

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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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:

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.

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	-
<i>Milestone Achieved: Local IRB approval at each site</i>	100%	9/25/18	-
<i>Milestone Achieved: HRPO approval for all protocols</i>	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	-
<i>Milestone Achieved: Project Research staff hired and trained</i>	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: 53% WRNMMC: 0%	ongoing	-
<i>Milestone Achieved: Study begins</i>	100%	9/2018	-
<i>Milestone Achieved: First subject consented, screened, and enrolled</i>	100%	10/2018	-
Major Task 4: Data Collection			
Subtask 1: Prosthetic Setup			
Alignment and fit of current prosthesis	NYHHS:47% WRNMMC:0%	ongoing	-
Fitting of powered prosthesis	NYHHS: 47% WRNMMC: 0%	ongoing	-
Subtask 2: Conduct Study			
Collect biomechanical, functional, pain, and neurocognitive data according to the project timeline	NYHHS: 47% WRNMMC: 0%	ongoing	-
<i>Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled</i>	Overall: 27%	ongoing	7/2021
<i>Milestone Achieved: 50% of participants have completed the 8-week physical therapy program and data has been collected.</i>	Overall: 20%	ongoing	2/2021
<i>Milestone Achieved: All subjects have completed the research protocol</i>	Overall: 23%	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: 27%	ongoing	-
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	-

Subtask 2: Manuscript Preparation:			
Roles for dissemination of findings (abstracts, scientific presentations and manuscripts) assigned			-
Plan for Subsequent clinical trials initiated	-	-	-
<i>Milestone Achieved: Analysis of 50% of patients</i>	-	-	-
<i>Milestone Achieved: 100% of Analysis complete</i>	-	-	-
<i>Milestone Achieved: Report findings from overall studies</i>	-	-	-
<i>Milestone Achieved: Manuscript Preparation and plans for next clinical trial</i>	-	-	-

What was accomplished under these goals?

Major Activities and specific objectives for Year 2 include:

COVID Administrative Hold

The VA Office of Research and Development has suspended all non-essential, in-person patient visits due to the ongoing COVID-19 pandemic. Protocol activities will resume upon further notice from VA ORD and any other guidance from the Department of Defense. However, a request to remove the administrative hold has been requested and we believe research activities will resume by 11/2020. There has been no enrollment or data collection since March 2020. To date, 8 subjects have been enrolled at VA New York Harbor Healthcare System (NYHHS). Preliminary data is presented below. Of note, a 1-year no-cost extension of the performance period was granted on 6/16/2020.

IRB Submission

Local IRB and HRPO approvals have been achieved at both NYHHS and WRNMMC. Approval dates are listed in Table 1. We are in the process of adding the James A. Haley VA Medical Center in Tampa, FL to increase our enrollment once protocol activities resume. Initial local IRB submission for the Tampa VA was performed on 06/01/2020, and the revised submission package was then forwarded by the local Privacy Officer and Information Security Officer for IRB and R&D committee review on 08/03/2020. Local site committee review and approval are pending as of the time of this report. NYHHS and the Narrows Institute discussed a project modification with grant specialist Christopher Meinberg on 2/21/2020 for a plan to increase enrollment. As agreed during the meeting, NYHHS and the Narrows will submit a project modification package to Mr. Meinberg to add the James A. Haley VA Medical Center (Tampa) as a recruitment and performance site. An IRB application was submitted for approval at the Tampa site and a subaward is under development. Once we receive local approval, the modifications will be submitted to HRPO for approval. Furthermore, the statement of work will be modified to add the Tampa site and to modify roles at WRNMMC. A revised budget for all sites will also be submitted to Mr. Meinberg. No additional funding will be requested at this time. We plan to submit the modification during Y4Q1, but we may experience some delays due to the ongoing pandemic.

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
James A Haley VA Medical Center	Submitted for Initial Review on 06/01/2020. Forwarded to IRB and R&D Committee review on 08/03/2020. Pending local site approval.	-

Recruitment and Enrollment

Table 2 outlines current enrollment at each site. At NYHHS, 11 subjects have been screened. There were 3 screen fails, and 8 subjects have been consented. Six subjects have completed all protocol activities and 0 have withdrawn. Two subjects are ongoing. Currently no subjects have been enrolled at WRNMMC. An administrative hold due to COVID-19 has suspended recruitment and enrollment until further guidance from VA ORD and DoD. We believe recruitment will begin again by 11/2020.

TABLE 2: Recruitment and Enrollment

Site	Screened	Screen Failure	Enrolled	Withdrawn
NYHHS	11	3	8	0
WRNMMC	-	-	-	-
Total	11	3	8	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.

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

Figure 1: Project Overview

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.

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 all completed subjects (n=6).

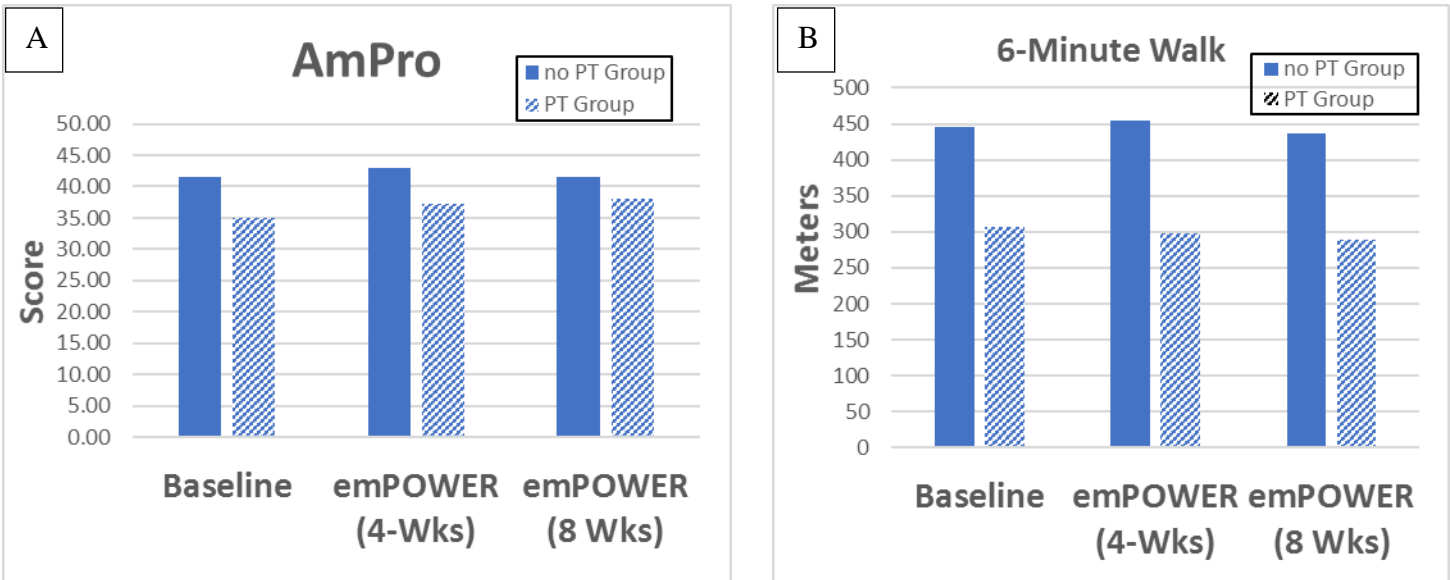


Figure 2: A) 6-min walk distances at baseline (ESR foot) and 4- and 8-weeks later using the emPOWER device for subjects randomized to the PT and non-PT groups. B) AmpPro scores comparing ESR versus emPOWER at 4- and 8-weeks for subjects randomized to PT or non-PT groups.

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.

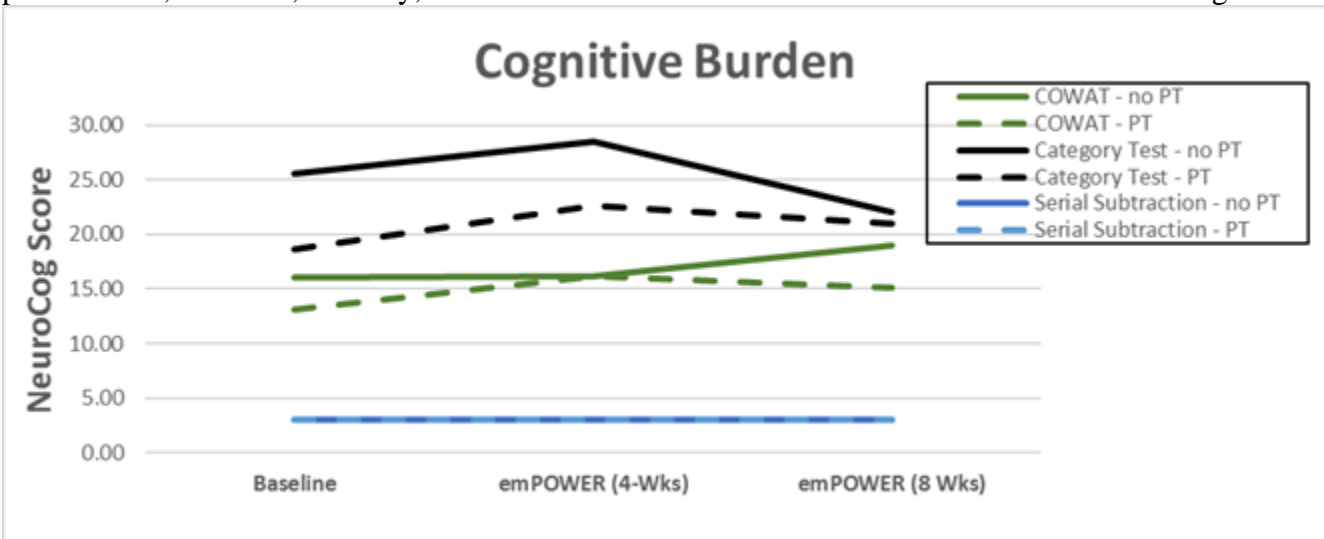


Figure 3: Average cognitive burden scores for subjects randomized to the PT and non-PT groups at baseline (ESR foot) and again 4- and 8- weeks later using the emPOWER. Higher scores indicate higher cognitive ability and less burden.

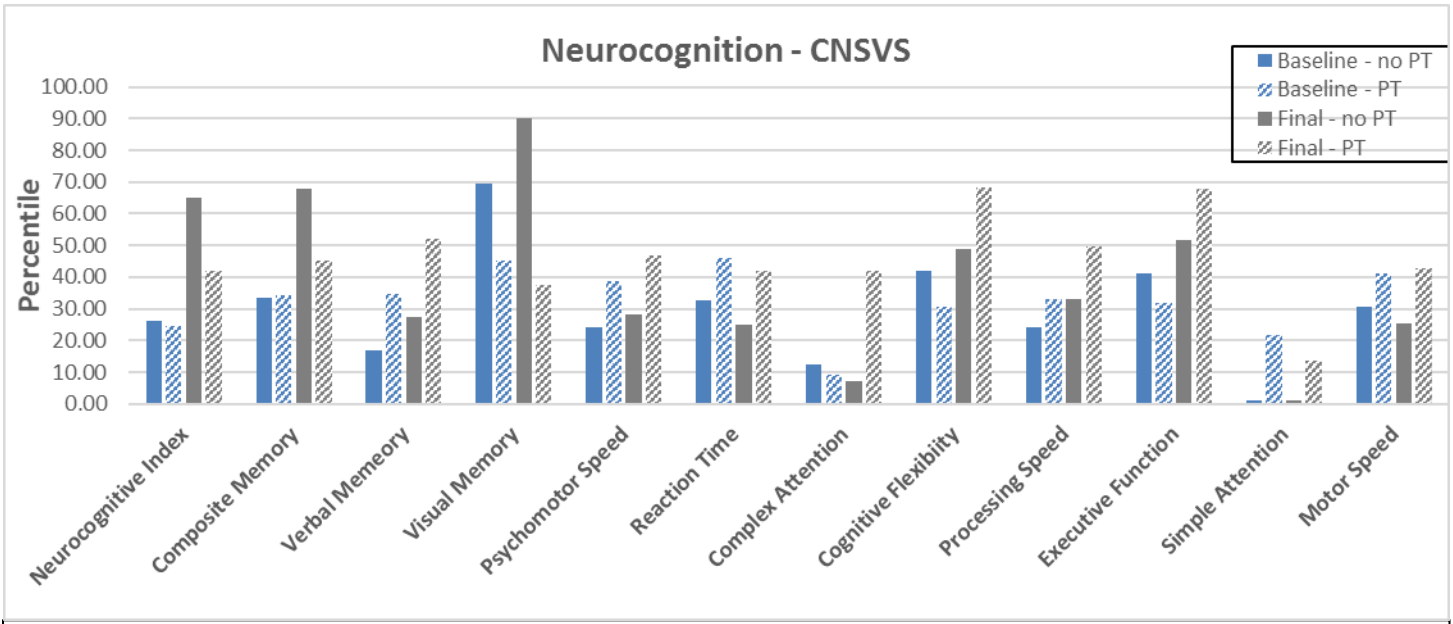


Figure 4: Average scores for the different neurocognitive domains, assessed utilizing CNSVS, which is a computerized assessment tool that utilizes validated and reliable computerized neuropsychological tests to evaluate the neurocognitive status of patients. Neurocognition is measured at baseline and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

Biomechanical Analysis

Figures 5, 6, and 7 represent sagittal plane kinematic, kinetic, and power scalar averages for 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)

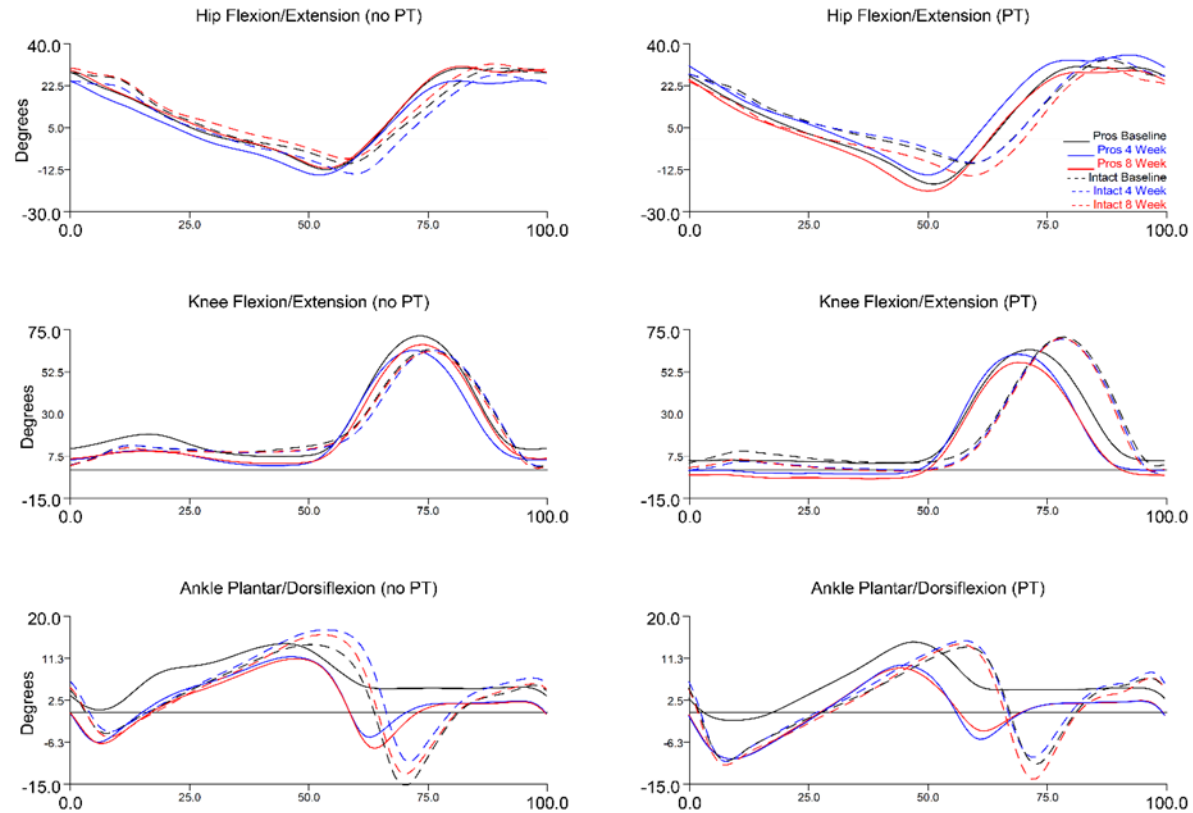


Figure 5: Level-ground sagittal plane kinematics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The intact limb is represented by dotted lines. The prosthetic limb is represented by solid lines.

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

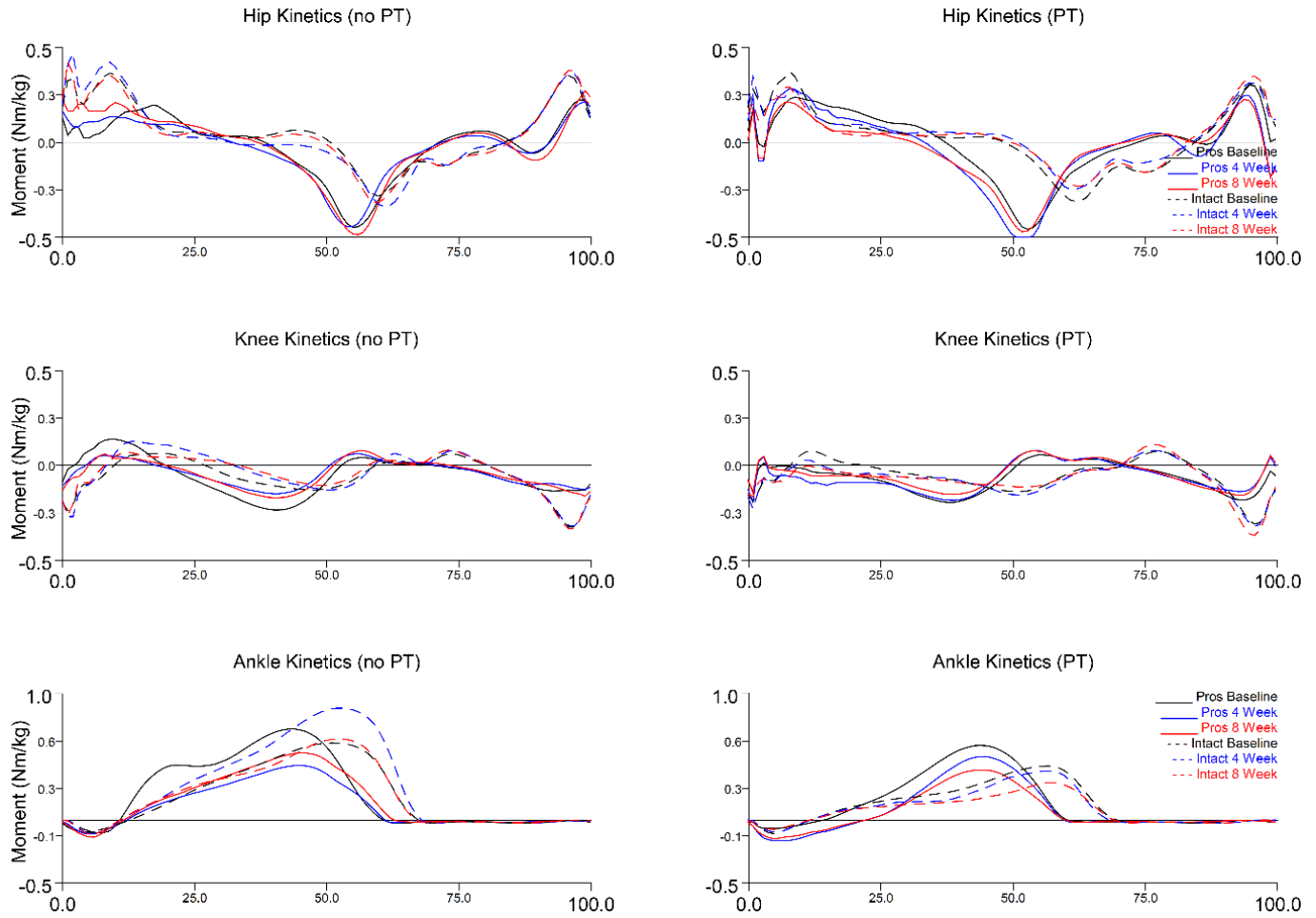


Figure 6: Level-ground sagittal plane kinetics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

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

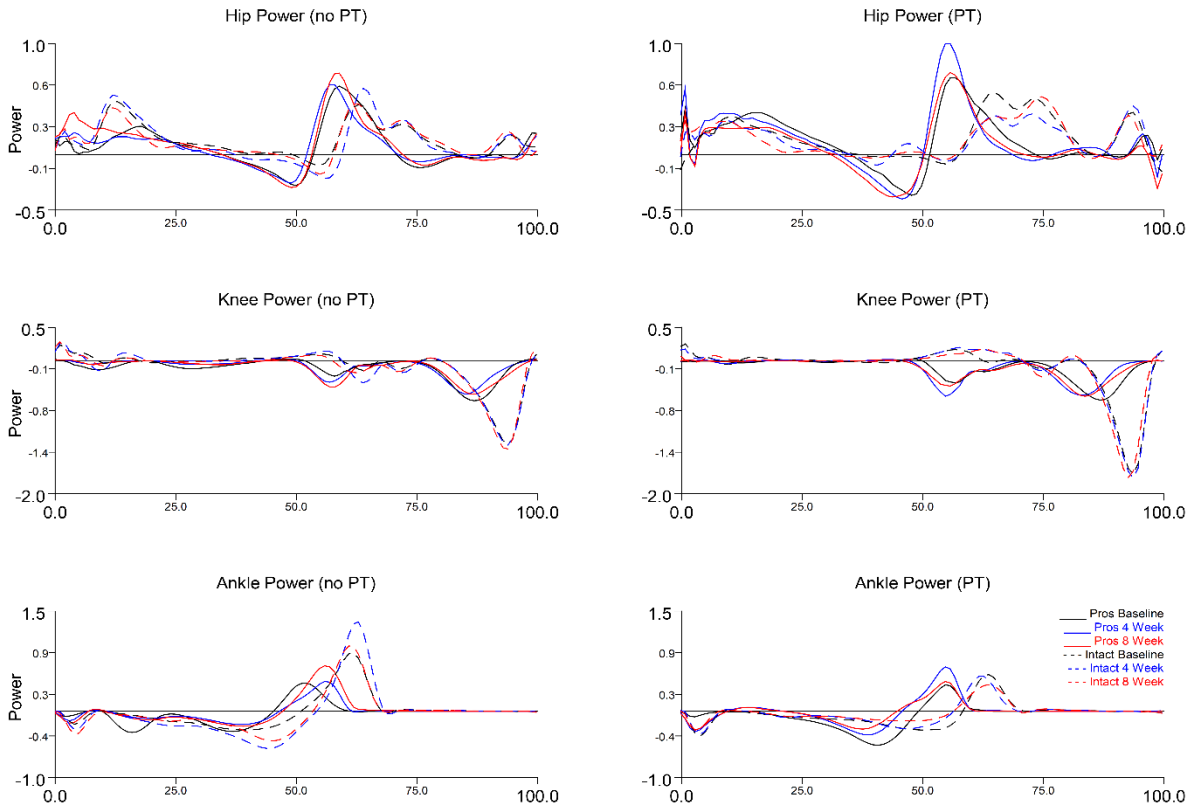


Figure 7: Level-ground sagittal plane joint powers for the PT and non-PT groups at baseline (Black) and at 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

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.

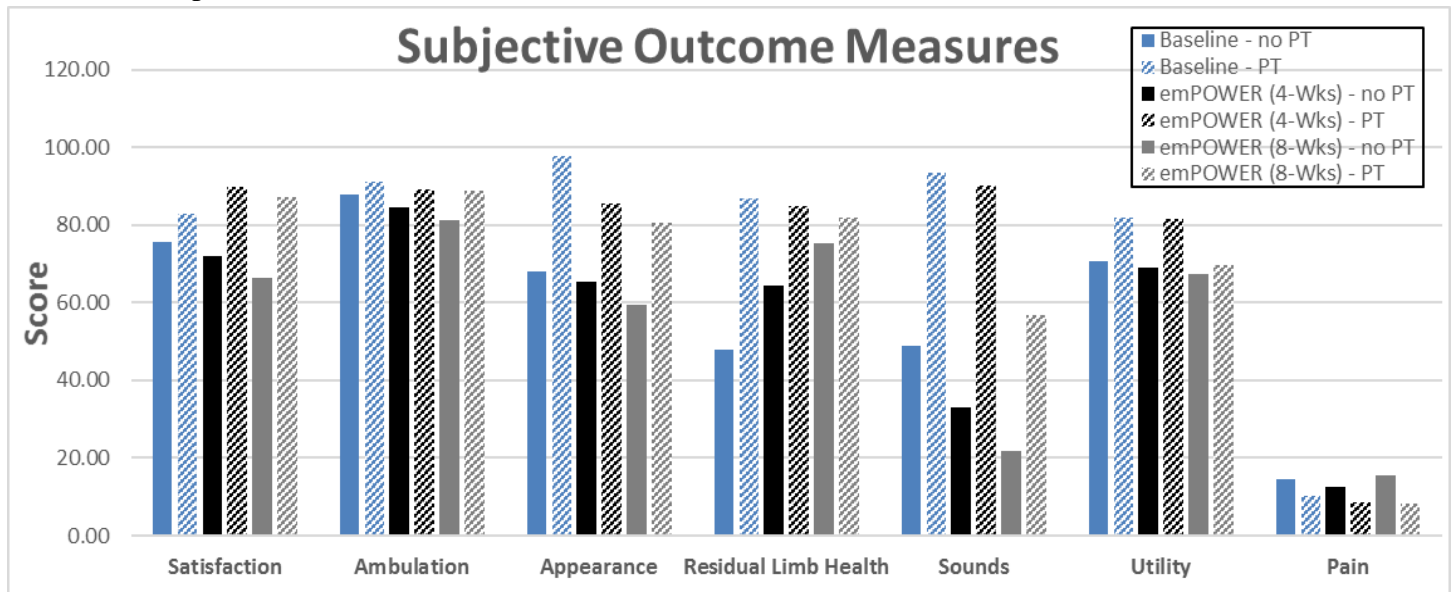


Figure 8: Baseline, 4- and 8-week follow up average scores for the PT and non-PT groups from the PEQ and the PROMIS Pain Interference Scale.

Goals Not Met:

The following goals have not been met:

- Due to the outbreak of the COVID-19 pandemic and as per guidance from the VA Office of Research and Development (ORD), all non-essential patient-related research visits have been placed on an administrative hold. Protocol activities will resume upon further guidance from VA ORD and the Department of Defense.
 - We believe the administrative hold will be lifted by 11/2020
- Projected recruitment is less than expected.
- No subjects have been enrolled at WRNMMC.
- Completion of project modification to add the James A. Haley VA Medical Center as a performance site and achieving local site regulatory approval.
 - We believe this will occur by 11/2020

Study recruitment is less than projected for both sites and has been further delayed due to the COVID-19 pandemic. NYHHS and WRNMMC have continued to meet on a biweekly basis to discuss updates and plans for restarting the protocol. Updated recruitment plans will be implemented at each site to increase enrollment. These strategies include presenting at virtual and in-person local amputation support groups, attending (in-person or virtually) national conferences and local chapter meetings targeted for individuals living with amputation, including civilians from affiliated medical centers and clinics, and continuing our biweekly conference calls. Upon restarting protocol activities, we will also seek participants from 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. We will continue to conduct group quarterly conference calls to review progress to date and discuss any problems that arise.

To meet our enrollment goals, the James A. Haley VA Medical Center is in the process of being added as a performance site. As agreed during our meeting with Mr. Meinberg on 2/21/2020, NYHHS and the Narrows will submit a project modification package for this addition. An IRB application has been submitted for local approval at the Tampa site and once achieved, the appropriate documentation will be submitted to HRPO for approval. The subaward is under development and the Tampa site will also be added to statement of work to outline roles and responsibilities, as well as to modify roles and responsibilities at WRNMMC. A revised budget for all sites will also be submitted. A no-cost extension of 12 months was approved on 6/16/2020.

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

While the project is not intended to provide training and professional development, we hosted a comprehensive training on December 3, 2019. Project management training (data collection, recruitment, and data sharing techniques), as well as a review of the device-specific training and project data to-date were reviewed. The agenda for this training is below.

Dates: December 3, 2019

Place: Adobe Connect and VANTS Line

Subject: Protocol Training for “Effects of a Powered Ankle-Foot Prosthesis and Device-Specific Physical Therapy on Function and Pain for Individuals Living With Transfemoral Limb Loss”

Invited

Participants: Jason Maikos, PhD; Michael Hyre, MS; John Chomack, MS; Michael Poppo, MS, Alexis Sidiropoulos, PhD, Ellen Godwin, PhD, PT; Bradford Hendershot, PhD; Jonathan Gladish, MS, Ashley Knight, PhD (WR);

Agenda

December 3, 2019

Session	Presenter
Specific Aims	JM
Study Timeline/Recruitment	JM
Screening/Enrollment	JM
Biomechanics Protocol	JM
Functional Outcomes	JM
Survey	JM
Cognitive Load	MP/EG
Neurocognitive Assessment	MP/EG

How were the results disseminated to communities of interest?

Nothing to Report. Prior to the global pandemic, we planned to submit abstracts to Military Health System Research Symposium (MHSRS) and Gait and Clinical Movement Analysis Society (GCMAS) annual conferences. Our goal now is to submit abstracts to MHSRS, GCMAS, and the American Society of Biomechanics meetings in 2021.

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

To accomplish the goals and objectives for year 4, we plan to:

- Restart the study protocol at all sites, as permitted by VA ORD, local IRB sites, and DoD.
- Carry out performance site duties at the James A. Haley VA Medical Center
- Complete enrollment at all sites.
- Conduct biweekly and quarterly conference calls to monitor recruitment goals/strategies and provide updates.
- Conduct protocol procedures and data collection, as permitted by VA and DoD.
- Continue/complete data analysis for completed subjects.
- 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?

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

Due to the COVID-19 outbreak, all patient-related research activities have been placed on administrative hold until further guidance from the Department of Defense and the VA Office of Research and Development. Once research activities resume, strategies discussed during team meetings will be implemented to increase enrollment at all sites. Biweekly calls between NYHHS and WRNMMC have continued during this pandemic to discuss site-specific updates. Online, telehealth, and other non-contact recruitment methods will be explored to increase enrollment once research activities resume.

The James A. Haley VA will be added as a third site to complete recruitment/enrollment. An IRB application has been submitted for review.

A year 4 extension without funds was also approved on 6/16/2020, which has extended the performance period of this investigation through 9/14/2021.

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 3 largely due to the COVID-19 pandemic.
- Once the administrative hold is removed, successful 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.
 - 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 3 expenditures were less than projected due to the ongoing pandemic, including less expenditures on study personnel at WRNMMC, prosthetic feet, and supplies/materials. However, expenditures are expected to return toward the projected budget with a year 4 extension and the addition of the Tampa site.

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 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.
Funding Support: CDMRP award number W81XWH-17-2-0014

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-17-2-0014

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: 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 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:	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.
Name:	Binni Khatri
Project Role:	Research Physical Therapist at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Performs all PT-related activities.

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