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

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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, multi-center, 8-week, randomized, cross-over clinical trial. Subjects randomly receive 3 prosthetic feet (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. Biomechanical differences are emerging in parameters for ankle roll-over shape and external adduction moment, but no significant differences have been found in functional outcomes.

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
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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

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 living 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 120 participants living with transtibial amputation.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

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: 60% WR: 43%	-
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: 51% WR: 40%	-
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: 51% WR: 40%	-

What was accomplished under these goals?

Major Activities and specific objectives for Year 3 include:

<u>Recruitment and Enrollment</u>

Due to the COVID-19 pandemic, all patient-related research activities have been placed on an administrative hold until further notice, as of 03/30/2020. Research activities for this study will resume upon further guidance from the VA Office of Research and Development and the Department of Defense. A reopening plan has been submitted to the VA New York Harbor Healthcare System (VANYHHS) Associate Chief of Staff for Research for approval. As of Year 3 Quarter 4, 21 subjects have been enrolled at VA New York Harbor, 17 at Walter Reed National Military Medical Center (WRNMMC), 32 at James A. Haley VA and 10 subjects at Puget Sound VA Medical Center. Recruitment is ongoing at all sites. Table 1 outlines current enrollment at each site:

TABLE 1: Recruitment and Enrollment at Each Site

Site	Enrolled	Withdrawn	Completed	In Protocol
NYHHS	21	2	16	3
Tampa VA	32	1	25	6
Seattle VA	10	1	8	1
WRNMMC	17	4	12	1
Total	**80**	**8**	**61**	**11**

<u>Significant Results and Key Outcomes for Year 3</u>

This investigation is a prospective multi-center study**,** including the NYHHS, Seattle VA, Tampa VA, and WRNMMC. 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 NYHHS and WRNMMC are 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, 15 subjects have completed biomechanical testing. The James A. Haley VA Medical was recently approved as a third biomechanics site (local IRB approval 4/2020, HRPO approval 5/2020) and will begin enrollment following the COVID-19 administrative hold. 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.

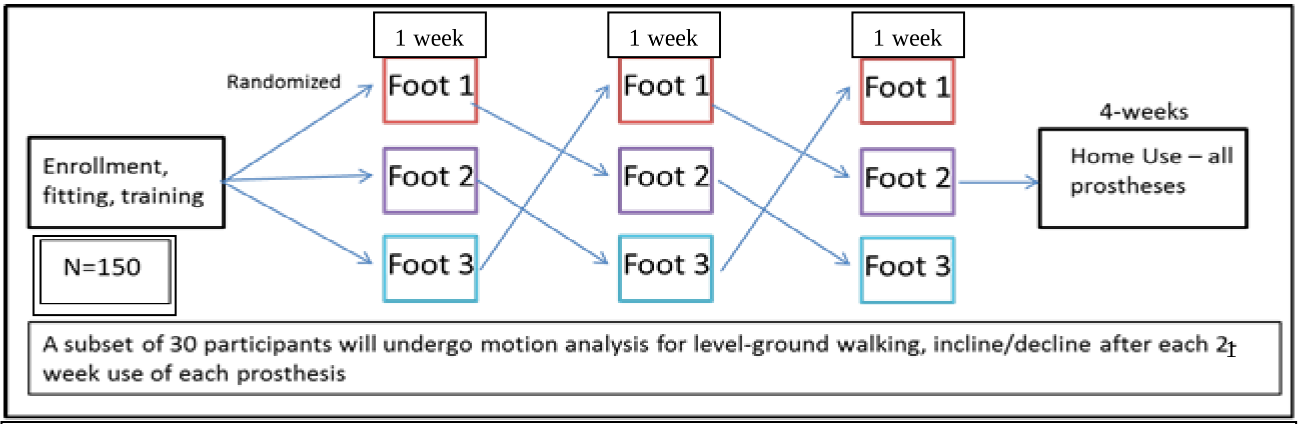


Figure 1: Research Design and Project Timeline for each Subject.

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 (Figure 2), and sagittal plane kinematics for ramp walking (Figure 3).

Mean Joint Kinematics/Kinetics During Level Ground Walking

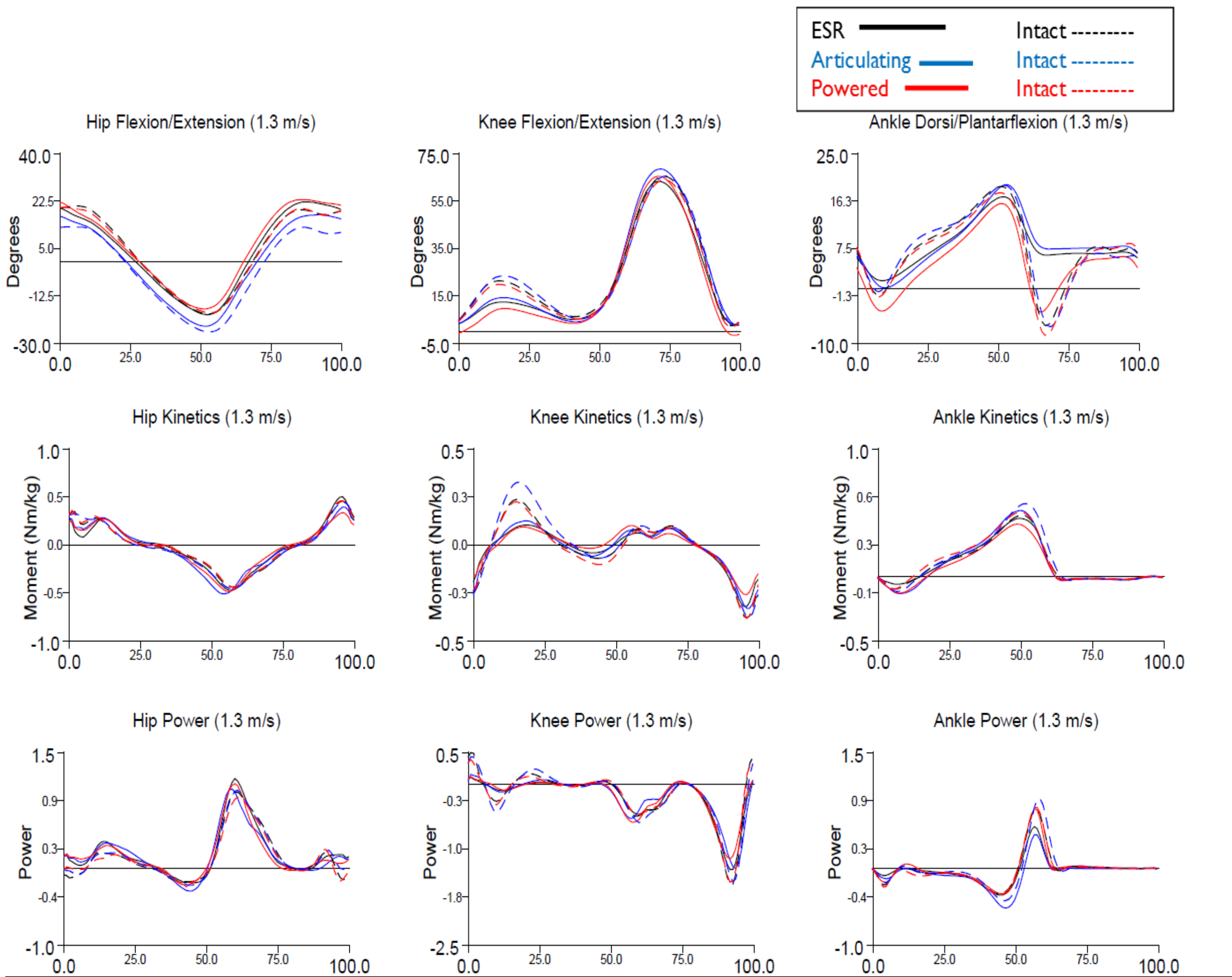


Figure 2: Average biomechanical data for completed subjects during level ground walking. Mean sagittal plane joint kinematics and kinetics are shown.

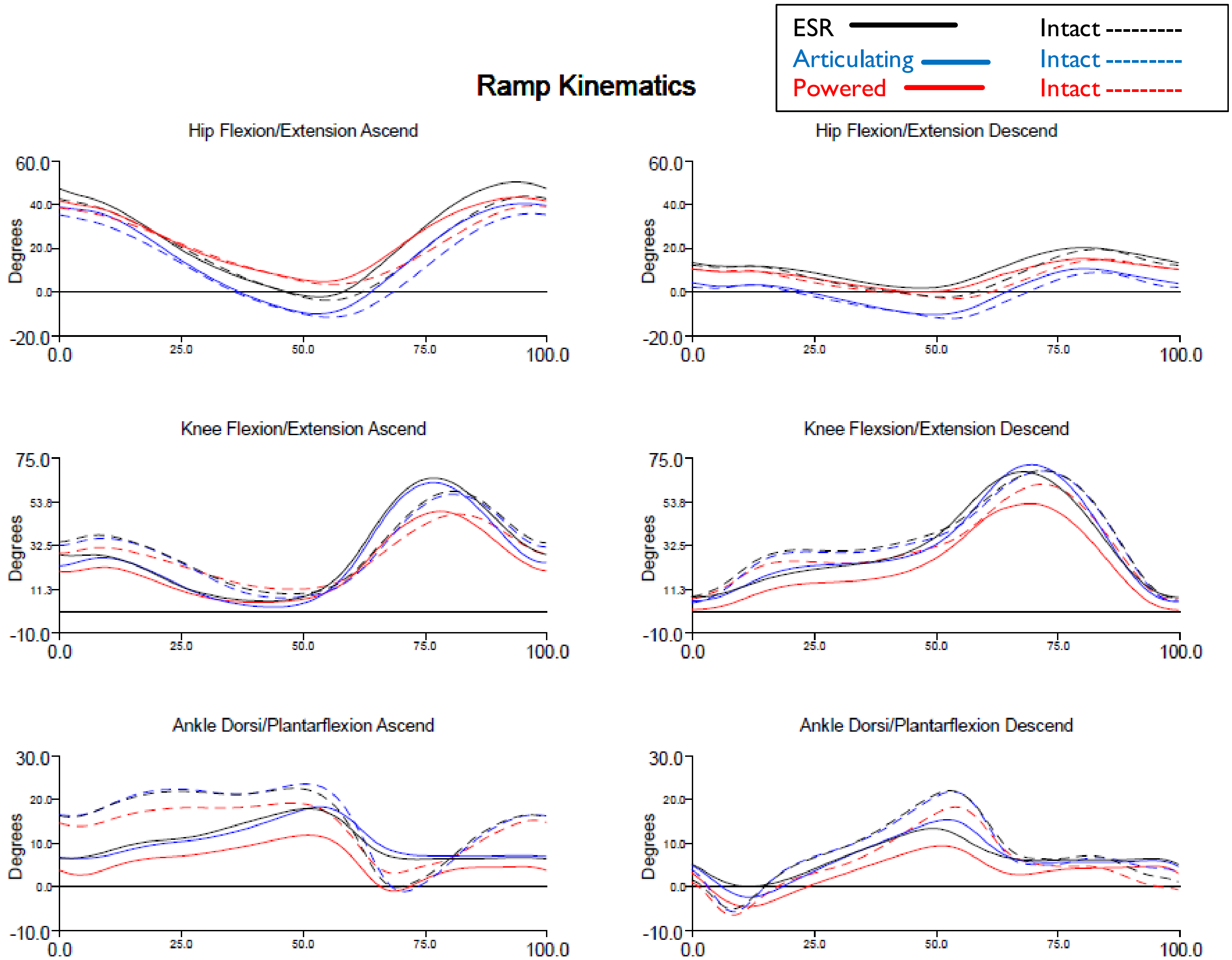


Figure 3: Average biomechanical data during ramp walking. Mean sagittal plane joint kinematics for ascent and descent are shown.

Biomechanical Analysis continued

Figure 4 illustrates the external knee adduction moments and vertical ground reaction forces 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.

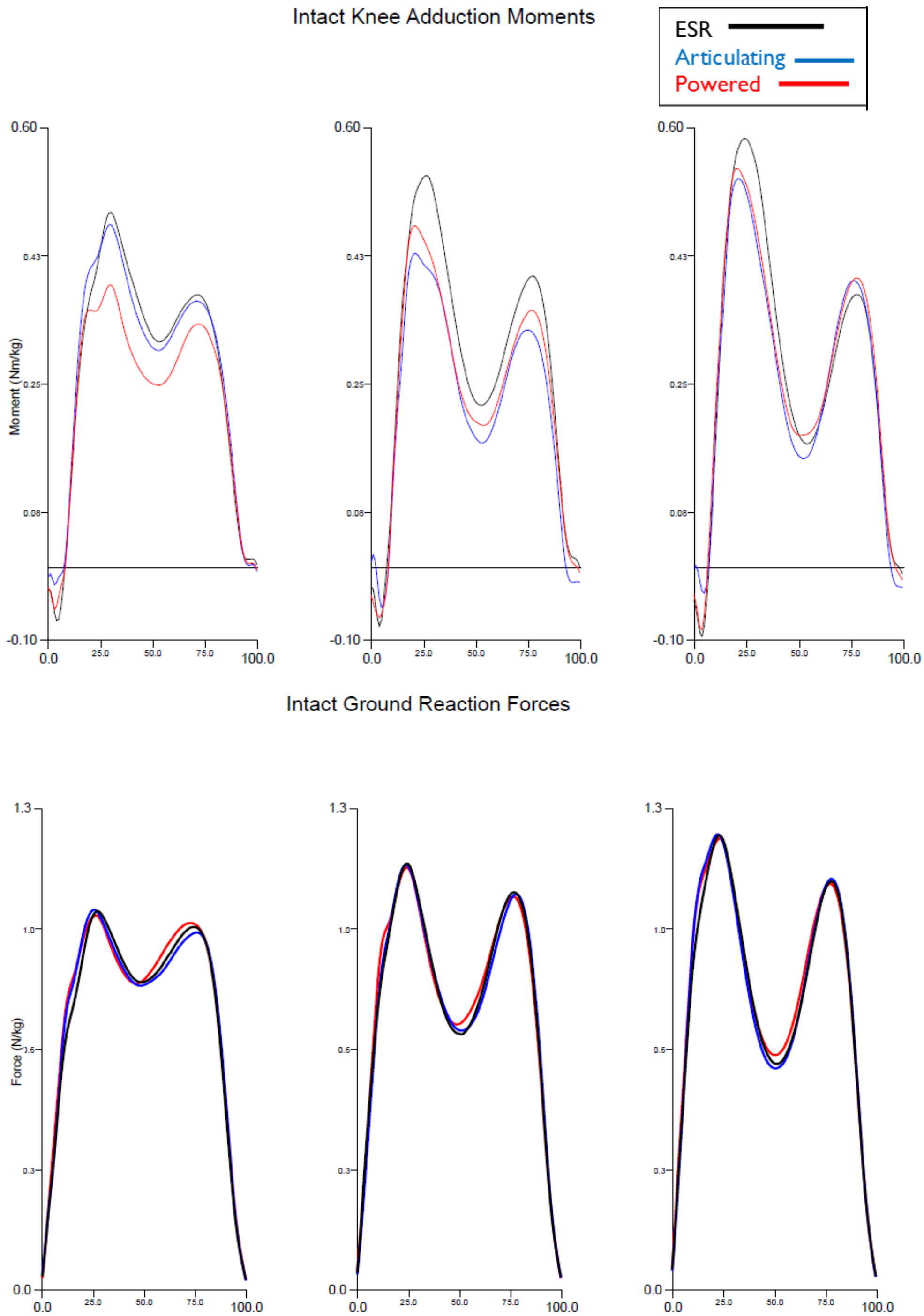


Figure 4: Average intact leg external adduction moments (top) and vertical ground reaction forces (bottom) at the 3 walking speeds.

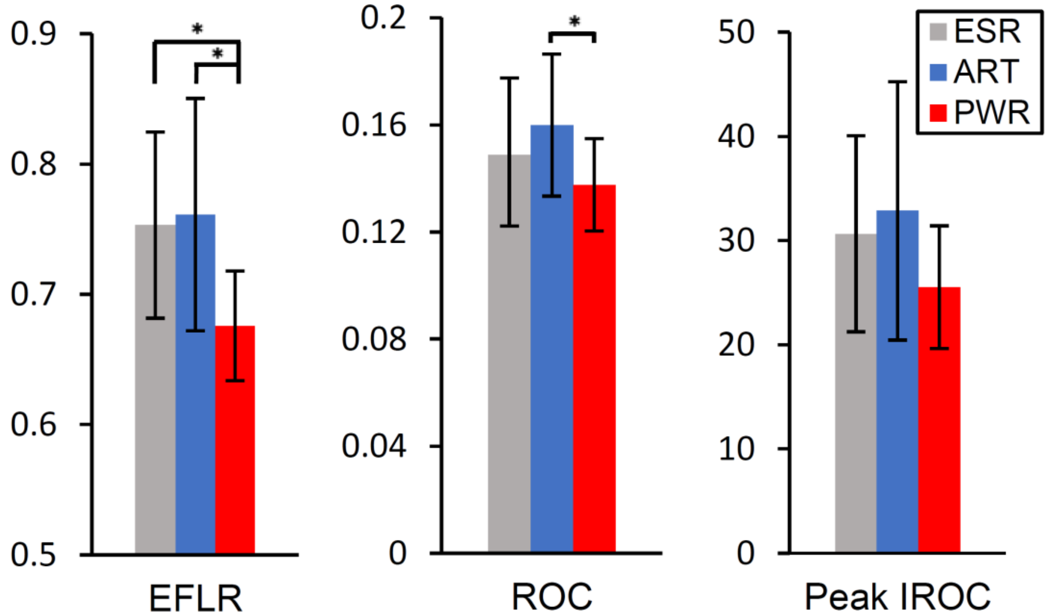


Figure 5: EFLR bar plot (left), height-normalized ROC (center), and peak IROC (cm) (right).
* Statistically significant change at $p < 0.05$.

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 enrolled 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)**
Time Up and Go (sec)	8.77 (3.4)	9.30 (3.5)	9.37 (3.5)
Four Step Square Test (sec)	10.46 (4.7)	10.66 (5.9)	10.98 (4.5)
Six Minute Walk Test (m)	421.48 (119.1)	419.03 (111.4)	421.84 (111.3)
Amputee Mobility Predictor (AmpPro)	41.42 (4.6)	41.52 (4.2)	41.14 (4.2)
Stair Assessment Index (SAI) - Ascent	10.90 (2.9)	10.75 (3.1)	10.67 (2.9)
Stair Assessment Index (SAI) - Descent	10.38 (3.3)	10.31 (3.4)	10.43 (3.1)
Hill Assessment Index (HAI) - Ascent	10.29 (1.3)	10.37 (1.2)	10.45 (1.4)
Hill Assessment Index (HAI) - Descent	10.25 (1.3)	10.29 (1.3)	10.29 (1.4)

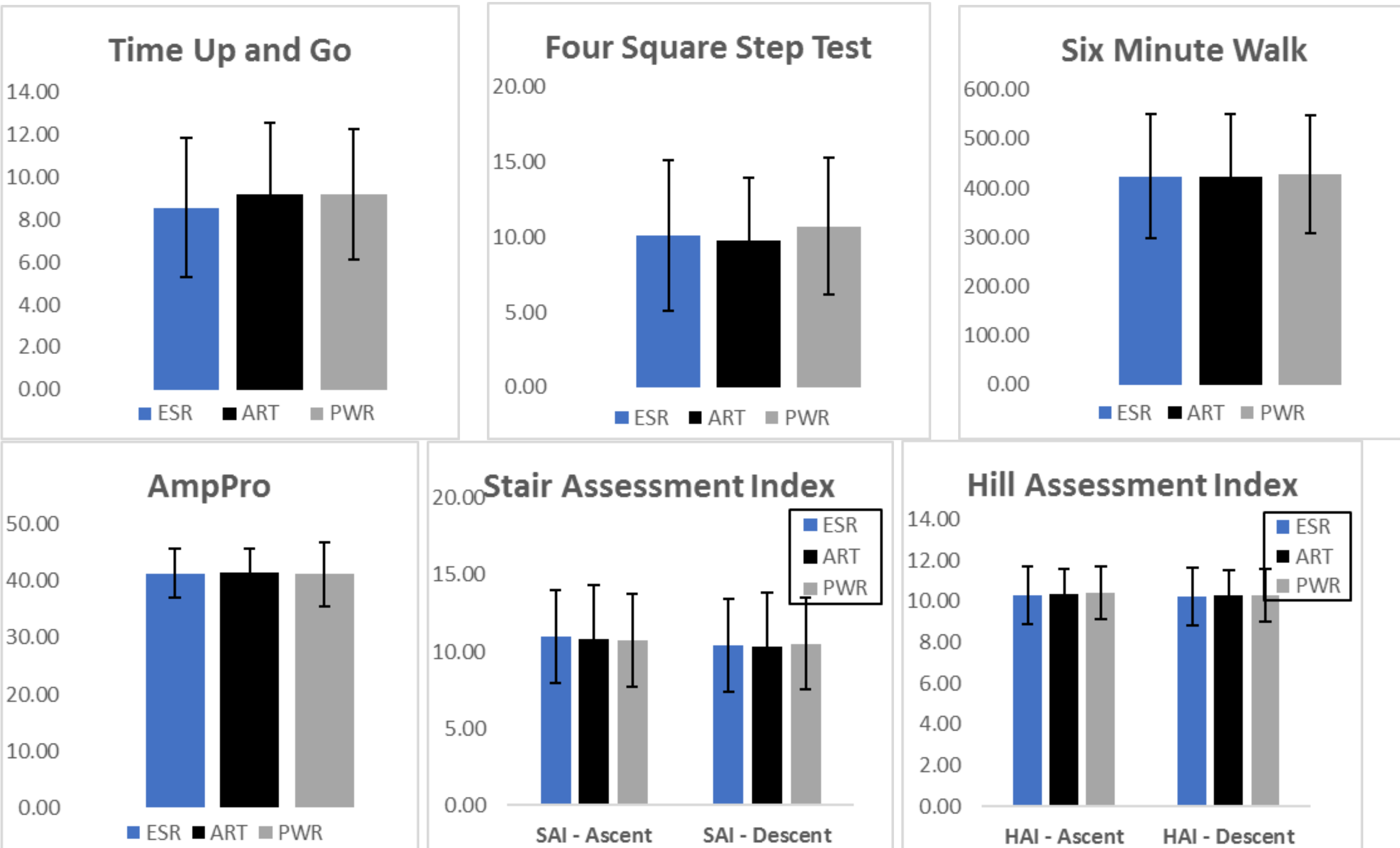
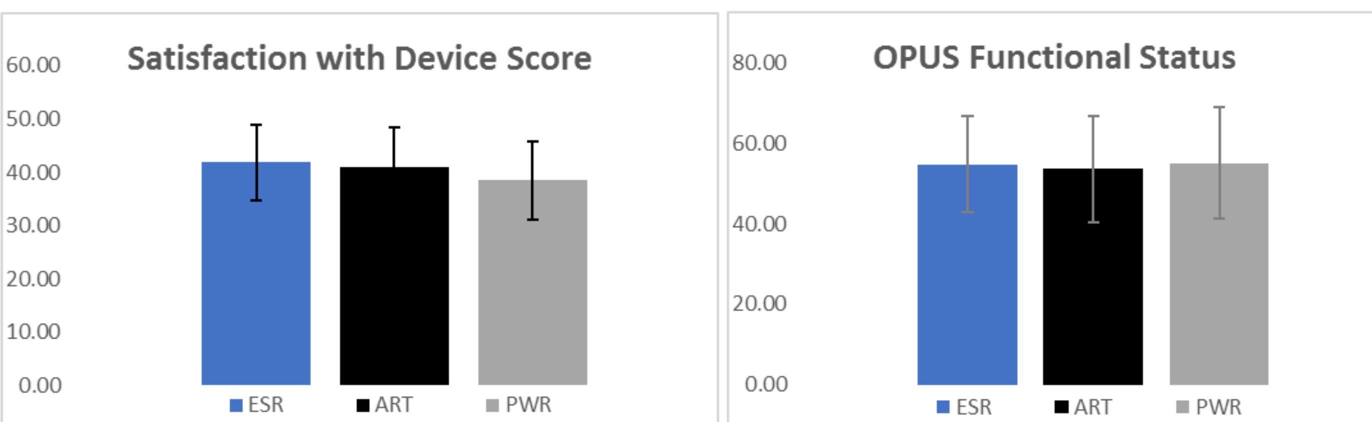


Figure 6: Functional outcome measures for completed subjects.

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.



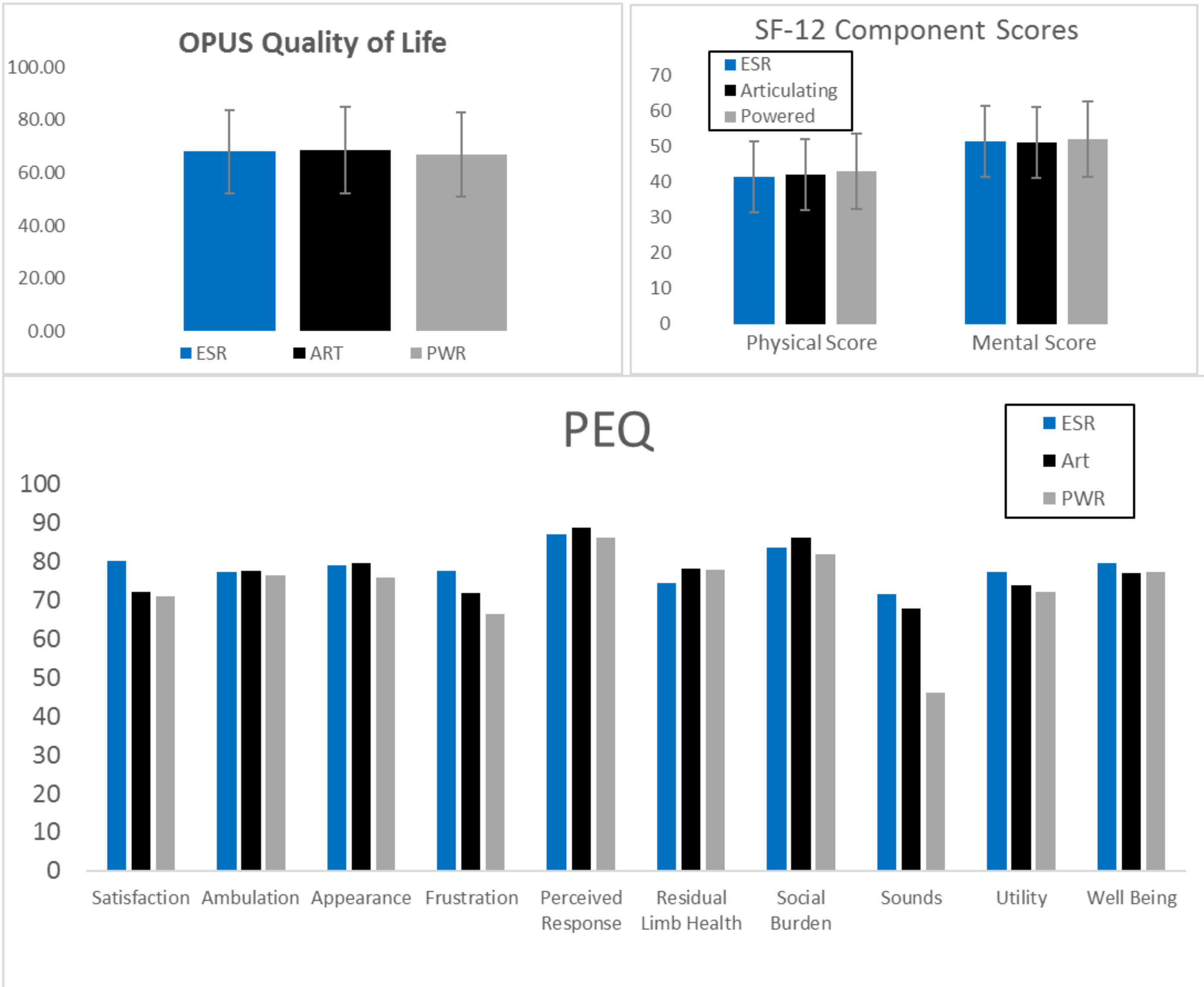


Figure 7: Average scores from self-report surveys, including the OPUS satisfaction with Devices, OPUS Functional Status, OPUS Quality of Life, SF-12, and the Prosthetic Evaluation Questionnaire (PEQ).

Goals Not Met:

All goals have not been met for Y3. This investigation has been placed on administrative hold since March 2020 due to the COVID-19 pandemic. As such, there was minimal recruitment during Q3 and Q4. Once research activities resume (as per VA ORD and DoD guidance), modified recruitment plans at each site will be enacted. These strategies include increasing the target enrollment at the James A. Haley VA to 45 participants, extending passive recruitment at Walter Reed 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 living with amputation (in-person or virtually), and continuing our biweekly conference calls. In the aftermath of COVID-19, it is expected that in-person clinical visits at the prosthetics and physical medicine departments will decrease and non-contact telehealth visits will increase. Non-contact recruitment methods will be evaluated and implemented at each site as necessary to increase enrollment. We will continue to conduct group quarterly conference calls with all sites to review progress to date and discuss any problems that arise.

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

While the project is not intended to provide training and professional development, we hosted a 1-day comprehensive meeting/training at James A. Haley VA Medical Center on November 19, 2019. Members from each site received project management training (data collection, recruitment, and data sharing techniques), as well as a review of the device-specific training and project data to-date. The agenda for this 1-day training is below. Furthermore, members of the study team attended the 2020 American Society of Biomechanics annual conference, which was held virtually due to the pandemic. Two abstracts were presented at the conference:

VA | 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: November 19th, 2019

Time: 8am – 3pm

Place: James A. Haley Veterans Hospital
Primary Care Annex – Education Conference Room 1B-109
13515 Lake Terrace Lane
Tampa, FL 33637

Subject: Year 3 Annual Meeting for "Criteria for Advanced Prosthetic Foot Prescription"

Invited Participants: Jason Maikos, PhD, Leif Nelson, DPT, Michael Hyre, MS, John Chomack, MS (VANYHHS); Ashley Knight, PhD, Jonathan Gladish, MS (WRNMMC); Jeffrey Heckman, DO, Ellen Ferris, PT (VAPSHCS); Sam Phillips, PhD, CP, Lisa Ballistrea, MSPT, DPT, Anh Du, CO, BOCP, Meghan Rosenbrock, DPT (JHVH)

Agenda

Tuesday, November 19th 2019

Time	Session	Presenter	Location
8:00 – 8:30am	Breakfast and Opening Remarks	JM	Conference Room 1B-109
8:30 – 9:15am	Study Overview (Enrollment, Results)	JM	Conference Room 1B-109
9:15am – 9:30am	Break		Conference Room 1B-109
9:30 – 10:15am	Regulatory Protocol Review (Deviations, Study Documentation, Adverse Events)	MH	Conference Room 1B-109
10:15pm – 12:00pm	Individual Meetings with each site	MH/JM	Conference Room 1B-109
12:00pm – 1:00pm	Lunch Break		Conference Room 1B-109
1:00pm – 2:00pm	Tour of Tampa Facility	SP	James A. Haley VA Medical Center
2:00-2:30pm	Individual Meetings Continued	MH/JM	Conference Room 1B-109
2:30-3:00pm	Closing Remarks; NCE, Open Forum	JM	Conference Room 1B-109

How were the results disseminated to communities of interest?

Two abstracts were presented at the American Society of Biomechanics Annual Conference, which was held virtually from August 4-7, 2020. The titles for the abstracts are:

- Ankle Roll-over Shape Comparisons of Different Prosthetic Foot Types
- Trunk Control during Walking with Below-Knee Amputation: Effects of Prosthetic Ankle-Foot Actuation

Additionally, we are preparing two manuscripts on the biomechanical data collected to-date.

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

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

- Restart the study protocol at all sites, as permitted by VA ORD, local IRB sites, and DoD.
- Complete enrollment at all sites.
- Conduct biweekly and quarterly conference calls to monitor recruitment goals/strategies and provide updates.
- Conduct protocol procedures and data collection, as permitted by VA and DoD.
- Continue/complete data analysis for completed subjects.
- Manuscript preparation for journal articles

4. IMPACT:

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

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

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

Additionally, the James A. Haley VA was added as a third biomechanics site to complete recruitment/enrollment of subjects who are randomized to the biomechanics protocol. Local IRB approval was granted on 4/16/2020 and the HRPO amendment approval memo was received on 5/18/2020.

A year 4 extension without funds was also approved on 3/2/2020, which has extended the performance period of this investigation through 7/31/2021.

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

The following problems/delays are detailed below:

- Recruitment: Recruitment to date is less than the projected target for the end of Year 3 largely due to the COVID-19 pandemic. Prior to the administrative hold, Y3 saw an increase in enrollment, but all recruitment/enrollment has been suspended until further notice.
- Once the administrative hold is removed, successful recruitment strategies at each will continue to be implemented including:
    - Presenting at local amputation support groups
    - Attending local and national conferences, as well as chapter meetings targeted for individuals living with amputation
        - This includes the national Amputee Coalition Conference, as well as local limb loss education days.
    - Including civilians from affiliated medical centers and clinics.
    - Continue bi-weekly calls with study sites to encourage recruitment efforts and mitigate any problems
        - The principal site team will continue to work with each site to optimize recruitment strategies to increase enrollment.

Changes that had a significant impact on expenditures

Expenditures on supplies/materials have decreased during the COVID-19 pandemic. However, salary for staff at all sites have continued to be paid for study activities (ex: data analysis, data processing, regulatory requirements). In September, we will perform an “end of fiscal year” burn rate analysis of expenses to date.

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

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to report. Currently preparing two manuscripts based on biomechanical data.

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

Nothing to Report

Other publications, conference papers and presentations.

Two abstracts were presented at the American Society of Biomechanics Annual Conference, which was held virtually from August 4-7, 2020. The titles for the abstracts are:

- Ankle Roll-over Shape Comparisons of Different Prosthetic Foot Types
- Trunk Control during Walking with Below-Knee Amputation: Effects of Prosthetic Ankle-Foot Actuation

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Jason Maikos, PhD
Project Role:	PI at NYHHS
Nearest person month worked:	2
Responsibilities/ Contributions:	Oversees overall integrity of the study, as well as 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 NYHHS
Nearest person month worked:	5
Responsibilities/ Contributions:	Oversees all regulatory activities at NYHHS and assists with IRB/HRPO submissions for each site. Coordinates data collection and entry from all sites. Provides support and troubleshooting to each site. Tracks and coordinates all study materials for each site. Aides in coordinating study meetings.
Name:	Eric Baksh
Project Role:	Prosthetic Technician at NYHHS
Nearest person month worked:	12
Responsibilities/ Contributions:	Fabricates all sockets for the study.
Name:	John Chomack, MS
Project Role:	Research Engineer at NYHHS
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 NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with biomechanical testing and data processing
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Ellen Godwin, PhD, PT
Project Role:	Research Physical Therapist at NYHHS
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 NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with biomechanical data collection
Funding Support	CDMRP award number W81XWH-17-2-0029
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:	Jeffrey Heckman, DO
Project Role:	Site-PI at VA Puget Sound
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, assists with subject enrollment.
Name:	Ellen Ferris, PT
Project Role:	Physical Therapist, PT at VA Puget Sound
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with subject recruitment, conducts functional outcome testing
Name:	Matthew Jerrell
Project Role:	Research Coordinator at VA Puget Sound
Nearest person month worked:	1
Responsibilities/ Contributions:	Assists with local IRB submissions
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 James A. Haley VA, coordinates local IRB submissions, assists with socket fittings.
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 and ensuring 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 and ensuring safe usage of prosthetic feet, coordinates subject enrollment, participated in Y2Q3 quarterly meeting.
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 VA Medical Center
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 American Society of Biomechanics 2020 annual conference is presented below:

Ankle Roll-over Shape Comparisons of Different Prosthetic Foot Types

Michael Poppo[1], Andrew Hansen[2,3], John Chomack[1], and Jason Maikos[1]
[1]Veterans Affairs New York Harbor Healthcare System, New York, NY
[2]Minneapolis Department of Veterans Affairs Health Care System, Minneapolis, MN
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Introduction

As the climate of prosthetic devices has evolved, the number of available prosthetic feet has greatly risen. Clinicians have limited guidelines to aid in prosthetic prescription for individuals with lower extremity amputation. Furthermore, most comparative research has been contradictory or non-committal, which makes it difficult for clinicians to understand which devices will maximally benefit a given user. The objective of this study was to examine the dynamic function (radius of curvature (ROC), effective foot length ratio (EFLR), and instantaneous radius of curvature (IROC)) of 3 different types of prosthetic feet: Energy Storing and Returning (ESR), Articulating (ART), and Powered (PWR). This information may be critical in advancing our understanding of the most effective prosthetic designs, which can aid in evidence-based clinical practice and prosthetic prescription guidelines. We hypothesized that the ART and PWR feet would generate similar roll-over shape characteristics that would suggest improved dynamic functionality compared to ESR feet.

Methods

Motion capture and kinetic data were captured for 12 people with unilateral transtibial amputation during overground walking at the Veterans Affairs New York Harbor Healthcare System (VA NYHHS) and Walter Reed National Military Medical Center (WRNMMC). Each patient completed data collection for each of the 3 feet after acclimating to each foot for one week. Center of pressure (COP) data were transformed into the shank coordinate system during single limb stance. EFLR, a measure of the percentage of the foot that is effectively used during a step, was calculated as the distance from the prosthetic heel to the most anterior point of the COP progression divided by the overall length of the foot. Circular arcs of best fit were also applied to the COP data to determine roll-over shape characteristics, such as height-normalized ROC (Hansen, 2003). The IROC was calculated by evaluating the first derivative of COP forward travel with respect to shank angle. The peak IROC is representative of the fastest COP forward travel.

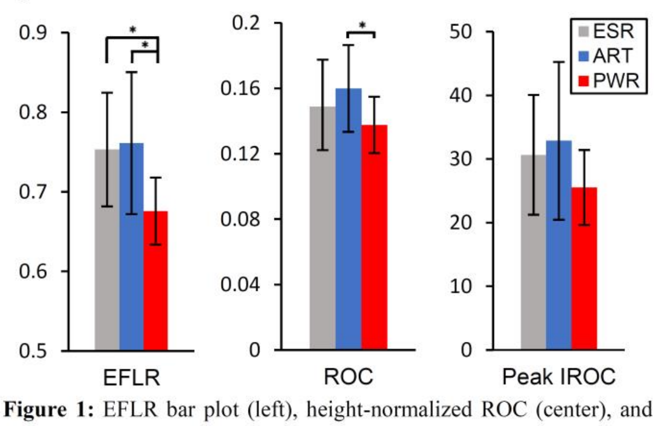

Figure 1: EFLR bar plot (left), height-normalized ROC (center), and peak IROC (cm) (right). * Statistically significant change at $p < 0.05$.

Results and Discussion

Figure 1 shows that 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) ($p < 0.05$). Reduced EFLR of the PWR device indicates that the COP did not progress as far anteriorly during single leg stance, which can correlate to a reduced ankle lever arm in late 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. However, it is unclear if the small differences found are clinically significant. Lastly, the PWR group had the lowest peak IROC (25.5±5.9 cm) and was trending towards significance compared to the ART group (32.8±12.4 cm) ($p = 0.066$), but not significantly different than the ESR group (30.6±9.4 cm) ($p = 0.11$). Decreased forward travel, as indicated by lower peak IROC, suggests reduced standing stability (Curtze, 2009). Of note, the PWR foot is specifically designed to provide powered plantarflexion at terminal stance and is therefore not active during the single limb stance phase in which this analysis was conducted. We believe the motor could be causing an angular load at the ankle which may play a role in limiting the effectiveness of the passive mechanical components of the foot.

Significance

Prosthetic prescription practices continue to be rooted in anecdotal evidence and manufacturer claims. Clinicians can use the information presented in this study to help prescribe devices that mimic effective rocker shapes to assist in dynamic activities. Manufacturers can design new componentry and prosthetic devices that better approximate the rocker shapes of the physiological ankle-foot complex to reduce interlimb asymmetries (Ferris, 2012). In this investigation, we showed that the PWR foot, while designed to provide biologically normative push-off power, provided less biomimetic function during single-leg stance and utilized less of the effective foot length. As the evolution of prosthetic feet continues, synergy between passive elements and advanced features must be maintained to effectively mimic the physiological ankle-foot complex.

Acknowledgments

This work was supported by a DoD Orthotics and Prosthetics Outcomes Research Program grant (W81XWH-17-2-0014). We would also like to acknowledge our collaborators at Walter Reed National Military Medical Center.

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Curtze et al. 2009. Comparitive roll-over analysis of prosthetic feet.
Ferris et al. 2012. Evaluation of a powered ankle-foot prosthetic system during walking.

Trunk Control during Walking with Below-Knee Amputation: Effects of Prosthetic Ankle-Foot Actuation

Adam J. Yoder[1,2], Jonathan R. Gladish[3,4], Ashley D. Knight[1,3,5], Shawn Farrokhi[1,2], John M. Chomack[6], Michael N. Poppo[6], Jason T. Maikos[6], Brad D. Hendershot[1,3,5]
[1]DoD-VA Extremity Trauma and Amputation Center of Excellence, [2]Naval Medical Center San Diego, [3]Walter Reed National Military Medical Center, [4]Henry M. Jackson Foundation, [5]Uniformed Services University of Health Sciences, [6]VA New York Harbor Healthcare System
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Introduction

Persons with below-knee amputation (BKA) often exhibit abnormal trunk motion during walking, with associations to low back pain and challenged balance [1–3]. We recently identified that altered mechanics of the affected-limb knee and prosthetic ankle have potential to adversely influence trunk rotational dynamics when walking with BKA [4]. As such, modifying prosthetic ankle-foot mechanics (e.g., torque, range of motion) may be an indirect means to influence trunk control. This preliminary analysis explores this concept by comparing ankle contributions to rotational trunk control while wearing three distinct, prosthetic ankle-foot devices.

Methods

Within scope of clinical trial NCT03505983, one subject with traumatic, unilateral BKA (F, 40yr, 172cm, 63kg, 25 years post-amputation) wore three different ankle-foot prostheses: (1) energy storage and return (ESR, Ossur Proflex XC), (2) ESR with articulation (ART, Ossur Proflex Pivot), and (3) powered with articulation (POW, Ottobock Empower). Each foot was aligned on a replicate socket and granted 1-week daily use acclimation (order: ART/POW/ESR), after which whole-body kinematics and kinetics were measured while walking overground at 1.3m/s. Data processing and simulation mirrored [4]. Briefly, a single patient model was generated by scaling OpenSim Gait2392 to session-averaged anthropometrics. Estimated joint angles and net moments were input to a torque-driven induced acceleration (IA) analysis. Trunk segment rotational accelerations induced by individual joint moments were then compared between prostheses and versus non-BKA normative (NORM) ranges [4].

Results and Discussion

Ankle push-off moment increased 27% with POW versus EST/ART, to within NORM (Fig 1; A*). This was concurrent with less frontal, ipsilateral ankle-trunk IA in POW (Fig 1, B*), but was consistently abnormal across feet (lesser frontal, greater sagittal). Larger differences in ankle-trunk IA were apparent during loading response, where earlier peaks above NORM acted to flex the trunk forward and ipsilaterally (Fig 1; C*, D*). This feature, greatest with POW and least with ART, may indicate high sensitivity of trunk stabilization to prosthetic actuation during weight acceptance; if not counter-acted by other joint IA contributions as observed in this subject (i.e., measured trunk kinematics were consistently within NORM), this may destabilize the trunk [2].

During push-off, peak lumbar moments were greater than NORM with ESR/ART (+42% frontal, Fig 1, E*; +53% sagittal Fig 1, F*), as were concurrent lumbar-trunk IAs (Fig 1; G*, H*). POW appeared to mitigate this, decreasing moments and IAs within NORM, which may indicate an improved whole-body strategy; less necessity with POW to actively modulate dynamic postural control via trunk inertia.

Significance

These observations, albeit patient-specific, highlight that contributions to trunk rotational control can be influenced by varied prosthetic ankle-foot actuation (passive/active power, variable articulation). Further analyses will help determine if similar trends are characteristic of BKA, or individualized. More broadly, this line of inquiry aims to inform clinically translatable strategies to modify problematic trunk motion, a key factor in dynamic balance and mitigating low back pain [1–3].

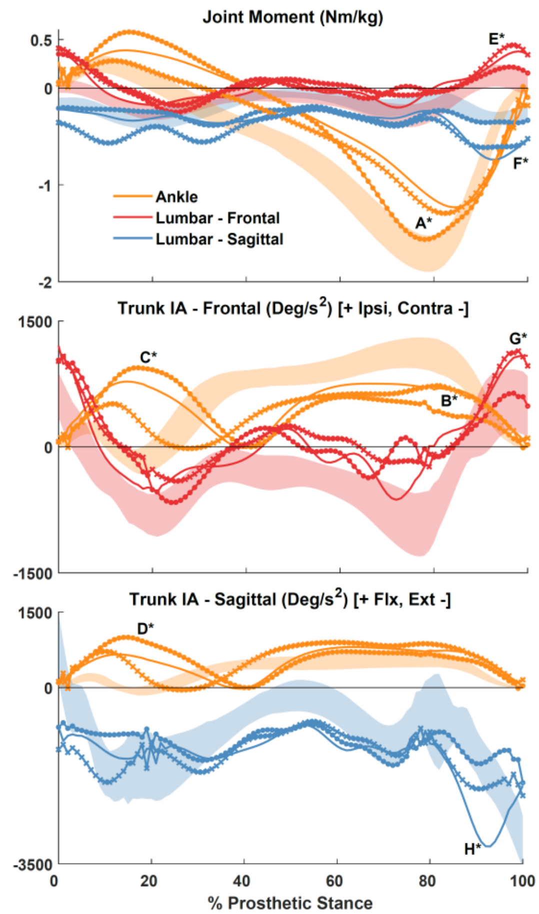

Figure 1: Joint moments (top) and trunk rotational induced accelerations (IA) in the frontal (middle) & sagittal (bottom) planes, for the ESR (solid line), ART (**x**), POW (●) ankle-foot prostheses. Shaded areas are mean±1std non-BKA normative ranges (NORM) [4].

Acknowledgments

Funding support CDMRP W81XWH-17-2-0014.

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