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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 and Education

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

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14. ABSTRACT

Lower limb prosthetic technology has evolved into advanced powered devices that can better replicate the gastroc-soleus complex for individuals with a lower extremity amputation. 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 amputation (TFA) to an advanced prosthetic and rehabilitative intervention. This investigation is a 2-site, 8-week, randomized, clinical trial. Individuals living with TFA will be 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 subjects will 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

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Individuals living with a transfemoral amputation (TFA) that 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 extremity amputation (LEA), 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 LEA 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 TFA 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 TFA, 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:** *Provide a brief list of keywords (limit to 20 words).*

Amputation, Transfemoral Amputation, 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 amputation (TFA).
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 TFA 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	-
Coordinate with Sites for Military 2nd level IRB** approval (ORP/HRPO)	100%	NYHHS: 06/27/2018 WRNMMC: 10/30/2018	-
Milestone Achieved: Local IRB approval at each site	100%	9/25/18	-
Milestone Achieved: HRPO approval for all protocols	100%	10/30/2018	-
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	Overall: 23% NYHHS: 46% WRNMMC: 0%	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	Overall: 23% NYHHS:40% WRNNMC:0%	ongoing	-
Fitting of powered prosthesis	Overall: 23% NYHHS: 40% WRNMMC: 0%	ongoing	-
Subtask 2: Conduct Study	-		
Collect biomechanical, functional, pain, and neurocognitive data according to the project timeline	Overall: 20% NYHHS: 40% WRNMMC: 0%	ongoing	-
Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled	Overall: 23%	ongoing	7/2021
Milestone Achieved: 50% of participants have completed the 8-week physical therapy program and data has been collected.	Overall: 10%	ongoing	1/2020
Milestone Achieved: All subjects have completed the research protocol	Overall: 17%	ongoing	9/2021

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: 20%	ongoing	-
Annual Meetings will be held at NYHHS to discuss the current progress of the study and data analysis related to Aims 1-3.	67%	ongoing	-
Subtask 2: Manuscript Preparation*:*			
Roles for dissemination of findings (abstracts, scientific presentations and manuscripts) assigned	-	-	-
Plan for Subsequent clinical trials initiated	-	-	-
Milestone Achieved: Analysis of 50% of patients	-	-	-
Milestone Achieved: 100% of Analysis complete	-	-	-
Milestone Achieved: Report findings from overall studies	-	-	-
Milestone Achieved: Manuscript Preparation and plans for next clinical trial	-	-	-

What was accomplished under these goals?
Major Activities and specific objectives for Year 2 include:

IRB Submission
Local IRB and HRPO approvals have been achieved at all sites. Approval dates are listed in Table 1.

TABLE 1: IRB and HRPO Approvals

Site	Local IRB Approval Date	HRPO Approval Date
VA New York Harbor Healthcare System (NYHHS)	10/17/2017	6/27/2018
Walter Reed National Military Medical Center (WRNMMC)	09/25/2018	10/30/2018

Subawards and Data Sharing Agreement
The data sharing agreement between WRNMMC and NYHHS was finalized 10/18/2018. The subaward for WRNMMC (via the Henry M. Jackson Foundation) was finalized 5/2/2019.

CRADA
The CRADA between WRNMMC and Henry Jackson Foundation (HJF) is currently being reviewed. The WRNMMC team had previously requested (7/3/2019) an interim start letter; however, the Department of Research Programs was not comfortable issuing one until the CRADA was at least assigned to ARC review. The WRNMMC team is hopeful the CRADA is assigned to ARC review in the next quarter, but they will continue to follow-up weekly with the local business office.

Recruitment and Enrollment
Recruitment and enrollment have begun at NYHHS. Recruitment at WRNMMC is pending a finalized CRADA. Table 2 outlines current enrollment at each site:

TABLE 2: Recruitment and Enrollment

Site	Screened	Screen Failure	Enrolled	Withdrawn
NYHHS	9	2	7	0
WRNMMC	-	-	-	-
Total	**9**	**2**	**7**	**0**

Significant Results and Key Outcomes for Year 2

Research Design and Project Timeline:

This research investigation proposes a multi-center, 8-week investigation, outlined in Figure 1. Briefly, 30 individuals living with TFA, enrolled equally at the VA NYHHS and WRNMMC, will be 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 subjects, a full gait analysis*, functional measures#, cognitive burden@, neurocognitive battery^, and pain assessment$ is captured at baseline on their current passive prosthesis. Subjects will then be 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 will then undergo the biomechanical, functional, pain, cognitive burden, and neurocognitive assessments according the schedule outlined in Figure 1.

#6-min Walk, AmpPro, CHAMP, $PROMIS, VAS ^CNS Vital Signs, @Serial Subtraction, COWAT, Category %PEQ, PEQ-A, QoL		Baseline	Week 2	Week 4	Week 6	Week 8
Group A: Powered, Device-Specific PT (n =15)	Biomechanical Assessment*	x		x		x
	Functional Assessment#	x		x		x
	Pain Assessment$	x		x		x
	Cognitive Burden Assessment@	x		x		x
	Neurocognitive Assessment^	x				x
	Surveys%	x		x		x
	Device-Specific PT	x	x	x		
Group B: Powered, Standard of Care (n =15)	Biomechanical Assessment*	x		x		x
	Functional Assessment#	x		x		x
	Pain Assessment$	x		x		x
	Cognitive Burden Assessment@	x		x		x
	Neurocognitive Assessment^	x				x
	Surveys%	x		x		x
	Device-Specific PT					

Figure 1: Project Overview

Preliminary Data Analysis

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

Subjects are evaluated with the 6-minute walk (Figure 2A) and Amputee Mobility Predictor (AmpPro) (Figure 1B) at baseline utilizing the ESR foot and again 4- and 8-weeks later using the emPOWER. Figure 1 illustrates average scores for all completed subjects (n=6).

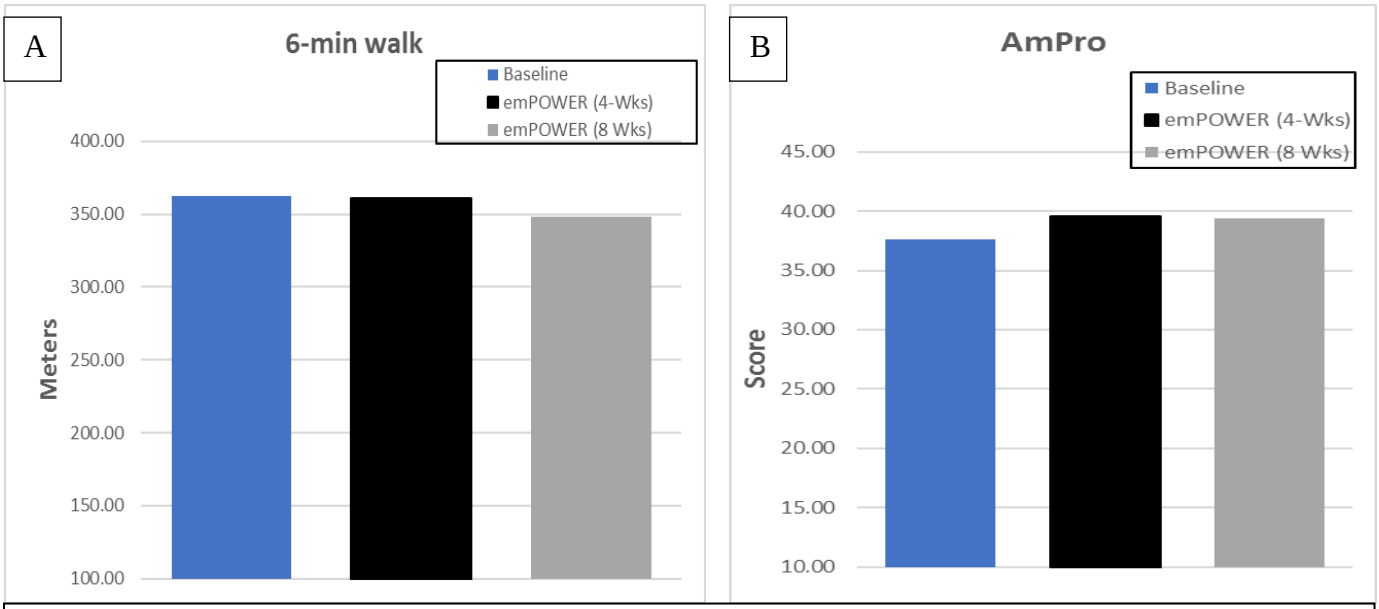

Figure 2: A) 6-min walk distances at baseline (ESR foot) and 4- and 8-weeks later using the emPOWER device. B) AmpPro scores comparing ESR versus emPOWER at 4- and 8-weeks. Higher values indicate greater functional abilities.

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) (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.

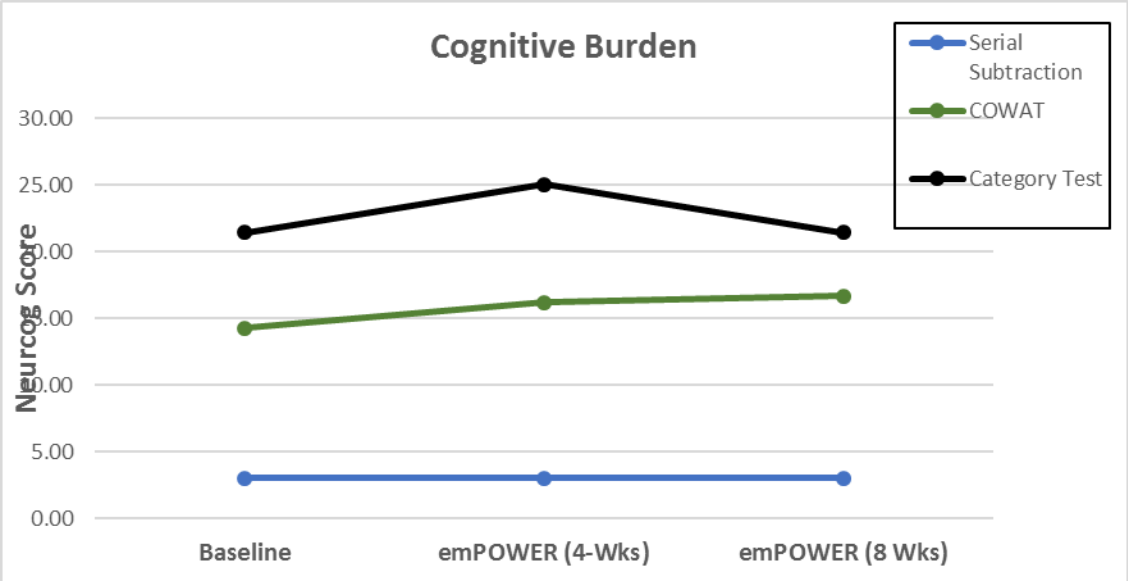

Figure 3: Average cognitive burden scores are shown at baseline (ESR foot) and again 4- and 8- weeks later using the emPOWER. Higher scores indicate higher cognitive ability and less burden.

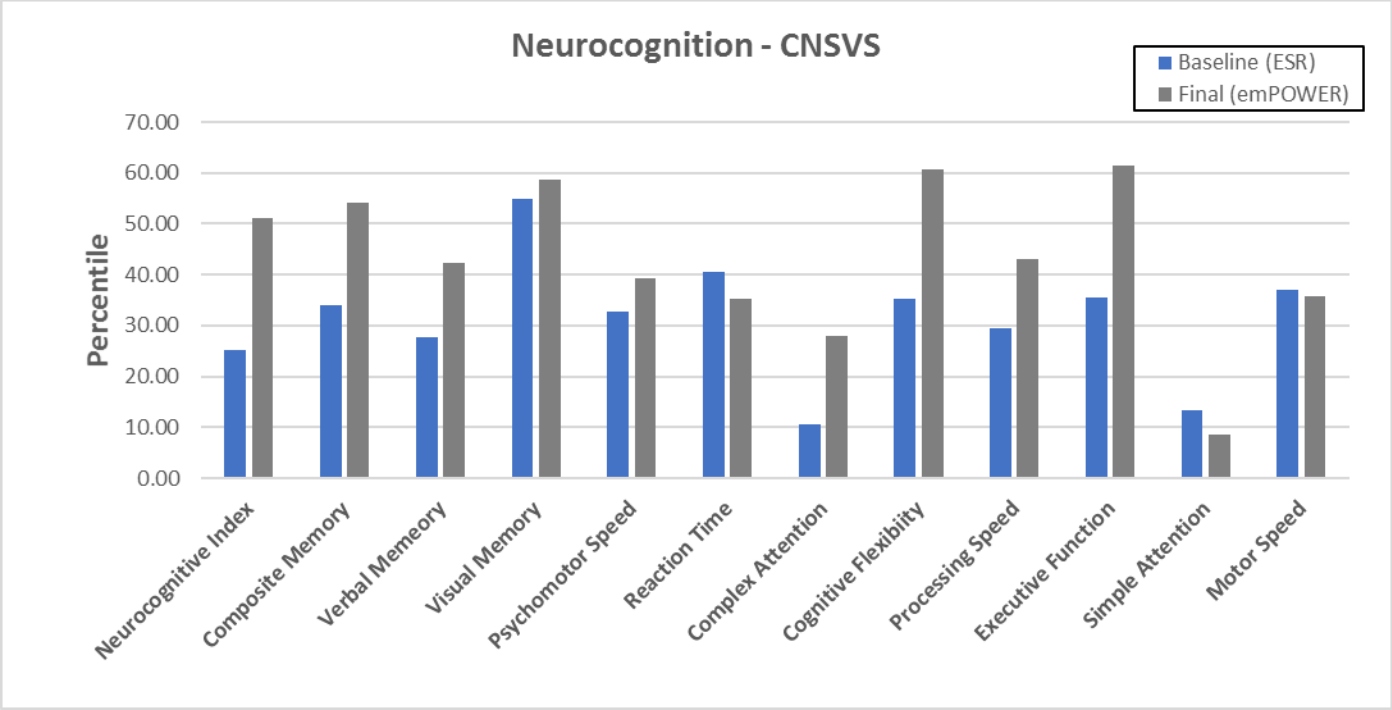

Figure 4: Average scores for the different neurocognitive domains, assessed utilizing CNSVS, which is a computerized assessment tool that utilizes validated and reliable computerized neuropsychological tests to evaluate the neurocognitive status of patients. Neurocognition is measured at baseline and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

Biomechanical Analysis

Figure 5 represents data for a representative subject randomized to standard of care (Column A) and a subject randomized to receive physical therapy (Column B). Sagittal plane kinematics and kinetics are shown during level ground walking at baseline using the ESR foot, and 4- and 8-weeks later using the emPOWER.

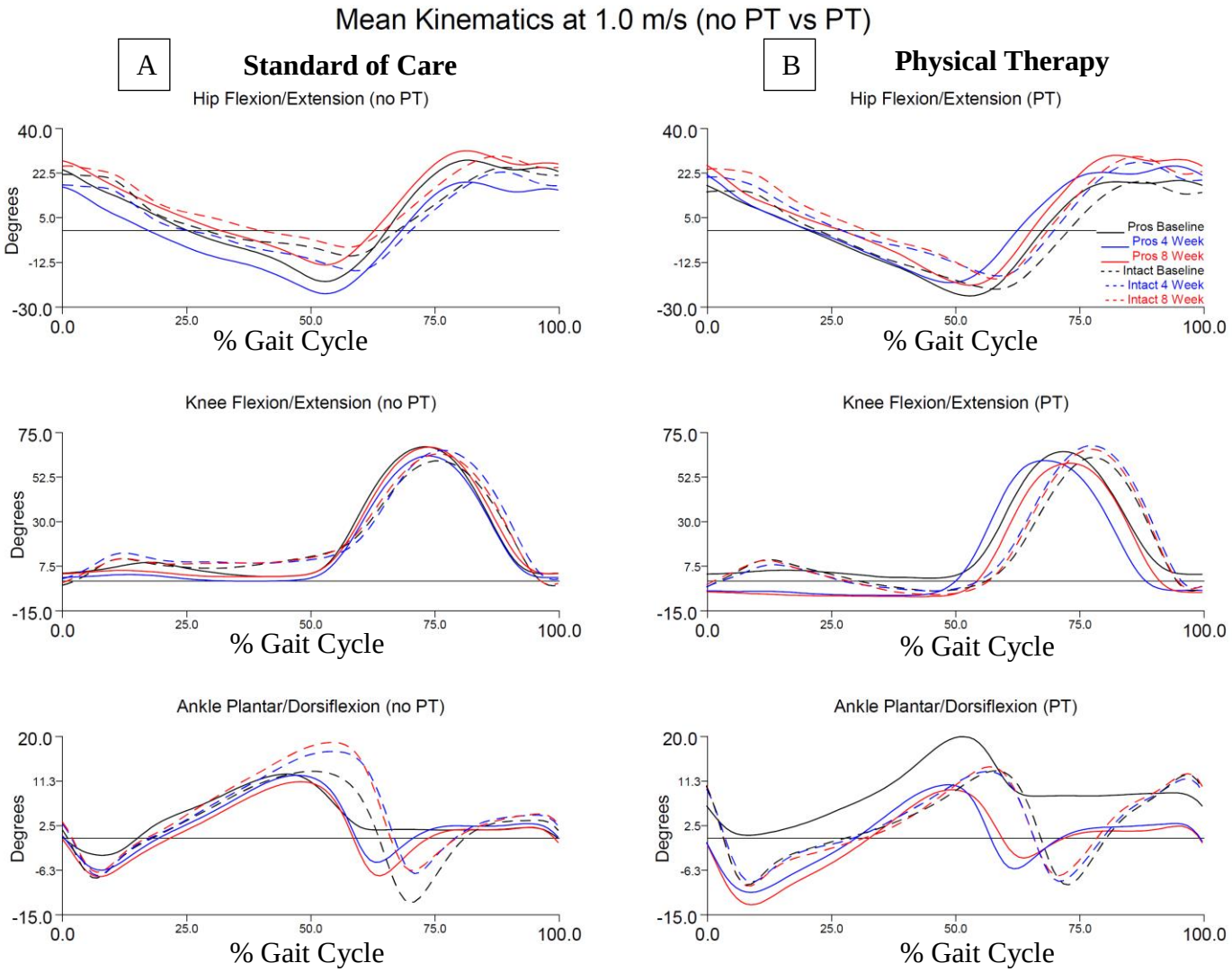

Figure 4: Sagittal plane kinematics, kinetics, and power scalar are shown for a representative subject randomized the standard of care treatment arm and another subject randomized to receive device-specific physical therapy.

Subjective Outcomes

Figure 5 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.

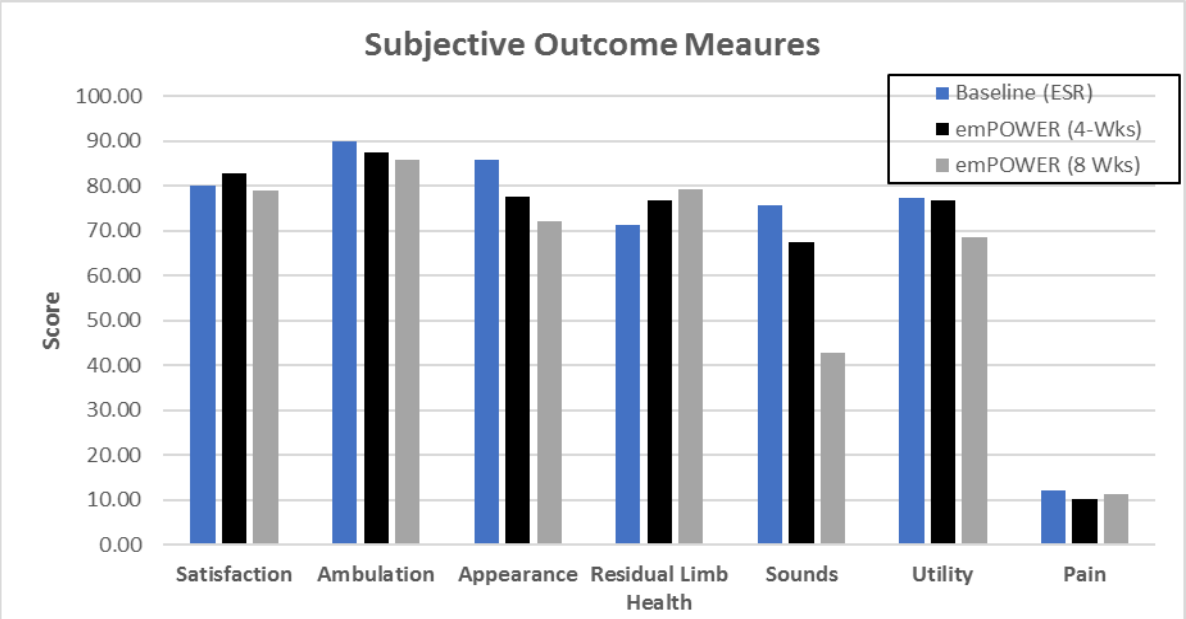

Figure 5: Baseline, 4- and 8-week follow up average scores from the PEQ and the PROMIS Pain Interference Scale.

Goals Not Met:

All goals have not been met for Y2. Study recruitment is less than projected at the end of Y2 for both sites, largely due to delays in CRADA development between WRNMMC and HJF. As the teams start year 3, additional recruitment strategies will be implemented to increase enrollment. These strategies will be discussed during our year 3 meeting (November 2019) to review successful recruitment strategies and implement additional strategies as necessary to increase enrollment.

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

While the project is not intended to provide training and professional development, our year 2 meeting provided professional development and training to the study staff on protocol procedures used in this study. This comprehensive training was held at WRNMMC on October 29, 2018. Staff received project management training (e.g. data collection, recruitment, and data sharing techniques) as well as protocol-specific training (e.g. cognitive burden and neurocognitive testing). The agenda is below.

Monday, October 29th 2018

Time	Session	Presenter	Location
12pm	Arrive at Walter Reed	All	
12:30 – 2:30pm	TF-emPOWER Protocol Review and Demonstration (Biomechanics, Functional Outcomes, Subjective Outcomes, Cognitive Burden, Neurocognitive Battery)	JC	PT Conference Room/Gait Lab
2:30-3:00pm	Break		
3:00-4:30pm	Biomechanics Review of Results	JM	PT Conference Room/Gait Lab

Furthermore, in August 2019, a knowledgeable representative from Otto Bock reviewed the emPOWER device, including prosthetic fitting and training techniques to the WRNMMC staff.

A Year 3 Meeting/training to review current data and project management techniques will be conducted with WRNMMC on November 19, 2019 at the James A. Haley VA Medical Center in Tampa, FL. This protocol review will cover avoiding pitfalls in data collection and reviewing the physical therapy protocol.

How were the results disseminated to communities of interest?

Nothing to Report. In year 3, we plan to submit abstracts to Military Health System Research Symposium and Gait and Clinical Movement Analysis Society annual conferences.

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

To accomplish the goals and objectives for year 3, we plan to:

- Conduct a year 3 on-site meeting.
- Initiate recruitment at WRNMMC.
- Modify recruitment strategies to increase recruitment at each site.
- Continue to conduct protocol procedures and data collection.
- Continue post-processing and data analysis for completed subjects.

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?

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:

Changes in approach and reasons for change

Nothing to Report

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 2. There are delays in finalizing the CRADA between WRNMMC and HJF to initiate patient enrollment. This agreement has required coordination by outside entities/institutions and despite continued efforts to encourage their progression, much of this process has been outside of the investigators' control. However, PIs and support staff at each site are continuing to push the process. All regulatory approvals have been received for both sites. Patient enrollment will begin at WRNMMC once the CRADA is finalized. Recruitment strategies will also be discussed at the Year 3 annual meeting on November 19th, 2019. New strategies for recruitment will include:
    - Presenting at local amputation support groups
    - Attending local and national conferences, as well as chapter meetings targeted for individuals living with amputation
        - This includes the national Amputee Coalition Conference, as well as local limb loss education days.
    - Including civilians from affiliated medical centers and clinics.
    - Continue bi-weekly calls to encourage recruitment efforts and mitigate any problems

Changes that had a significant impact on expenditures

Delays in completing agreements have ultimately reduced year 2 expenditures. Year 2 expenditures on prosthetic feet were less than projected due to delays in recruitment. However, as both sites enroll more subjects in Year 3, these expenditures are expected to return toward the projected budget.

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.

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:	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. Conducted annual meeting.
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:	Christopher Fantini, MSPT, CP, BOC
Project Role:	Co-I at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees preparation for all prosthetic fitting activities.
Name:	Ken Breuer, CP, BOC
Project Role:	Prosthetist at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees and performs preparation for all prosthetic fitting activities.
Name:	Michael Hyre, MS
Project Role:	Study Coordinator at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees IRB and HRPO submissions, assisted with development of data collection forms.
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Hannah Tadley
Project Role:	Study Coordinator at NYHHS
Nearest person month worked:	6
Responsibilities/ Contributions:	Oversees all regulatory activities at NYHHS and assists with IRB at WRNMMC. Coordinates data collection and entry from all sites. Provides support and troubleshooting to each site. Tracks and coordinates all study materials for each site. Aides in coordinating study meeting.
Name:	Michael Poppo, MS
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:	Ellen Godwin, PT, PhD, PCS
Project Role:	Research Physical Therapist at NYHHS
Nearest person month worked:	6
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
Funding Support	CDMRP award number W81XWH-17-2-0029
Name:	Brad Hendershot, PhD
Project Role:	Site-PI at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, coordinated local IRB submissions, assisted with data collection form development
Name:	Pete Anderson, CP
Project Role:	Prosthetist at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with local IRB submission, protocol development, preparation for prosthetic fittings.

Name:	Christopher Dearth, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with local IRB and protocol development.
Name:	Alison Pruziner, DPT
Project Role:	Consultant at 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:	Will be responsible for subject enrollment/data collection
Name:	Jenny Nguyen
Project Role:	Protocol Coordinator at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees IRB and HRPO submissions, assisted with development of data collection forms.

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

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: None