

**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

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**CONTRACTING ORGANIZATION:** Narrows Institute for Biomedical Research and Education

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# REPORT DOCUMENTATION PAGE

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<b>6. AUTHOR(S)</b> Jason Maikos, PhD and Bradford Hendershot, PhD (WRNMMC Site PI)  E-Mail: jason.maikos@va.gov and bradford.d.hendershot2.civ@health.mil					<b>5d. PROJECT NUMBER</b>	
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<b>14. ABSTRACT</b>  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 multi-site, 8-week, randomized, clinical trial. Individuals living with TFA 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 subjects undergo a full gait analysis, as well as functional, neuro cognitive, cognitive, and pain assessments. Results from this investigation will drive prosthetic and PT prescriptions for use of powered devices in this population.						
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## 1. INTRODUCTION:

Individuals living with a transfemoral amputation (TFA) 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 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:

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.

<b>Major Task 1: IRB Submission</b>	<b>% Completion</b>	<b>Completion Date</b>	<b>Expected completion</b>
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	-
<i>Milestone Achieved: Local IRB approval at each site</i>	100%	VA NYHHS: 10/17/2017 WRNMMC: 09/25/2018 JAHVH: 02/16/2021	-
<i>Milestone Achieved: HRPO approval for all protocols</i>	100%	VA NYHHS: 06/27/2018 WRNMMC: 10/30/2018 JAHVH: 04/08/2021	-
<b>Major Task 2: Coordinate Study Staff for Clinical Trials</b>			
Subtask 1: 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	-
<i>Milestone Achieved: Project Research staff hired and trained</i>	100%	4/2018	-
<b>Major Task 3: Participant Recruitment</b>			
Subtask 1: Subject recruitment			
Coordinate with Prosthetics and Rehabilitation Clinic for Subject Recruitment	ongoing-		
Assign participants to one of the two randomized groups	NYHHS: 67% WRNMMC: 0% JAHVH: 40%	ongoing	-
<i>Milestone Achieved: Study begins</i>	100%	9/2018	-
<i>Milestone Achieved: First subject consented, screened, and enrolled</i>	100%	10/2018	-
<b>Major Task 4: Data Collection</b>			
Subtask 1: Prosthetic Setup			
Alignment and fit of current prosthesis	NYHHS: 53% WRNMMC: 0% JAHVH: 40%	ongoing	-
Fitting of powered prosthesis	NYHHS: 47% WRNMMC: 0% JAHVH: 40%	ongoing	-
Subtask 2: Conduct Study			
Collect biomechanical, functional, pain, and neurocognitive data according to the project timeline	NYHHS: 47% WRNMMC: 0% JAHVH: 27%	ongoing	-

<i>Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled</i>	Overall: 57%	Ongoing	6/2023
<i>Milestone Achieved: 50% of participants have completed the 8-week physical therapy program and data has been collected.</i>	Overall: 33%	Ongoing	3/2023
<i>Milestone Achieved: All subjects have completed the research protocol</i>	Overall: 23%	Ongoing	9/2023
<b>Major Task 5: Data Analysis</b>			
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	10/2023
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: 16 subjects have been screened. There were 5 screen fails, and 11 subjects have been consented. Six subjects have completed all protocol activities and 1 has withdrawn. Four subjects are ongoing.

WRNNMC: Currently no subjects have been enrolled. WRNNMC is the process of modifying their local protocol to submit an IRB amendment to enroll participants with osseointegration. The SOW has been updated. Local IRB/HRPO amendment submission is pending at the time of this report.

JAHVH: Eight subjects have been screened. There were 2 screen fails and 6 subjects have been enrolled. One subject has completed all protocol activities and 1 subject is ongoing. 4 subjects 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
NYHHS	16	5	11	1
WRNNMC	1	1	0	0
JAHVH	8	2	6	4
<b>Total</b>	<b>25</b>	<b>8</b>	<b>17</b>	<b>5</b>

## 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 at VANYHHS, WRNNMC, 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 subjects, a full gait analysis\*, functional measures<sup>#</sup>, cognitive burden<sup>@</sup>, neurocognitive battery<sup>^</sup>, and pain assessment<sup>\$</sup> 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 then undergo the biomechanical, functional, pain, cognitive burden, and neurocognitive assessments according the schedule outlined in Figure 1.

**Preliminary Data Analysis**

Data presented below is from completed subjects 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.

		#6-min Walk, AmpPro, CHAMP, SPROMIS, 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	x	x	
	Functional Assessment <sup>#</sup>	x	x	x	x	x	
	Pain Assessment <sup>S</sup>	x	x	x	x	x	
	Cognitive Burden Assessment <sup>@</sup>	x	x	x	x	x	
	Neurocognitive Assessment <sup>^</sup>	x	x	x	x	x	
	Surveys <sup>%</sup>	x	x	x	x	x	
	Device-Specific PT	x	x	x	x	x	
Group B: Powered, Standard of Care (n =15)	Biomechanical Assessment*	x	x	x	x	x	
	Functional Assessment <sup>#</sup>	x	x	x	x	x	
	Pain Assessment <sup>S</sup>	x	x	x	x	x	
	Cognitive Burden Assessment <sup>@</sup>	x	x	x	x	x	
	Neurocognitive Assessment <sup>^</sup>	x	x	x	x	x	
	Surveys <sup>%</sup>	x	x	x	x	x	
	Device-Specific PT	x	x	x	x	x	

Figure 1: Project Overview

**Functional Outcome Measures**

Subjects 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.

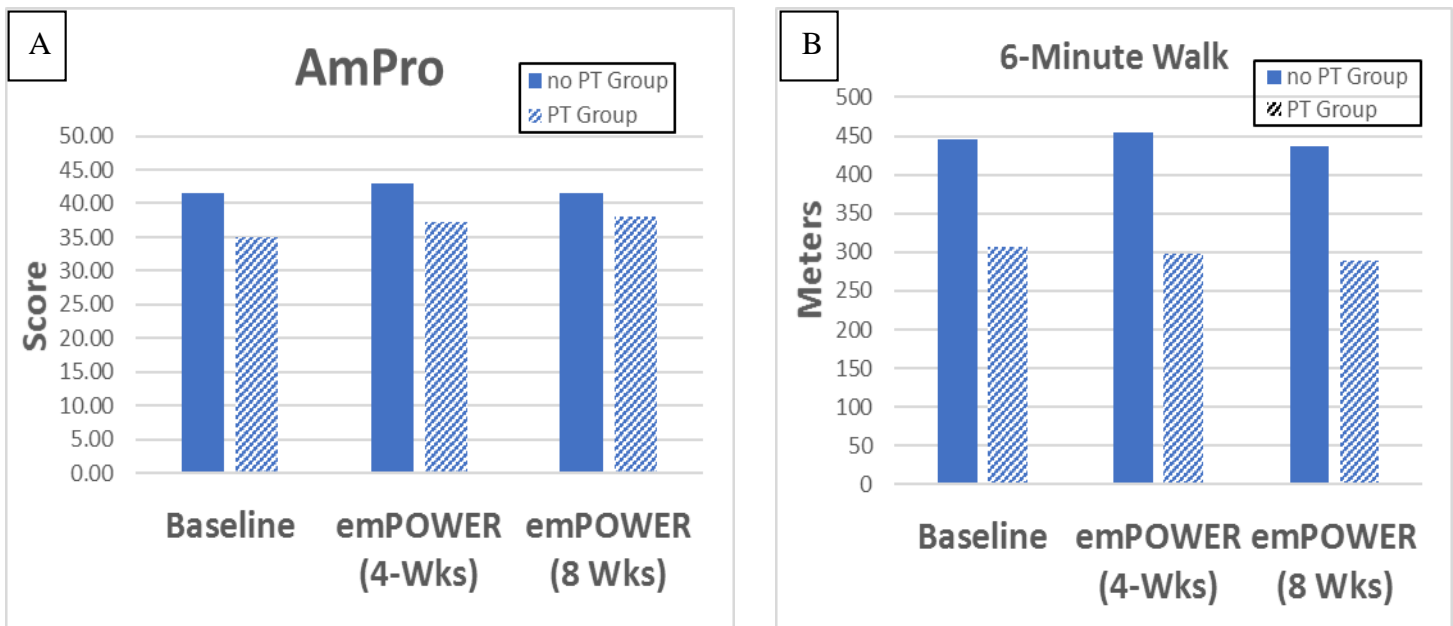


Figure 2: A) AmpPro scores comparing ESR versus emPOWER at 4- and 8-weeks for subjects randomized to PT or non-PT groups. B) 6-min walk distances at baseline (ESR foot) and 4- and 8-weeks later using the emPOWER device for subjects randomized to the PT and non-PT groups. Higher values indicate greater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

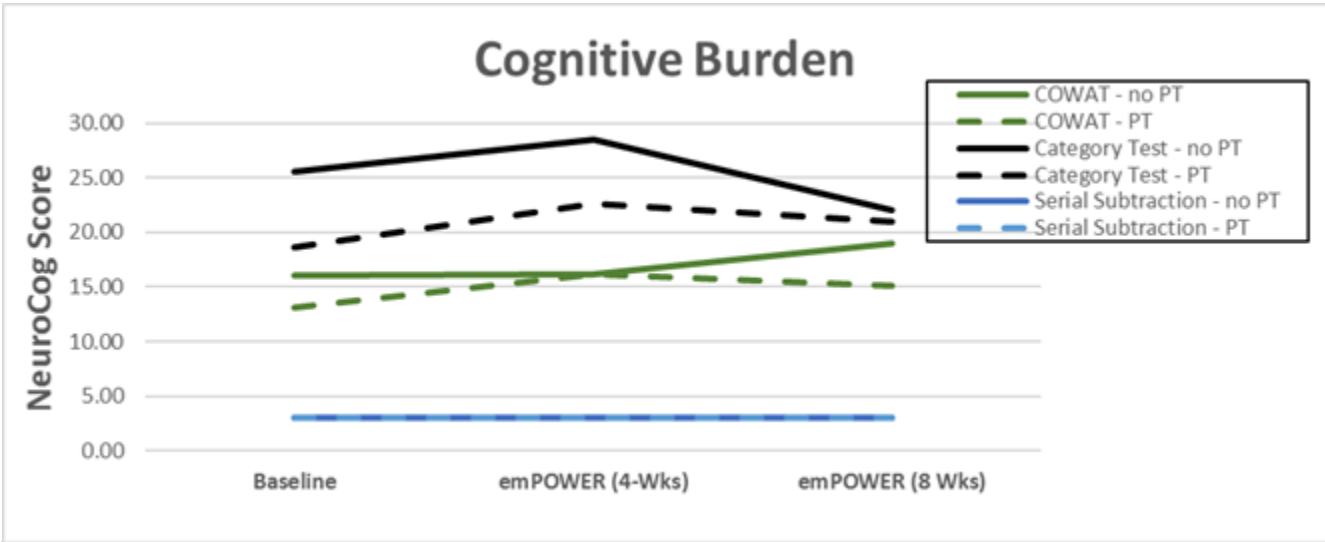


Figure 3: Average cognitive burden scores for subjects randomized to the PT and non-PT groups at baseline (ESR foot) and a gain 4- and 8- weeks later using the emPOWER. Higher scores indicate higher cognitive ability and less burden.

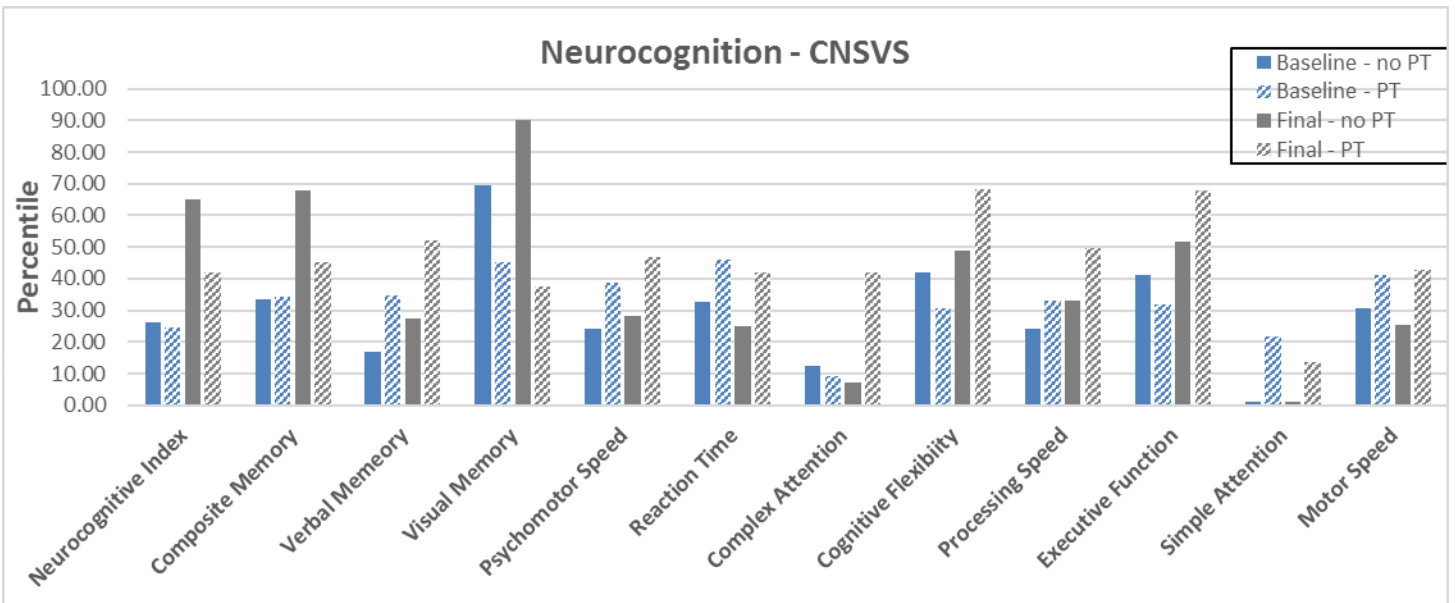


Figure 4: Average scores for the different neurocognitive domains, assessed utilizing CNSVS, which is a computerized assessment tool that utilizes validated and reliable computerized neuropsychological tests to evaluate the neurocognitive status of patients. Neurocognition is measured at baseline and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

### Biomechanical Analysis

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

### Mean Kinematics at 1.0 m/s (no PT vs PT)

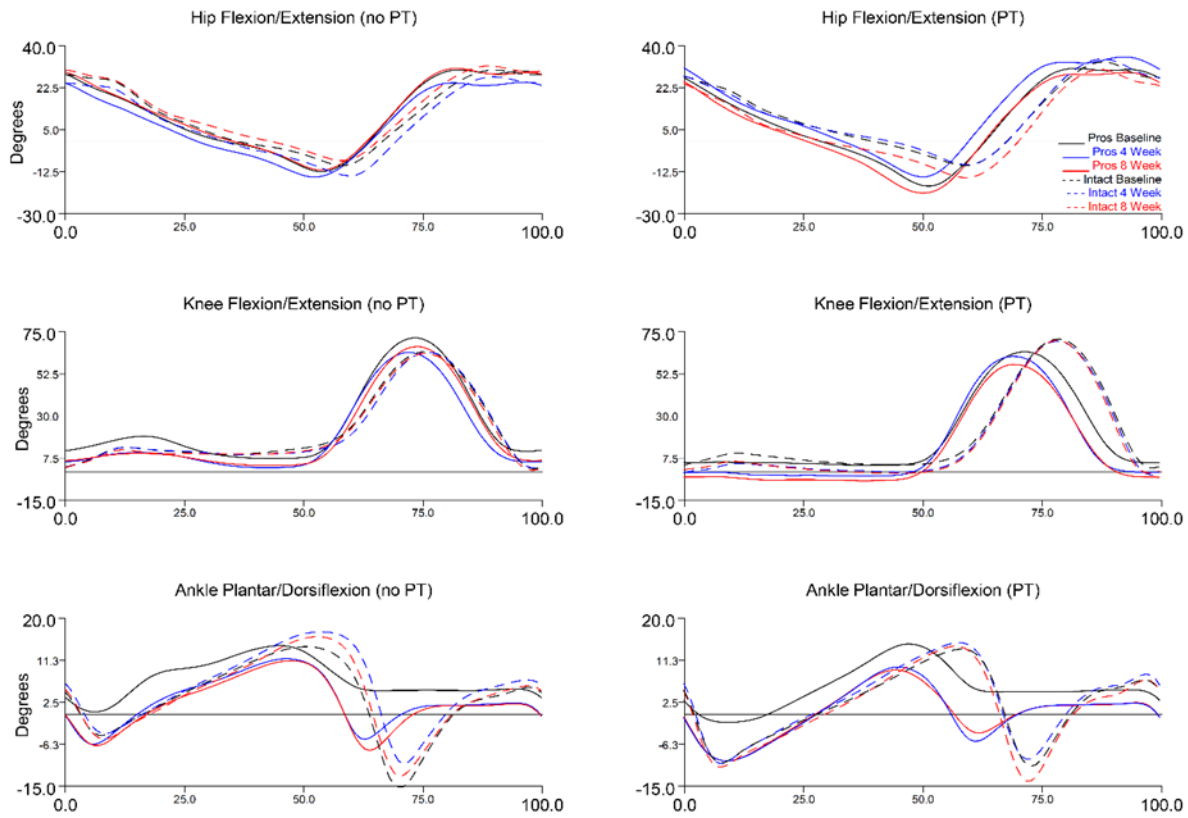


Figure 5: Level-ground sagittal plane kinematics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The intact limb is represented by dotted lines. The prosthetic limb is represented by solid lines.

## Mean Kinetics at 1.0 m/s (no PT vs PT)

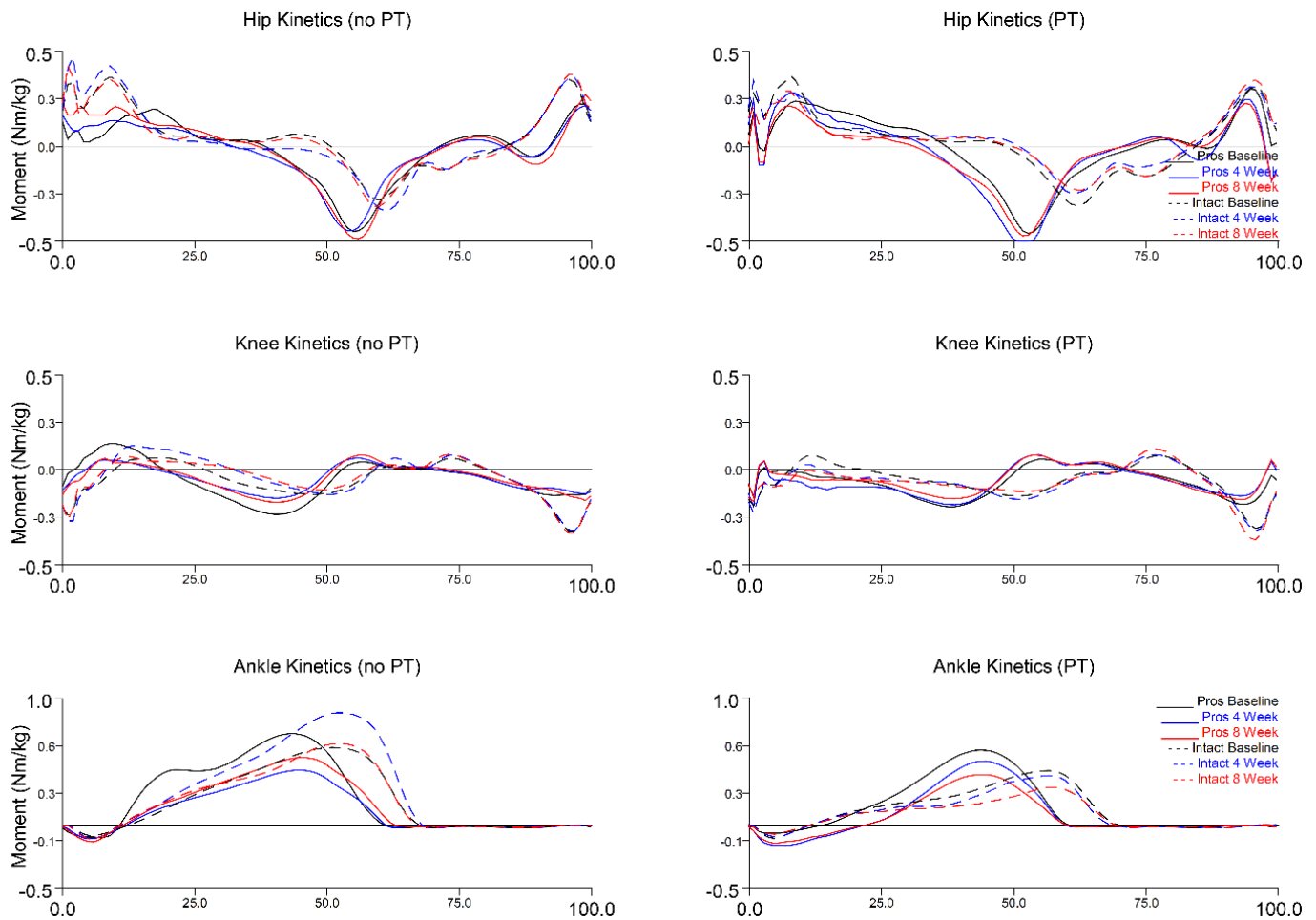


Figure 6: Level-ground sagittal plane kinetics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

### Mean Power at 1.0 m/s (no PT vs PT)

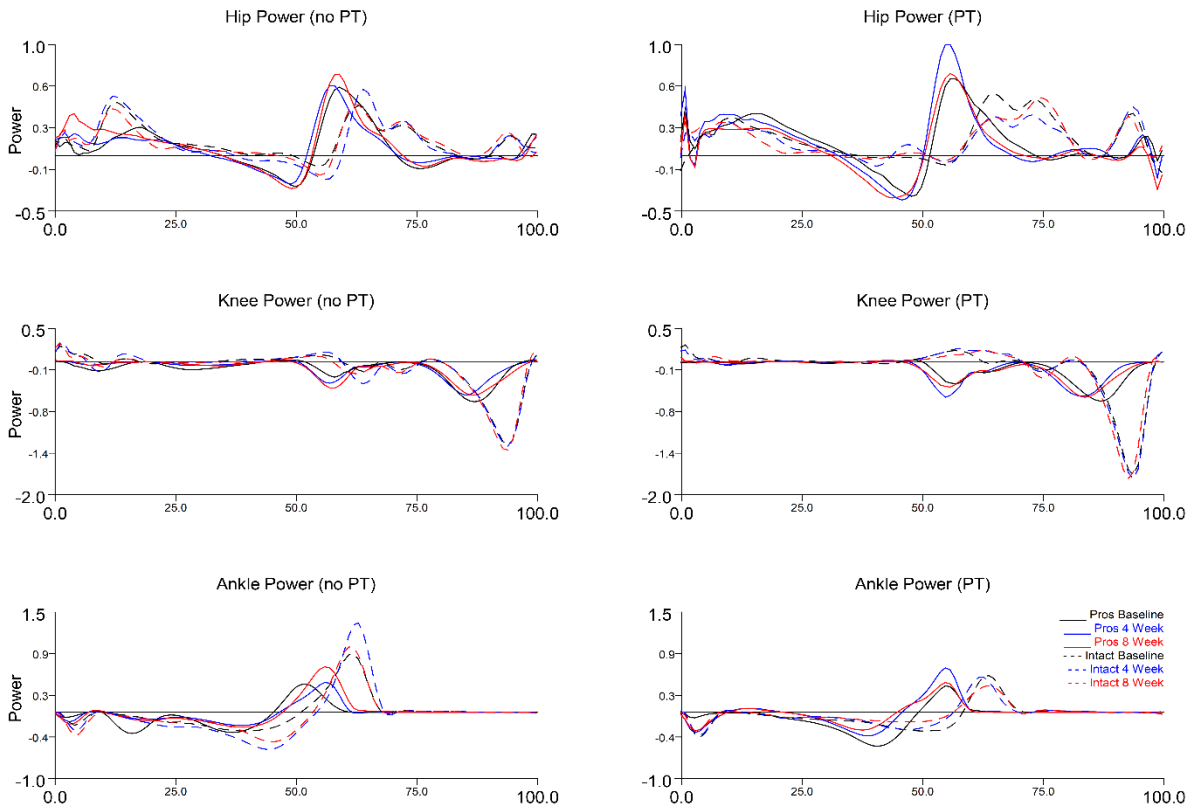


Figure 7: Level-ground sagittal plane joint powers for the PT and non-PT groups at baseline (Black) and at 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

### Subjective Outcomes

Figure 8 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.

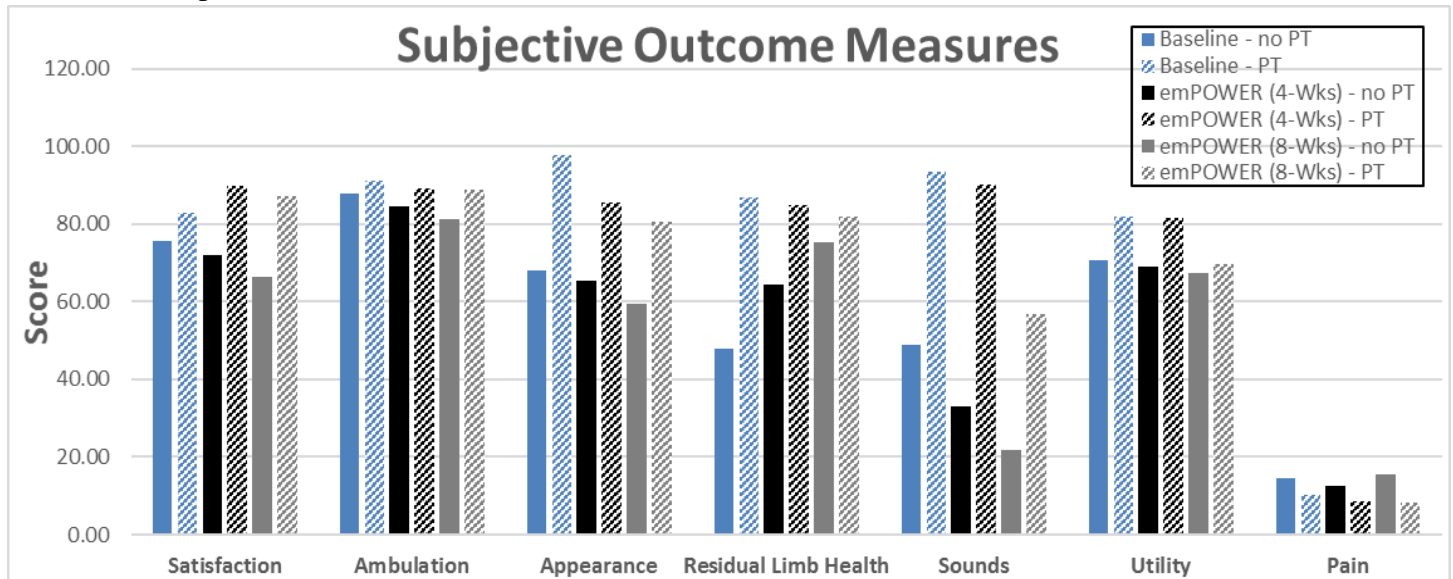


Figure 8: Baseline, 4- and 8-week follow up average scores for the PT and non-PT groups from the PEQ and the PROMIS Pain Interference Scale.

## **Other Achievements**

- One abstract was accepted for presentation at the American Physical Therapy Association (APTA) Combined Sections Meeting (CSM) annual conference, which was held from February 2-5, 2022 in San Antonio, TX. The title for the abstract is:
  - Physical Effects of Isolation Due to COVID-19 on Individual with Transfemoral Amputation

## **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 granted to complete enrollment goals. Advanced funding has been requested and received. Patient clinic visits are increasing at each study site and screenings at each site have been scheduled. We expect to have a significant increase in enrollment during the next quarter.
- Due the population of servicemembers who have undergone osseointegration (OI) and are now 2 years post-surgery, WRNMMC is in the process of submitting an IRB amendment to enroll participants with OI. The local OI team has communicated with the FDA and will continue coordination with them. The SOW has been updated to reflect these changes at WRNMMC.

Study recruitment is less than projected due to COVID-19 recovery efforts. Clinical visits have been slowly increasing over the last year, with a noted uptick in enrollment since September 2022. 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 amputation, 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 subjects who have previously participated in other research studies. Additionally, WRNMMC will recruit patients with OI following IRB/HRPO approval. 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 2 conferences this past year to learn about ongoing and future developments in the fields of prosthetics and limb loss. Members attended the Gait and Clinical Movement Analysis Society annual conference and the Military Health System Research Symposium, where they attended presentations and poster sessions of researchers in associated fields.

Additionally, team members at VANYHHS have provided ongoing trainings to collaborators at JAHVH. These trainings covered all aspects of the rehabilitation protocol including recruitment, randomization, frequency and duration of PT, and study-related physical therapy documentation. Additionally, VANYHHS study staff have provided training materials for JAHVH study staff that detail the procedures for all functional, subjective, neurocognitive, and biomechanical activities.

**How were the results disseminated to communities of interest?**

**American Physical Therapy Association Combined Sections Meeting annual conference**

One abstract was accepted for presentation at the American Physical Therapy Association (APTA) Combined Sections Meeting (CSM) annual conference, which was held from February 2-5, 2022 in San Antonio, TX. The title for the abstract is:

- Physical Effects of Isolation Due to COVID-19 on Individual with Transfemoral Amputation

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

To accomplish the goals and objectives for year 6, we plan to:

- Complete enrollment at all sites and add individuals with OI at WRNMMC.
- Conduct biweekly and quarterly conference calls to monitor recruitment goals/strategies and provide updates.
- Conduct protocol procedures and data collection.
- Continue/complete data analysis for completed subjects.
- 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 the amputation care team, 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?

The Clinical Practice Guidelines associated with prosthetic prescription for Veterans and Service Members with transfemoral amputation 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 amputation 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 Y5. We expect enrollment to continue to increase in the next year. NYHHS, JAHVH, and WRNMMC have continued to meet on a biweekly basis to discuss updates and possible solutions to increase enrollment.

Furthermore, as discussed with Dr. Ghannadian and Mr. Adosci, WRNMMC is in the process of submitting an IRB amendment to enroll servicemembers with OI (now 2 years post-surgery). This patient population has not been explored for this investigation but could serve as a potential source to increase enrollment. The OI-specific protocol has been refined and finalized for this sub-population as part of the IRB amendment. Data for this subpopulation will likely be treated as a separate cohort given the OI protocol-specific changes.

## 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 5 largely due to the COVID-19 pandemic and the subsequent recovery efforts.
- 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 living with amputation
    - 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.
- Enroll participants with OI at WRNMMC

## Changes that had a significant impact on expenditures

Year 5 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 6 extension and enrollment of OI patients. Advanced funding has been requested and 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.**

Nothing to Report; A protocol paper is expected to be published in January 2023.

### **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.
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: 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 submitted the Combined Sections Meeting are included below:

## Physical Effects of Isolation Due to COVID-19 on Individual with Transfemoral Amputation

**Background and Purpose:** Health effects of social isolation have been previously researched in the general population, with evidence suggesting an increase in risk of premature death at a rate comparable to cigarette smoking.<sup>1</sup> After a yearlong isolation in the United States due to COVID-19, the physical effects have begun to manifest.<sup>2</sup> Individuals with lower limb loss are a unique population that may be more susceptible to physical decline in isolation. This population often presents with complicated medical histories, psychosocial challenges, and unique mobility needs which may amplify the effects of prolonged isolation.<sup>3</sup>

**Case Description:** This case study examines the impact of a 13-month isolation on the strength and mobility an individual with transfemoral amputation. The patient is a 67-year-old male with history of hypertension, peripheral vascular disease, and heart disease. He reported a sedentary lifestyle throughout isolation. He did not contract COVID-19, nor develop any additional conditions to affect his health during isolation. This patient was assessed prior to and 13-months after isolation. Data gathered included biomechanical gait analysis at speeds of 0.7 m/s and 1.0 m/s, manual muscle strength testing (MMT), the Amputee Mobility Predictor (AmpPro), and the 6 Minute Walk Test (6MWT).

**Outcomes:** Pre-isolation lower limb strength was 5/5 for residual limb hip extension, and 5/5 in all major muscle groups on the intact limb, while post-isolation all decreased to 4/5. AmpPro scores declined from 33 to 29 out of a possible 47 points pre-and-post isolation, respectively. Distance on the 6MWT decreased by 77 meters (m) post-isolation, from 209m to 132m. Gait analysis revealed a shorter and wider stride, and decrease in peak hip flexion range of motion (ROM) from pre-to-post isolation.

**Discussion:** The decline observed in this patient post-isolation is likely a consequence of his reported sedentary lifestyle during the pandemic. The decrease in strength may be indicative of muscle mass lost due to inactivity and may have resulted in the restricted hip flexion ROM observed during gait post-isolation. The pre-and-post differences in AmpPro scores surpassed the minimal detectable change (MDC) of 3.4 points for this test, representing a decline in functional mobility.<sup>4</sup> Similarly, the change in 6MWT results exceeded the MDC of 55m for this test, suggesting cardiovascular deconditioning and reduced endurance.<sup>5</sup> Finally, the shortened and widened stride observed post-isolation is typical of pathological gait of an individual with balance impairment.<sup>6</sup> The overall findings for this patient suggest that quarantine led him to live a more sedentary lifestyle resulting in reduced strength, mobility, endurance, and balance. While the effects of quarantine here represent a single case study, these findings may be indicative of similar physical detriments in a larger population of individuals with lower limb loss. Therefore, it is critical that physical therapy interventions be implemented as soon as possible to return this population to pre-pandemic physical health.