

AWARD NUMBER: W81XWH-17-2-0014

TITLE: Criteria for Advanced Prosthetic Foot Prescription

PRINCIPAL INVESTIGATOR: Leif Nelson, DPT

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. Enrollment has begun at all sites. There are no significant findings to report at this time.					
15. SUBJECT TERMS Amputation, Limb Loss, Prosthetic Prescription, Prosthetic Feet, Prosthesis					
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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
<i>Milestone Achieved: Local IRB approval at each site</i>	100%	James A. Haley VA: 11/06/2017 VA Puget Sound: 11/07/2017 Walter Reed: 12/05/2017
<i>Milestone Achieved: HRPO approval for all protocols</i>	100%	James A. Haley VA: 02/26/2018 VA Puget Sound: 03/15/2018 Walter Reed: 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
<i>Milestone Achieved: Project Research staff hired and trained</i>	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 1 week trials then provide devices/sockets for final take home trial	Ongoing	-
<i>Milestone Achieved: Study begins</i>	100%	Overall Study: 01/09/2018 Walter Reed: 05/17/2018
<i>Milestone Achieved: First subject consented, screened, and enrolled</i>	100%	Overall Study: 01/09/2018 Walter Reed: 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	-
<i>Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled</i>	10%	Walter Reed: 10%
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	-
<i>Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled</i>	ongoing	-
<i>Milestone Achieved: 50% of participants have completed testing of in each prosthetic device</i>	ongoing	-
<i>Milestone Achieved: All subjects have completed the research protocol</i>	ongoing	-

What was accomplished under these goals?

Major Activities and specific objectives for Year 1 include:

IRB Submission

Local IRB and HRPO approval has been achieved at all sites. Approval dates are listed in Table 1.

TABLE 1: IRB and HRPO Approvals

Site	Local IRB Approval Date	HRPO Approval Date
VA New York Harbor Healthcare System (NYHHS)	3/27/2017	6/13/2017
James A. Haley VA Medical Center (Tampa VA)	11/06/2017	02/26/2018
VA Puget Sound Medical Center (Seattle VA)	11/07/2017	03/15/2018
Walter Reed National Military Medical Center (WRNMMC)	12/05/2017	01/22/2018

Subawards

Subawards have been finalized between New York Harbor Healthcare System (NYHHS) and James A. Haley VA (Tampa VA) and VA Puget Sound (Seattle VA). A CRADA agreement between Walter Reed National Military Medical Center (WRNMMC) and NYHHS is currently under final review and pending approval. However, a start letter for WRNMMC was issued 05/17/2018 and enrollment has commenced.

Study Staff

All staff have been hired at NYHHS, WRNMMC, James A Haley VA Medical Center, and Puget Sound VA Medical Center.

Recruitment and Enrollment

Recruitment and enrollment has begun at all sites. Table 2 outlines current enrollment at each site:

TABLE 2: Recruitment and Enrollment

Site	Screened	Screen Failure	Enrolled	Withdrawn	Completed
NYHHS	6	1	5	0	3
Tampa VA	3	0	3	0	2
Seattle VA	1	0	1	0	1
WRNMMC	3	0	3	1	0
Total	13	1	12	1	6

Significant Results and Key Outcomes for Year 1

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, 3 of the enrolled subjects were assigned for biomechanical testing and 2 have completed this 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.

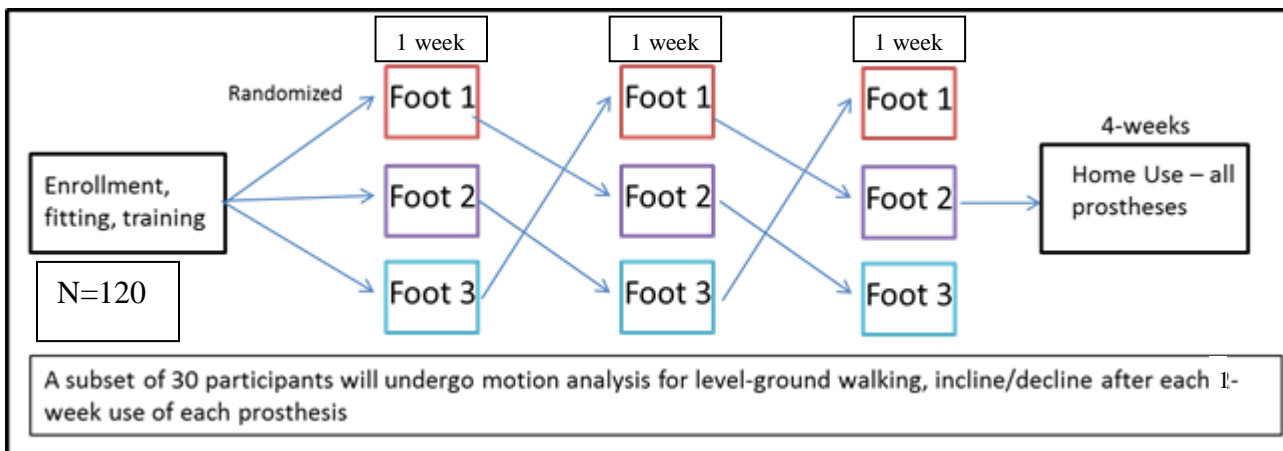
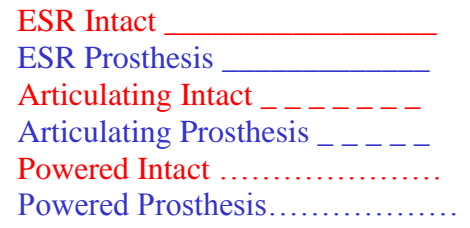


Figure 1: Research Design and Project Timeline for each Subject

Biomechanical Analysis

Figures 2 and 3 illustrate a series of representative graphs of a single subject who completed biomechanical testing on all prosthetic feet. 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 Kinematic/Kinetics

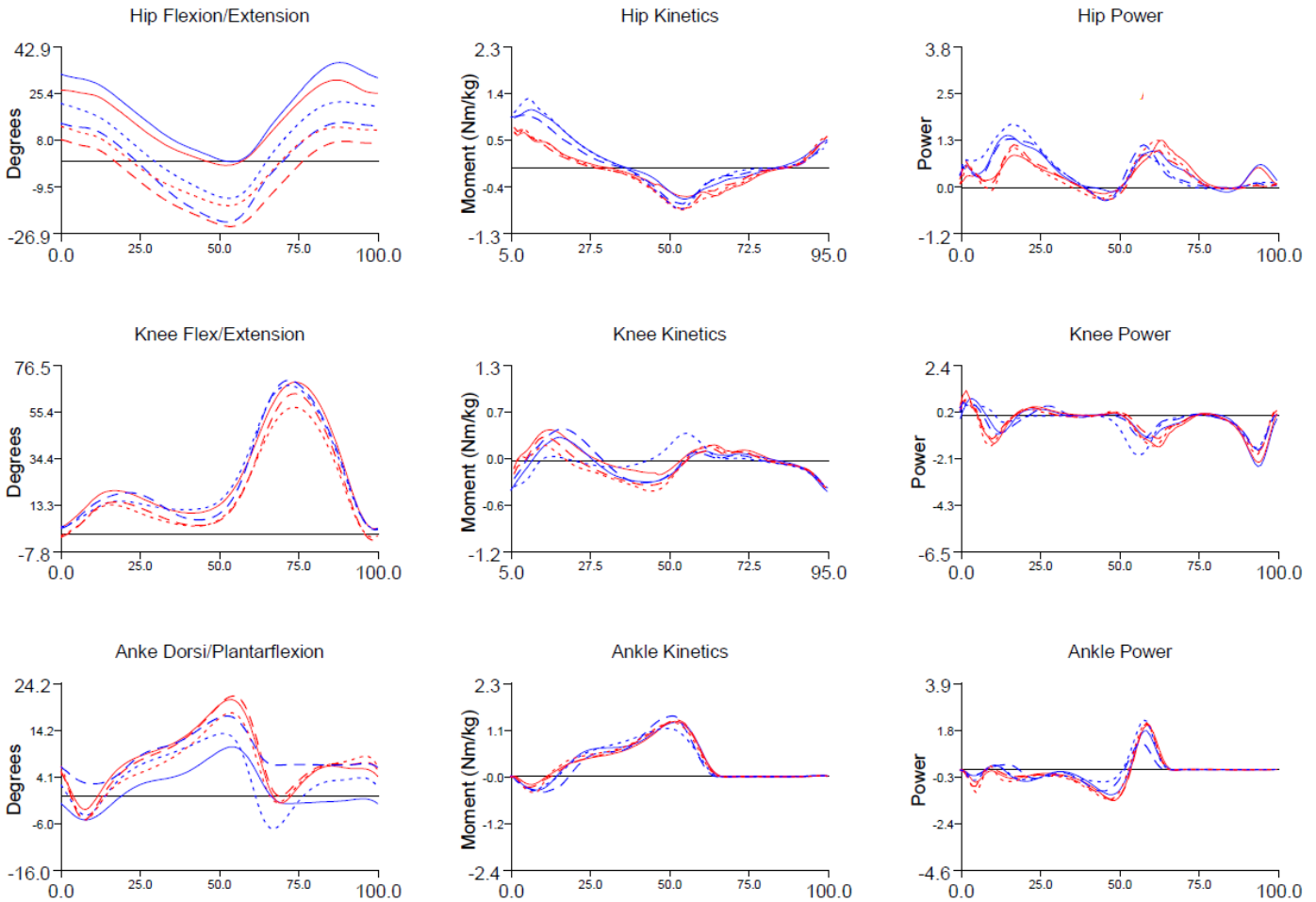


Figure 2: Representative biomechanical data for a single subject during level ground walking. Mean sagittal plane joint kinematics and kinetics are shown for the hip, knee, and ankle.

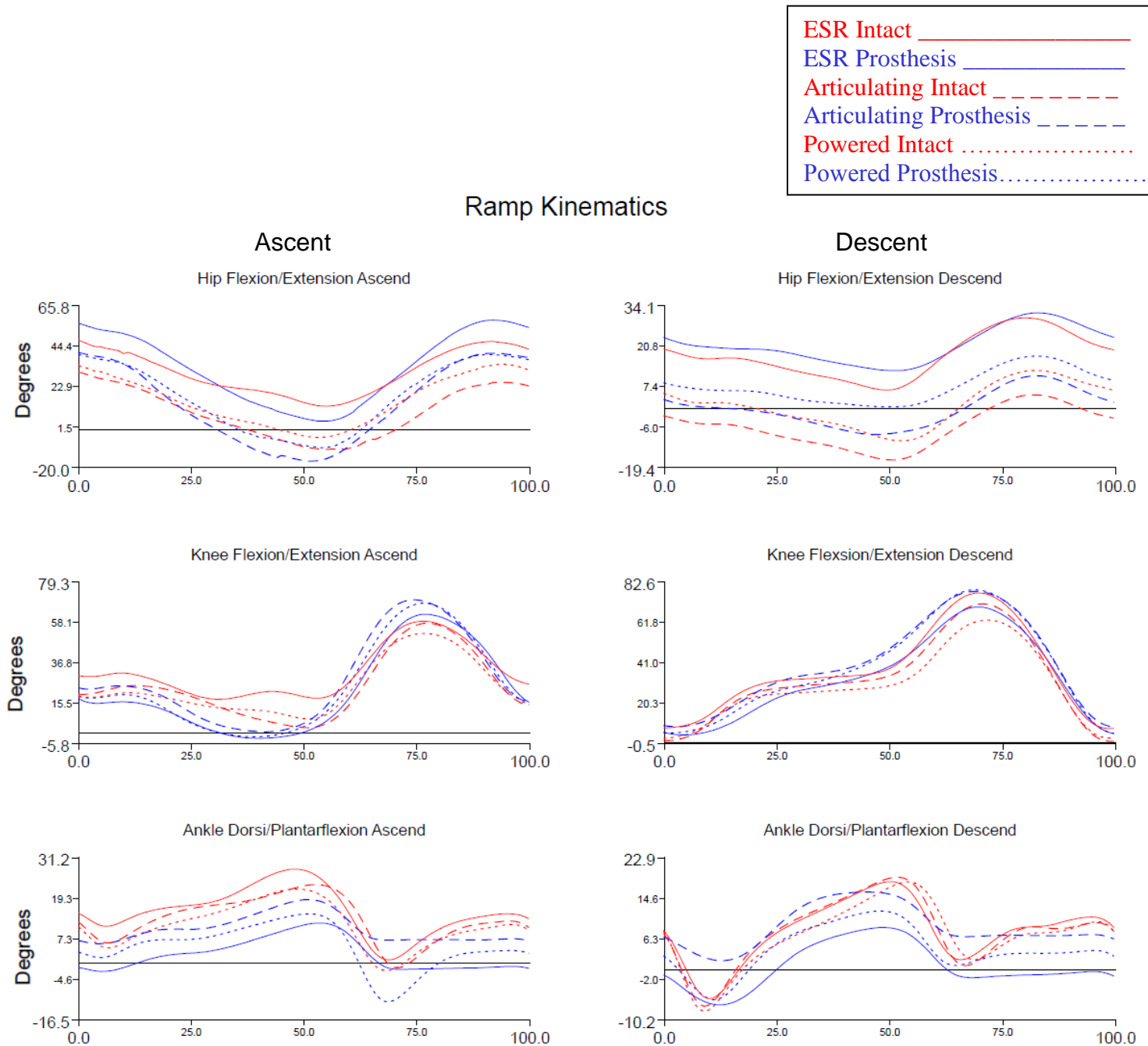


Figure 3: Representative biomechanical data for a single subject during ramp walking. Mean sagittal plane joint kinematics and kinetics are shown.

Functional Outcomes

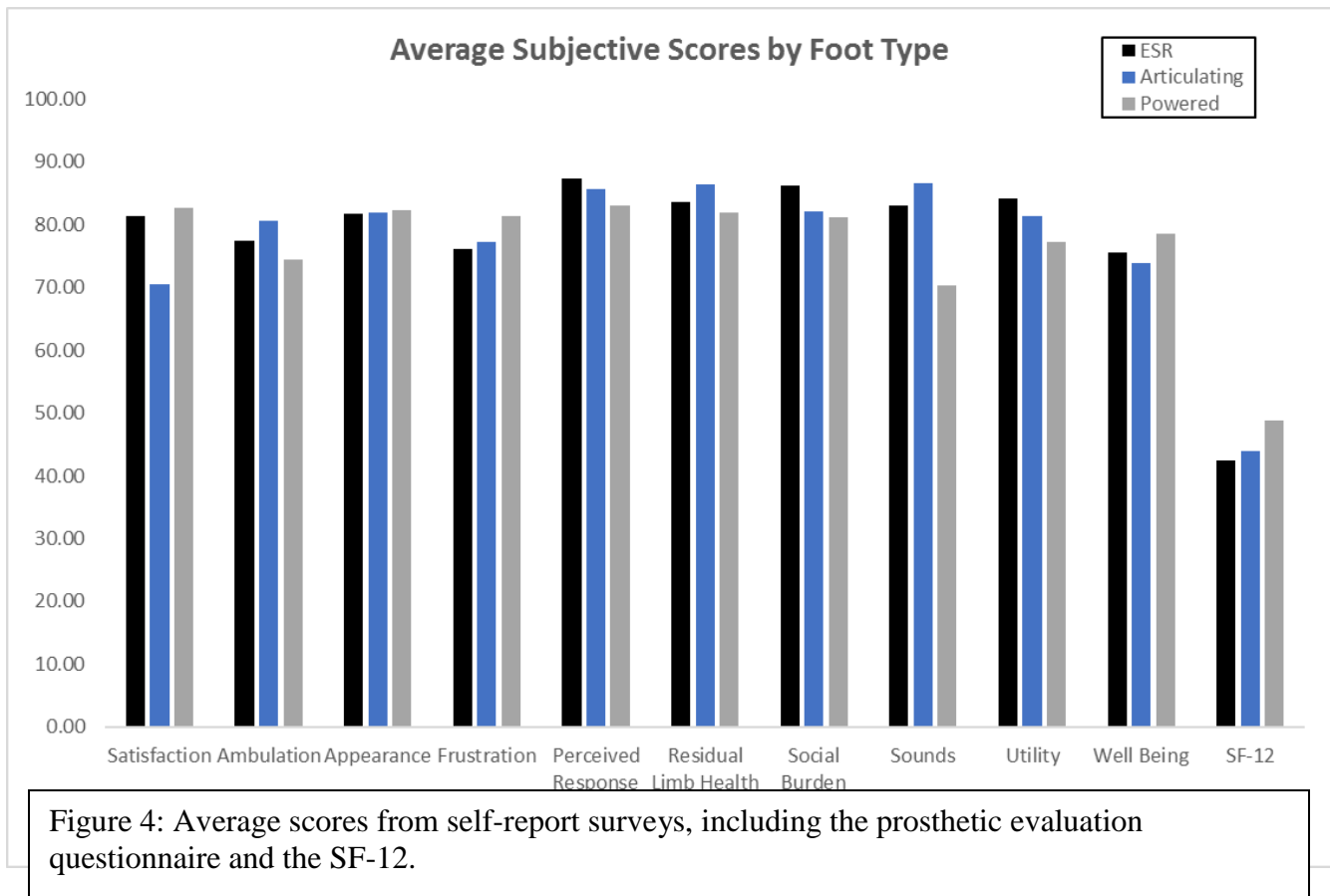
Subjects are evaluated with several functional measures, including the 6-minute walk, Timed-up-and-go (TUG), 4-Square Step Test (4SST), AmpPro, stair assessment index (SAI), and hill assessment index (HAI). Means and standard deviations for all enrolled subjects to date are listed in Table 3.

TABLE 3: 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)	9.7 (2.0)	10.9 (2.7)	10.1 (1.8)
Four Step Square Test (sec)	14.0 (7.5)	12.7 (5.1)	14.5 (5.4)
Six Minute Walk Test (m)	348.1 (53.3)	373.8 (95.9)	346.1 (87.0)
Amputee Mobility Predictor (AmpPro)	39.3 (3.8)	38.5 (2.4)	35.2 (7.0)
Stair Assessment Index (SAI) - Ascent	9.7 (3.88)	8.2 (4.4)	7.8 (4.6)
Stair Assessment Index (SAI) - Descent	9.4 (4.3)	9.3 (3.6)	7.8 (4.6)
Hill Assessment Index (HAI) - Ascent	10 (1.6)	11.0 (0.0)	10.8 (0.4)
Hill Assessment Index (HAI) - Descent	9.8 (1.5)	10.8 (0.4)	10.5 (0.8)

Subjective Outcomes

Subjects also complete self-report instruments that 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. Preliminary results are shown in Figure 4.



Goals Not Met:

All goals have not been met for Y1. Study recruitment is less than projected at the end of Y1Q4 for all sites, largely due to site specific regulatory delays. During study set-up, an initial recruitment plan was established to enroll subjects on a one-by-one basis to mitigate any potential protocol problems, with minimal inconvenience to the subjects. As the teams start year 2, multiple subjects will be enrolled simultaneously to increase enrollment. Furthermore, during our year 2 meeting (October, 2018), a major focus will be to review recruitment strategies for each site and modify as necessary to increase enrollment.

The CRADA between WRNMMC and NYHHS has not been finalized. Final approvals are pending and the CRADA is expected to be finalized by 10/2018. However, WRNMMC has issued the project team a start letter for the investigation and recruitment has begun.

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

While the project is not intended to provide training and professional development, our 2-day project kick-off meeting provided professional development and training to the study staff on the prosthetic devices used in this study. This comprehensive training was held at NYHHS in October, 2017. Site-PIs, prosthetists, physical therapists, and other staff received project management training (e.g. data collection, recruitment, and data sharing techniques) as well as receiving device-specific training (e.g. device fitting programming, and device-specific rehabilitation/utilization techniques). Knowledgeable representatives from each of the prosthetic foot companies presented this device-specific training techniques for each of the prosthetic feet used in this investigation. The agenda for this 2-day training is below. A follow-up teleconference training on project management was also conducted for all sites just prior to initiation of data collection.

Agenda from Workshop/ Training at NYHHS:

Dates: October 11th – October 12th, 2017
Times: 8am – 4:45pm
Place: VA New York Harbor Health Care System, 1st Floor, Atrium A & B; Gait and Motion Analysis Laboratory, Rm 7054S
Subject: Kickoff Training for “Criteria for Advanced Prosthetic Foot Prescription”

Agenda

Wednesday, October 11th, 2017

Time	Session	Location
8:00 – 8:30am	Pledge of Allegiance, Introduction, and Opening Remarks	Atrium A (1 st floor)
8:30 – 10:30am	Otto Bock and BionX Medical Technologies (Triton, emPOWER)	Atrium A
10:45am – 12:15pm	Freedom Innovations (Kinnex, Kintera)	Atrium A
12:15 – 1:15pm	Break	
1:15pm – 2:45pm	Fillauer (Motion Foot, Raize)	Atrium A
3:00pm – 4:30pm	Protocol Review/Project Timeline/Expected Milestones	Atrium A
4:30pm – 4:45pm	Question and Answer Session and Daily Summary	Atrium A
4:30pm – 4:45pm	Closing Remarks; Question and Answer Session	Gait Lab

Thursday, October 12th, 2017

Time	Session	Location
8:00 - 8:05am	Pledge of Allegiance	Gait Lab (7 th floor, Rm 7054S)
8:00 – 9:00am	Data Entry and Sharing	Gait Lab
9:00 – 10:00am	Outcome Measures Training	Gait Lab
10:00am – 11:30am	Ossur (K2 Sensation DP Flexion, Proflex, Proprio)	Gait Lab
11:30am – 12:30pm	Break	Gait Lab
12:30pm – 2:00pm	College Park (Odyssey, TruStep, Venture)	Gait Lab
2:15pm – 3:45pm	Endolite (Echelon, Echelon VT, Elan, Avalon K2)	Gait Lab
3:45pm – 4:30pm	Recruitment/Enrollment Strategies/Roles and Responsibilities	Gait Lab

A follow-up teleconference training on project management was also conducted with each of the collaborating sites just prior to initiation of data collection in April 2018. It was run as a refresher training for the study, and it occurred after all the sites had obtained HRPO approval and were cleared to begin recruitment. The agenda for this refresher training is listed below:

Agenda

Agenda Items	Task Assignment
Introductions and Opening Remarks	JM
Visit 1 – Screening/FIM Determination/Baseline/Prosthesis Order	JM/MH
Visit 2 – Training, FIM, and Foot Randomization	JM
Regulatory Binder	MH
Visits 3-5 – Protocol Review	JM
At-Home Use/SAMs/Daily Activity Logs	JM
Visit 6 – Final Visit/Guided Interview	JM
Miscellaneous Forms – Protocol Deviation/Adverse Events/Change in Status	MH
Data Transfer and Shipping	MH

How were the results disseminated to communities of interest?

Nothing to Report

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

To accomplish the goals and objectives for year 2, we plan to:

- Conduct a year 2 on-site meeting.
- Modify recruitment strategies to increase recruitment at each site.
- Continue to conduct protocol procedures and data collection.
- Begin data analysis for completed subjects.

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 Dr. Nelson accepting a new position, the study team is seeking to pursue a change to the overall award PI of the study, from Dr. Leif Nelson to Dr. Jason Maikos. The change has been approved by the local IRB, as well as HRPO. However, the study team was informed that a change in award PI will require Approval by the Grants Officer. A formal request will be processed through the contracting team.

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 1. During initial enrollment, each site elected to enroll the first subjects on a one-by-one basis to mitigate any potential protocol problems and reduce any inconveniences for the subjects. Currently, all sites have initiated the protocol and now will enroll multiple subjects simultaneously. Furthermore, during the year 2 kick-off meeting, the principal site team will be working with each site to modify recruitment and optimize strategies to increase enrollment.
- **Finalizing the CRADA between WRNMMC and NYHHS:** Development and review of the CRADA has been delayed. However, final approvals are pending and are expected by 10/2018. Because of this extensive delay, WRNMMC has already issued a start letter and enrollment has begun.

Changes that had a significant impact on expenditures

Delays in recruitment and approval of the final CRADA have had an impact on year 1 expenditures. Year 1 expenditures on prosthetic feet were less than projected due to delays in recruitment. As sites enroll more subjects in Year 2, these expenditures are expected to increase to the projected budget. Furthermore, due to the delay in approval of the final CRADA, WRNMMC did not begin enrollment until Y1Q4, and therefore did not start expending their personnel budget until Y1Q4 when the start letter was issued and enrollment could begin.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

There have been no significant changes in use or care of human subjects.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

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

Journal publications.

Nothing to Report

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

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

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

Nothing to Report

- **Technologies or techniques**

Nothing to Report

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

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Leif Nelson, DPT
Project Role: PI at NYHHS
Nearest person month worked: 2
Responsibilities/ Contributions: Responsible for overall coordination and integrity of study, coordinated IRB submission, kickoff training, and oversaw staff hiring.

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 re-fresher training.

Name: Michael Hyre, MS
Project Role: Study Coordinator at NYHHS
Nearest person month worked: 5
Responsibilities/ Contributions: Oversees all regulatory activities as NYHHS, and assists with IRB at each site. Coordinated all HRPO submissions and assisted with development of data collection forms. Aided in coordinating refresher training.

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: Responsible for biomechanical testing
Funding Support CDMRP award number W81XWH-17-1-0568

Name: Benjamin Ayzenberg, DPT
Project Role: Research Physical Therapist at NYHHS
Nearest person month worked: 2
Responsibilities/ Contributions: Performed functional outcome testing for subjects.

Name: Alison Pruziner, DPT
Project Role: Site-PI at WRNMMC
Nearest person month worked: 1
Responsibilities/ Contributions: Oversees site-specific activities, coordinated local IRB submission and amendments, assisted with CRADA development. Participated in refresher training.

Name: Pete Anderson, CP
Project Role: Prosthetist at WRNMMC
Nearest person month worked: 1
Responsibilities/ Contributions: Participated in the refresher training and preparation for prosthetic fittings.

Name: Christopher Dearth, PhD
Project Role: Co-I at WRNMMC
Nearest person month worked: 1
Responsibilities/ Contributions: Assisted with local IRB submissions and CRADA development

Name: Bradford Hendershot, PhD
Project Role: Co-I at WRNMMC
Nearest person month worked: 1
Responsibilities/ Contributions: Participated in refresher training and preparation for local biomechanical testing.

Name: Heidi Mahatan, MA, LCPC, NCC
Project Role: Study Coordinator at WRNMMC
Nearest person month worked: 1
Responsibilities/ Contributions: Assisted in IRB amendments and updates to case report form. Participated in refresher training.
Funding Support CDMRP award number W81XWH-17-1-0568

Name: Elizabeth Husson, BA, CCRC
Project Role: Study Coordinator at WRNMMC
Nearest person month worked: 1
Responsibilities/ Contributions: Assisted in local IRB amendments

Name:	Jonathan Gladish, MS
Project Role:	Research Engineer at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Responsible for subject enrollment/data collection and biomechanical testing
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Jeffrey Heckman, DO
Project Role:	Site-PI at Puget Sound VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities at Puget Sound, coordinated local IRB submission, assisted with subject enrollment preparation. Participated in refresher training.
Name:	Ellen Ferris, PT
Project Role:	Physical Therapist, PT at Puget Sound VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted with local IRB amendments, participated in refresher training.
Name:	Matthew Jerrell
Project Role:	Research Coordinator at Puget Sound VA
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted with local IRB submission
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, coordinated local IRB submission, assisted with development of socket fabrication/foot order data collection forms, participated in kickoff training
Name:	Lisa 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, assisted with local IRB submission, assisted with development of training data collection form, participated in kickoff training

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: None

Criteria for Advanced Prosthetic Foot Prescription

Log Number: OP150095

Award Number: W81XWH-17-2-0014



PI: Leif Nelson, DPT, ATP, CSCS

Org: VA New York Harbor Healthcare System

Award Amount: \$2,491,350.62

Study/Product Aim(s)

Aim 1 :To evaluate the differences in functional performance and subjective outcomes between non-articulating ESR, articulating ESR, and active plantarflexion ESR feet.

Aim 2– To evaluate the kinematic and kinetic differences of non-articulating ESR, articulating ESR, and active plantar flexion ESR feet in individuals with transtibial amputation

Aim 3 – To correlate biomechanical findings with functional and subjective outcome measures and with user preference determined through activity monitoring and user satisfaction to develop guidelines for appropriate prosthetic prescription.

Approach

This research investigation proposes a 4-site, multi-center, 7 week, randomized, cross-over clinical trial. We plan to enroll a total of 120 participants. Subjects will receive 3 prosthetic feet (ESR, Articulating, Powered) and will be evaluated weekly with each prosthesis. Evaluations will include functional measures and surveys/guided interviews . A subset of participants (n=30) will be randomly chosen to undergo a full biomechanical gait analysis to collect kinematic and kinetic data during walking . Following the 3-week data collection period, all participants will be given the 3 separate prostheses for home evaluation to determine overall user preference.



Accomplishments: Local IRB submission was submitted and approved, including secondary review through HRPO approval. Additionally, study staff has been hired, and patient enrollment has commenced.

Timeline and Cost

Activities	CY	17	18	19	20
Evaluate Functional/Subjective outcomes			[Green bar]		
Evaluate Biomechanics				[Green bar]	
Develop Prosthetic Prescription Guidelines				[Green bar]	
Estimated Budget (\$2.5M)			\$1.4M	\$574K	\$523K

Goals/Milestones

CY17-18 Goals –

- IRB approval/ submission
- Coordinate study staff for clinical trials
 - Site-Wide Training at VA NYHHS
- Enroll 50 Subjects

CY18-19 Goals –

- Continue recruitment and testing of participants
- Enroll 100 Subjects total

CY19-20 Goal –

- Complete testing and enrollment of 120 subjects
- Formulate Prosthetic Prescription Guidelines
- Compile and disseminate results

Budget Expenditure to Date

Projected Expenditure: \$2,491,350.62

Actual Expenditure: \$545,545.00

Updated: (8/31/18)