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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

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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 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, 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
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Unclassified	Unclassified	Unclassified	Unclassified	23	19b. TELEPHONE NUMBER *(include area code)*

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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 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: 53% WRNMMC: 0% JAHVH: 7%	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:47% WRNNMC:0% JAHVH: 7%	ongoing	-
Fitting of powered prosthesis	NYHHS: 47% WRNMMC: 0% JAHVH: 7%	ongoing	-
Subtask 2: Conduct Study	-		
Collect biomechanical, functional, pain, and neurocognitive data according to the project timeline	NYHHS: 47% WRNMMC: 0% JAHVH: 7%	ongoing	-

Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled	Overall: 30%	ongoing	3/2022
Milestone Achieved: 50% of participants have completed the 8-week physical therapy program and data has been collected.	Overall: 20%	ongoing	5/2022
Milestone Achieved: All subjects have completed the research protocol	Overall: 23%	ongoing	9/2022
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: 30%	ongoing	9/2022
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

VA New York Harbor Healthcare System (VANYHHS): The COVID administrative hold was removed on 1/12/2021. Enrollment is ongoing. The most recent local IRB Continuing Review approval was granted 09/12/2021. HRPO Acknowledgement of the Continuing Review Documents was received 10/06/2021.

Walter Reed National Military Medical Center (WRNMMC): The COVID administrative hold was lifted in September 2020. Enrollment is ongoing. The most recent local WRNMMC IRB Continuing Review approval was granted 07/16/2021. HRPO Acknowledgement of the Continuing Review Documents was received 07/28/2021.

James A. Haley Veterans' Hospital (JAHVH): JAHVH was added as a study site in Y4Q3. Enrollment is ongoing.

Protocol Training at James A. Haley Veterans' Hospital

Two separate protocol trainings were held during Y4Q3 to complete the onboarding of JAHVH as a study site. First, on 6/14, the research physical therapist at VANYHHS trained study staff at JAHVH on the emPOWER-specific PT rehabilitation protocol. The training covered all aspects of the rehabilitation protocol including recruitment, randomization, frequency and duration of PT, and study-related physical therapy documentation. Second, on 6/17, the VANYHHS study staff conducted a protocol training for JAHVH study staff, which detailed the procedures for all functional, subjective, neurocognitive, and biomechanical activities. Recruitment plans and study timelines were also discussed to help JAHVH reach their target enrollment specified in the statement of work.

Recruitment and Enrollment

Table 1 outlines current enrollment at each site.

NYHHS: 12 subjects have been screened. There were 4 screen fails, and 8 subjects have been consented. Six subjects have completed all protocol activities and 0 have withdrawn. Two subjects are ongoing. Another participant screening is scheduled on October 22nd. Three other participants are currently being tracked and will be screened in Y5Q1.

WRNNMC: Currently no subjects have been enrolled. One subject has been screened and is expected to be enrolled by the end of October 2021.

JAHVH: 3 subjects have been screened. There were 2 screen fails and 1 subject has been enrolled.

TABLE 1: Recruitment and Enrollment

Site	Screened	Screen Failure	Enrolled	Withdrawn
NYHHS	12	4	8	0
WRNMMC	1	-	0	0
JAHVH	3	2	1	0
Total	**16**	**6**	**9**	**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 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 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 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

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).

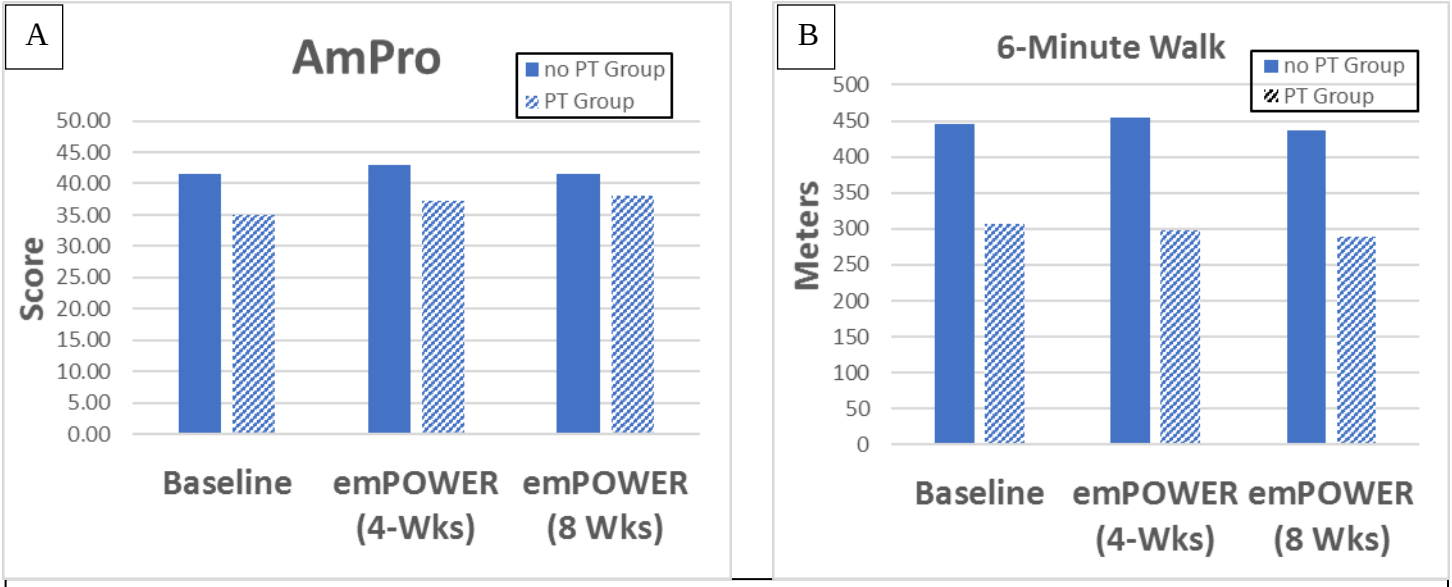

Figure 2: A) 6-min walk distances at baseline (ESR foot) and 4- and 8-weeks later using the emPOWER device for subjects randomized to the PT and non-PT groups. B) AmpPro scores comparing ESR versus emPOWER at 4- and 8-weeks for subjects randomized to PT or non-PT groups.

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.

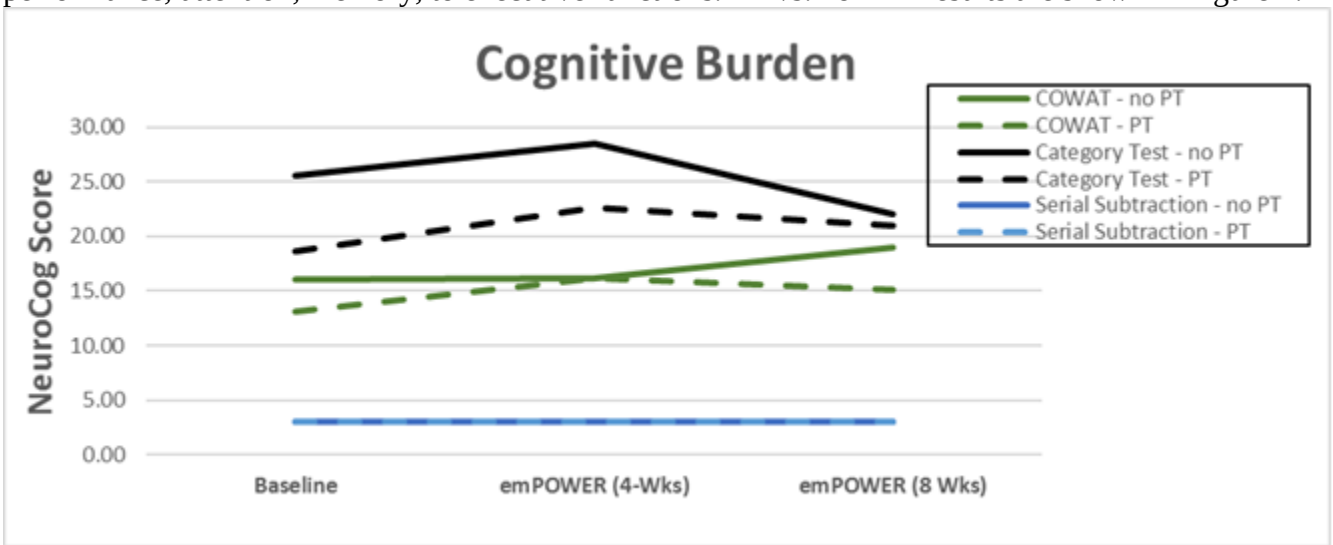

Figure 3: Average cognitive burden scores for subjects randomized to the PT and non-PT groups at baseline (ESR foot) and again 4- and 8- weeks later using the emPOWER. Higher scores indicate higher cognitive ability and less burden.

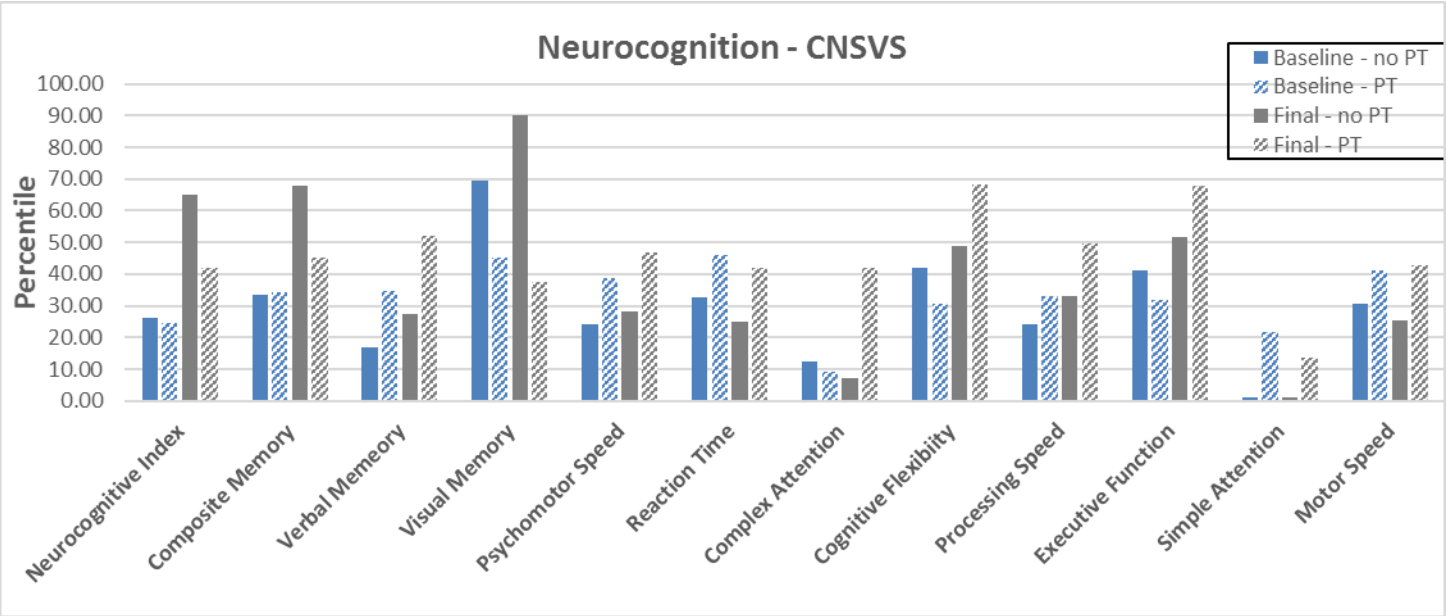

Figure 4: Average scores for the different neurocognitive domains, assessed utilizing CNSVS, which is a computerized assessment tool that utilizes validated and reliable computerized neuropsychological tests to evaluate the neurocognitive status of patients. Neurocognition is measured at baseline and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

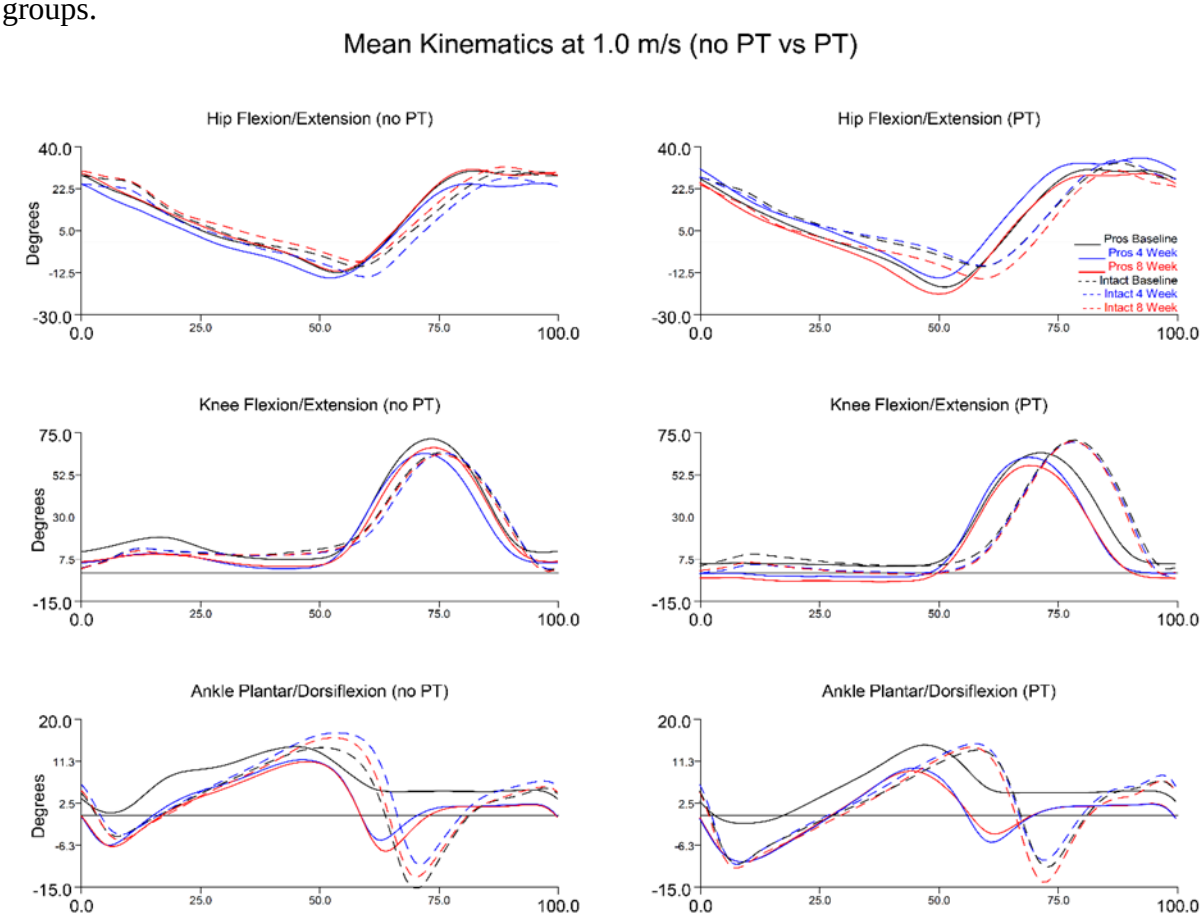

Figure 5: Level-ground sagittal plane kinematics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The intact limb is represented by dotted lines. The prosthetic limb is represented by solid lines.

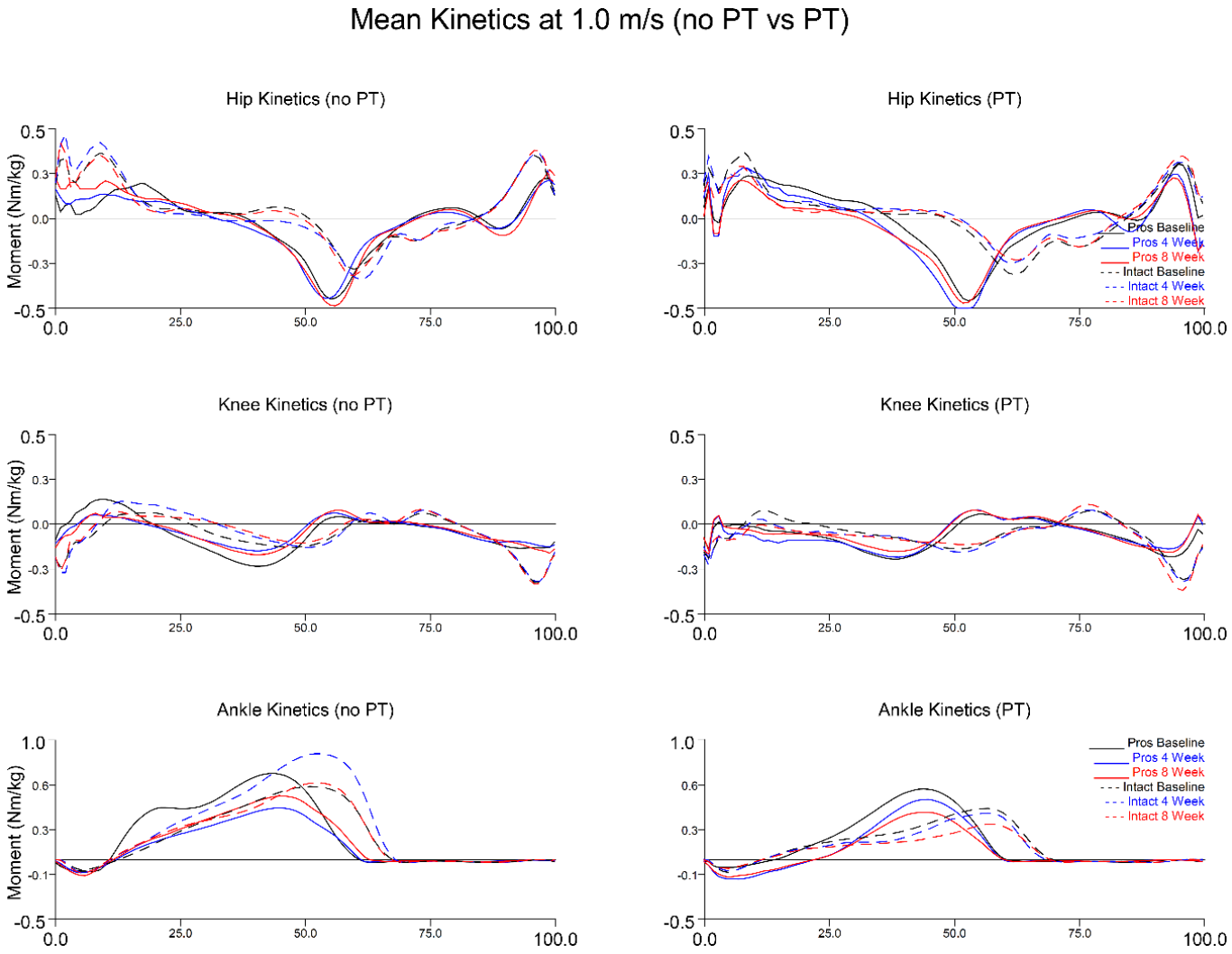

Figure 6: Level-ground sagittal plane kinetics for the PT and non-PT groups at baseline (Black) and after 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

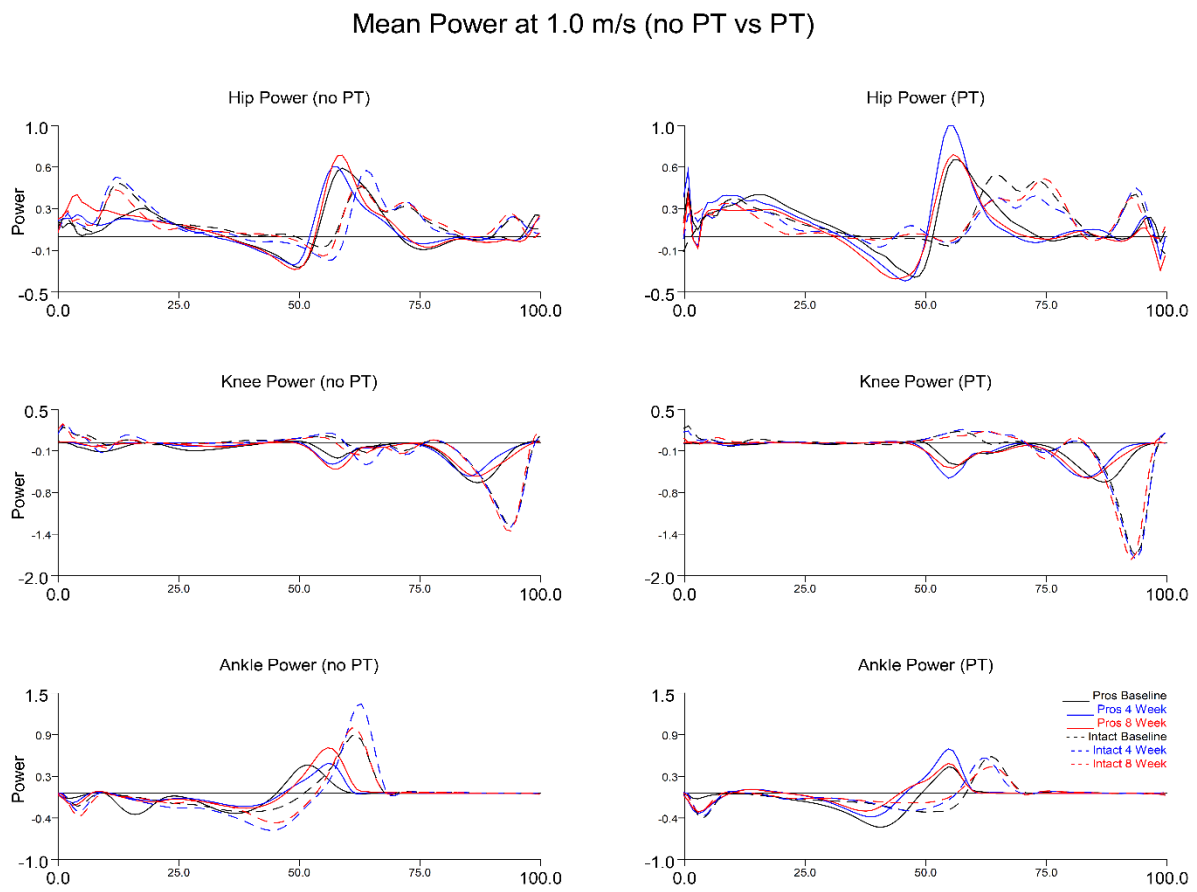

Figure 7: Level-ground sagittal plane joint powers for the PT and non-PT groups at baseline (Black) and at 4-weeks (Blue) and 8-weeks (Red) of emPOWER use. The solid lines represent the prosthetic side; dotted lines represent the intact limb.

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.

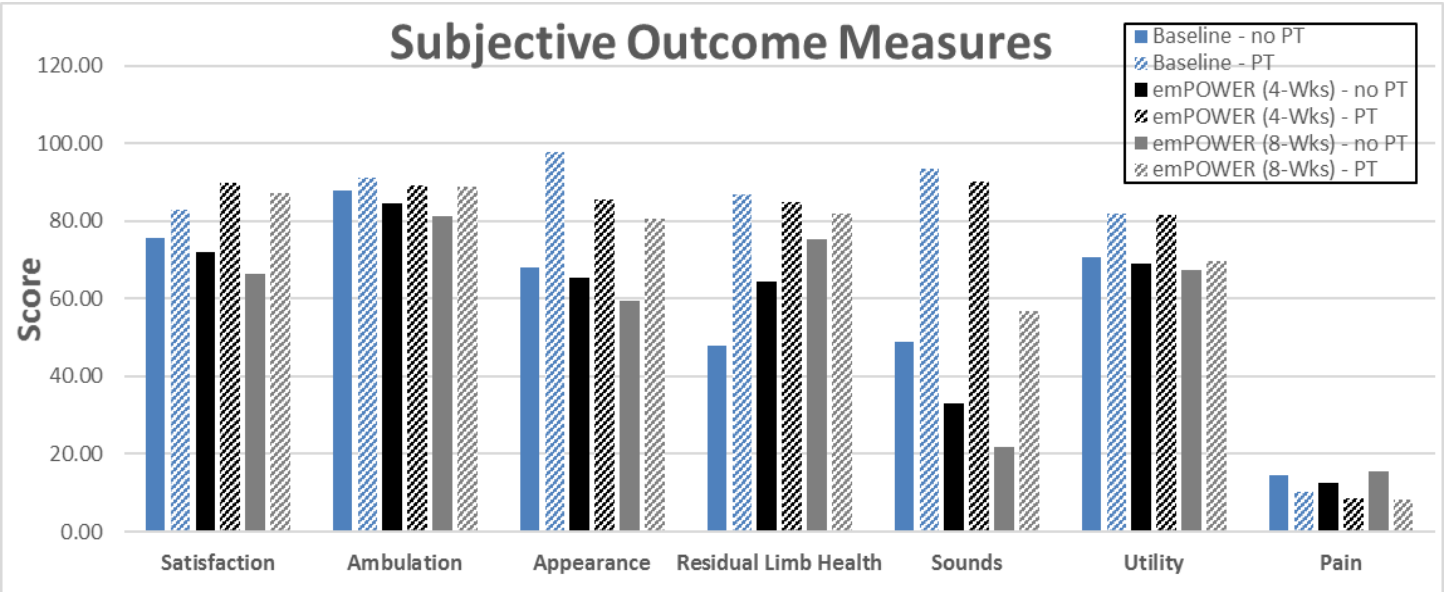

Figure 8: Baseline, 4- and 8-week follow up average scores for the PT and non-PT groups from the PEQ and the PROMIS Pain Interference Scale.

Other Achievements

- One abstract was accepted for poster presentation at the Summer Biomechanics, Bioengineering, and Biotransport Conference, which was held virtually from June 14-18, 2021. The title for the abstract is:
    - Comparative ankle-foot rollover shape analysis of powered and unpowered prosthetic feet in individuals with transfemoral amputation
- One abstract was accepted for a poster presentation at the American Society of Biomechanics annual conference, which was held virtually from August 10-13, 2021.
    - Comparative Ankle-Foot Rollover Shape Analysis of the Effects of Device-Specific Physical Therapy for the Prescription of Powered Feet in Individuals with Transfemoral Amputation
- One abstract was accepted for the Military Health Systems Research Symposium (conference canceled)
    - Comparative Ankle-foot Rollover Shape Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation
- One abstract was accepted for presentation at the American Physical Therapy Association (APTA) Combined Sections Meeting (CSM) annual conference, which is being 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. Patient clinic visits are increasing at each study site and screenings at each site have been scheduled. We expect to have an increase in enrollment during the next quarter.
- No subjects have been enrolled at WRNMMC, though we expect first enrollment by the end of October.

Study recruitment is less than projected due to COVID-19 recovery efforts. Clinical visits have been slowly increasing over the last quarter and patients are resuming in-person appointments. 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 virtual amputation support groups, attending virtual 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. We will continue to conduct group quarterly conference calls to review progress to date and discuss any problems that arise.

A no-cost extension was approved on 9/27/2021.

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

While the project is not intended to provide training and professional development, two separate protocol trainings were held during Y4Q3 to complete the onboarding of JAHVH as a study site. First, on 6/14, the research physical therapist at VANYHHS trained study staff at JAHVH on the emPOWER-specific PT rehabilitation protocol. The training covered all aspects of the rehabilitation protocol including recruitment, randomization, frequency and duration of PT, and study-related physical therapy documentation. Second, on 6/17, the VANYHHS study staff conducted a protocol training for JAHVH study staff, which detailed the procedures for all functional, subjective, neurocognitive, and biomechanical activities. Recruitment plans and study timelines were also discussed to help JAHVH reach their target enrollment specified in the statement of work.

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Date: June 17th, 2021

Time: 2pm – 4pm ET

Place: Zoom

Subject: JAHVH 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"

Agenda

Thursday, June 17th 2021

Item	Presenter
Study Overview	JM
COVID-19 Discussion	JM
Presentation (Enrollment, Results, Stats)	JM
Protocol Training	
Background and Specific Aims	JM
Screening and Enrollment	JM
Biomechanics (Marker placement, Functional Joints, Protocol)	JM/JC/MP
Functional Outcome Measures	JM/JC
Surveys	JM/JC
Cognitive Load	JM
Neurocognitive	JM/JC
Regulatory Updates	MH
Open Forum	All
Closing Remarks, Questions, Concerns	All

How were the results disseminated to communities of interest?

Summer Biomechanics, Bioengineering, and Biotransport Conference
One abstract was accepted for poster presentation at Summer Biomechanics, Bioengineering, and Biotransport Conference, which was held virtually from June 14-18, 2021.

- Comparative ankle-foot rollover shape analysis of powered and unpowered prosthetic feet in individuals with transfemoral amputation

American Society of Biomechanics annual conference
One abstract was accepted for a poster presentation at the American Society of Biomechanics annual conference, which was held virtually from August 10-13, 2021.

- Comparative Ankle-Foot Rollover Shape Analysis of the Effects of Device-Specific Physical Therapy for the Prescription of Powered Feet in Individuals with Transfemoral Amputation.

Military Health Systems Research Symposium
One abstract was accepted for the Military Health Systems Research Symposium (conference canceled)

- Comparative Ankle-foot Rollover Shape Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation

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 is being 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 5, we plan to:

- 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.
- Continue/complete data analysis for completed subjects.
- Presentation of abstracts at accepted 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

Due to the COVID-19 outbreak, patient recruitment is less than expected. Strategies discussed during team meetings will be implemented to increase enrollment at all sites. Biweekly calls between VANYHHS and each site have continued during this pandemic to discuss site-specific updates. Online, telehealth, and other non-contact recruitment methods will continue to be explored to increase enrollment.

Furthermore, JAHVH was added as a third site to complete recruitment/enrollment of subjects who are randomized to the biomechanics protocol.

A year 5 extension without funds was also approved on 9/27/2021, which has extended the performance period of this investigation through 9/14/2022.

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 4 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.

Changes that had a significant impact on expenditures

Year 4 expenditures were less than projected due to the ongoing pandemic, including less expenditures on materials, supplies, and some salaries. However, expenditures are expected to return toward the projected budget with a year 5 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.

Summer Biomechanics, Bioengineering, and Biotransport Conference
One abstract was accepted for poster presentation at SB3CConference, which was held virtually from June 14-18, 2021.

- Comparative ankle-foot rollover shape analysis of powered and unpowered prosthetic feet in individuals with transfemoral amputation

American Society of Biomechanics annual conference
One abstract was accepted for a poster presentation at the ASB annual conference, which was held virtually from August 10-13, 2021.

- Comparative Ankle-Foot Rollover Shape Analysis of the Effects of Device-Specific Physical Therapy for the Prescription of Powered Feet in Individuals with Transfemoral Amputation.

Military Health Systems Research Symposium
One abstract was accepted for the MHSRS (conference canceled)

- Comparative Ankle-foot Rollover Shape Analysis of Powered and Unpowered Prosthetic Feet in Individuals with Transfemoral Amputation

American Physical Therapy Association Combined Sections Meeting annual conference
One abstract was accepted for presentation at the APTA CSM, which is being 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

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:	Christopher Fantini, MSPT, CP, BOC
Project Role:	Co-I at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for 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 NYHHS and assists with IRB at WRNMMC and James A. Haley VA Medical Center. Coordinates data collection and entry from all sites. Provides support and troubleshooting to each site. Tracks and coordinates all study materials for each site.
Funding Support	CDMRP award number W81XWH-17-1-0568
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:	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, coordinated 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:	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:	Samuel Phillips, PhD
Project Role:	PI at JAHVH
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, coordinated local IRB submissions.
Name:	Meghan Kern, DPT
Project Role:	Research Physical Therapist/Study Coordinator at JAHVH
Nearest person month worked:	4
Responsibilities/ Contributions:	Perform all PT-related activities. Assist 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:

Abstracts submitted to the American Society of Biomechanics 2021 annual conference, Summer Biomechanics, Bioengineering, and Biotransport Conference, the Combined Sections Meeting are presented below:

EFFECTS OF PHYSICAL THERAPY ON ANKLE-FOOT ROLLOVER SHAPE FOR A POWERED PROSTHESIS

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Introduction

As prosthetic technology evolves, advanced devices for individuals with lower extremity amputation strive to offer more biomimetic features and benefits to users. The objective of this preliminary analysis was to determine the effects of an Empower (Ottobock, Germany) ankle-foot device (PWR), as well as a device-specific physical therapy (PT) intervention, on dynamic function (effective foot length ratio (EFLR), instantaneous radius of curvature (IROC), and radius of curvature (ROC)) for individuals with transfemoral amputation (TFA) compared to traditional energy storing and returning (ESR) prosthetic feet. We hypothesized that the PT group would generate improved roll-over shape characteristics at 4 and 8 weeks compared to the non-PT group.

Methods

Motion capture and kinetic data were captured for 5 people with unilateral TFA during overground walking at the Veterans Affairs New York Harbor Healthcare System (VA NYHHS). Participants were then randomized to two different groups during the initial 4 weeks of acclimation to the PWR foot. One group received the standard of care (non-PT group), which included training on the proper use and care of the foot by the study prosthetist and physical therapist (2 participants). The second group also received standard of care, but additionally underwent twice weekly, device-specific PT sessions with the study physical therapist (3 participants) (PT group). Neither group received PT between the 4-week and 8-week data collections. The PT program specifically targeted strengthening muscle groups to potentially improve the effectiveness of the PWR foot. Center of pressure (COP) data were transformed into the shank coordinate system during single limb stance. EFLR, a measure of the percentage of the foot that is effectively used during a step, was calculated as the distance from the prosthetic heel to the most anterior point of the COP progression divided by the overall length of the foot. Circular arcs of best fit were also applied to the COP data to determine roll-over shape characteristics, such as height-normalized ROC [1]. The IROC was calculated by evaluating the first derivative of COP forward travel with respect to shank angle. The peak IROC is representative of the fastest COP forward travel.

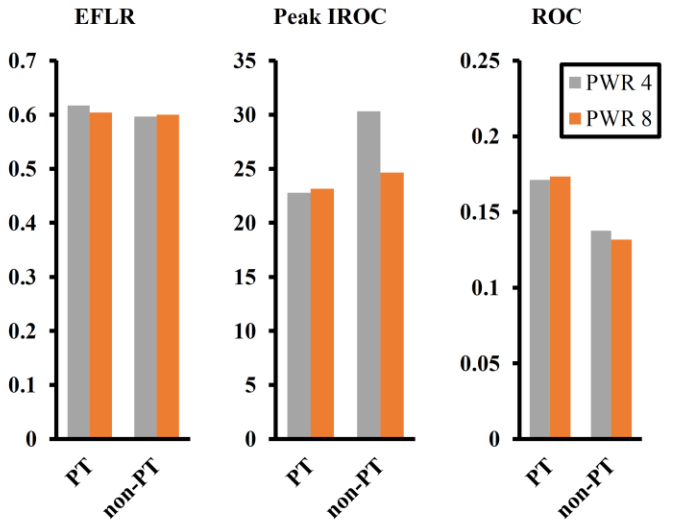

Figure 1: Comparison of PT and non-PT groups for average EFLR, Peak IROC (cm), and height-normalized ROC.

Results and Discussion

Although currently only a small sample size, PT intervention may slightly improve EFLR after the 4-week PT intervention (0.62) compared to the non-PT group (0.60). This may indicate that a device-specific PT intervention can improve anterior progression of the COP during single-leg stance, improving the walking efficiency of the PWR foot. However, the acute effects were not sustained beyond the PT intervention as shown by the lower EFLR (0.60) at 8-weeks in Figure 1. This suggests the need for a more-focused home exercise program to help sustain the long-term EFLR improvements. Figure 1 also shows that the non-PT group produced slightly higher peak IROC (PWR 4: 30.3 cm; PWR 8: 24.6 cm) compared to the PT group (PWR 4: 22.8 cm; PWR 8: 23.2 cm) which suggests improved stability in the non-PT group [2]. PT training focused on initiating pelvis movement may have promoted a smoother transition from heel to toe rocker. The non-PT group (PWR 4: 0.14; PWR 8: 0.13) showed reduced ROC compared to the PT group (PWR 4: 0.17; PWR 8: 0.17). This could suggest improved stability for the PT group during single leg stance because the foot is rotating about a larger rocker which may be resultant from focused muscle strengthening over the 4-week intensive PT program.

Significance

Although large changes in roll-over shape parameters have been shown to affect aspects of gait, it is unclear if the changes seen in this study are clinically relevant. The PT group is showing trends of improvement in some parameters and may generate benefits over the standard of care. These results can inform clinicians of the benefits of prescribing the PWR foot along with a device-specific treatment.

Acknowledgments

This work was supported by a DoD Orthotics and Prosthetics Outcomes Research Programs grant (W81XWH-17-1-0568). We would also like to acknowledge our collaborators at Walter Reed National Military Center.

References

[1] Hansen, A.. et al. *Clinical biomechanics (Bristol, Avon)*, *19*(4), 407–414, 2003.
[2] Curtze, C. Et al. *Journal of biomechanics*, *42*(11), 1746–1753, 2009.

COMPARATIVE ANKLE-FOOT ROLLOVER SHAPE ANALYSIS OF POWERED AND UNPOWERED PROSTHETIC FEET IN INDIVIDUALS WITH TRANSFEMORAL AMPUTATION

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INTRODUCTION

As prosthetic technology evolves, advanced devices for individuals with lower extremity amputation strive to offer more biomimetic features and benefits to users. The Empower (Ottobock, Germany) is one of the most advanced ankle-foot devices currently on the market offering powered push-off at terminal stance. As this technology becomes more widely available, it is important to understand how these devices affect critical gait parameters, such as ankle-foot roll-over shape characteristics. The objective of this preliminary analysis was to determine the effects of using an Empower ankle-foot device (PWR), as well as a device-specific PT intervention, on dynamic function (effective foot length ratio (EFLR), instantaneous radius of curvature (IROC), and radius of curvature (ROC)) for individuals with transfemoral amputation (TFA) compared to traditional energy storing and returning (ESR) prosthetic feet.

Ankle-foot roll-over shape characteristics may be critical in advancing our understanding of the most effective prosthetic designs, which can aid in evidence-based clinical practice and prosthesis prescription guidelines. We hypothesized that the PWR foot would generate roll-over shape characteristics that would suggest improved dynamic functionality compared to ESR feet. We also hypothesized that the PT group would generate improved roll-over shape characteristics at 4 and 8 weeks compared to the non-PT group.

METHODS

Motion capture and kinetic data were captured for 5 people with unilateral TFA during overground walking at the Veterans Affairs New York Harbor Healthcare System (VA NYHHS). Participants were biomechanically assessed at baseline on their current ESR foot and then fit with the Empower device. Participants were then randomized to two different groups during the initial 4 weeks of acclimation to the PWR foot. One group received the standard of care (non-PT group), which included training on the proper use and care of the foot by the study prosthetist and physical therapist (2 participants). The second group also received standard of care, but additionally underwent twice weekly, device-specific PT sessions with the study physical therapist (3 participants) (PT group). The PT program specifically targeted strengthening muscle groups to potentially improve the effectiveness of the PWR foot. Each patient completed a baseline data collection using their ESR foot as well as data collections after acclimating to the PWR foot for 4 and 8 weeks. Center of pressure (COP) data were transformed into the shank coordinate system during single limb stance. EFLR, a measure of the percentage of the foot that is effectively used during a step, was calculated as the distance from the prosthetic heel to the most anterior point of the COP progression divided by the overall length of the foot. Circular arcs of best fit were also applied to the COP data to determine roll-over shape characteristics, such as height-normalized ROC [1]. The IROC was calculated by evaluating the first derivative of COP forward travel with respect to shank angle. The peak IROC is representative of the fastest COP forward travel.

RESULTS

Figure 1 shows that EFLR of the ESR foot at baseline had a value of 0.67±0.04. The PWR foot at 4- and 8-weeks had EFLR values of -0.61±0.04 and 0.60±0.05, respectively for all subjects (n=5). A one-way between subjects Analysis of Variance (ANOVA) suggested a trend toward lower EFLR values of the PWR foot at 4- and 8- weeks compared to the ESR foot ($p=0.07$). Furthermore, the PWR foot at 4- and 8- weeks had peak IROC values of 25.8±7.9 cm and 23.8±4.0 cm, respectively, while the ESR foot at baseline had an average peak IROC value of 31.5±10.7 cm, although differences were not significantly different ($p=0.37$ and $p=0.17$ for 4- and 8- weeks respectively). The

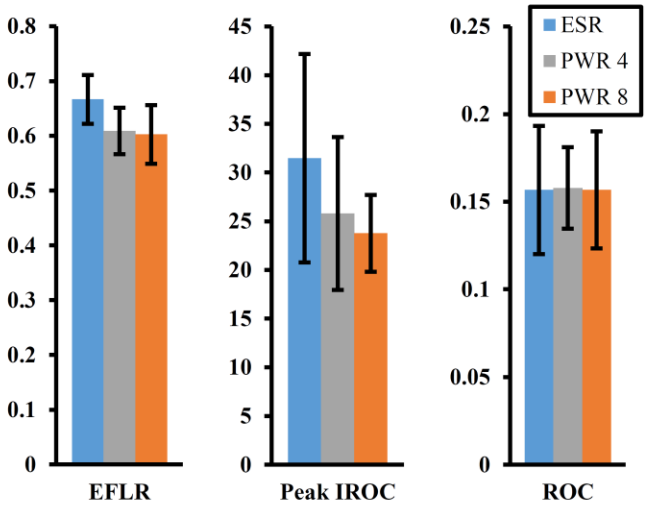

Figure 1: Average EFLR, Peak IROC (cm), and height-normalized ROC for ESR, PWR 4, and PWR 8.

height-normalized ROC of the ESR and PWR feet at 4- and 8- weeks were nearly identical (0.16±0.04 ESR; 0.16±0.02 PWR 4; 0.16±0.03 PWR 8).

Figure 2 represents a comparison of ankle-foot rollover shape characteristics between the PT and non-PT PWR groups, though statistical analysis between these groups was not conducted due to the small sample size. Figure 2 shows that the EFLR for the PT group after 4 weeks had a value of 0.62±0.05, while the non-PT group after 4 weeks had an EFLR value of 0.60±0.05. The EFLR of the PT and non-PT groups was similar at 8 weeks (0.60±0.07 and 0.60±0.06, respectively). After 4 weeks, the PT group averaged peak IROC values of 22.8±4.4 cm compared to the non-PT group 30.3±11.9 cm, however peak IROC results may be skewed by an outlier. Finally, the height-normalized ROC for the PT group at 4- and 8- weeks were both 0.17±0.01. The non-PT group had height-normalized ROC values of 0.14±0.03 at 4 weeks and 0.13±0.05 at 8 weeks.

DISCUSSION

The ELFR of the PWR foot at both 4- and 8-weeks showed a trend of being reduced in comparison to the ESR foot. This indicates that the COP did not progress as far anteriorly during single leg stance, which may correlate to a reduced ankle lever arm in late stance, decreasing walking efficiency. Reduced EFLR effectively shrinks the lever arm, potentially limiting the transmission of joint power that the PWR foot is designed to produce. This could highlight an area of improvement for the PWR foot as ESR foot designs may emulate more efficient passive mechanical properties. Although currently only 3 subjects, the PT intervention may slightly improve EFLR after the 4-week PT intervention compared to the non-PT group. This may indicate that a device-specific PT intervention can improve anterior progression of the COP during single-leg stance, improving the walking efficiency of the PWR foot. However, the acute effects were not sustained beyond the PT intervention as shown by the lower EFLR at 8-weeks in Figure 2. This suggests the need for a more-focused home exercise program to help sustain the long-term EFLR improvements. As more participants complete the protocol, EFLR may become a key parameter that shows improvement from a PT intervention.

The PWR foot also demonstrated decreased forward travel, as indicated by lower peak IROC compared to ESR feet, which suggests reduced stability [2]. Figure 2 shows that the non-PT group showed

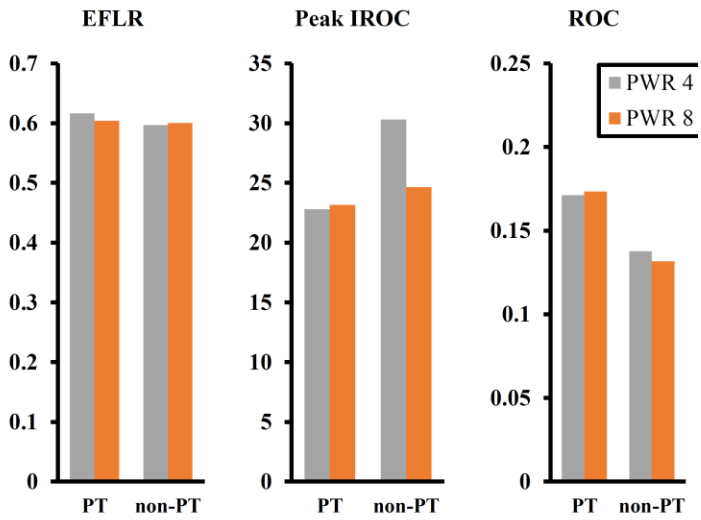

Figure 2: Comparison of PT and non-PT groups average EFLR, Peak IROC (cm), and height-normalized ROC.

slightly higher peak IROC compared to the PT group however, the non-PT group saw a reduction in peak IROC from 4 to 8 weeks. PT training focused on initiating pelvis movement may have promoted a smoother transition from heel to toe rocker.

This preliminary data set showed no overall differences in ROC between the ESR and PWR feet. Potential differences in ROC can be seen between the PT and non-PT groups, though ROC values did not change from 4 to 8 weeks for either group. The non-PT group showed reduced ROC compared to the PT group. This result could suggest improved stability for the PT group during single leg stance because the foot is rotating about a larger rocker which may be resultant from focused muscle strengthening over the 4-week intensive PT program.

Although large changes in roll-over shape parameters have been shown to affect aspects of gait, it is unclear if the changes seen in this study are clinically relevant. Of note, the PWR foot is specifically designed to provide powered plantarflexion at terminal stance and is therefore not active during the single limb stance phase in which this analysis was conducted. This preliminary analysis of ankle rollover shape characteristics suggests that overall, the PWR foot may exhibit less efficient passive mechanical properties than the ESR feet. The PT group is showing trends of improvement in some parameters and may generate benefits over the standard of care. These results can inform clinicians of the benefits of prescribing the PWR foot along with a device-specific treatment. Additionally, manufacturers can design new componentry and devices to improve the current design with more attention to the passive components.

ACKNOWLEDGEMENTS

This work was supported by a DoD Orthotics and Prosthetics Outcomes Research Program grant (W81XWH-17-1-0568). We would also like to acknowledge our collaborators at Walter Reed National Military Medical Center.

REFERENCES

[1] Hansen, A. et al. *Clinical biomechanics (Bristol, Avon)*, *19*(4), 407–414, 2003.

[2] Curtze, C. et al. *Journal of biomechanics*, *42*(11), 1746–1753, 2009.

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.[1] After a yearlong isolation in the United States due to COVID-19, the physical effects have begun to manifest.[2] 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.[3]

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.[4] Similarly, the change in 6MWT results exceeded the MDC of 55m for this test, suggesting cardiovascular deconditioning and reduced endurance.[5] Finally, the shortened and widened stride observed post-isolation is typical of pathological gait of an individual with balance impairment.[6] 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.