AWARD NUMBER: W81XWH-17-2-0014

TITLE: Criteria for Advanced Prosthetic Foot Prescription

PRINCIPAL INVESTIGATOR: Jason Maikos, PhD

CONTRACTING ORGANIZATION: Narrows Institute for Biomedical Research and Education
Brooklyn, NY

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

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6. AUTHOR(S)
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U.S. Army Medical Research and Development Command
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14. ABSTRACT

Prescription of prosthetic ankle-foot devices within the Veterans Affairs (VA) and Department of Defense (DoD) healthcare systems is often based on anecdotal evidence or manufacturer driven research. This study proposes to determine which patient goals and outcome measures are most indicative of an appropriate ankle-foot prosthesis that will yield the most successful and appropriate prescription. This investigation is a 4-site, 8-week, randomized, cross-over clinical trial. Participants randomly receive 3 prosthetic feet (Energy storing and returning (ESR), Articulating, and Powered) with duplicate sockets. Each device is worn for 1 week of home use. Following each 1-week session, participants are evaluated with several functional measures and subjective surveys. A subset of participants is randomly chosen to undergo a full biomechanical gait analysis for each foot. Following the data collection, participants receive all 3 prostheses for home use to determine self-selected user preference. Currently, 6 measures are sensitive to device type: PEQ Satisfaction/Frustration/Perceived Response/Sounds/Utility and OPUS Satisfaction with Device (Sum). All 6 measures indicate that ART>ESR>PWR.

15. SUBJECT TERMS
Amputation, Limb Loss, Prosthetic Prescription, Prosthetic Feet, Prosthesis

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	20	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION:

Prescription of prosthetic ankle-foot devices within the Veterans Affairs (VA) and Department of Defense (DoD) healthcare systems is often based on anecdotal evidence or manufacturer driven research. Energy storing and returning (ESR) feet are the most commonly prescribed devices in the VA and DoD systems for individuals with amputation – even those with limb loss that are only able to ambulate at a fixed cadence and limited community distance. Less commonly prescribed by the amputation care team are the more complex articulating ESR feet, partially due to limited evidence to support the prescription of these more complex feet despite the potential for improved ambulation on level ground and inclines/stairs. Lastly, the most advanced commercially available prostheses include powered foot-ankle devices that work to replicate the dynamic contractile tissues of the gastroc-soleus complex for individuals with a lower extremity amputation (LEA). Biomimetic prosthetic devices have the potential to normalize ankle power, which may reduce kinetic asymmetries that lead to musculoskeletal imbalances. Much of the current prosthetic research efforts and clinical practice have focused on the design and function of prosthetic technology, rather than understanding which devices are most appropriate to prescribe for individuals with LEA. Furthermore, limitations in the research studies conducted to date, including small sample sizes and non-standardization of feet, make it difficult to directly apply scientific evidence to clinical decision making. The goal of this investigation is to fill this critical unmet need. Through a multi-centered clinical trial, the standardization of prosthetic foot characteristics, and matching real-world testing environments, this study proposes to determine which patient goals and outcome measures are most indicative in yielding the most successful and appropriate ankle-foot prosthesis prescription. The investigation includes four medical centers, capturing 92 participants with transtibial amputation.

2. KEYWORDS:

Amputation, Transtibial Amputation, Biomimetic, Prosthesis, Energy Storing and Returning, Articulating, Powered, Prosthetic Prescription

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The overall goals for study OP150095:

1. Determine the appropriate functional outcome tests and measures to support the prescription of a type of ESR prosthetic ankle-foot for a Veteran or Service Member with transtibial limb loss.
2. Correlate patient goals and subjective measures with objective data to determine the appropriate prosthetic ankle-foot category that will facilitate the greatest overall function to the user.
3. Develop criteria for the appropriate prescription of non-articulating ESR, articulating ESR, and active plantarflexion ESR ankle-foot units.

The major goals and tasks as stated in the approved SOW for Project OP150095 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/Expected Completion Date
Subtask 1: Prepare IRB Documents and Research Protocol		
Coordinate with Sites for Subaward/ submission	100%	10/13/2017
Refine eligibility criteria, exclusion criteria, screening protocol	100%	09/13/2017
Finalize consent form & human subjects protocol	100%	09/13/2017
Coordinate with Sites for IRB protocol submission	100%	10/24/2017
Coordinate with Sites for Military 2nd level IRB** review (ORP/HRPO)	100%	12/08/2017
Milestone Achieved: Local IRB approval at each site	100%	James A. Haley VA: 11/06/2017 VA Puget Sound: 11/07/2017 WRNMMC: 12/05/2017
Milestone Achieved: HRPO approval for all protocols	100%	James A. Haley VA: 02/26/2018 VA Puget Sound: 03/15/2018 WRNMMC: 01/22/2018
Major Task 2: Coordinate Study Staff for Clinical Trials		
Subtask1: Hiring and Training of Study Staff		-
Coordinate with Sites for job descriptions design	100%	04/26/2017
Advertise and interview for project related staff	100%	06/22/2017
Coordinate with Sites for hiring, training, supervision and fidelity checks as needed for attrition	100%	01/12/2018
Milestone Achieved: Project Research staff hired and trained	100%	01/12/2018
Major Task 3: Participant Recruitment		
Subtask 1: Subject recruitment		-
Coordinate with Prosthetics and Rehabilitation Clinic for Subject Recruitment	Ongoing	-
Randomize subjects into each group for 1week trials then provide devices/sockets for final take home trial	Ongoing	-
Milestone Achieved: Study begins	100%	01/09/2018; WRNMMC: 05/17/2018
Milestone Achieved: First subject consented, screened, and enrolled	100%	01/09/2018; WRNMMC: 06/11/2018
Major Task 3: Participant Recruitment		
Subtask 1: Prosthetic Setup		
Alignment and fit of each prosthesis	Ongoing	-
Fitting/Training of each prosthesis	Ongoing	-
Subtask 2: Conduct Study		-
Collect functional measures, assessments, surveys, and interviews (all sites), as well as the subset of biomechanical data at NY and WR, according to the project timeline and protocol.	Ongoing	-
Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled	Overall: 97% WR: 85% Control: 100%	-
Major Task 4: Data Collection		
Subtask 1: Prosthetic Setup		
Alignment and fit of each prosthesis	Ongoing	-
Fitting/Training of each prosthesis	Ongoing	-
Subtask 2: Conduct Study	Ongoing	-

Collect functional measures, assessments, surveys, and interviews (all sites), as well as the subset of biomechanical data at NY and WR, according to the project timeline and protocol.	Ongoing Overall: 88% WR: 85% Control: 100%	-
Milestone Achieved: 50% of participants have completed testing of in each prosthetic device		03/28/2020
Milestone Achieved: All subjects have completed the research protocol	Overall: 88% WR: 85% Control: 100%	-

What was accomplished under these goals?
Major Activities and specific objectives for Year 5 include:

Recruitment and Enrollment

The ongoing effects of the global pandemic have slowed overall recruitment efforts. As of Year 5 Quarter 4, 26 subjects have been completed the protocol at VANYHHS, 17 at WRNMMC, 30 at JAHVA and 8 subjects at VAPSHCS. Additionally, WRNMMC has enrolled and completed 10 control subjects. Table 1 outlines current enrollment at each site. To satisfy the randomization scheme and preserve the study power, we expect to enroll 92 participants, including a subset of 32 participants who undergo biomechanical analysis. As such, we have requested a short extension of the performance period through February 2023 to allow ongoing participants to complete all protocol activities, and to enroll an additional 3 participants.

TABLE 1: Recruitment and Enrollment at Each Site

Site	Enrolled	Withdrawn	Completed	In Protocol
VANYHHS	30	2	26	2
JAHVH	39	3	30	6
VAPSHCS	10	2	8	0
WRNMMC	22	5	17	1
Total	**101**	**12**	**81**	**8**

Significant Results and Key Outcomes for Year 4

This investigation is a prospective multi-center study**,** including VANYHHS, JAHVH, WRNMMC, and VAPSHCS. Prosthetic ankle-foot devices included in this study are grouped in to three categories:

1) Non-articulating Energy Storing and Returning (ESR). This group contains over 100 commercially available prosthetic feet.
2) Articulating ESR – this group includes all commercially available options that have an articulating ankle and also have ESR qualities.
3) Active (Powered) Plantarflexion - the final group contains all commercially available ESR ankle-foot units with active plantarflexion.

Research Design and Project Timeline:

The project timeline is outlined in Figure 1. Subjects randomly receive 3 prosthetic feet (ESR, Articulating, and Powered) with duplicate sockets. Subjects are fit and trained with each device and then separately utilize each prosthetic foot for 1 week of home use. Following each 1-week session, subjects are evaluated with several functional measures and subjective surveys. Furthermore, a subset of participants (n=30) at VANYHHS, WRNMMC, and JAHVH is randomly chosen to undergo a full biomechanical gait analysis to collect kinematic and kinetic data during level-ground and incline/decline walking for each foot. To date, 28 subjects have completed biomechanical testing. Following the 3-week data collection, participants are given all 3 prostheses

at the same time for home use to determine self-selected user preference. Activity monitoring and user satisfaction/guided interview surveys are used to determine overall user preference.

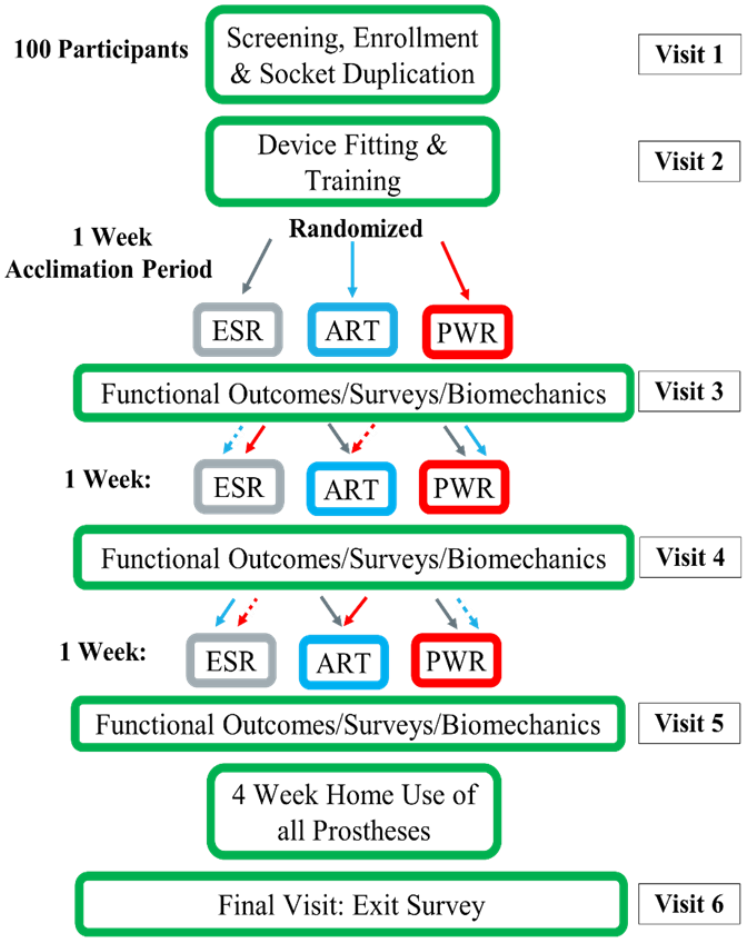

Figure 1: Research Design and Project Timeline for each Subject.

1

Biomechanical Results

Figures 2 illustrates average kinematic, kinetic and power graphs for the different prosthetic foot types. Sagittal plane kinematics and kinetics are shown for all 3 prosthetic feet during level ground walking at 1.3 m/s (Figure 2). Average sagittal plane kinematics for ramp walking at self-selected speed is illustrated in Figure 3.

Mean Joint Kinematics/Kinetics During Level Ground Walking

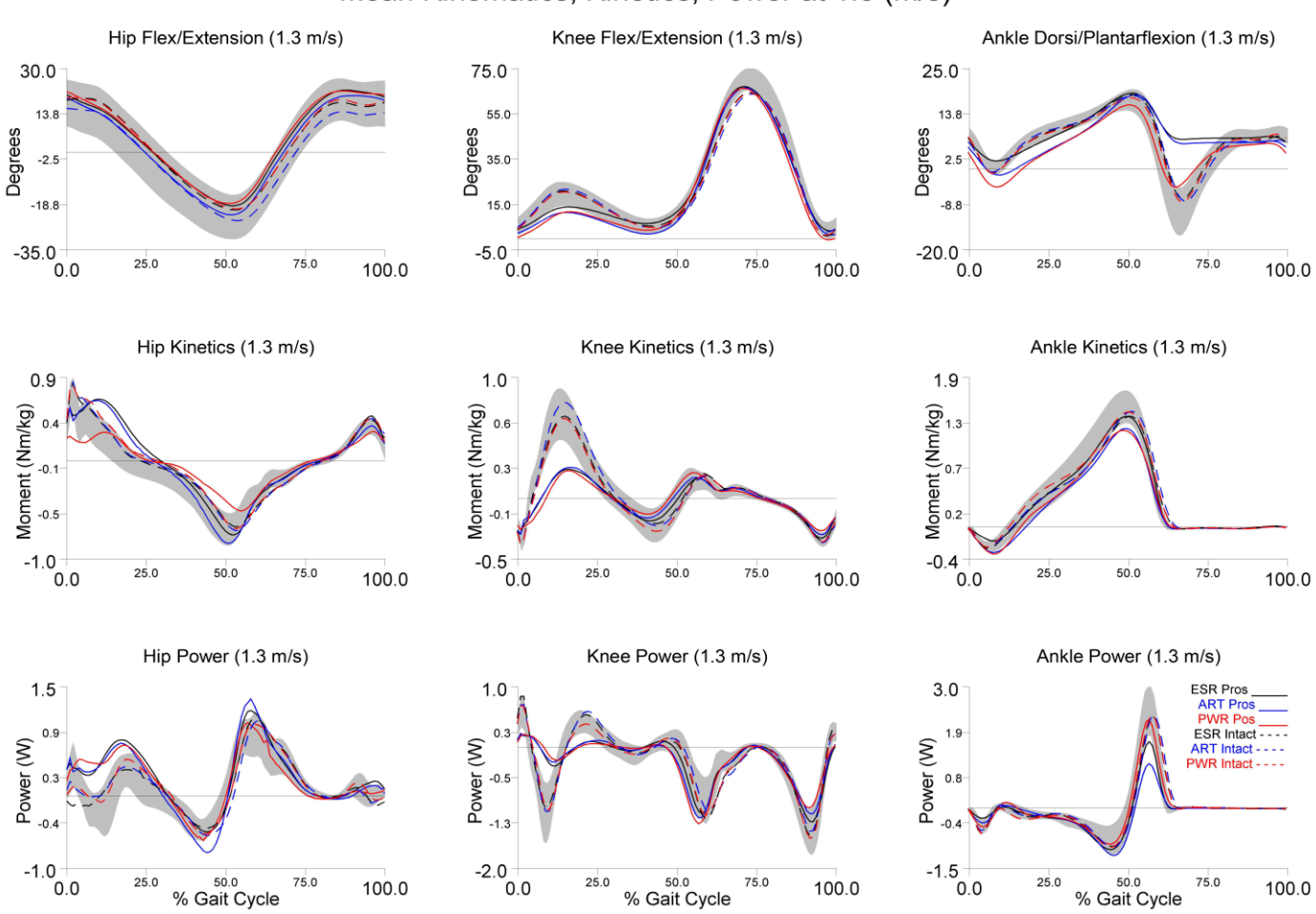

Figure 2: Mean biomechanical data for completed subjects during level ground walking at 1.3m/s. Mean sagittal plane joint kinematics and kinetics are shown. Shaded regions indicate control subject values.

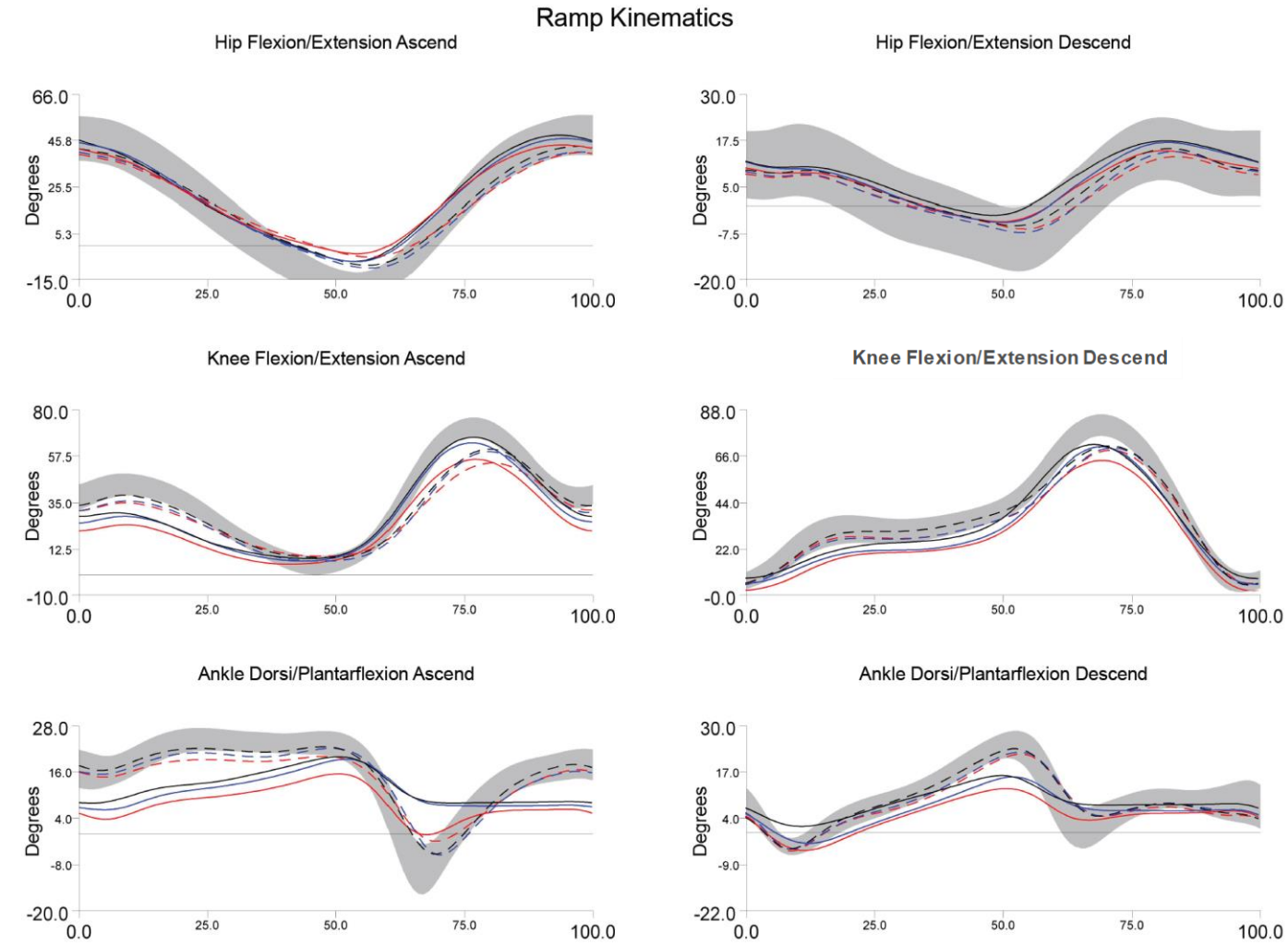

Figure 3: Average kinematic data during ramp walking. Mean sagittal plane joint kinematics for ascent and descent are shown. Shaded regions indicate control subject values.

Biomechanical Analysis continued

Figure 4 illustrates the external knee adduction moments for the intact (non-amputated) side. Higher forces on the unaffected leg may predispose individuals with amputation to secondary musculoskeletal injuries, such as knee osteoarthritis.

The dynamic function, including radius of curvature (ROC), effective foot length ratio (EFLR), and instantaneous radius of curvature (IROC) of 3 different types of prosthetic feet are examined in Figure 5. EFLR of the PWR foot (0.68±0.04) was significantly lower compared to ESR (0.75±0.07) and ART feet (0.76±0.09) ($p < 0.05$), which indicates that the COP did not progress as far anteriorly during single leg stance, decreasing walking efficiency. Furthermore, the PWR group also had a significantly smaller ROC (0.14±0.02) than the ART group (0.16±0.03) ($p < 0.05$), but not compared to the ESR group (0.15±0.03) ($p = 0.24$). Reduced ROC suggests less stability during single leg stance because the foot is rotating about a smaller rocker. Lastly, the PWR group had the lowest peak IROC (25.5±5.9 cm), but not significantly different than the ESR (30.6±9.4 cm; $p = 0.11$) or ART group (32.8±12.4 cm) ($p = 0.066$). Decreased forward travel suggests reduced standing stability.

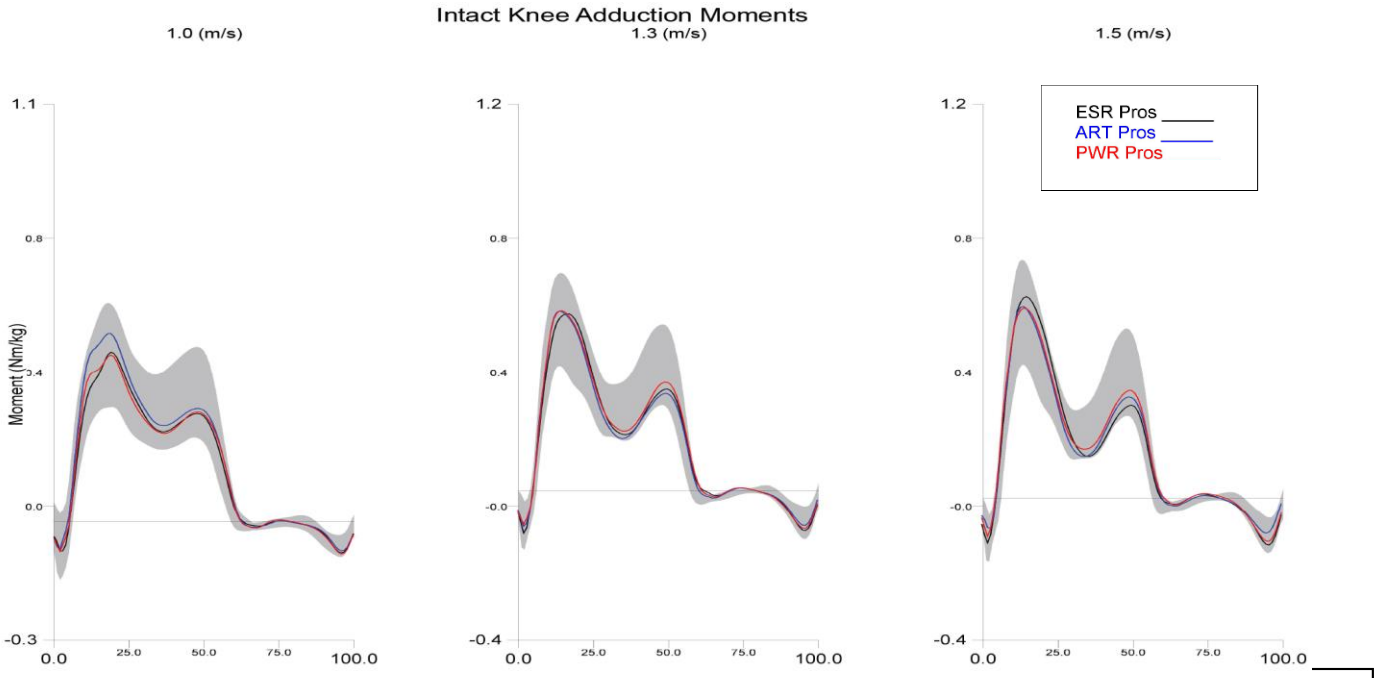

Figure 4: Average intact leg external adduction moments at the 3 walking speeds.

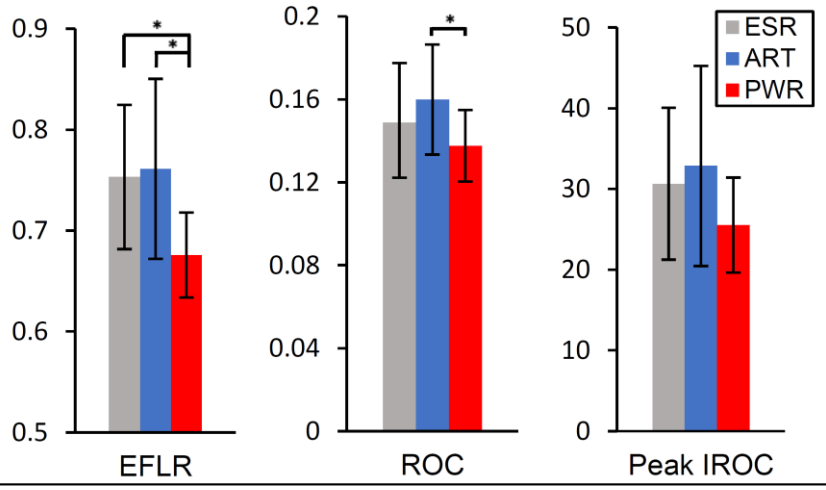

Figure 5: EFLR bar plot (left), height-normalized ROC (center), and peak IROC (cm) (right).
* Statistically significant change at $p < 0.05$.

Functional Outcomes

Subjects are evaluated with several functional measures, including the 6-minute walk, Timed-up-and-go (TUG), 4-Square Step Test (4SST), AmpPro, stair assessment index (SAI), and hill assessment index (HAI). Means and standard deviations for all completed subjects to date are listed in Table 2 and graphs are presented in Figure 6.

TABLE 2: Functional Outcome Measures

	ESR	**Articulating**	**Powered**
Functional Measures	*Average Scores (Std Dev)*	*Average Scores (Std Dev)*	*Average Scores (Std Dev)*
Timed-Up-And-Go (s)	8.7 (3.1)	9.2 (3.3)	9.3 (3.3)
Four Square Step Test (s)	10.7 (4.6)	11.2 (6.1)	11.5 (5.1)
Six-Minute Walk (m)	427.7 (123.3)	419.5 (124.0)	429.3 (120.4)
Amputee Mobility Predictor	41.6 (4.2)	41.4 (4.5)	41.1 (4.6)
Stair Assessment Index – Ascent	10.7 (3.0)	10.5 (3.2)	10.3 (3.2)
Stair Assessment Index – Descent	10.2 (3.5)	9.93 (3.7)	9.9 (3.6)
Hill Assessment Index – Ascent	10.2 (1.3)	10.2 (1.5)	10.2 (1.7)
Hill Assessment Index – Descent	10.2 (1.2)	10.2 (1.6)	10.1 (1.6)

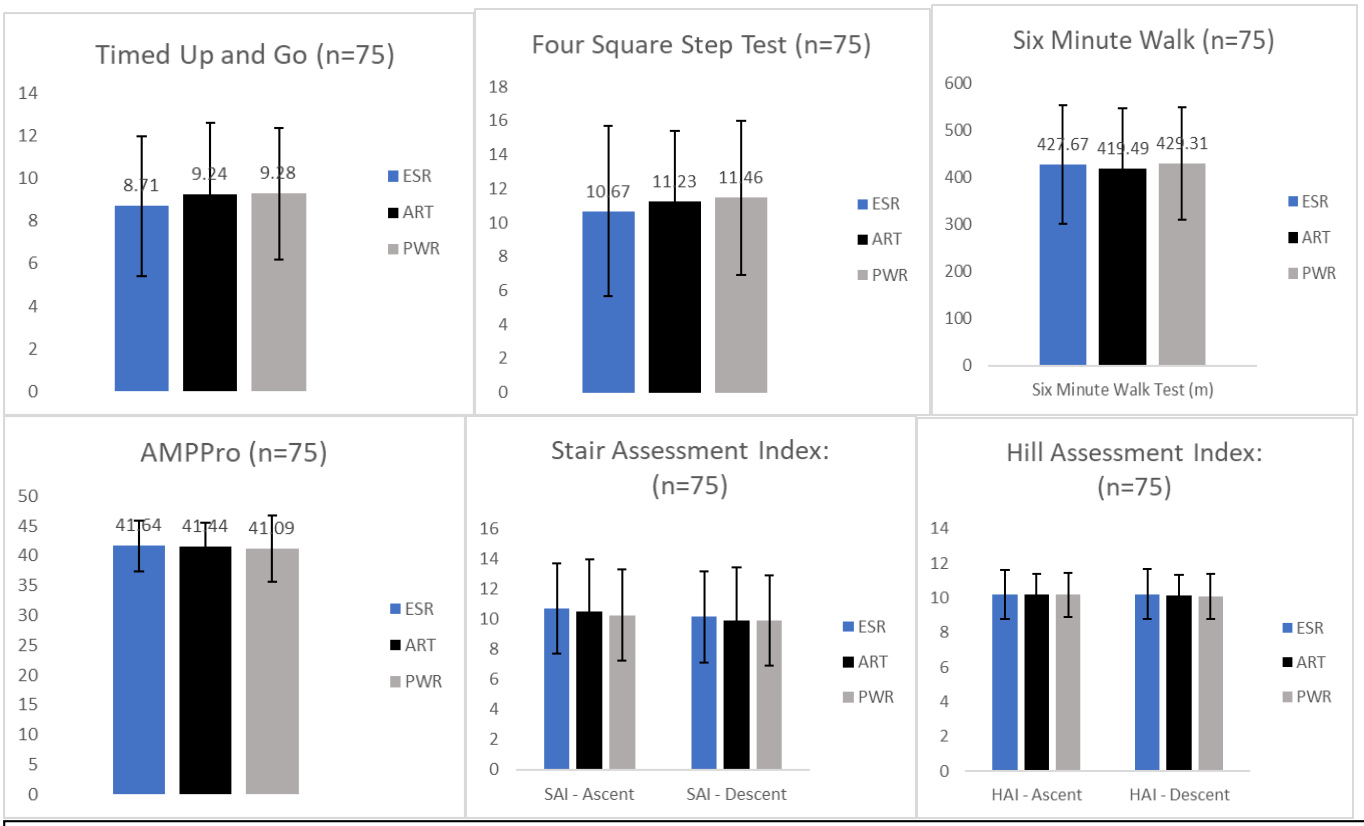

Figure 6: Functional outcome measures for completed subjects.

Subjective Outcomes

Subjects also complete self-report instruments to assess functional status, quality of life, and satisfaction, including the Prosthetic Evaluation Questionnaire (PEQ), the SF-12, and the Orthotics and Prosthetics User Satisfaction (OPUS) survey. Results to-date are shown in Figure 7.

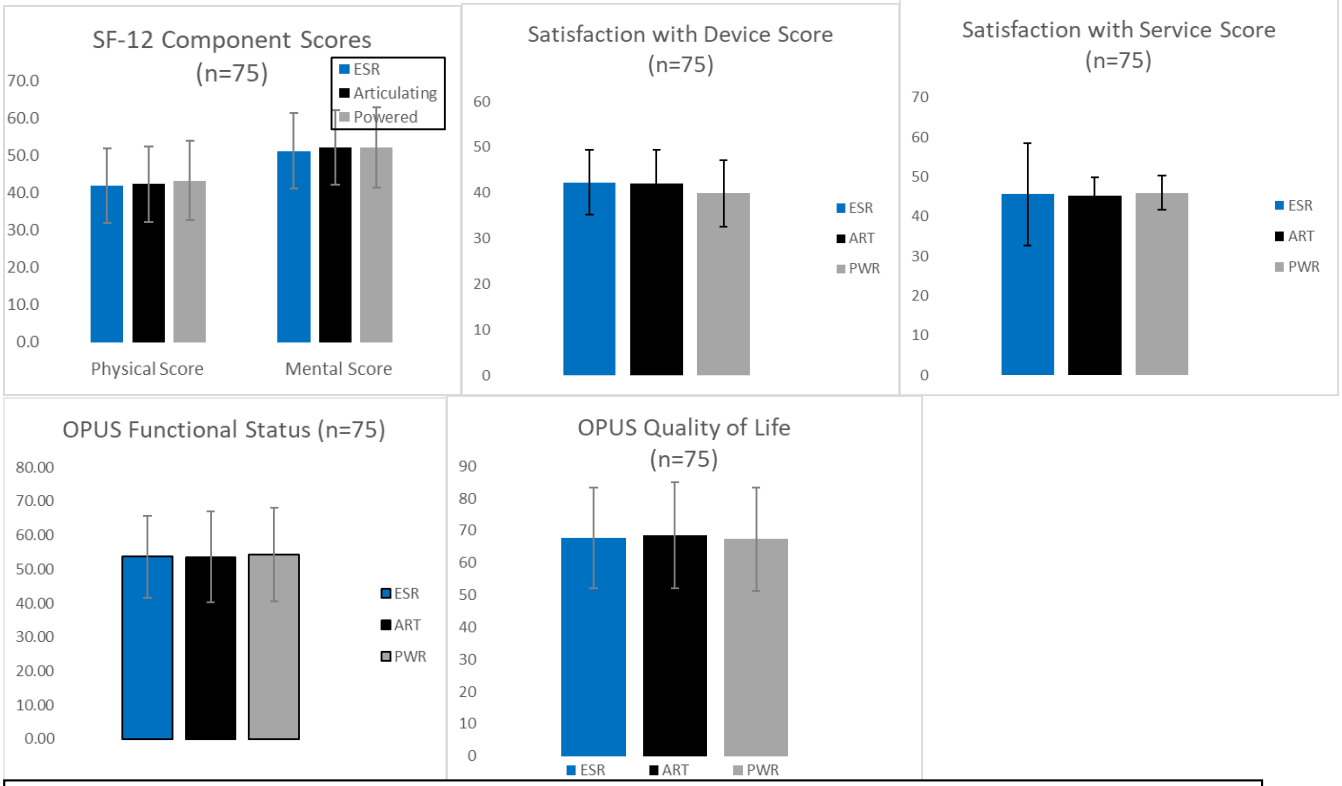

Figure 7: Average scores from self-report surveys, including the SF-12, OPUS Satisfaction with Devices, OPUS Satisfaction with Services, OPUS Functional Status, and OPUS Quality of Life.

Statistical Analysis: Six measures were sensitive to device type: PEQ Satisfaction/Frustration/Perceived Response/Sounds/Utility and OPUS Satisfaction with Device (Sum). All 6 measures indicate that ART>ESR>PWR.

Other Achievements

- One abstract was accepted for poster presentation at Gait and Clinical Movement Analysis Society Conference, which was held in June 2022. The title for the abstract is:
    - Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment
- One abstract was accepted for the Military Health Systems Research Symposium, which will be held in September 2022. The title for the abstract is:
    - Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment
- One poster was present for the VA New York Harbor Healthcare System Research Week, which was held in May 2022. The title of the poster is:
    - Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment
- Obtained and hosted a virtual exhibit hall booth at the Warrior Care Coalition Conference in February 2022.

Goals Not Met:

All goals have not been met for Y5. The ongoing effects of the global pandemic have impacted the progress of study goals. Modified recruitment plans at each site have been enacted and have been successful. Currently, 89 participants have completed the study or are currently enrolled. We expect to enroll the final 3 participants by mid-September 2022. These recruitment strategies that showed success included increasing the target enrollment at JAHVH to 45 participants, extending passive recruitment at WRNMMC via study advertisements at the Washington DC VA Medical Center, as well as presenting (in-person or virtually) at local amputation support groups, attending national conferences (in-person or virtually) and local chapter meetings targeted for individuals with amputation (in-person or virtually), and continuing our biweekly conference calls. We will continue to conduct group quarterly conference calls with all sites to review progress to date and discuss any problems that arise.

Lastly, a short extension of the performance period through February 2023 has been requested to complete the study. We are currently waiting for approval.

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 an annual meeting in Year 5. The meeting was held on 10/4/2021 to discuss study progress to-date with all sites. Members from each site received project management training (data collection during COVID, recruitment during COVID, and data sharing techniques), as well as a review of the project data to-date. The agenda for this meeting is below. Additionally, members of the study team attended the 2022 Gait and Clinical Movement Analysis Society annual conference.

U.S. Department of Veterans Affairs

NY/NJ VA Health Care Network
VA NY Harbor Healthcare System
800 Poly Place | Brooklyn, NY 11209
718-836-6600

423 East 23rd Street | New York, NY 10010
212-686-7500

179-00 Linden Boulevard | Jamaica, NY 11425
718-526-1000

www.nyharbor.va.gov

Date: October 4th, 2021

Time: 2pm – 3pm ET

Place: https://us02web.zoom.us/j/81102691607

Subject: Year 5 Annual Meeting for "Criteria for Advanced Prosthetic Foot Prescription"

Agenda

Monday, October 4th 2021

Item	Presenter
Study Overview	JM
COVID-19 Discussion	JM
Presentation (Enrollment, Results, Stats)	JM
Regulatory Updates	MH
General Updates	MH
Open Forum	All
Closing Remarks, Questions, Concerns	All

How were the results disseminated to communities of interest?

Gait and Clinical Movement Analysis Society Annual Conference
One abstract was presented as a poster at the Gait and Clinical Movement Analysis Society Annual Conference, which was held virtually from 6/7-6/8.

- Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.

Military Health Systems Research Symposium
One abstract was accepted for the Military Health Systems Research Symposium, which will be held in September.

- Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.

VA New York Harbor Healthcare System Research Week
One poster was accepted and presented at the VA New York Harbor Healthcare System Research Week, which was held May 16-20:

- Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.

Warrior Care Coalition Conference
Hosted a virtual exhibit hall booth at from February 8-9, 2022.

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

To accomplish the goals and objectives, 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.
- Complete data analysis for completed subjects.
- Presentation of abstracts at accepted conferences and manuscript preparation for journal articles.
- Publish 2-3 peer-reviewed journal articles.

4. IMPACT:

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

While data collection and analysis are ongoing, preliminary statistical analysis of the data to-date has demonstrated that specific functional, subjective, and biomechanical parameters are sensitive to differences between the 3 prosthetic foot devices. This preliminary evidence suggests that the data from this study may provide guidance for outcome measures that are most indicative in yielding the most successful and appropriate ankle-foot prosthesis prescription for our Veterans and Service Members with transtibial amputation.

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 transtibial amputation may be updated based on the outcomes of this research study. It is necessary for clinicians to prescribe the most appropriate ankle-foot device to enhance function and satisfaction. By understanding which functional, subjective, and biomechanical parameters are indicative of yielding the most optimal satisfaction and performance, clinicians can use this "toolbox" to help prescribe an appropriate prosthetic device. While the VA/DoD lower limb amputation Clinical Practice Guidelines provide guidance on critical decision points in the rehabilitation healthcare plan, prosthetic prescription is still rooted in anecdotal evidence and manufacturer claims. 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. 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 ongoing effects of COVID-19, patient recruitment was challenging. However, strategies discussed during team meetings were implemented to increase enrollment at all sites. At this time, only 3 more participants are required to meet our recruitment goals. Biweekly calls between VANYHHS and each site have continued during this pandemic to discuss site-specific updates. Also, during the past performance year, the VA Puget Sound Health Care System site in Seattle, WA (Site A-19931.d) was closed by the study team and local IRB and subsequently submitted to HRPO, as enrollment was ceased there as a performance site. Lastly, a short extension of the performance period was requested to extend this investigation through 2/28/2023. This extension will permit the ongoing patients to complete the protocol, as well as allow us to recruit and enroll the remaining 3 participants. Approval is pending.

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

The following problems/delays are detailed below:

- Recruitment: Recruitment is less than projected for the end of Year 5 largely due to the COVID-19 pandemic. We expect to complete enrollment by mid-September and complete all protocol activities by January 2023.
- Recruitment strategies at each site will continue to be implemented including:
    - Presenting at local amputation support groups and attending local and national conferences
    - Including civilians from affiliated medical centers and clinics.
    - Online, telehealth, and other non-contact recruitment methods will continue to be explored to increase enrollment.
    - Continuing bi-weekly calls with study sites to encourage recruitment efforts and mitigate any problems.

Changes that had a significant impact on expenditures

Advanced funding was requested and approved. All funds will be expended by the end of the requested performance period.

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. Currently preparing a protocol manuscript.

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

Nothing to Report

Other publications, conference papers and presentations.

Gait and Clinical Movement Analysis Society Annual Conference
One abstract was presented as a poster at the Gait and Clinical Movement Analysis Society Annual Conference, which was held virtually from 6/7 - 6/8.

- Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.

Military Health Systems Research Symposium
One abstract was accepted for the Military Health Systems Research Symposium, which will be held in September.

- Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.

VA New York Harbor Healthcare System Research Week
One poster was accepted and presented at the VA New York Harbor Healthcare System Research Week, which was held May 16-20:

- Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.

- **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 VANYHHS
Nearest person month worked:	2
Responsibilities/ Contributions:	Oversees overall integrity of the study, as well as biomechanical activities. Coordinates recruitment efforts at all sites. Conducted annual meeting.
Name:	Leif Nelson, DPT
Project Role:	Consultant
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for enrollment eligibility and review of study data.
Name:	Michael Hyre, MS
Project Role:	Study Coordinator at VANYHHS
Nearest person month worked:	5
Responsibilities/ Contributions:	Oversees all regulatory activities at VANYHHS and assists with IRB/HRPO submissions for each site. Coordinates data collection/entry from all sites. Tracks and coordinates all study materials for each site.
Name:	Eric Baksh
Project Role:	Prosthetic Technician at VANYHHS
Nearest person month worked:	12
Responsibilities/ Contributions:	Fabricates all sockets for the study.
Name:	John Chomack, MS
Project Role:	Research Engineer at VANYHHS
Nearest person month worked:	9
Responsibilities/ Contributions:	Responsible for subject enrollment/data collection and biomechanical testing
Name:	David Herlihy
Project Role:	Research Engineer at VANYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with biomechanical testing and data processing
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Cristina Roy, DPT
Project Role:	Research Physical Therapist at VANYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Performs functional outcome testing for subjects.
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Alexis Sidiropoulos, PhD
Project Role:	Research Scientist at VANYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with biomechanical data interpretation
Name:	Alison Pruziner, DPT
Project Role:	Consultant
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for data analysis
Name:	Bradford Hendershot, PhD
Project Role:	PI at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Coordinates all data collection activities and biomechanical analysis. Assists with data analysis.
Name:	Louise Hassinger, CP
Project Role:	Prosthetist at Walter Reed
Nearest person month worked:	1
Responsibilities/ Contributions:	Prepares all sockets for central fabrication and performs all prosthetic fittings at WRNMMC.
Name:	Jonathan Gladish, MS
Project Role:	Research Engineer at WRNMMC
Nearest person month worked:	8
Responsibilities/ Contributions:	Responsible for subject enrollment/data collection and biomechanical testing

Name:	Christopher Dearth, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for data analysis
Name:	Samuel Phillips, PhD, CP
Project Role:	Site-PI at James A. Haley VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities at JAHVA, coordinates local IRB submissions
Name:	Lisa Ballistrea (*Goff*), DPT
Project Role:	Physical Therapist at James A. Haley VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Responsible for all device training/safe usage of prosthetic feet, assists with local IRB submissions
Name:	Meghan Kern (*Rosenbrock*), DPT
Project Role:	Physical Therapist at James A. Haley VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Responsible for device training/ensuring safe usage of prosthetic feet, coordinates subject enrollment.
Name:	Anh Du, CP
Project Role:	Prosthetist at James A. Haley VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Preparation of socket fittings, assists in subject recruitment

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Maikos received a VA Merit Review grant, though there is no overlap with any ongoing studies and this additional effort does not over-commit his total percent effort.

What other organizations were involved as partners?

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

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:

The abstract submitted to the Gait and Clinical Movement Analysis Society annual conference is included below:

Effects of Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment

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INTRODUCTION

Individuals with a transtibial amputation (TTA) who use traditional energy storing and returning (ESR) devices often experience increased kinematic and kinetic asymmetries, particularly on their intact limb [1,2]. Research has correlated increased intact joint discomfort and knee osteoarthritis (OA) to abnormally high 1st peak knee adduction moments (KAM) of the intact limb [1,3]. Experienced TTA prosthesis users have been shown to have increased intact KAM of 46% and 17% compared to the prosthetic side and normative data, respectively [3]. Advanced prosthetic componentry, such as powered ankle-foot devices that mimic the gastroc-soleus complex, have the potential to reduce compensatory loading of the intact limb, which could reduce the risk of musculoskeletal injuries. The Empower foot (PWR) (Ottobock, Inc.) is the only commercially available prosthetic device able to provide the user with biomimetic power generation at push off. The aim of this study was to analyze the gait of individuals with TTA with different prosthetic foot conditions. We hypothesized that use of a PWR device would significantly reduce the 1st peak of the intact KAM with respect to an ESR device and would be normalized to the control group.

CLINICAL SIGNIFICANCE

Powered prosthetic devices could be used as a preventative measure to reduce compensatory affects during gait or to mitigate risks of knee OA caused by high 1st peak KAM within the intact limb of those with a TTA.

METHODS

Twenty-two individuals with TTA (age 52 ± 14.5 years, height 1.79 ± 0.1 m, and weight 87.6 ± 16.6 kg) with at least 1 year of prosthesis experience, and 8 control subjects were recruited from Veteran Affairs New York Harbor Healthcare System (NYHHS) and Walter Reed National Military Medical Center (WRNMMC). Study procedures were approved by each site's respective Institutional Review Board. Participants were randomized to wear both an ESR and PWR device, each for a 1-week acclimation period followed by a biomechanical gait evaluation. Control participants underwent a single biomechanical gait evaluation. Motion and force data were collected using an optical motion capture system (Qualisys, Goteborg, Sweden) and force platform system (AMTI, Waterford, MA). Participants were fit with 78 retroreflective markers placed symmetrically about the entire body. Participants performed level ground walking at 3 speeds: 1.0, 1.3, and 1.5 m/s. Data was analyzed using Visual3D software (C-Motion Inc.) to derive kinematic, kinetic, power, and ground reaction force results. A one-way, between subjects, repeated measures analysis of variance (ANOVA) was used to determine if significant differences ($p<0.05$) were present for the 1st peak intact KAM between each foot and between individuals with and without TTA for all speeds.

RESULTS

The average time since amputation was 15.6 ± 13.7 years. The major cause of amputation was trauma (72%), followed by cancer (17%), and dysvascular disease/diabetes (11%). The control participants consisted of all male individuals, age 32 ± 4.8 years, height 1.78 ± 0.05m, and weight 85.7 ± 12.4 kg. First peak intact KAMs for the PWR device at each speed (1.0, 1.3, and 1.5m/s) were not significantly lower than the ESR device (p>0.05). Table 1 shows the average 1st peak intact KAMs (Nm/Kg) for ESR (0.45, 0.52, 0.59), PWR (0.45, 0.52, 0.58), and the Controls (0.46, 0.47, 0.54) at 1.0, 1.3 and 1.5m/s, respectively. The one-way between subject, repeated measures ANOVA showed each were not significantly different (p>0.5). Upon further analysis, there were no significant difference in KAM between the prosthetic devices and the control participants at any speed (p > 0.05).

1st Peak Knee Adduction Moment (Nm/kg) and % Differences Between Feet and Control						
Moment	N = 22		N = 8	Difference		
Speeds (m/s)	ESR	PWR	Control	Control to ESR	Control to PWR	PWR to ESR
1.0	0.45	0.45	0.46	1.0	1.0	0
1.3	0.52	0.52	0.47	-5.0	-5.0	0
1.5	0.59	0.58	0.54	-5.0	-4.0	-1.0

Table 1: 1st Peak KAM and % Differences Between Feet and Control.

DISCUSSION

Biomimetic devices like the Empower can generate normative ankle power during push off and have been previously reported to reduce peak KAM of the intact knee [1]. Previous research has shown that the 1st peak of the intact KAM for individuals with TTA who utilized a powered device was significantly reduced by 20.6% and 12.2% at walking speeds of 1.5 and 1.75 m/s (p = 0.03, 0.05) compared to the ESR condition [1]. However, at slower walking speeds, comparable to the speeds used in this investigation, KAM was not significantly different between the ESR and PWR devices. These differences may be attributable to the net positive work performed at faster speeds by the PWR, whereas at slower speeds the net mechanical work is nearly zero across the entire stance phase [1]. Furthermore, while the PWR device provided biomimetic push-off power, the uniaxial movement cannot replicate the biarticular nature of the gastrocnemius, which may reduce the efficiency of the load transmission to the intact limb [2]. As such, the reduction in intact KAM reported in this investigation could be the result of continued compensatory strategies of the intact limb and reduced stability of the knee in the frontal plane. Additionally, the average age of the control subjects was approximately 20 years younger than the participants with TTA, which may influence the 1st peak KAM for control subjects. Future work will include age-matched control subjects along with additional TTA participant KAM data.

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DISCLOSURE STATEMENT

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