AWARD NUMBER: W81XWH-17-2-0014

TITLE: Criteria for Advanced Prosthetic Foot Prescription

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

REPORT DATE: August 2021

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
August 2021	Annual	01Aug2020-31Jul2021

4. TITLE AND SUBTITLE

Criteria for Advanced Prosthetic Foot Prescription

5a. CONTRACT NUMBER
W81XWH-17-2-0014

5b. GRANT NUMBER
OP150095

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

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. Subjects 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, subjects 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**			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	24	**19b. TELEPHONE NUMBER** *(include area code)*

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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 100 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: 76% WR: 60% Control: 90%	-
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: 67% WR: 56% Control: 80%	-
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: 67% WR: 56% Control: 80%	-

What was accomplished under these goals?
Major Activities and specific objectives for Year 3 include:

COVID-19 Administrative Hold Status for each site:
VA New York Harbor Healthcare System (VANYHHS): The administrative hold was removed on 1/12/2021. Enrollment is ongoing.

Walter Reed National Military Medical Center (WRNMMC): The administrative hold was lifted in September 2020. Enrollment is ongoing.

James A. Haley Veterans' Hospital (JAHVH): The administrative hold was lifted in Y4Q4. Six subjects are currently in protocol and will resume research activities in the next quarter.

VA Puget Sound Health Care System (VAPSHCS): Per our Y5 extension request (approved), Seattle will no longer serve as an actively enrolling performance site after the end of Y4.

Recruitment and Enrollment
The pandemic has impacted the progress of study enrollment as there was an 11-month delay of no enrollment. Furthermore, the ongoing effects of the global pandemic have slowed recruitment efforts. In Year 5, 3 sites will be actively enrolling participants, but are subject to COVID regulations/guidelines per each facility. As per our Year 5 extension, VAPSHCS will no longer serve as a study site in Year 5.

As of Year 4 Quarter 4, 24 subjects have been enrolled at VANYHHS, 20 at WRNMMC, 32 JAHVH and 10 subjects at VAPSHCS. Table 1 outlines current enrollment at each site:

TABLE 1: Recruitment and Enrollment at Each Site

Site	Enrolled	Withdrawn	Completed	In Protocol
VANYHHS	24	2	20	2
JAHVH	32	1	25	6
VAPSHCS	10	2	8	0
WRNMMC	20	5	14	1
Total	**86**	**10**	**67**	**9**

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, 22 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.

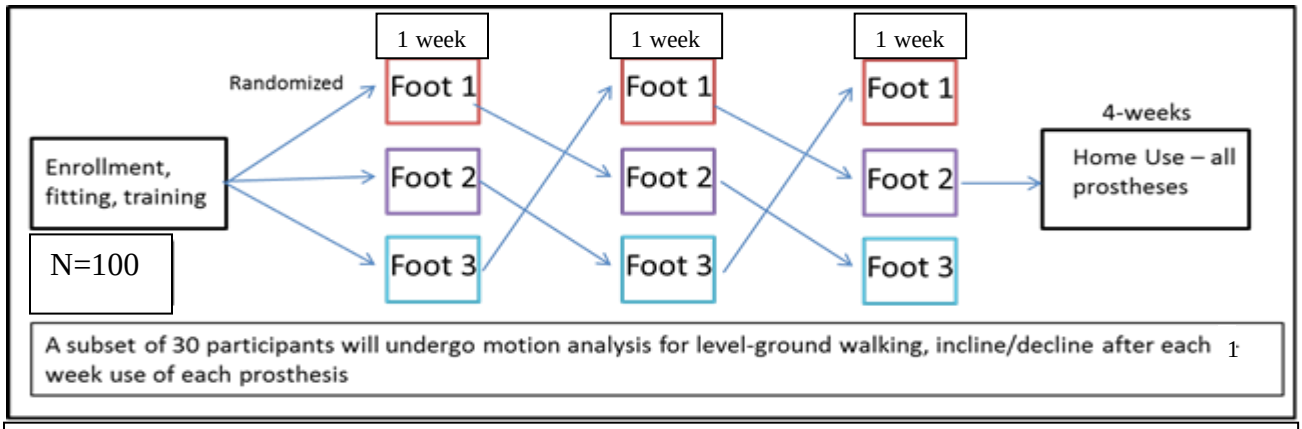


Figure 1: Research Design and Project Timeline for each Subject.

Biomechanical Results

Figures 2 and 3 illustrate 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), and sagittal plane kinematics for ramp walking at self-selected speed (Figure 3).

Mean Joint Kinematics/Kinetics During Level Ground Walking

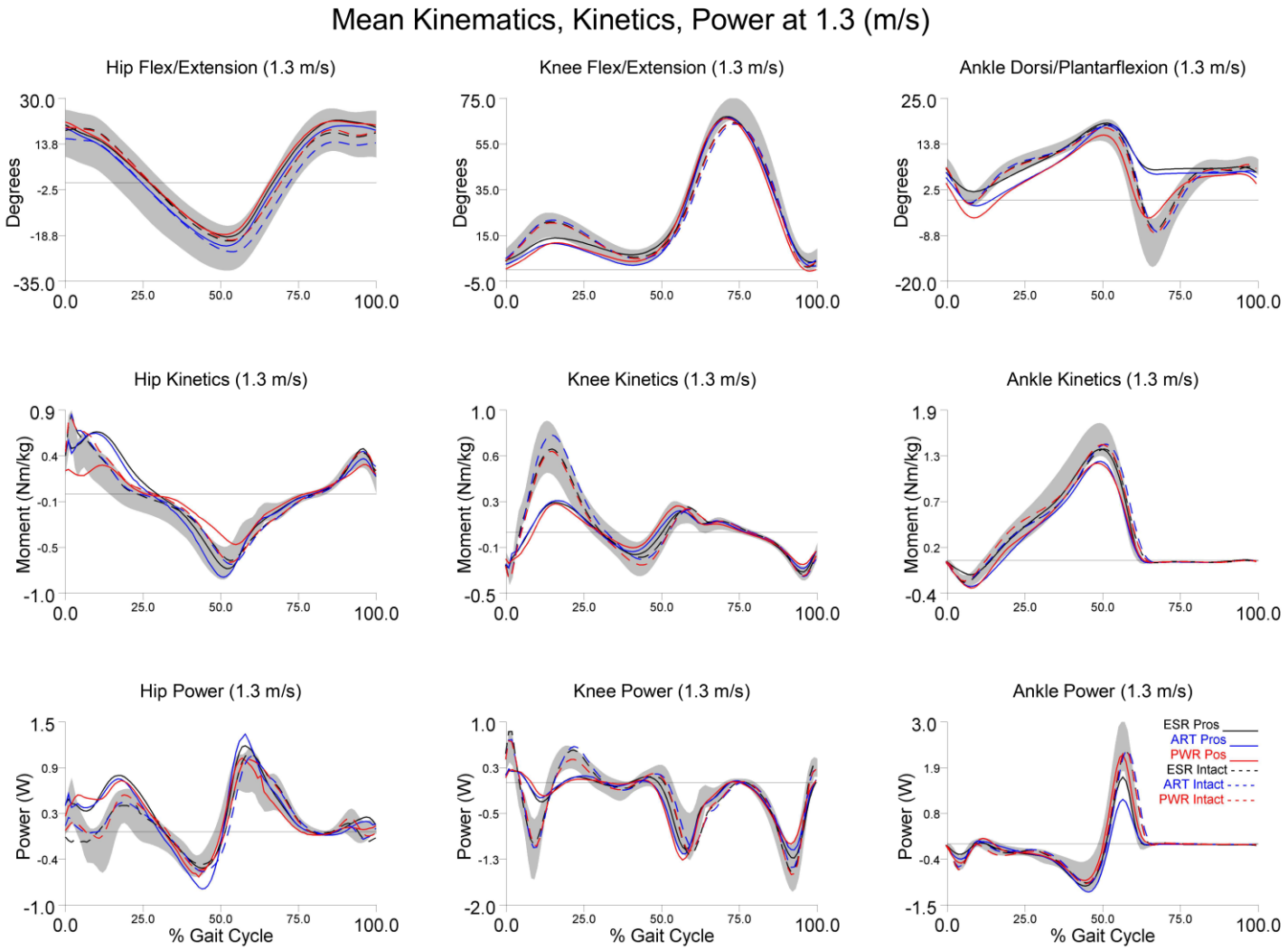


Figure 2: Mean biomechanical data for completed subjects during level ground walking at 1.3m/s. Mean sagittal plane joint kinematics and kinetics are shown. Shaded regions indicate control subject values.

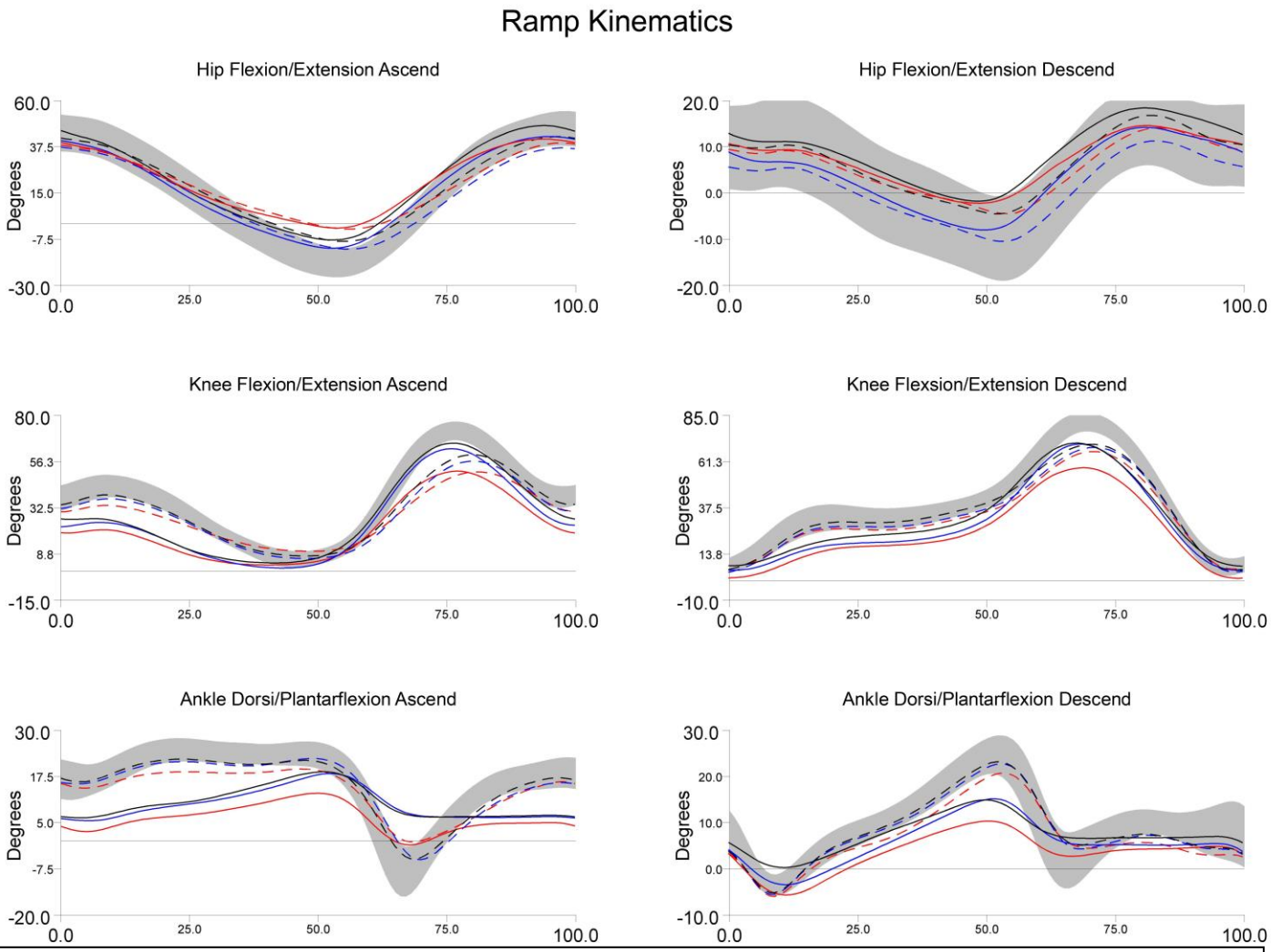


Figure 3: Average biomechanical data during ramp walking. Mean sagittal plane joint kinematics for ascent and descent are shown. Shaded regions indicate control subject values.

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.

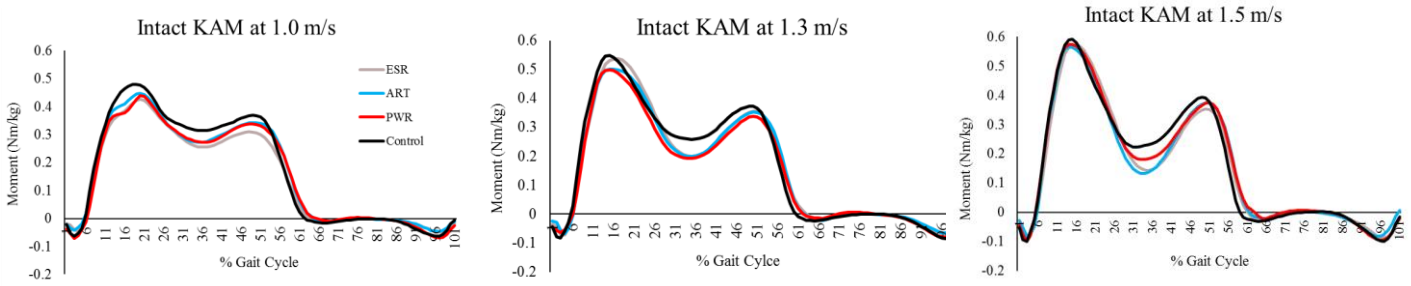


Figure 4: Average intact leg external adduction moments at the 3 walking speeds.

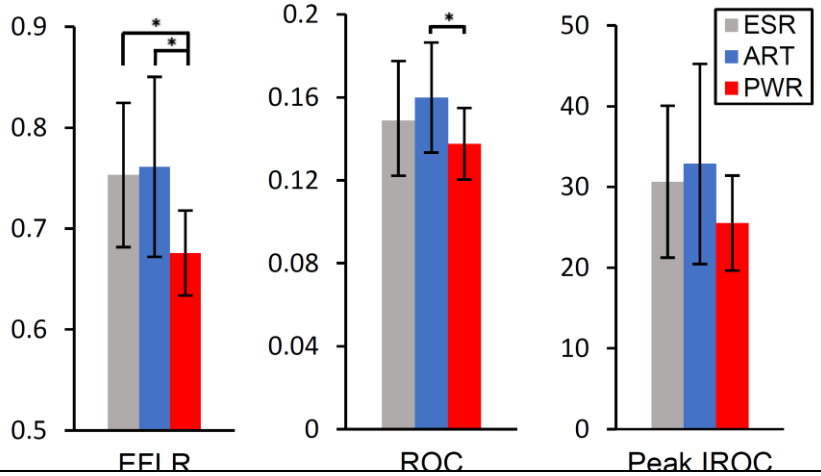


Figure 5: EFLR bar plot (left), height-normalized ROC (center), and peak IROC (cm) (right).
* Statistically significant change at $p < 0.05$.

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 (3.2)	9.2 (3.4)	9.3 (3.4)
Four Square Step Test (s)	10.5 (4.6)	11.1 (6.2)	11.3 (5.1)
Six-Minute Walk (m)	425.9 (124.1)	420.8 (126.7)	426.4 (120.0)
Amputee Mobility Predictor	41.6 (4.4)	41.5 (4.5)	41.1 (4.7)
Stair Assessment Index – Ascent	10.8 (3.0)	10.5 (3.2)	10.4 (3.2)
Stair Assessment Index – Descent	10.2 (3.5)	10.0 (3.7)	10.4 (3.2)
Hill Assessment Index – Ascent	10.3 (1.3)	10.3 (1.3)	10.3 (1.6)
Hill Assessment Index – Descent	10.3 (1.2)	10.2 (1.4)	10.2 (1.6)

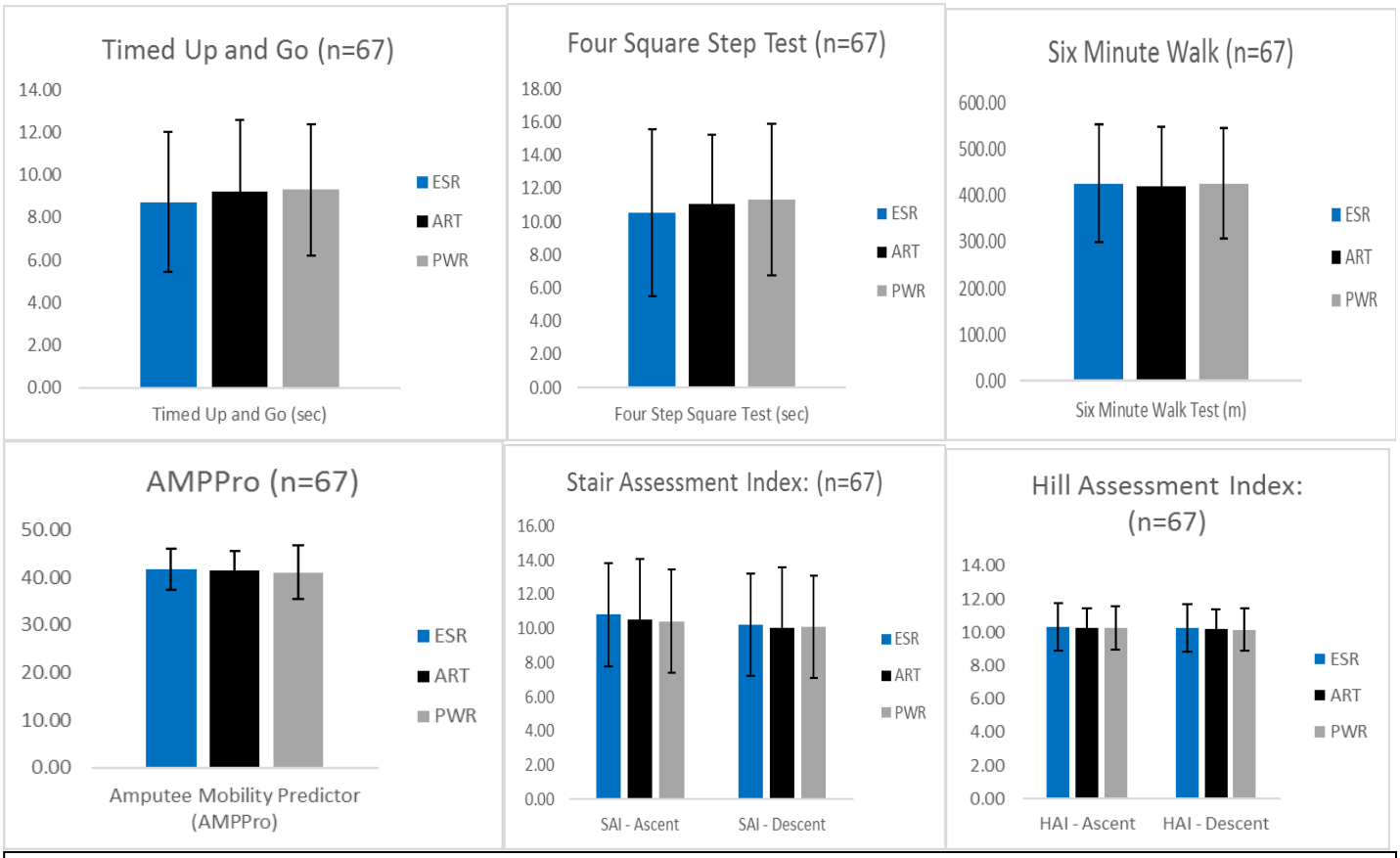
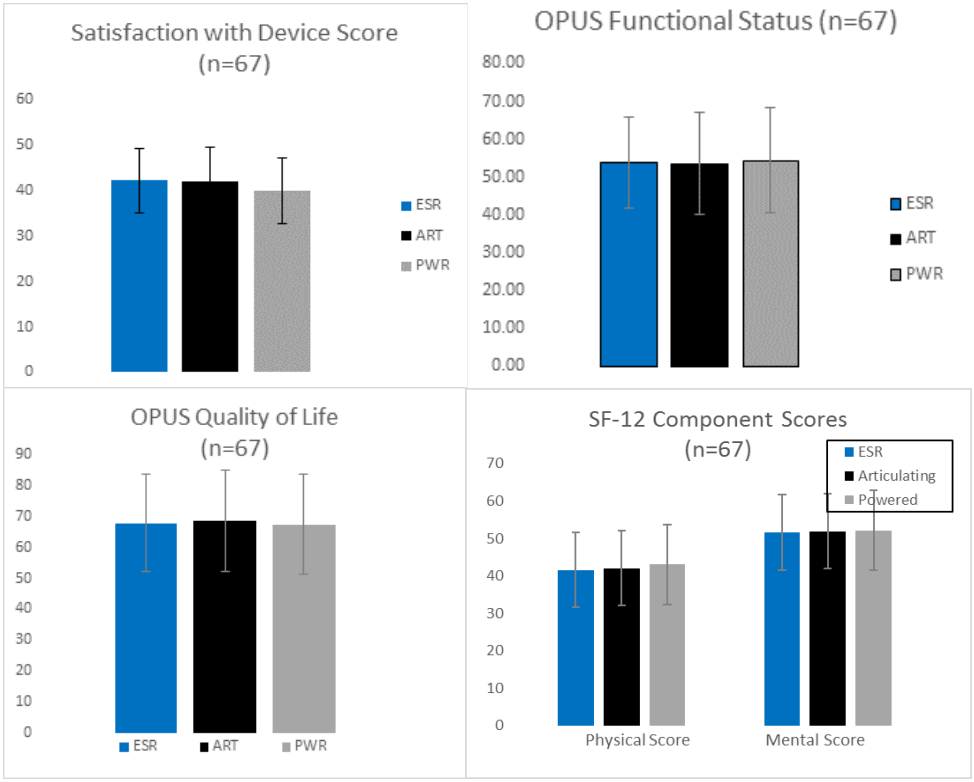


Figure 6: Functional outcome measures for completed subjects.

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.



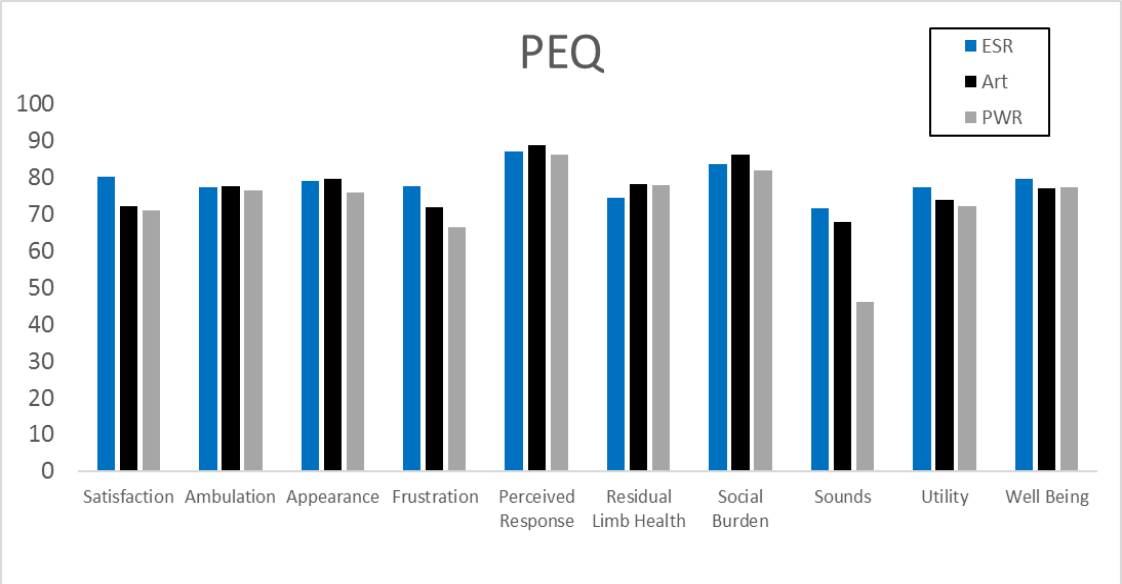


Figure 7: Average scores from self-report surveys, including the OPUS Satisfaction with Devices, OPUS Functional Status, OPUS Quality of Life, SF-12, and the Prosthetic Evaluation Questionnaire (PEQ).

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 presentation at the Summer Biomechanics, Bioengineering, and Biotransport Conference, which was held virtually from June 14-18, 2021. The title for the abstract is:
  - Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring
- One abstract was accepted for presentation at the American Society of Biomechanics annual conference, which was held virtually from August 10-13, 2021.
  - Effects of a Powered Ankle-Foot Prosthesis on Intact Knee Adduction Moment.
- Two abstracts were accepted for poster presentation at the American Society of Biomechanics annual conference
  - Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring
  - Influences of Passive and Powered Articulating Prosthetic Feet on Trunk Motion
- One abstract was accepted for the Military Health Systems Research Symposium (conference canceled)
  - Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring
- Obtained and hosted a virtual exhibit hall booth at the Warrior Care Coalition Conference from April 6-7, 2021.

Goals Not Met:

All goals have not been met for Y4. The pandemic has impacted the progress of study goals as there was an 11-month delay of no enrollment. All sites are now actively enrolling participants, but remain subject to COVID regulations/guidelines per each facility. Modified recruitment plans at each site have been enacted. These strategies include 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 Year 5 cost extension with supplemental funding has been requested and approved. We are currently waiting for the modified contract, which is expected at the start of fiscal year 2022. Given the 11-month delay in recruitment/enrollment due to COVID-19, we project enrollment will now extend into Y5Q2. However, with the increase in COVID infections across the country, specifically in Florida, we will continue to monitor the safety of the study participants and follow all site-specific COVID guidelines.

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 2 trainings in Year 4. First, we held a meeting on 11/24/2020 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. Second, in Y4 JAHVH was added as a 3rd biomechanics data collection site. As such, a comprehensive biomechanics protocol training for JAHVH was held on June 17, 2021. This training provided a detailed overview of biomechanical data collection techniques currently employed in the study protocol. Additionally, members of the study team attended the 2021 Summer Biomechanics, Bioengineering, and Biotransport Conference and the 2021 American Society of Biomechanics annual conference.

VA | U.S. Department of Veterans Affairs

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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: November 24th, 2020

Time: 11am – 12pm ET

Place: Click here to join the meeting

Subject: Year 4 Annual Meeting for "Criteria for Advanced Prosthetic Foot Prescription"

Agenda

Tuesday, November 24th 2020

Item	Presenter
Study Overview	JM
COVID-19 Discussion	JM
Status of Administrative Hold	All Sites
Presentation (Enrollment, Results, Step Activity Data)	JM/JC
Regulatory Updates	MH
General 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 presentation at the Summer Biomechanics, Bioengineering, and Biotransport Conference, which was held virtually from June 14-18, 2021. The title for the abstract is:

- Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring

American Society of Biomechanics
One abstract was presented at the American Society of Biomechanics annual conference, which was held virtually from 8/10-8/13.

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

Additionally, 2 posters were presented at the American Society of Biomechanics annual conference

- Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring
- Influences of Passive and Powered Articulating Prosthetic Feet on Trunk Motion

Military Health Systems Research Symposium
Lastly, 1 abstract was accepted for the Military Health Systems Research Symposium, though the conference was canceled. Accepted abstracts will be published.

- Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring

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.
- 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?

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 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 biomechanics site to complete recruitment/enrollment of subjects who are randomized to the biomechanics protocol.

Lastly, a year 5 extension with supplemental funds was also approved, which has extended the performance period of this investigation through 7/31/2022.

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 4 largely due to the COVID-19 pandemic. Enrollment is ongoing at each site, but is subject to site-specific guidelines. A Year 5 extension with supplemental funds has been approved. We expect enrollment to continue into Y5Q2, which will provide enough buffer to complete all patient visits prior to the end of the study.
- 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

During the COVID-19 administrative hold at all sites, salary for staff at all sites continued to be paid for study activities (ex: data analysis, data processing, regulatory requirements). A Year 5 extension with supplemental funds has been requested and approved.

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. Currently preparing a protocol manuscripts.

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 presentation at the Summer Biomechanics, Bioengineering, and Biotransport Conference, which was held virtually from June 14-18, 2021. The title for the abstract is:

- Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring

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Military Health Systems Research Symposium
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- Measuring Prosthetic Foot Use by Activity Level with Step Activity Monitoring

- **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:	Michael Poppo, MS
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 collection
Name:	Ashley Knight, PhD
Project Role:	Site-PI at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities at WRNMMC, assists with subject recruitment/enrollment.
Name:	Alison Pruziner, DPT
Project Role:	Consultant
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for 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:	Bradford Hendershot, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Coordinates all data collection activities and biomechanical analysis. Assists with data analysis.
Name:	Leigh Anne Lechanski, PT, DPT
Project Role:	Supporting Clinician at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Responsible for device training and ensuring safe usage of prosthetic feet.
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
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Christopher Dearth, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Consultant for data analysis
Name:	Rebecca Speckman, MD, PhD
Project Role:	Site-PI at VA Puget Sound
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, assists with subject enrollment.
Name:	Matthew Jerrell
Project Role:	Research Coordinator at VA Puget Sound
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with local IRB submissions
Name:	Virginia Kudritzki, PT
Project Role:	Physical Therapist at Puget Sound VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Participates in local subject recruitment and data collection.
Name:	Wayne Biggs, CP
Project Role:	Prosthetist at VA Puget Sound
Nearest person month worked:	1
Responsibilities/ Contributions:	Prepares sockets for prosthetic fittings.
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?

Nothing to Report.

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

VA Puget Sound Medical Center
1660 South Columbian Way
Seattle, WA 98108
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:

Abstracts submitted to the Summer Biomechanics, Bioengineering, and Biotransport Conference and the American Society of Biomechanics 2020 annual conference are presented below:

EFFECTS OFA POWERED ANKLE-FOOT PROSTHESIS ON INTACT KNEE ADDUCTION MOMENT

John M. Chomack[1], A. Sidiropoulos[1], M. Poppo[1], J.R. Gladish[2,3], A.D. Knight[2,4], B.D. Hendershot[2,4], and J. Maikos[1]
[1]Veteran Affairs New York Harbor Healthcare System, [2]Walter Reed National Military Medical Center,
[3]Henry M. Jackson Foundation, [4]Uniformed Services University of Health Sciences
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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 of their intact limb [1,2]. Experienced TTA prosthetic users have been shown to have increased intact 1st peak knee adduction moments (KAM) of 46% and 17% compared to the prosthetic side and normative data, respectively [3]. Research has correlated increased intact joint discomfort and knee osteoarthritis (OA) to abnormally high KAM of the intact limb [1,3]. Advanced prosthetic componentry, such as powered ankle foot devices that mimic that gastric-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. We hypothesized that use of a PWR device would significantly reduce the 1st peak of the intact KAM with respect to both ESR and articulating ESR (ART) devices and would be normalized to the control group.

Methods

Seventeen individuals living with TTA (age 52 ± 14.5 years, height 1.79 ± 0.1, and weight 85.9 ± 17.3) with at least 1 year of prosthetic experience, as well as 6 control subjects were recruited from Veteran Affairs (VA) New York Harbor Healthcare System (NYHHS) and Walter Reed National Military Medical Center (WRNMMC). Study procedures were approved by each sites' respective Institutional Review Board. Participants were randomized to wear 3 types of prosthetic feet: ESR, ART, and PWR. Each device was randomly used for a 1-week acclimation period followed by biomechanical testing. Motion and force data were collected using an optical motion capture system (Qualisys, Goteborg, Sweden) and a force platform system (AMTI, Waterford, MA). Subjects were fit with 78 retroreflective markers and walked over level ground at 3 speeds: 1.0, 1.3, and 1.5 m/s. Data was analysed using Visual3D software (C-Motion Inc.) to derive kinetic results. A one-way, between subjects repeated measures ANOVA was used to determine if any significant differences ($p < 0.05$) were present for the 1st peak intact KAM values between each foot and the control data for all speeds.

Results and Discussion

Results show that the intact KAM for PWR device was 3.0%, 7.1%, and 0.1% lower compared to the ESR foot at 1.0, 1.3, and 1.5m/s, respectively, though results were not significant ($p = 0.135, 1.06, 0.76$). No other significant differences ($p < 0.05$) were found between the 1st peak of the ESR, ART, PWR devices, and the control at all speeds. Figure 1 shows KAM for all devices and control participants at 1.3 m/s. At 1.3 m/s, the percent difference of the 1st peak KAM between each device and the control were: ESR 2.2%, ART 8.8%, and PWR 9.2%, however the results were not significantly different ($p = 0.991$).

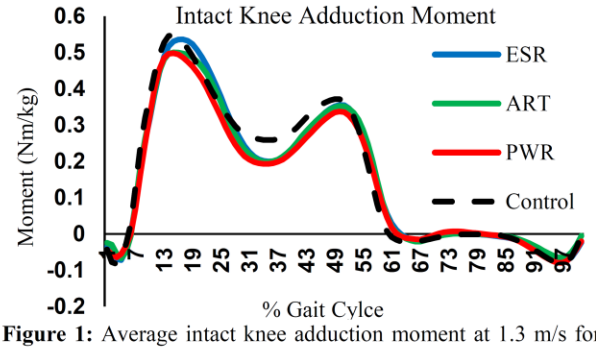

Figure 1: Average intact knee adduction moment at 1.3 m/s for ESR, ART, PWR, and control.

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 m/s 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, EAM was not significantly different between ESR and powered devices. These differences may be attributable to the net positive work performed at faster speeds by the powered prosthesis, whereas at slower speeds the net mechanical work is nearly zero across the entire stance phase [1]. Furthermore, while the powered device provided biomimetic push-off power, the uniaxial movement of the device 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 minimal reduction in intact KAM reported in this investigation could be the result of continued compensatory strategies of the intact limb and reduced stability in the knee frontal plane. Lastly, a longer acclimation period or the inclusion of a strength training/rehabilitation protocol could reduce some of the compensatory strategies. While the PWR device can produce biomimetic ankle power, device-specific training may need to be introduced to reduce joint loading on the intact side.

Significance

Biomimetic devices like the Empower have been shown to reduce some asymmetries during prosthetic gait, such as peak ankle power. However, this investigation did not indicate any significant reductions in peak KAM compared to ESR devices. Devices that could reduce peak KAM could potentially mitigate the risk of musculoskeletal injury, specifically knee OA of the unaffected leg.

Acknowledgments

This work was supported by a DoD Orthotics and Prosthetics Outcomes Research Program grant (W81XWH-17-2-0014). We also acknowledge our co-investigators at WRNMMC.

References

[1] Grabowski A. et al. J. NeuroEng & Rehab vol 10(49) (2013).
[2] Esposito E. et al. Pros & Orth Int vol 40(3) 311-19 (2016).
[3] Royer T. et al. Gait & Posture vol 23(3), 303-6 (2006).

INFLUENCES OF PASSIVE AND POWERED ARTICULATING PROSTHETIC FEET ON TRUNK MOTION AMONGST SERVICE MEMBERS AND VETERANS WITH TRANSTIBIAL LIMB LOSS

Jonathan R. Gladish[1,2], J. Chomack[3], M. Poppo[3], A.D. Knight[2,4], J. Maikos[3], and B.D. Hendershot[2,4]

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Introduction

Fifty-two to eighty-nine percent of persons with lower limb loss (LL) report experiencing persistent, bothersome low back pain [1,2]. While it is difficult to isolate risk factors for the onset/recurrence of low back pain, particularly among persons with LL [3], compensational movement strategies likely play a more substantial role in this population. Specifically, persons with versus without LL demonstrate larger and asymmetric trunk-pelvic motions [4] associated with elevated spinal loads [5]; these altered movement and loading patterns are influenced by level of LL and walking speed, but the specific influences of prosthesis type/features remain unclear.

Ankle-foot prostheses are often broadly sorted into three categories: non-articulating Energy Storing and Returning (ESR), articulating ESR (ART), and articulating powered (POW). Compared to ESR feet, the biomimicry of POW and ART feet improve lower-body biomechanical outcomes [6]; however, there is still a knowledge gap in terms of the residual effects on trunk mechanics. The aim of this analysis was therefore to compare trunk movement patterns during over-ground walking amongst persons with unilateral transtibial LL wearing three different ankle-foot prostheses (ESR, ART, and POW). We hypothesized that, compared to ESR prostheses, ART and POW prostheses would be associated with reduced sagittal lean, lateral trunk range of motion (ROM), and peak lateral flexion on the affected side. An auxiliary aim was to evaluate the influences of walking speed on trunk motion across these three foot types.

Methods

Seventeen persons (15 M/2 F) with unilateral transtibial LL were recruited to participate; six of which were classified as K3, eleven as K4, on the Medicare Functional Classification Level, as determined by the Amputee Mobility Predictor. Participants were randomly assigned an ART and POW foot, and utilized their personal ESR foot (or were prescribed one by a study prosthetist). In a random order, participants sequentially wore each foot for one week prior to biomechanical testing, consisting of walking at three forced speeds (1.0, 1.3, and 1.5 m/s). Trunk kinematics were collected (120Hz) using an optical motion capture system (Qualisys), and trunk segment angles were calculated using Visual3D (C-Motion) relative to the lab coordinate system with a Cardan sequence of X-Y-Z. K3 and K4 data were analyzed separately with a two-way (or three-way; for lateral flexion peaks) repeated measures ANOVA using R (p<0.05).

Results and Discussion

Anterior sagittal lean was greater at increasing speeds for K3 (p<0.01); sagittal ROM was greater at 1.5m/s compared to both 1.3m/s (p=0.01) and 1.0m/s (p<0.01). Walking speed did not affect sagittal lean or ROM for K4. Speed did not affect peak trunk lateral flexion in prosthetic or intact stance (Figure 1) for K3, but these peaks were greater with increasing speed for K4 (all p<0.01). For K3, sagittal ROM was greater in POW than ART (p<0.01) and ESR (p=0.02); however, foot type had no effect for K4. Foot type did not affect sagittal lean or lateral flexion for either K3 or K4. Peak lateral flexion was greater in prosthetic stance for both K3 (Δ=5.9°, p<0.01) and K4 (Δ=2.9°, p<0.01).

The results did not support the hypothesis that POW and/or ART prostheses would reduce trunk motions. Amongst K3, sagittal ROM increased with the use of the POW prosthesis. Apart from influences of walking speed, trunk motions amongst K4 were similar across all three feet. These results reinforce that walking speed generally influences trunk mechanics, even for highly functional persons with LL. However, while prosthetic ankle-foot type clearly influences overall gait outcomes [6], the effects on overall trunk motion are not as readily apparent.

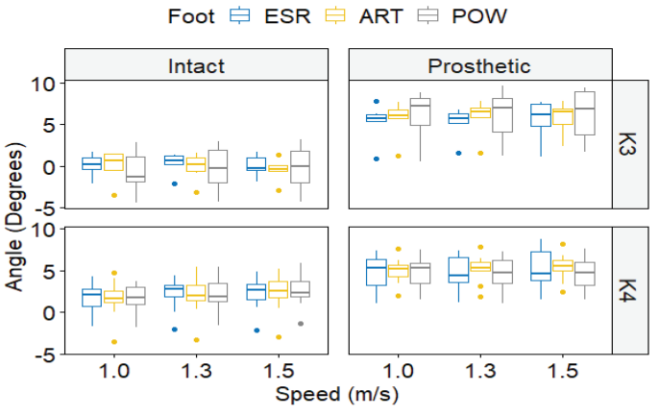

Figure 1: Box plots of peak trunk lateral flexion angles during intact and prosthetic limb stance, by walking speed, for K3 and K4 participants. Positive values indicate flexion in the direction of the denoted limb.

Significance

The lack of discernible differences in trunk motions across feet might suggest the need for advanced analyses examining internal joint contributions which may offset each other holistically (e.g., induced acceleration analyses). Although we distinguished three categories of device type, a wide variety of devices were ultimately used; further subcategorization may identify specific devices or features which influence trunk motion and, subsequently, risk for low back pain. Furthermore, the wide range of functional level of these cohorts illustrates that presumed effects may not be generalizable to the entire LL population (i.e., specific to persons below a K3 level).

Acknowledgments

Supported by DoD Award W81XWH-17-2-0014. The views expressed are those of the authors, and do not reflect the official policy of HJF, USU, the U.S. Departments of the Army/Navy/Air Force, Veterans Affairs, Defense, nor the U.S. Government.

References

[1] Dougherty. (2001) *JBSA* 89(3), 383-389
[2] Farrokhi, et. al. (2018) *Arch Phys Med Rehab* 99, 348-354
[3] Farrokhi, et.al. (2017) *Med Hypotheses* 108, 1-9
[4] Sagawa Jr, et. al. (2011) *Gait & Posture* 33(4), 511, 526
[5] Hendershot, et. al. (2018) *J Biomech* 70, 249-254
[6] Müller, et. al. (2019) *PloS One* 14(11)

MEASURING PROSTHETIC FOOT USE BY CADENCE LEVEL WITH STEP ACTIVITY MONITORING

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Introduction

As advanced prosthetic foot technology becomes more readily available, patients with lower limb amputation will have increased opportunities to access a range of energy storing, articulating, and powered devices. Therefore, it is critical to use objective measures for prosthetic prescription to meet the biomechanical and functional needs of each patient outside of the clinic. Capturing a patient's prosthetic performance while navigating his/her everyday environment is a key piece of information that has yet to be effectively utilized in the prescription process [1]. Activity monitoring devices, such as the Modus™, StepWatch 3™ (Modus Health LLC, Edmonds, WA) used in this study, offer the potential to capture this critical information due to their accuracy for those ambulating with a prosthesis [2]. This study sought to capture the community ambulation activity levels for individuals with transtibial amputation (TTA) while using 3 different types of prosthetic feet over 4 weeks. The purpose of the investigation was to determine if a specific foot type promoted higher activity levels as determined through cadence; and if the activity per level correlated with the outcome measures used in this study.

Methods

Fifty-eight individuals living with TTA (age 56.1±12.8 years, height 1.79±0.08 m, and weight 94.7±18.4 kg) with at least 1 year of prosthesis experience completed the protocol to-date. Participants were recruited from Veteran Affairs (VA) New York Harbor Healthcare System (NYHHS), James A. Haley VA Medical Center, VA Puget Sound Healthcare System, and Walter Reed National Military Medical Center. All procedures were approved by their respective Institutional Review Boards. Participants were randomized to wear 3 types of prosthetic feet: an energy storing and returning device (ESR), an ESR device with articulation (ART), and a powered articulating device (PWR). Each device was attached to a duplicated, well-fitting socket. Study participants wore each foot for a 1-week acclimation period and then separately completed a series of functional outcomes, questionnaires, and a biomechanical assessment for each device. After testing concluded for all devices, a Modus™, StepWatch 3™ step activity monitor (SAM) was affixed to each device and subjects were asked to use each prosthesis as desired for 4 weeks of home use. The SAMs were programmed to record the number of steps taken at each minute. Upon conclusion of the 4-week at-home portion, a close-out survey of the subject's device preference was conducted. Of the 58 participants, 45 used 2 or more feet during the at-home portion and were included in this analysis. Cadence was calculated at each minute, and then categorized into activity levels: low (1-15 steps/min), moderate (16-40 steps/min), and high (>40 steps/min). A one-way ANOVA and linear regression compared the effects of the percent of steps taken to each prosthetic type per activity level, and correlation to the FOs.

Results and Discussion

Figure 1 represents the frequency of the greatest percentage of steps taken at each activity level for each foot type as determined through cadence. Statistical analysis indicated there were no significant effects of prosthetic device type on percent steps taken at any activity levels ($p>0.05$). However, a trend towards significance occurred at the moderate activity level for ESR devices ($p=0.08$). While none of the 3 devices promoted greatest percent of steps at high activity, the trend of greatest percentage of steps taken at moderate activity by ESR devices may be partially explained by foot preference and self-selected walking speed. Based on data from the close-out survey regarding foot preferences, 47% of subjects who preferred the ESR device also performed their greatest percentage of steps at moderate activity with the ESR device. Because the majority of daily steps were taken at moderate activity levels, these findings suggests that participants may prefer to walk at this cadence and select/prefer the prosthetic device that matches the greatest percent of steps at moderate activity levels. Subjects had the most familiarity with the ESR device since they used their currently prescribed ESR device for this study. Lastly, the regression revealed that only the Time-Up & Go (TUG) was able to predict the percent steps at moderate activity ($p=0.03$) for the ESR device with moderate correlative strength ($R=0.60$).

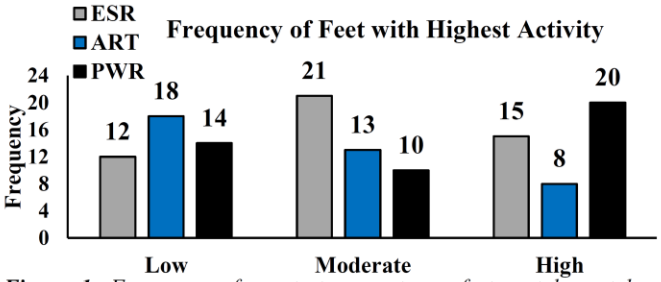

Figure 1: *Frequency of greatest percentage of steps taken at low, moderate, and high activity levels by foot type.*

This investigation sought to determine if a specific foot type promoted higher activity levels, and if those associated values correlated to objective metrics. While current results potentially indicate a correlation between moderate activity and use of the ESR device, factors such as the number of days of use or accounts of a device being used specifically for high level activities will need further investigation.

Significance

Step activity monitoring can be a valuable tool to use in the prosthetic prescription process since it can help evaluate community ambulation activities. Use of objective measures for prosthetic prescription can help meet the biomechanical and functional needs of each patient outside of the clinic.

Acknowledgments

Our work was supported by a DoD Orthotics and Prosthetics Outcomes Research Program Grant (W81XWH-17-2-0014). We acknowledge our co-investigators for their efforts.

References

[1] Halsne, E et al. *JRRD*, 30(4):515-530. (2013).
[2] Coleman, D et al. *JRRD*, 36(1):8-18. (1999).

MEASURING PROSTHETIC FOOT USE BY ACTIVITY LEVEL WITH STEP ACTIVITY MONITORING

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(1) Veteran Affairs New York Harbor
Healthcare System
New York, NY, USA

INTRODUCTION

As prosthetic foot technology advances and becomes more readily available, patients will have increased opportunities to access a range of energy storing, articulating, and powered devices. Therefore, it is critical to use objective measures for prosthetic prescription to meet the biomechanical and functional needs of each patient outside of the clinic. Capturing a patient's prosthetic performance while navigating his/her everyday environment is a key piece of information that has yet to be effectively utilized in the prescription process [1].

Step activity monitoring for individuals with lower extremity amputation has been previously studied to determine compliance and reporting of community ambulation activity in the prosthetic population. Activity monitoring devices, such as the Modus™, StepWatch 3™ used in this study, have been utilized in over 360 peer reviewed publications. The StepWatch 3™ device boasts a 99.7% accuracy for those walking at low speeds and a 92% accuracy for those ambulating with a prosthesis [2]. This study sought to capture the community ambulation activity levels for individuals with transtibial amputation (TTA) while using three different types of prosthetic feet over four weeks. The purpose of the investigation was to determine if a specific foot type promoted higher activity levels as determined through cadence; and if the activity per level correlated with the outcome measures used in this study.

METHODS:

Fifty-one individuals living with TTA age 56.1±12.8 years, height 1.79±0.08 m, and weight 94.7±18.4 kg with at least 1 year of experience with their prosthesis have completed the study protocol to date. These participants were recruited from the Veteran Affairs (VA) New York Harbor Healthcare System (NYHHS), the James A. Haley VA Medical Center, VA Puget Sound Healthcare System, and Walter Reed National Military Medical Center. All procedures were approved by their respective Institutional Review Boards. Participants within this study were randomized to use 3 types of prosthetic feet: energy storing and return foot (ESR), an ESR with articulation (ART), and a powered articulating foot (PWR). Each study device was attached with duplicated, well-fitting below knee sockets.

Study participants wore each foot for a 1-week acclimation period and then completed a series of functional outcomes (FO), questionnaires, and a biomechanical assessment. Participants repeated this process for each subsequent foot type. After wearing each foot for 1 week, participants were instructed to take all study feet home for 4 weeks and to wear the feet as desired. Modus™, StepWatch 3™ step activity monitors (SAMs) were fixed to each prosthesis to track daily steps and activity levels. At the conclusion of the 4-week at home portion, the study devices were returned, and a close-out survey of the participant's device preference was conducted.

Of the 51 participants to complete the study, 38 used 2 or more feet during the at-home portion. Only these 38 participants were included in this analysis. The SAMs were programmed to record the number of steps taken at each minute for 30 consecutive days. Cadence was calculated for each minute, which was then categorized into activity levels: low (1-15 steps/min), moderate (16-40 steps/min), and high (>40 steps/min). Percent of steps taken while active at each activity level was then calculated. At each activity level, we determined the frequencies of the feet with the greatest percent of steps, and, if these feet corresponded to the subject's foot preference. A one-way between subjects Analysis of Variance (ANOVA) was conducted to compare the effects of prosthetic device type to percent steps taken in low, moderate, and high activity levels. Additionally, a simple linear regression was calculated to predict percent steps based on the following FOs: Orthotics Prosthetics User Survey Functional Status, Prosthesis Evaluation Questionnaire Ambulation section, Timed Up-And-Go, 6-

Minute Walk Test, Amputee Mobility Predictor, Stair Assessment Index, and Hill Assessment Index.

RESULTS

Figure 1 represents the frequency of greatest percentage of steps taken at low, moderate, and high activity levels for each foot type as determined through cadence. Results of the ANOVA indicated that there were no significant effects of prosthetic device type on percent steps taken in any of the 3 activity levels ($p>0.05$ in all cases). However, a trend towards significance was observed for the PWR foot at the high activity level ($p=0.06$), with a frequency of 18 of 37 subjects utilizing the PWR for the greatest percent of steps at the high activity level.

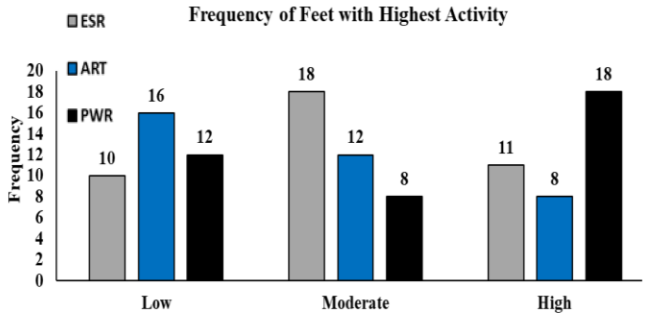

Figure 1:Frequncy of greatest percentage of steps at low, moderate and high activity levels by foot type. (Low, Moderate: N=38)(High: N=37)

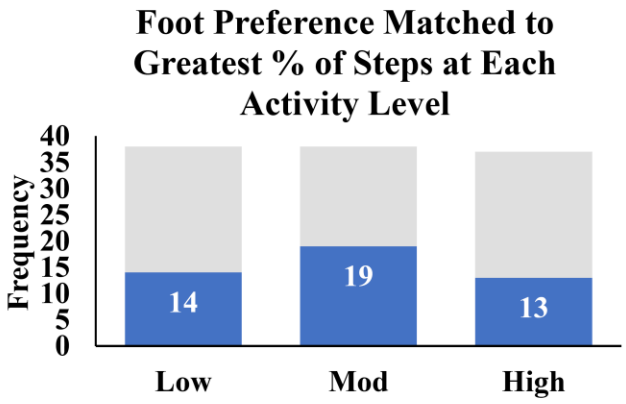

Figure 2: Frequency of subjective foot preference when matched to greatest percentage of steps at low, moderate, and high activity.

Figure 2 represents the frequency of subjective foot preference that matched to the greatest percent of steps taken at each activity level (preference determined by the close-out survey). At high activity 13 of 37 participant (35%) chose the foot that accounted for the greatest percentage of steps. Of the 18 occurrences that the PWR foot provided the greatest percent of steps at high activity, only 6 participants preferred the PWR foot (33%). We observed at low and moderate activity, 37% and 50% of subjects preferred the device that provided the greatest percent of steps. Regression analysis indicated that none of the functional outcome measures were able to predict the percent steps at any of the activity levels ($p>0.05$ in all cases).

DISCUSSION

Step activity monitoring can be a valuable tool to use as part of the prosthetic prescription process since it can help evaluate community ambulation activities. Currently, this key information has been underutilized for this process [1]. This investigation sought to determine if a foot type (ESR, ART, PWR) promoted higher activity levels, and if those associated values correlated to objective metrics. SAM data was recorded for participants using 3 different types of prosthetic feet within their home and community environments over a 4-week period. Percent of steps performed at low-, moderate-, and high-activity were determined and frequencies of prosthetic devices that resulted in the greatest activity at each level were reported.

This preliminary analysis of activity levels for 38 participants showed no significant differences between prosthetic device and percent steps taken at the 3 activity levels. The regression analysis between the objective testing criteria and high activity percent steps taken yielded weak correlative values, suggesting the FO may not be indicative of a subject's activity outside the clinic. However, a trend towards significance was observed for the PWR foot at the high activity level. This trend may be attributed to the powered plantarflexion at terminal stance, which aims to replicate the function of the gastroc-soleus complex. This may allow the user to walk at a consistently higher cadence (>40 steps/min), reducing overall energy expenditure.

Of note, only 35% of users preferred the prosthetic device that promoted the greatest percent of steps taken at high activity (regardless of foot type). Furthermore, of the 18 occurrences in which the PWR foot showed the greatest percent of steps at high activity, only 33% of subjects (n=6) preferred the PWR foot. Participants may not have consistently preferred the PWR foot due to inherent drawbacks of the device, such as heavier weight, increased noise, and the need for daily battery charging. There was an increased percentage of participants who preferred the foot that provided the greatest percent of steps at moderate (50%) activity levels. Because the majority of daily steps were taken at moderate activity levels, these findings suggests that participants may prefer to walk at moderate cadences and select/prefer the prosthetic device that matches the greatest percent of steps at these activity levels.

As more participants complete the protocol, they will be added to this analysis to determine if significance levels can be achieved. Factors such as the number of days of use or accounts of a foot being used specifically for high level activities will need further investigation.

ACKNOWLEDGEMENTS

This work was supported by a DoD Orthotics and Prosthetics Outcomes Research Program grant (W81XWH-17-2-0014). We also acknowledge our co-investigators at the James Haley VA Medical Center, VA Puget Sound Healthcare System, and Walter Reed National Military Medical Center for their work and compliance.

REFERENCES

[1] Halsne, E et al. *JRRD*, 30(4):515-530. (2013).
[2] Coleman, D et al. *JRRD*, 36(1):8-18. (1999).
[3] Stepien, J et al. *Arch. PM&R*, 88(7):896-900. (2007).