurocognitive Measures

Measures for cognitive burden (Serial Subtraction, Controlled Oral Word Association Test (COWAT), and Category Test) are evaluated at baseline utilizing the ESR foot and again 4- and 8-weeks later using the emPOWER. Higher scores indicate higher cognitive ability (less burden). PT vs. Non-PT groups are shown in Figure 3. Furthermore, neurocognition is assessed utilizing CNSVS, a computerized neuropsychological test to evaluate neurocognitive status of patients (Figure 4). It covers a range of mental processes from simple motor performance, attention, memory, to executive functions. PT vs. non-PT results are shown in Figure 4. Preliminary analysis was performed to assess the correlation between neurocognition and gait symmetry. It was hypothesized that neurocognitive index scores >80 would correlate with improved gait symmetry. While preliminary, a moderate correlation of 0.37 was found between neurocognitive index and gait symmetry.

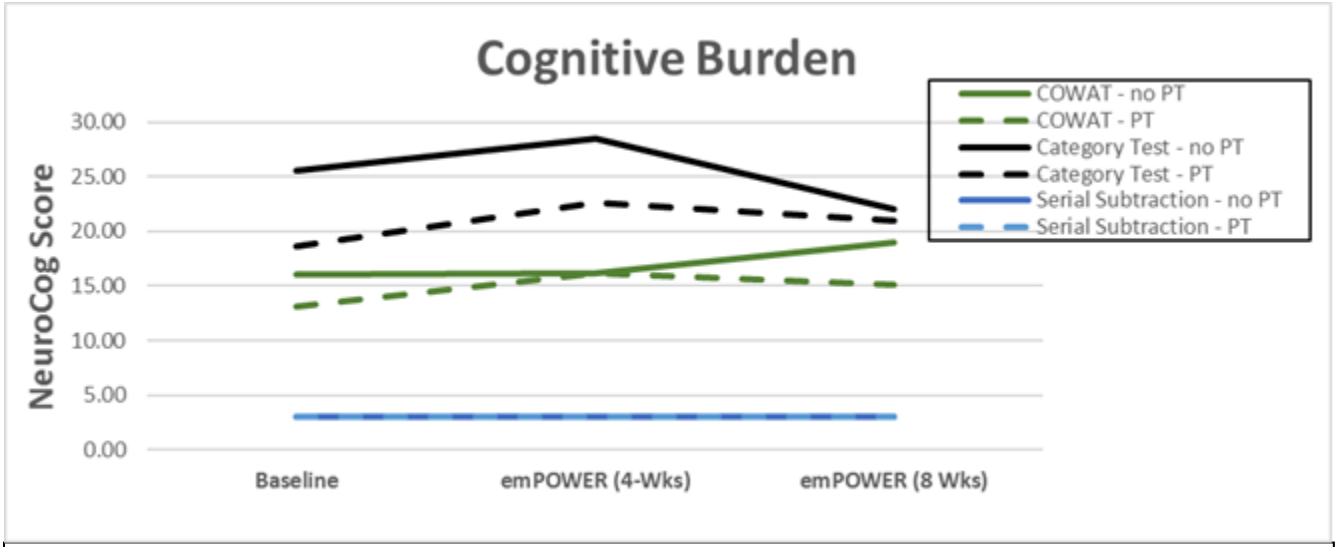

Figure 3: Average cognitive burden scores for subjects randomized to the PT and non-PT groups at baseline (ESR foot) and again 4- and 8- weeks later using the emPOWER. Higher scores indicate higher cognitive ability and less burden.

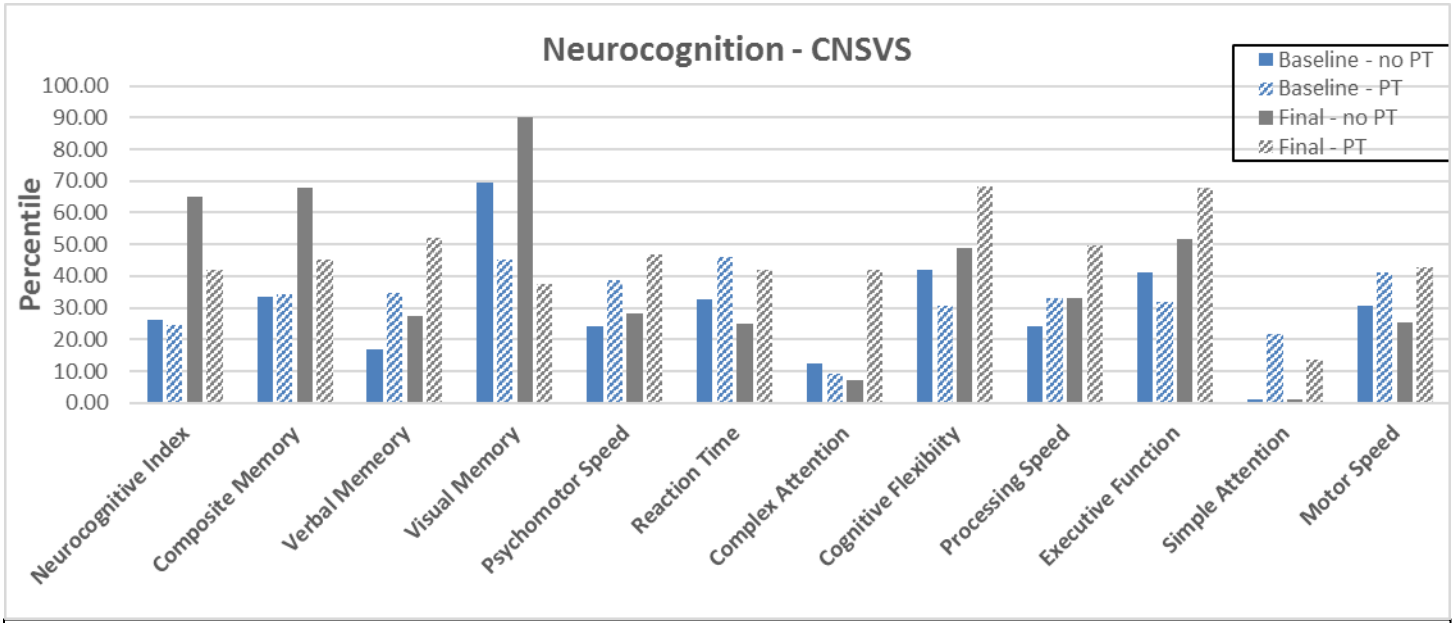

Figure 4: Average scores for the different neurocognitive domains, assessed utilizing CNSVS, which is a computerized assessment tool that utilizes validated and reliable computerized neuropsychological tests to evaluate the neurocognitive status of patients. Neurocognition is measured at baseline and again at the final visit.

Biomechanical Analysis

Figures 5, 6, and 7 represent sagittal plane kinematic, kinetic, and power scalar averages for participants at baseline (ESR), and again 4- and 8-weeks later using the emPOWER. The graphs are separated by the PT and non-PT groups.

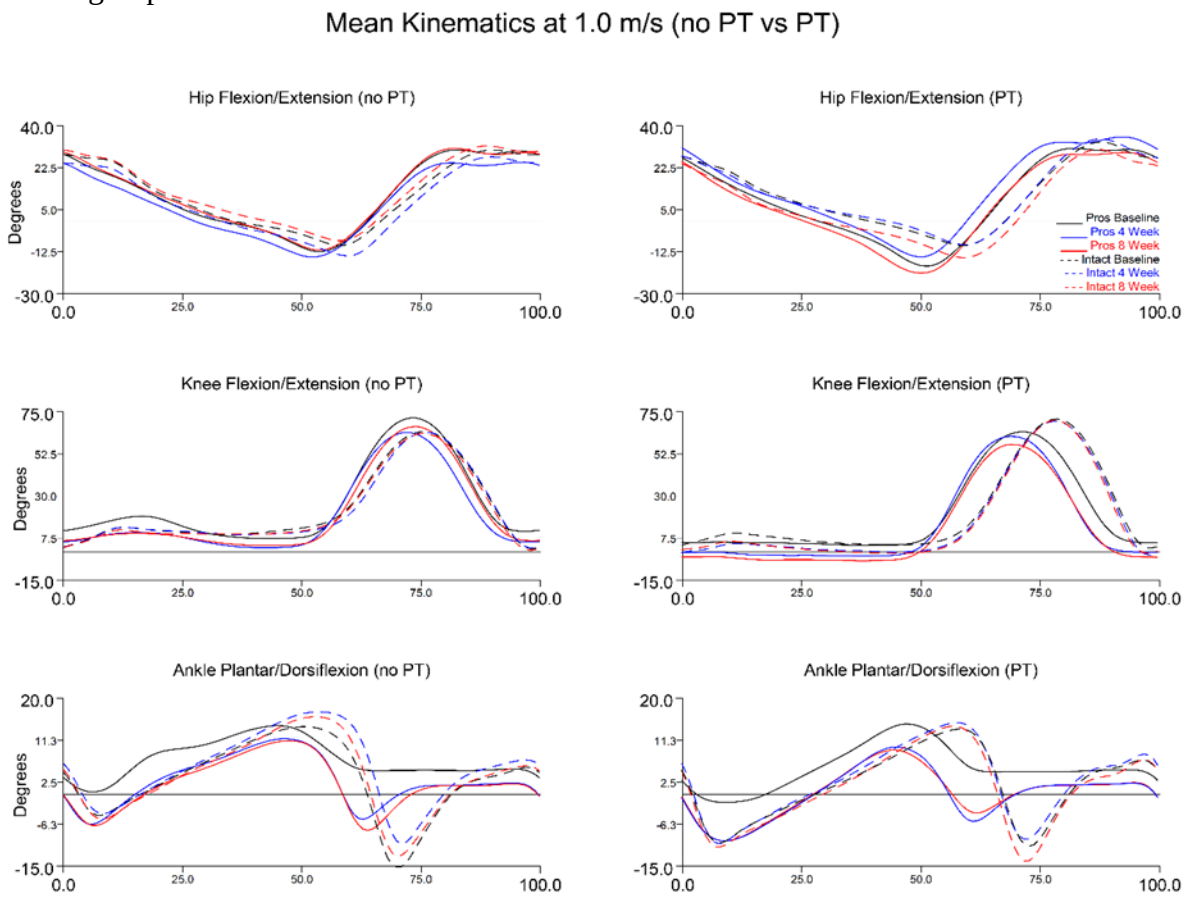

Figure 5: Level-ground sagittal plane kinematics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The intact limb is represented by dotted lines. The prosthetic limb is represented by solid lines.

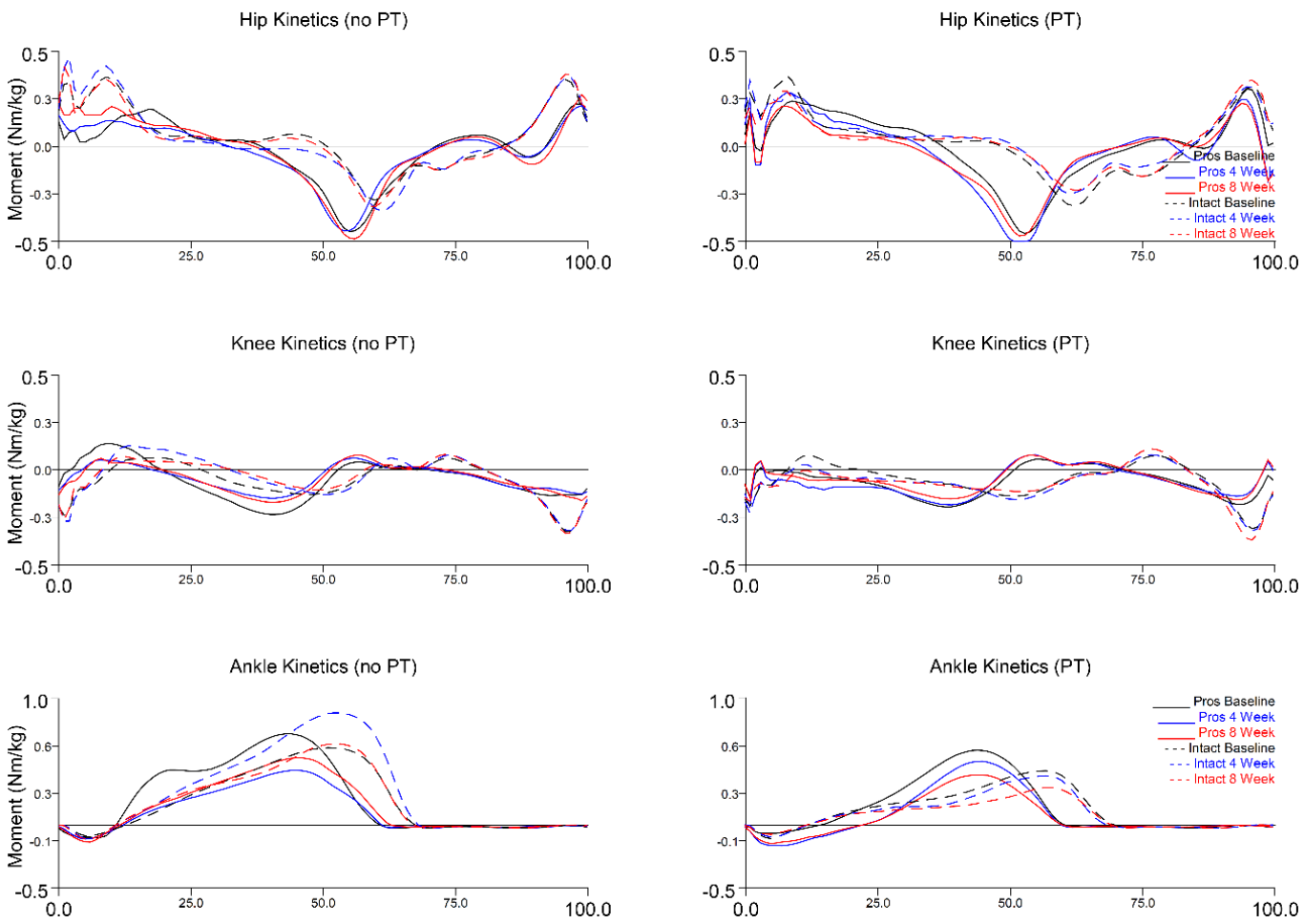

Figure 6: Level-ground sagittal plane kinetics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

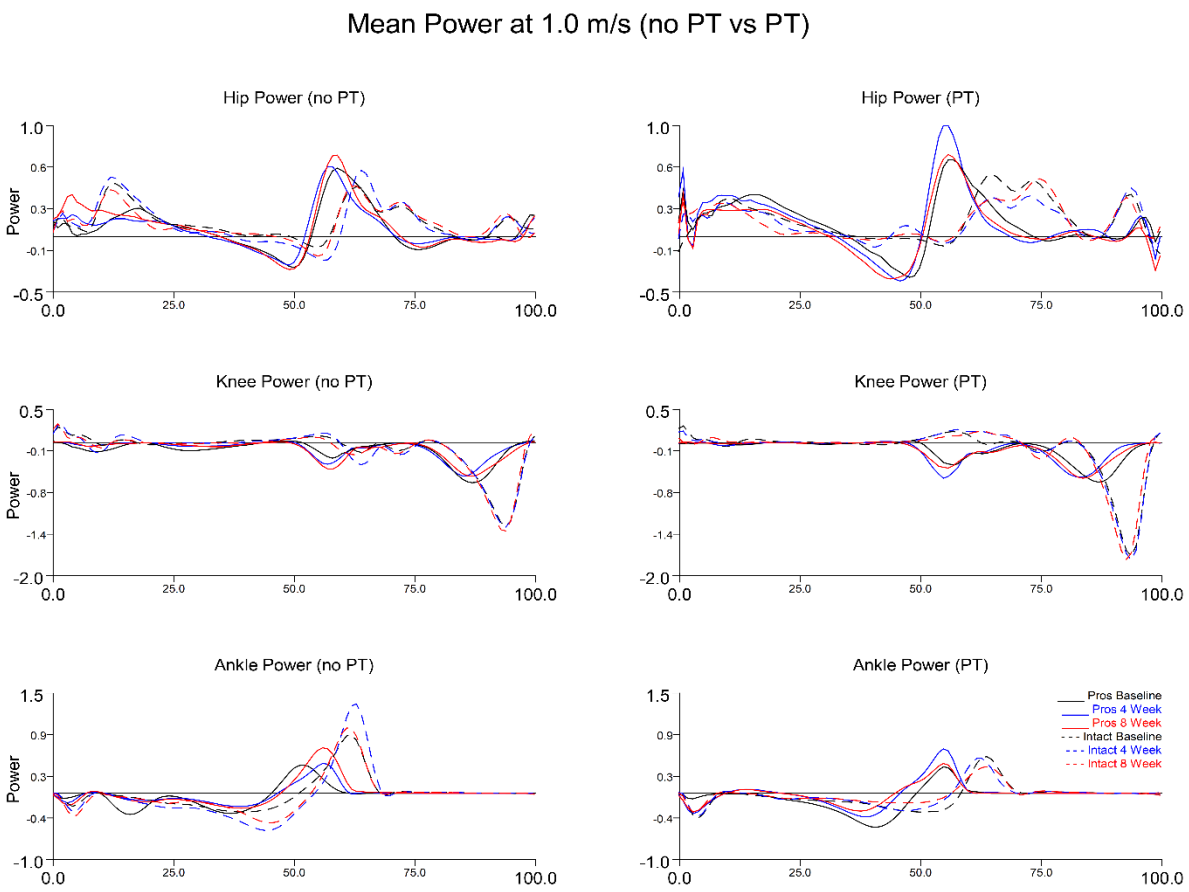

Figure 7: Level-ground sagittal plane joint powers for the PT and non-PT groups at baseline (Black) and at 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

A preliminary analysis of key biomechanical parameters was performed for the intact and prosthetic limbs (regardless of PT intervention) while wearing the ESR device and powered device (Figure 8). Angle range of motion, peak sagittal ankle moment, hip range of motion, and peak sagittal hip moment are shown for the ESR device (blue) and the powered device (red – week 4; black – week 8) with their corresponding kinematic/kinetic graphs. Preliminary analysis indicated no significant differences ($p > 0.05$) between the ESR and PWR devices for the selected kinematic and kinetic parameters. However, there was a trend towards significant differences between peak ankle moments using the PWR vs ESR devices for both the intact and prosthetic sides (and greater ankle joint symmetry using the PWR device), but no kinematic/kinetic differences were reported for the hip between devices. As additional data is analyzed, participants will be separated by intervention group to determine the effects of the device-specific PT program.

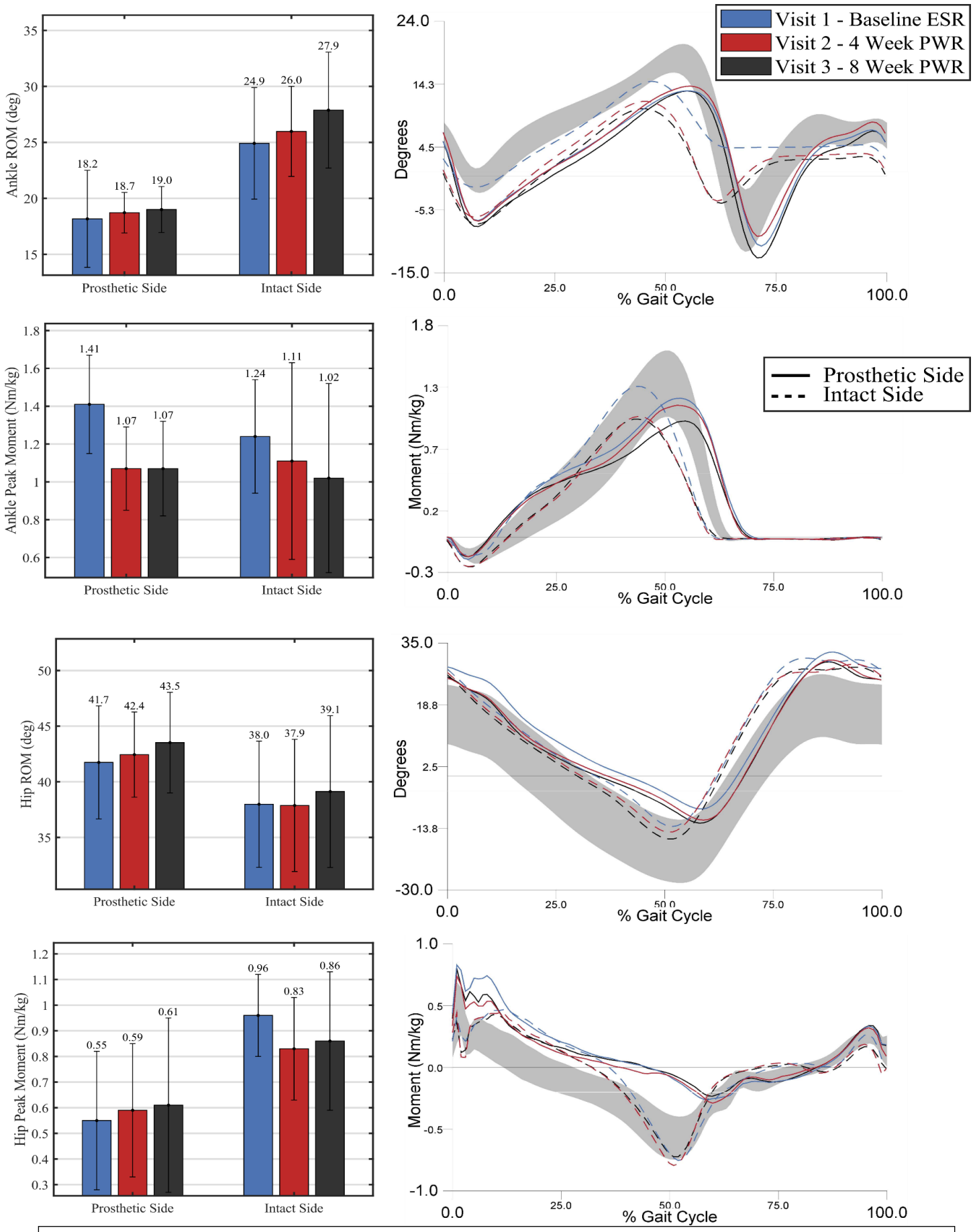

Figure 8: Key biomechanical parameters comparing the intact and prosthetic limbs while wearing the ESR device (Blue – Visit 1) vs. the powered device (Red Visit 2; Black Visit 3).

Subjective Outcomes

Figure 9 illustrates average subjective outcome results for the Prosthetic Evaluation Questionnaire (PEQ) and Promis Pain Interference Scale. The ESR scores are from baseline and Empower scores are from the 4-and 8-week follow-up visits.

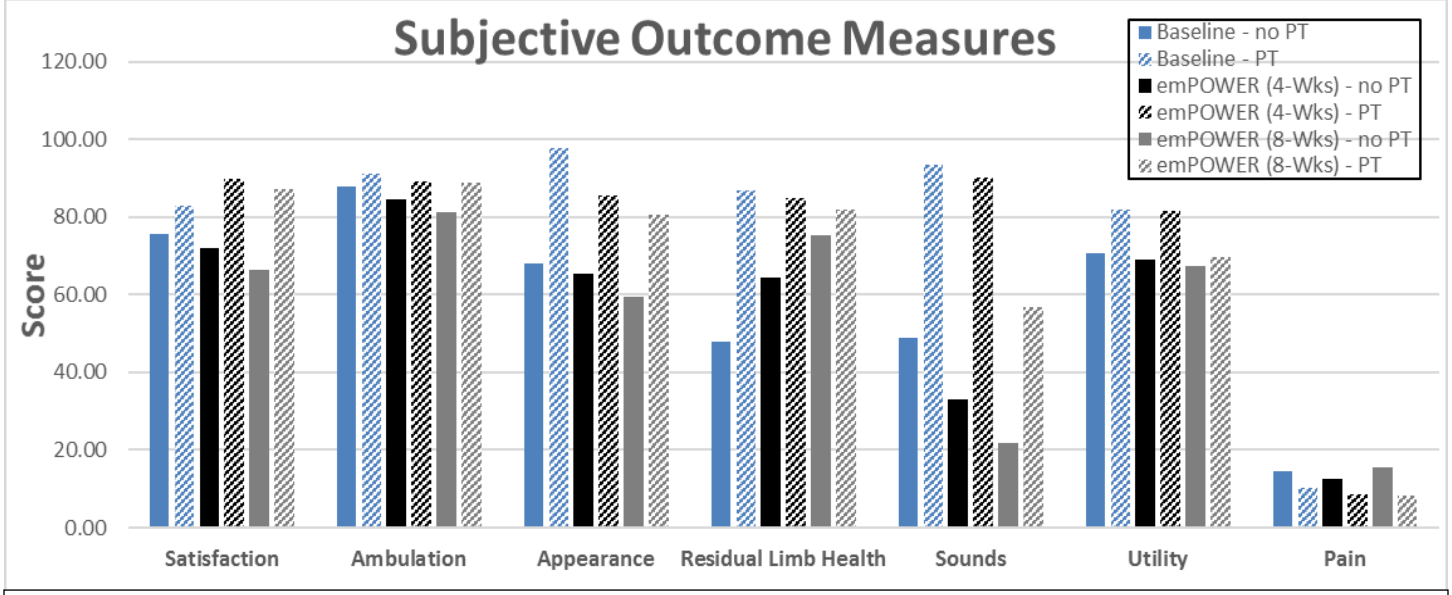

Figure 9: Baseline, 4- and 8-week follow up average scores for the PT and non-PT groups from the PEQ and the PROMIS Pain Interference Scale.

Other Achievements

- One abstract was presented as a poster at the Military Health System Research Symposium, which was held from August 14-17, 2023, at Kissimmee FL. The title for the abstract was:

  Comparative Biomechanics Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation
- A manuscript was submitted for review to the Journal of Medical Internet Research, entitled, "Effects of a Powered Ankle-Foot Prosthesis and Physical Therapy on Function for Individuals with Transfemoral Limb Loss: Rationale, Design, and Protocol for a Multi-Site Clinical Trial".

Goals Not Met:

The following goals have not been met:

- Projected recruitment is less than expected due to recovery efforts from the ongoing global pandemic. A 1-year no cost extension has been requested to complete enrollment goals, specifically for enrollment of servicemembers at WRNMMC. Advanced funding has been received. Patient clinic visits have increased at each study site and screenings at each site have been scheduled. We expect to have a completed enrollment by April 2024.

- WRNMMC has been approved by the local IRB to enroll servicemembers who have undergone osseointegration (OI). However, there were significant delays in approval by OHRO and further delays during the subaward modification process. All delays have been resolved and the first participant with OI has been enrolled. Due to the delay in approval, a no cost extension was requested to extend the enrollment period, particularly to allow sufficient recruitment of participants with OI at WRNMMC.

Study recruitment is less than projected. However, enrollment has increased over the last quarter, and we expect continued increases in enrollment, particularly for OI participants. VANYHHS, JAHVH, and WRNMMC have continued to meet on a biweekly basis to discuss updates. Updated recruitment plans have been implemented at each site to increase enrollment. These strategies include leveraging a database of eligible patients who visited

the prosthetic clinic and agreed to be contacted for research opportunities. Recruitment methods also include presenting at amputation support groups, attending national conferences and local chapter meetings targeted for individuals with limb loss, including civilians from affiliated medical centers and clinics, and continuing our biweekly conference calls. We have also contacted local VA and community-based clinics to increase recruitment. Each site will continue to utilize existing registries to recruit participants who have previously participated in other research studies. Additionally, WRNMMC will continue to recruit patients with OI. We will continue to conduct group quarterly conference calls to review progress to date and discuss any problems that arise.

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

While the project is not intended to provide training and professional development, members of the study attended the Military Health Systems Research Symposium in August to learn about ongoing and future developments in the fields of prosthetics and limb loss.

Additionally, team members at VANYHHS have provided ongoing trainings to collaborators at JAHVH. These trainings covered all aspects of the biomechanical data collection, including marker placement, capturing the appropriate motion trials, and all aspects of post-processing the data.

How were the results disseminated to communities of interest?

- One abstract was presented as a poster at the Military Health System Research Symposium, which was held from August 14-17, 2023, at Kissimmee FL. The title for the abstract was: Comparative Biomechanics Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation
- A manuscript was submitted for review to the Journal of Medical Internet Research, entitled, "Effects of a Powered Ankle-Foot Prosthesis and Physical Therapy on Function for Individuals with Transfemoral Limb Loss: Rationale, Design, and Protocol for a Multi-Site Clinical Trial".

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

To accomplish the goals and objectives for year 7, we plan to:

- Complete enrollment at all sites.
- Conduct biweekly and quarterly conference calls to enrollment and discuss study outcomes.
- Conduct and complete all data collection.
- Complete data analysis for all participants.
- Presentation of abstracts at conferences and manuscript preparation for journal articles.

4. IMPACT:

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

Nothing to Report

What was the impact on other disciplines?

Findings from this study can directly influence the Clinical Practice Guidelines utilized in the prosthetic prescription process and potentially impact the care provided by limb loss care teams, including physical therapists, physiatrists, and prosthetists, after the patient has been prescribed an appropriate device.

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

As powered devices continue to become more prevalent options for prosthetic prescription, particularly with advances in volitional control, Clinical Practice Guidelines associated with prosthetic prescription for Veterans and Service Members with transfemoral limb loss may be updated based on the outcomes of this research study. It is necessary for clinicians to prescribe the most appropriate prosthetic devices to enhance function and satisfaction. By understanding the effects of a powered prosthetic ankle-foot device, as well as a PT intervention on (a) lower extremity kinematic and kinetic patterns, (b) functional efficacy, and (c) pain for individuals with TFA, clinicians can use this "toolbox" to help prescribe an appropriate prosthetic device and rehabilitation plan to return our Veterans and Servicemember to their highest levels of physical and psychosocial function. While the VA/DoD lower limb loss Clinical Practice Guidelines provide guidance on critical decision points in the rehabilitation healthcare plan, results from this novel research have the potential to directly impact the healthcare provided to both Veterans and Service Members by the VA and DoD, as the new information will allow for more evidence-based prescription of prosthetic devices and services. Information gained from this study will allow VA and DoD to more adequately address the healthcare needs of Veterans and Service Members with lower limb loss, helping them to live higher quality, active lives.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Study recruitment is less than projected due to COVID-19 recovery efforts, but enrollment has increased in Y6. A no-cost extension has been requested and approval is pending. We expect enrollment to continue to increase in the next year. VANYHHS, JAHVH, and WRNMMC have continued to meet on a biweekly basis to discuss updates and possible solutions to increase enrollment.

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

The following problems/delays are detailed below:

- Recruitment: Recruitment to date is less than the projected target for the end of Year 6 largely due to the recovery efforts of the COVID-19 pandemic.
- Recruitment strategies at each performance site will continue to be implemented including:
    - Presenting at local amputation support groups
    - Attending local and national conferences, as well as chapter meetings targeted for individuals limb loss
        - This includes the national Amputee Coalition Conference, as well as local limb loss education days.
    - Including civilians as research participants from affiliated medical centers and clinics.
    - Online, telehealth, and other non-contact recruitment methods will continue to be explored to increase enrollment.
    - Continue bi-weekly calls with study sites to encourage recruitment efforts and mitigate any problems
        - The principal site team will continue to work with each site to optimize recruitment strategies to increase enrollment.

Changes that had a significant impact on expenditures

Year 6 expenditures were less than projected due to the recovery efforts from COVID-19, including less expenditures on materials, supplies, and some salaries. However, expenditures are expected to return toward the projected budget with a year 7 extension and enrollment of OI patients. Advanced funding has been received.

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

There have been no significant changes in use or care of human subjects.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**
  Journal publications.

  - A manuscript was submitted for review to the Journal of Medical Internet Research, entitled, "Effects of a Powered Ankle-Foot Prosthesis and Physical Therapy on Function for Individuals with Transfemoral Limb Loss: Rationale, Design, and Protocol for a Multi-Site Clinical Trial".

  Books or other non-periodical, one-time publications.

  Nothing to Report

  Other publications, conference papers and presentations.

  - One abstract was presented as a poster at the Military Health System Research Symposium, which was held from August 14-17, 2023, at Kissimmee FL. The title for the abstract was: Comparative Biomechanics Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation

- **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:	Jason Maikos, PhD
Project Role:	PI at NYHHS
Nearest person month worked:	2
Responsibilities/ Contributions:	Oversees overall integrity of the study, as well as all protocol activities. Coordinates recruitment efforts at all sites.
Name:	Leif Nelson, PT, DPT
Project Role:	Consultant at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for enrollment eligibility and physical therapy-related activities.
Name:	Eric Hubbs, CPO
Project Role:	Study Prothetist at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Performs all prosthetic fitting activities.
Name:	Ken Breuer, CP, BOC
Project Role:	Prosthetist at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees preparation for all prosthetic fitting activities.
Name:	Michael Hyre, MS
Project Role:	Study Coordinator at NYHHS
Nearest person month worked:	2
Responsibilities/ Contributions:	Oversees all regulatory activities at VANYHHS and assists with IRB at WRNMMC and JAHVH. Coordinates data collection and entry from all sites.
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	David Herlihy, BS
Project Role:	Research Engineer at NYHHS
Nearest person month worked:	12
Responsibilities/ Contributions:	Assists with subject enrollment, performs all protocol activities, including biomechanical data captures.
Name:	John Chomack, MS
Project Role:	Research Engineer at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with biomechanical data collection.
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Cristina Roy, PT, PhD
Project Role:	Research Physical Therapist at NYHHS
Nearest person month worked:	9
Responsibilities/ Contributions:	Conducts all PT sessions, assists with protocol activities and data collection.
Name:	Alexis Sidiropoulos, PhD
Project Role:	Research Scientist at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with biomechanical data collection.
Name:	Bradford Hendershot, PhD
Project Role:	PI at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, coordinates local IRB submissions.

Name:	Christopher Dearth, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Local oversight of research activities.
Name:	Alison Pruziner, DPT
Project Role:	Consultant for WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for physical therapy protocol and data analysis
Name:	Jonathan Gladish, MS
Project Role:	Research Engineer at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Responsible for subject enrollment and data collection.
Name:	Binni Khatri
Project Role:	Research Physical Therapist at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Performs all PT-related activities.
Name:	Samuel Phillips, PhD
Project Role:	PI at JAHVH
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, coordinates local IRB submissions.
Name:	Meghan Kern, DPT
Project Role:	Research Physical Therapist/Study Coordinator at JAHVH
Nearest person month worked:	4
Responsibilities/ Contributions:	Performs all PT-related activities. Assists staff during data collection.
Name:	Stephanie Carey, PhD
Project Role:	Co-I at JAHVH
Nearest person month worked:	1
Responsibilities/ Contributions:	Data collection support for biomechanics visits.
Name:	Anh Du, CO/BOCP
Project Role:	Prosthetist at JAHVH
Nearest person month worked:	1
Responsibilities/ Contributions:	Recruitment and prosthetic fitting/adjustments.
Name:	Lisa Ballistrea, DPT
Project Role:	Study Coordinator at JAHVH
Nearest person month worked:	1
Responsibilities/ Contributions:	Data Collection; Back-up Physical Therapist

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?

Walter Reed National Military Medical Center
8901 Wisconsin Ave Bethesda, MD 20889
Contributions to the Project: Collaboration and Facilities

James A. Haley Veterans' Hospital
13000 Bruce B. Downs Blvd.
Tampa, FL 33612
Contributions to the Project: Collaboration and Facilities

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: This report covers the reporting period for both NYHHS and WRNMMC. Tasks have been clearly marked with the responsible PI and research site. Achievements at each site have been clearly delineated.

QUAD CHARTS: Included.

9. APPENDICES:

The abstract accepted for the Military Health Systems Research Symposium is included below:

Comparative Biomechanics Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation

Introduction: Individuals with Transfemoral Amputation (TFA) encounter unequal lower limb load distribution that results in stress-related gait anomalies, increasing their risk of developing comorbidities [1]. Energy storing and returning (ESR) feet, commonly prescribed to individuals with TFA, are unable to generate normative biological power levels [2]. This force deficiency results in compensatory mechanisms that can lead to biomechanical asymmetries. Due to the inherent loss of the knee joint and surrounding musculature, individuals with TFA experience more dramatized asymmetries [3]. This study aims to examine the effects of a biomimetic powered ankle-foot prosthesis, by comparing targeted device specific physical therapy, versus standard of care in individuals with a TFA. Additionally, we are seeking to explore the effects of the device on potential cognitive load on users during walking. The objective of this preliminary analysis is to analyze several key biomechanical parameters to better understand the effects of a powered foot within the TFA population. We hypothesize that the powered prosthesis, the Empower (PWR) (Ottobock, Duderstadt, Germany), will normalize key biomechanical parameters and neurocognitive assessments would correlate positively to improved gait symmetry.

Methods: To date, six participants have been recruited from Veterans Affairs (VA) New York Harbor Healthcare System (NYHHS). All study activities were conducted after informed consent. Participants were randomized to either a control standard of care group or device-specific physical therapy group. First, they completed an overground walking analysis at NYHHS on their current ESR foot. Motion and force data were collected using an optical motion capture system (Qualisys, Goteborg, Sweden) and force platform system (AMTI, Waterford, MA). During the baseline assessment, a neurocognitive exam was conducted using Central Nervous System Vital Signs (CNSVS) software (Morrisville, NC). Domains tested included a summarized neurocognitive index, composite memory, verbal and visual memory, psychometer, processing, and motor speed, reaction time, complex and simple attention, cognitive flexibility, and executive function. After baseline testing, all participants were aligned with the PWR device and given device education training and standard of care. The standard of care group then went home for a 4-week acclimation period. Participants in the device specific therapy group received device education training and bi-weekly patient-specific physical therapy sessions during the acclimation period. This therapy focused on a targeted strengthening program to potentially improve the effectiveness of the PWR foot. After 4 weeks, participants returned for a second biomechanics data collection. Both groups of participants continued using the PWR foot for 4 more weeks with no added device-specific physical therapy. Participants then returned for a third biomechanical data collection and neurocognitive testing with the PWR. The data was processed using Visual 3D (C-Motion Inc.) and a custom MATLAB script calculated the biomechanical parameters of interest. A repeated measures one-way analysis of variance was conducted to compare biomechanical measure between groups with a student t-test to compare limb conditions. A linear regression analysis was performed to derive Pearson's Correlation Coefficient between gait biomechanical and neurocognitive results.

Results:
This preliminary analysis focused on the key kinematic and kinetic parameters and their relationship with the neurocognitive outcomes. For the purposes of this analysis, only the hip and ankle biomechanics were analyzed. As a preliminary analysis, the sample size was small and statistics did not show significant differences in the key parameters.

Below compares the first baseline visit (V1) and the first and second visit with the PWR foot (V2 & V3).

Prosthetic Ankle Range of Motion (ROM) (deg): V1: 18.17 ± 4.34, V2: 18.72 ± 1.84, V3: 19.00 ± 2.05

Intact Ankle ROM (deg): V1: 24.91 ± 4.98, V2: 25.98 ± 4.02, V3: 27.88 ± 5.18
No significant differences occurred between visits for either intact or prosthetic ankle range of motion.

Prosthetic Ankle Peak Moment (Nm/kg): V1: 1.41 ± 0.26, V2: 1.07 ± 0.22, V3: 1.07 ± 0.25

Intact Ankle Peak Moment (Nm/kg): V1: 1.24 ± 0.30, V2: 1.11 ± 0.52, V3: 1.02 ± 0.50
The PWR tended to reduce the peak ankle moment relative to the baseline visit, though the differences were not found to be significant.

Prosthetic Ankle Peak Power (W/kg): V1: 1.22 ± 0.23, V2: 1.39 ± 0.50, V3: 1.44 ± 0.55

Intact Ankle Peak Power (W/kg): V1: 1.72 ± 0.66, V2: 1.64 ± 0.97, V3: 1.53 ± 1.07
Peak power tended to increase between the baseline and PWR, though differences were not found to be significant.

Prosthetic Hip ROM (deg): V1: 41.74 ± 5.08, V2: 42.44 ± 3.83, V3: 43.52 ± 4.52

Intact Hip ROM (deg): V1: 37.98 ± 5.67, V2: 37.87 ± 5.94, V3: 39.12 ± 6.82
The hip ROM did not vary significantly between the ESR and PWR visit, though prosthetic side ROM tended to be lower than intact side.

Prosthetic Hip Peak Moment (Nm/kg): V1: 0.55 ± 0.27, V2: 0.588 ± 0.257, V3: 0.61 ± 0.34

Intact Hip Peak Moment (Nm/kg): V1: 0.96 ± 0.16, V2: 0.83 ± 0.20, V3: 0.86 ± 0.27
The hip peak moment tended to be greater on the intact side, and no values varied significantly between visits.

Prosthetic Hip Peak Power (W/kg): V1: 1.13 ± 0.70, V2: 1.10 ± 0.51, V3: 1.123 ± 0.75

Intact Hip Peak Power (W/kg): V1: 1.00 ± 0.19, V2: 0.86 ± 0.20, V3: 1.13 ± 0.34
The peak prosthetic side hip power did not vary significantly between the ESR and PWR visit, and was only slightly greater than intact side.

Neurocognitive Index Score Correlation to Joint Asymmetry:
The average percent difference between the prosthetic and intact limb ankle ROM and hip ROM showed a 7.88% and 3.69% decrease in asymmetry respectively. By the 3rd visit, all participants had reached a neurocognitive index score >80 signifying low average or higher, representing a slight deficit to high capacity of average neurocognitive status. There was a moderate correlation of 0.37 between the 3rd visit neurocognitive index score and the reduction of prosthetic and intact limb asymmetry at the ankle.

Discussion: Biomimetic devices, such as the Empower, offer the ability to provide normative ankle power and ROM. This ability can influence the intact limb, offering a relief from increased mechanical work by decreasing the severity of learned gait compensations [4]. This investigation sought to understand the biomechanical and neurocognitive effects of the PWR device within 2 groups: a standard of care group and a device-specific physical therapy group over 8 weeks. While no significant differences ($p > 0.05$) were found between groups or in the selected kinematic and kinetic parameters, some trends emerged. Both ankle and hip ROM asymmetries decreased from visit 1 to 3 for both groups. Ankle kinetics for both limbs also trended towards statistically significant differences between the ESR and PWR foot. This may suggest that while the PWR's biomimetic power produces an effect on the intact ankle, it may not be sufficient to influence the kinematic and kinetic asymmetric compensations at the hip. This may indicate individuals with a TFA require more specialized device or therapeutic attention to hip strength. It was hypothesized that neurocognitive index scores >80 would correlate with improved gait symmetry. With this preliminary analysis, a moderate correlation of 0.37 at the ankle joint was found, suggesting the added functionality of the PWR does not cause a significant cognitive burden on the participant. Future work will include exploring correlation between gait kinematic, kinetic, and power data with all cognitive domains within the CNSVS and functional outcome measures.

Disclaimer: The views and opinions expressed herein do not necessarily state or reflect those of the Departments of Defense or Veterans Affairs and shall not be used for advertising or product endorsement purposes. The authors have no conflicts of interest.

Learning Objectives:

1. Compare selected biomechanics parameters of individuals with transfemoral amputation using powered and non-powered prosthetic devices.
2. Analyze the cognitive effects a powered prosthetic foot may have on individuals with TFA compared to a traditional unpowered prosthetic device.
3. Discuss the potential effects of device specific physical therapy and how utilizing it as a form of standard of care practice could benefit individuals with TFA overcoming gait abnormalities caused by gait asymmetries.

References

[1] Ehde, D.M., et al., *Back Pain as a Secondary Disability in Persons With Lower Limb Ampuations.* Arch Phys Med Rehabil, 2001. 82: p. 731-734.

[2] Winter, D.A., *Energy generation and absorption at the ankle and knee during fast, natural, and slow cadences.* Orthop Relat Res, 1983. 175: p. 147-154.

[3] Jaegers, S.M., J.H. Arendzen, and H.J. de Jongh, *Prosthetic gait of unilateral transfemoral amputees: a kinematic study.* Arch Phys Med Rehabil, 1995. 76(8): p. 736-43.

[4] Herr, H.M. and A.M. Grabowski, *Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation.* Proc Biol Sci, 2012. 279(1728): p. 457-64.