AWARD NUMBER: W81XWH-20-1-0409

TITLE: Gait Coordination and Stability of Individuals Living with Transtibial Limb Loss

PRINCIPAL INVESTIGATOR: Alexis Sidiropoulos, PhD

CONTRACTING ORGANIZATION: Narrows Institute of Biomedical Research, Inc.
Brooklyn, NY

REPORT DATE: July 2022

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
July 2022	Annual	01Jun2021-31May2022

4. TITLE AND SUBTITLE

Gait Coordination and Stability of Individuals Living with Transtibial Limb Loss

5a. CONTRACT NUMBER
W81XWH-20-1-0409

5b. GRANT NUMBER
OP190020

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Alexis Sidiropoulos, PhD

E-Mail: alexis.sidiropoulos@va.gov

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

NARROWS INSTITUTE FOR BIOMEDICAL RESEARCH
800 POLY PL 151
BROOKLYN, NY 11209-7104

8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Medical Research and Development Command
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

The short-term goal of the study is to understand the coordination and stability deficits in Veterans and Service Members (SM) with transtibial amputation (TTA). The overall aim is to determine if these critical factors can be improved with specific prosthetic devices or device types. If improvements are observed, the long-term goal is to advocate for the prescription of specific prosthetic devices for Veterans and SMs with TTA and examine the effects of intensive, device-specific therapy to optimize these parameters. Preliminary data analysis indicates that Veterans and SMs with TTA experience stability deficits compared to individuals without lower limb loss while using all three prosthetic devices included in this study (Energy Storing and Returning (ESR), Articulating ESR, and Powered ESR). Both the Powered ESR and ESR devices differ from the Control group in stability level. However, the ESR device indicates poor coordination values compared to the Powered ESR device. These findings may differ with the addition of the remaining participant data.

15. SUBJECT TERMS Prosthetics, Coordination, Stability, Transtibial Amputation, Gait					
16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRDC
a. REPORT Unclassified	**b. ABSTRACT** Unclassified	**c. THIS PAGE** Unclassified	Unclassified	26	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. INTRODUCTION:

Due to the growing population of Veterans and Service Members with transtibial amputation, it is expected that conclusive research is available to clinicians for proper prosthetic prescription. Unfortunately, most research lacks the guidance required for clinical practice. This study aims to contribute evidence-based research to identify the prosthetic devices or device types that provide the highest levels of gait coordination and stability to support appropriate Clinical Practice Guidelines. Relative phase analysis, which is more sensitive to subtle changes in movement patterns compared to traditional biomechanical measures, is used to identify deficits in coordination and stability in Veterans and Service Members compared to individuals without lower limb loss, and to determine which prosthetic device or type is most advantageous for achieving the highest levels of coordination and stability in this population. Preliminary data highlights the coordination and stability deficits experienced by Veterans and Service Members with transtibial amputation compared to those without amputation and the coordination advantages associated the powered prosthetic device. This information will significantly advance our understanding of the complex biomechanical interactions between continuous inter-limb coordination and stability and the different types of ankle-foot devices. In turn, the Department of Veteran Affairs (VA) and the Department of Defense (DoD) can tailor treatments to maximize these important features of gait and improve functional mobility of these individuals, thereby allowing the VA and DoD to provide these individuals with the most comprehensive healthcare possible.

2. KEYWORDS:

Continuous Inter-limb Coordination, Stability, Transtibial Amputation, Gait, Prosthetics, Biomechanics, Relative Phase Analysis

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The overall goals for study OP190020:

1. Determine the continuous gait inter-limb coordination and stability levels of Veterans and Service Members with transtibial amputation.
2. Determine the extent to which continuous gait inter-limb coordination and stability of Veterans and Service Members with transtibial amputation are influenced by different energy storing and returning (ESR) ankle-foot devices (i.e., ESR, Articulating ESR, and Powered ESR).

The major goals and tasks for May 2021-June 2022 of Project OP190020 are listed in the table below. The table includes % completion of each task and, where appropriate, completion dates.

Major Task 1: IRB Submission and Team Meetings	% Completion	Completion/Expected Completion Date
Subtask 1: Prepare and Submit IRB Documents		

IRB protocol Submission: *Requesting Exemption from IRB Review*	*100%*	Completed: 06/20/2020
Milestone Achieved: IRB Approval/Exemption from Review *R&D Committee Review and Approval*	*100%*	Completed: 9/14/2020
Milestone Achieved: HRPO Approval/Concurrence	*100%*	Completed: 3/1/2021
Subtask 2: Team Meetings		
Kick-Off Meeting	*100%*	Completed: 6/24/2020
Y1Q1 Meeting	*100%*	Completed: 9/2/2020
Major Task 2: Data Analysis – Specific Aim 1		
Subtask 1: Analyze biomechanical data using relative phase analysis		
Combine data from collection sites (VANYHHS and WRNMMC)	*ongoing*	
Implement relative phase analysis to control data	*100%*	Completed: 11/30/2021
Perform statistical analysis to compare output from two groups	*80%*	Expected: 7/15/2022
Subtask 2: Team Meeting		
Y2Q3 Meeting	*100%*	Completed: 4/17/2022
Major Task 3: Data Analysis – Specific Aim 2		
Subtask 1: Determine which device is related to the highest levels of coordination and stability		
Perform statistical analysis to compare output from different prosthetic devices	*73%*	Expected: 8/15/2022
Milestone Achieved: 100% of analysis complete	*73%*	Expected: 8/15/2022
Milestone Achieved: Identified which prosthetic device is associated with the highest levels of coordination and stability	*ongoing*	Expected: 9/15/2022

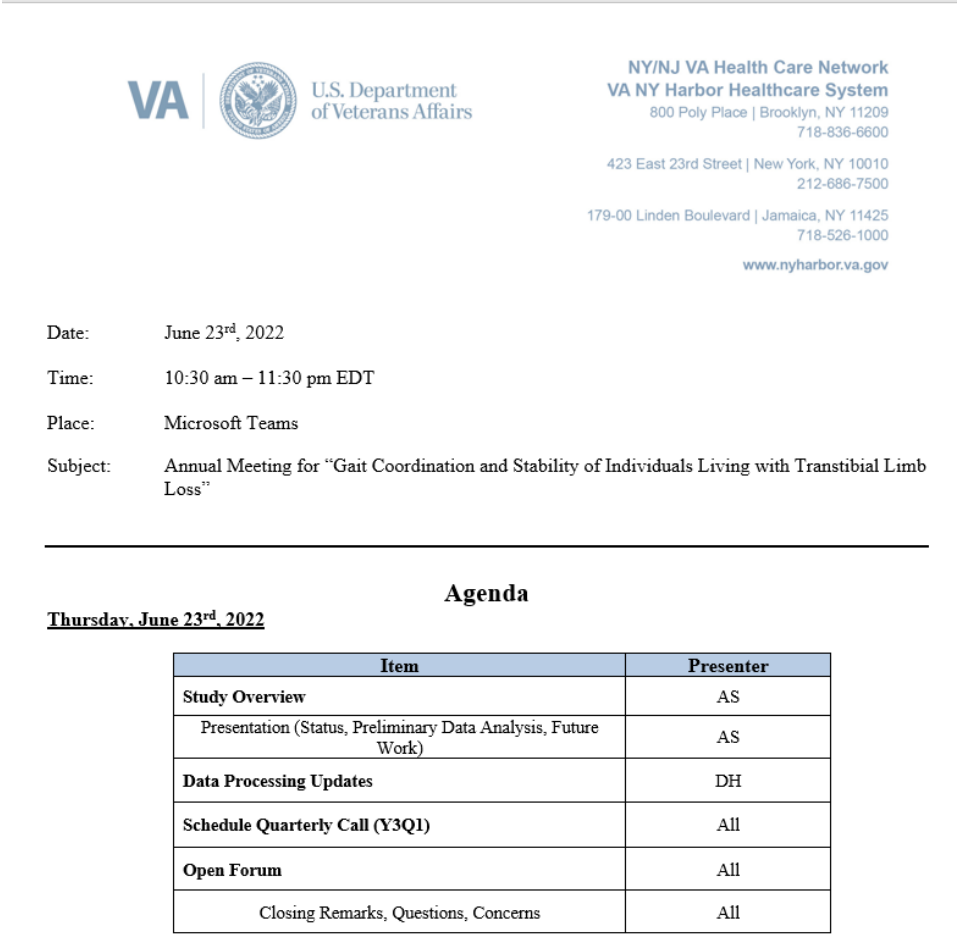
What was accomplished under these goals?

Major Activities

Quarterly Meetings between Study Sites

Each quarter of this study has ended with a joint meeting between the two research sites, VA New York Harbor and Walter Reed National Military Medical Center (WRNMMC). These meetings are scheduled by the Principal Investigator and include an official agenda and PowerPoint presentation. The purpose of the presentation is to share information related to the

study status, preliminary data analysis, and future work, provide data processing updates, create an opportunity for an open forum, and schedule the following quarterly meeting. Quarterly meetings occurred in September, December, and March. The annual meeting is scheduled to occur on 06/23/2022. Please see the agenda below:



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: June 23rd, 2022

Time: 10:30 am – 11:30 pm EDT

Place: Microsoft Teams

Subject: Annual Meeting for "Gait Coordination and Stability of Individuals Living with Transtibial Limb Loss"

Agenda

Thursday, June 23rd, 2022

Item	Presenter
Study Overview	AS
Presentation (Status, Preliminary Data Analysis, Future Work)	AS
Data Processing Updates	DH
Schedule Quarterly Call (Y3Q1)	All
Open Forum	All
Closing Remarks, Questions, Concerns	All

Data Processing

Data for 22 (74% complete) individuals with transtibial limb loss and 10 (100% complete) individuals without amputation have been processed, leaving 3 participants to complete the protocol and analyzed. Though delayed due to the COVID-19 pandemic, data processing and analysis is expected to be completed by August 2022.

	Individuals with TTA		**Individuals without TTA**	
	Completed	Remaining	Completed	Remaining
Collected	27	3	10	0
Processed	22	8	10	0

Significant Results and Key Outcomes

Preliminary Data Analysis

The intent of the preliminary data analysis is for the purpose of data quality and no formal statistical analyses have been performed to test study hypotheses at this time.

Relative Phase Analysis has been implemented on the available data using the customized MatLab code. Preliminary results indicate better stability between the legs associated with the Control group compared to the ART and PWR groups, with no differences associated with the ESR group. No other differences between stability were observed. For coordination, the PWR group is more coordinated between the legs compared to the ESR group. No other significant differences in coordination were observed between groups. These observations are supported by the values shown in Tables 1-6.

Figure 1. Coordination between the arms and between the legs.
Figure 2. Stability between the arms and between the legs.

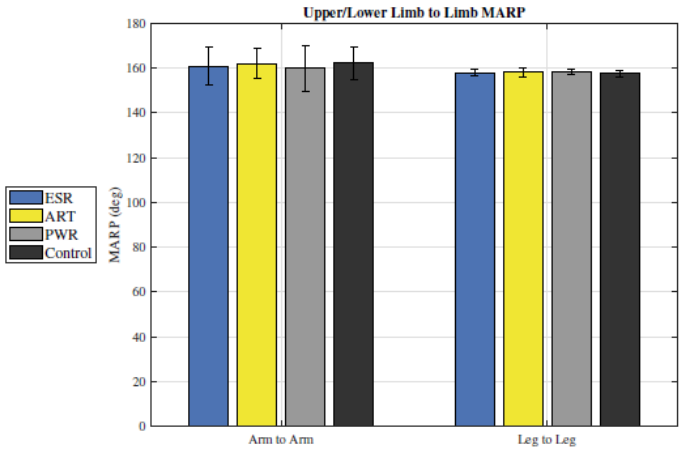


Figure 1

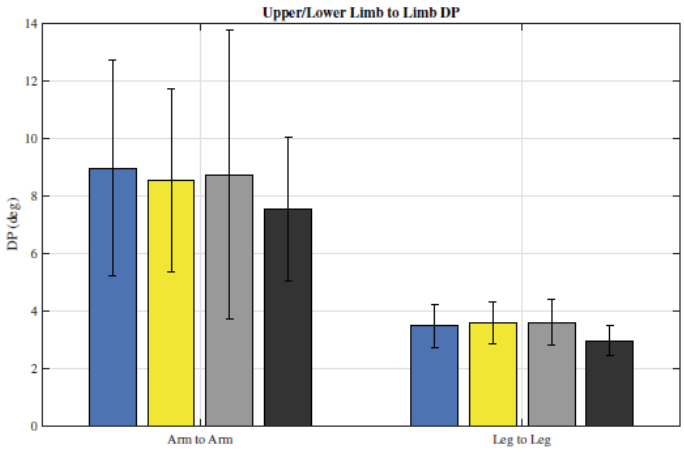


Figure 2

Foot	ESR	ART	PWR	Control
MARP (deg)	160.78 ± 8.30	161.93 ± 6.57	159.94 ± 10.27	162.14 ± 7.41
DP (deg)	8.98 ± 3.76	8.57 ± 3.18	8.74 ± 5.03	7.55 ± 2.49

Table 1: Arm to Arm MARP and DP Values (Av ± Std.)

Foot	ESR	ART	PWR	Control
MARP (deg)	157.94 ± 1.46	158.20 ± 1.99	158.35 ± 1.19	157.57 ± 1.55
DP (deg)	3.48 ± 0.75	3.60 ± 0.74	3.61 ± 0.78	2.97 ± 0.54

Table 2: Leg to Leg MARP and DP Values (Av ± Std.)

Figure 3. Coordination between ipsilateral arms and legs.
Figure 4. Stability between ipsilateral arms and legs.

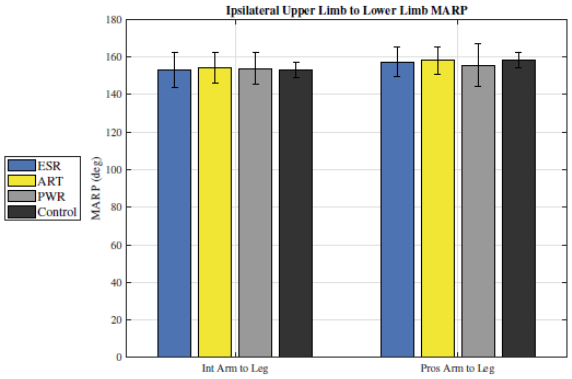


Figure 3

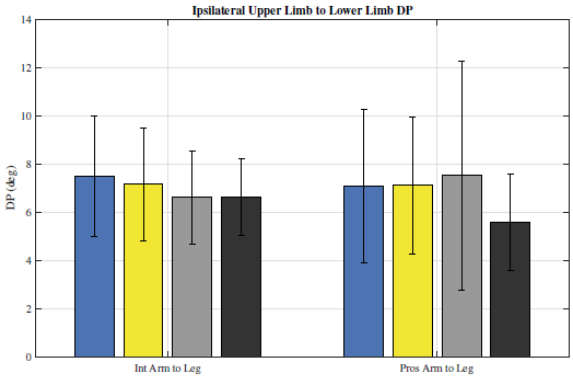


Figure 4

Foot	ESR	ART	PWR	Control
MARP (deg)	153.00 ± 9.33	154.20 ± 7.99	153.90 ± 8.33	153.26 ± 4.18
DP (deg)	7.50 ± 2.50	7.17 ± 2.36	6.62 ± 1.93	6.64 ± 1.59

Table 3: Int Arm to Leg MARP and DP Values (Av ± Std.)

Foot	ESR	ART	PWR	Control
MARP (deg)	157.35 ± 7.82	158.09 ± 7.14	155.73 ± 11.13	158.32 ± 3.90
DP (deg)	7.10 ± 3.20	7.13 ± 2.83	7.53 ± 4.76	5.60 ± 2.00

Table 4: Pros Arm to Leg MARP and DP Values (Av ± Std.)

Figure 5. Coordination between contralateral upper and lower extremities.
Figure 6. Stability between contralateral upper and lower extremities.

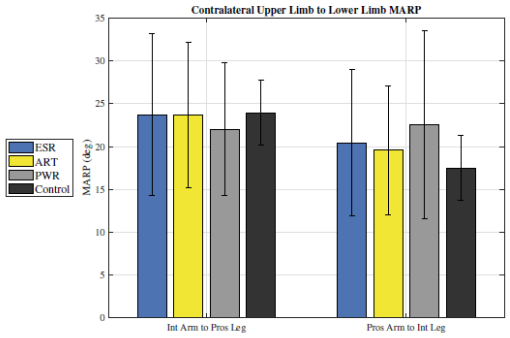


Figure 5

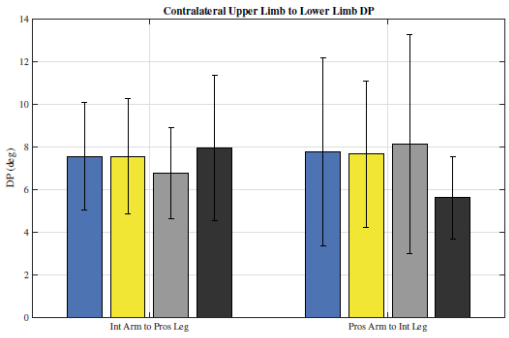


Figure 6

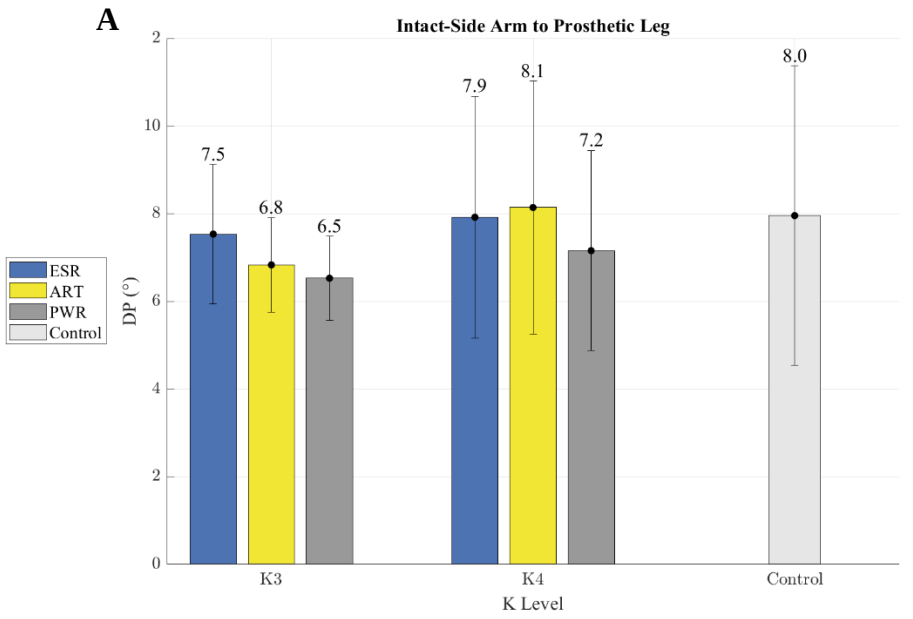
Foot	ESR	ART	PWR	Control
MARP (deg)	23.73 ± 9.46	23.65 ± 8.46	22.05 ± 7.70	23.96 ± 3.83
DP (deg)	7.54 ± 2.52	7.55 ± 2.69	6.77 ± 2.14	7.95 ± 3.41

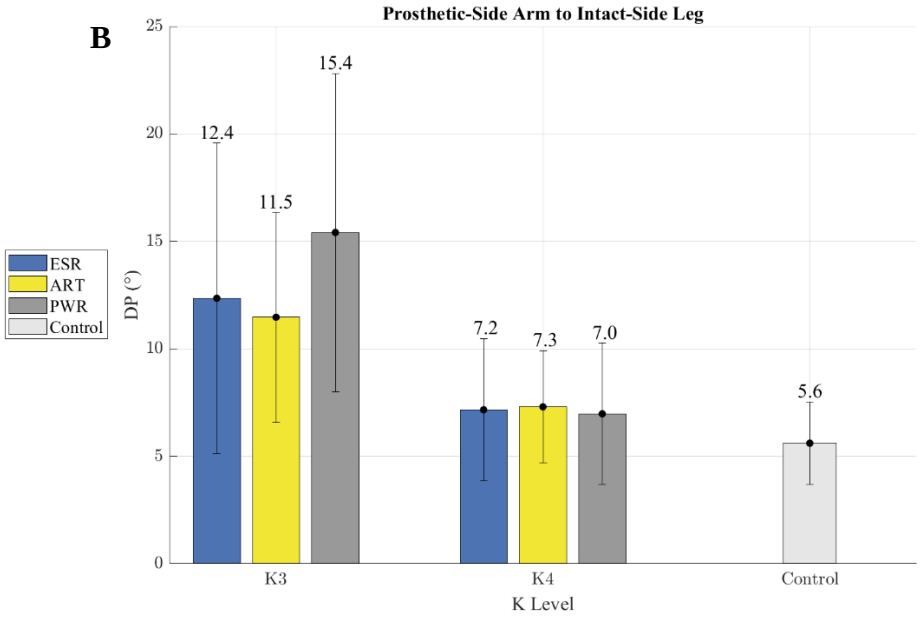
Table 5: Int Arm to Pros Leg MARP and DP Values (Av ± Std.)

Foot	ESR	ART	PWR	Control
MARP (deg)	20.44 ± 8.51	19.57 ± 7.50	22.56 ± 11.01	17.50 ± 3.80
DP (deg)	7.76 ± 4.41	7.65 ± 3.43	8.11 ± 5.13	5.61 ± 1.92

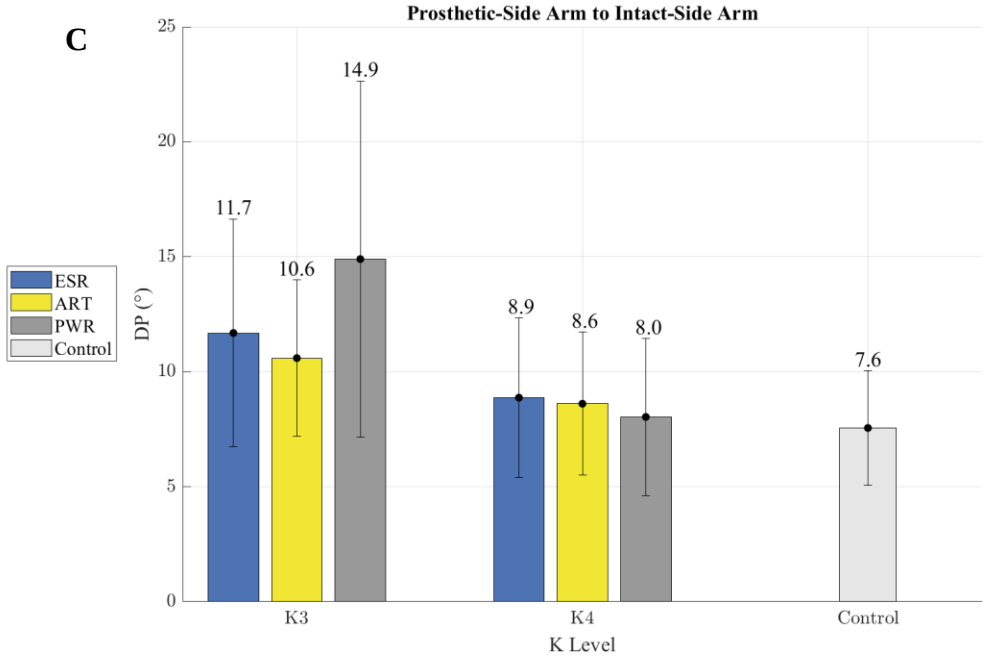
Table 6: Pros Arm to Int Leg MARP and DP Values (Av ± Std.)

Preliminary analysis of the relationship between foot preference and coordination and stability has also been explored to address the secondary aim of the study. Participants have been grouped by k-level to identify potential differences due to functional ability. Figures A-E represent stability while Figures F-J represent coordination.

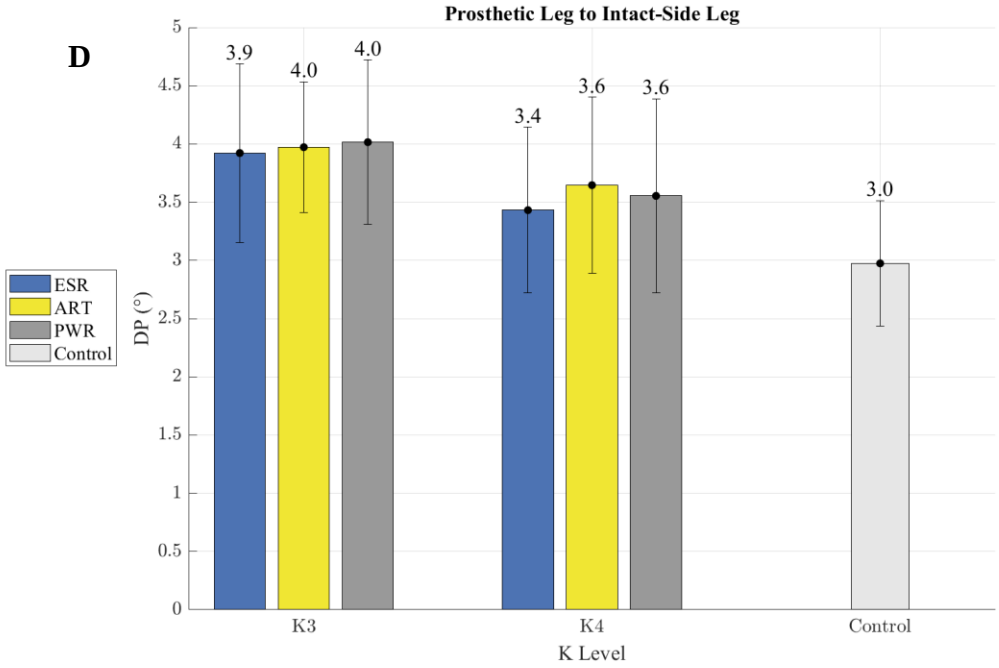




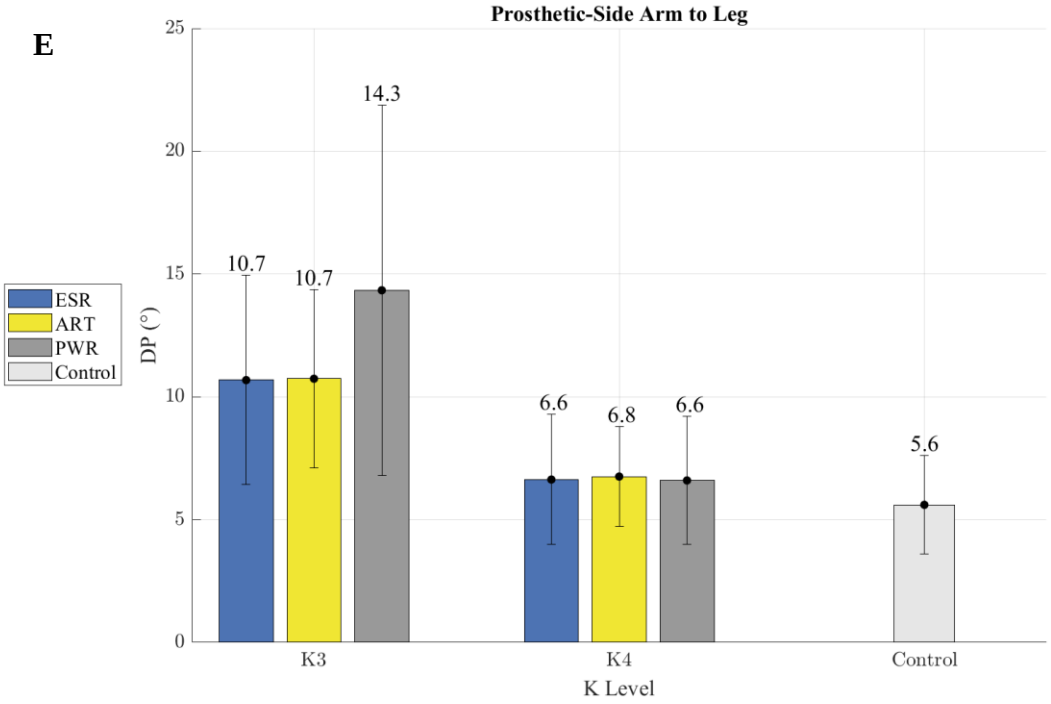
C


Prosthetic-Side Arm to Intact-Side Arm
ESR
ART
PWR
Control
DP (°)
25
20
15
10
5
0
11.7
10.6
14.9
8.9
8.6
8.0
7.6
K3
K4
Control
K Level

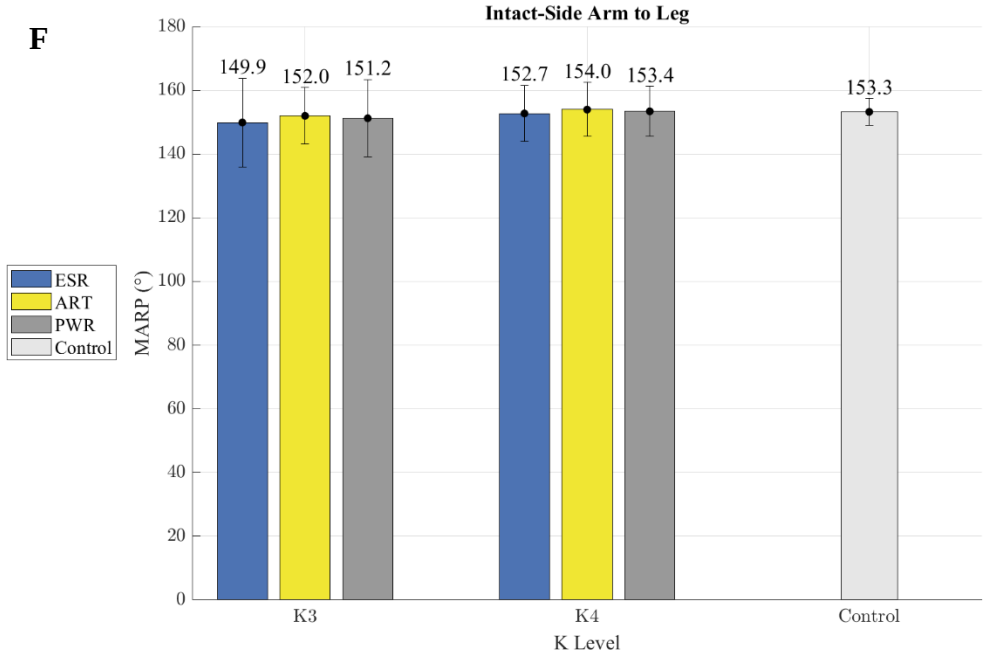
D


Prosthetic Leg to Intact-Side Leg
ESR
ART
PWR
Control
DP (°)
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
3.9
4.0
4.0
3.4
3.6
3.6
3.0
K3
K4
Control
K Level

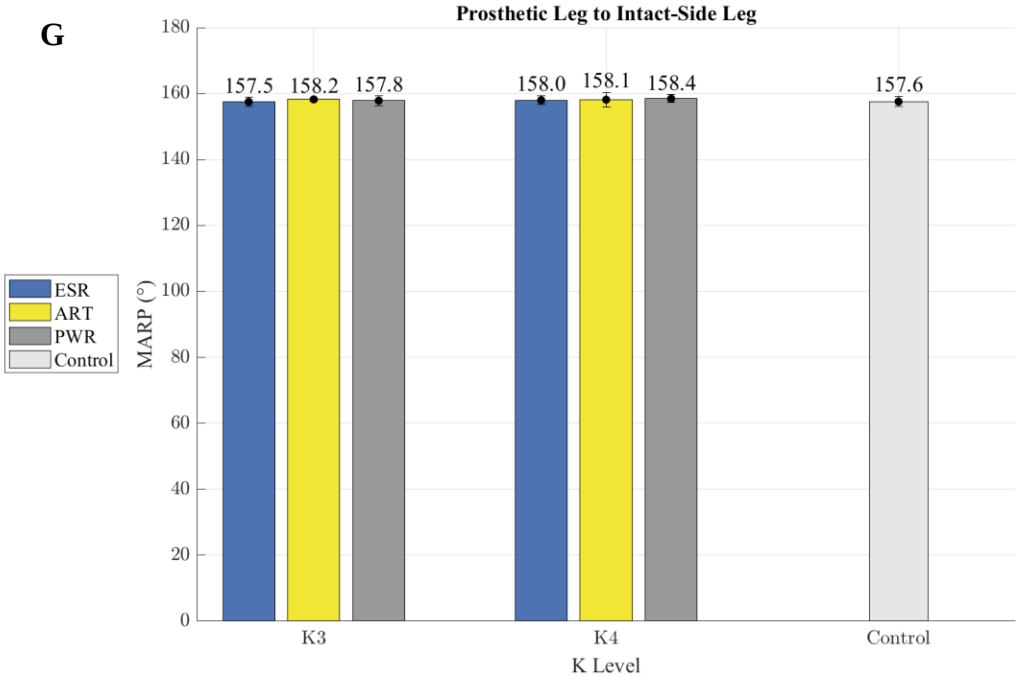
E


Prosthetic-Side Arm to Leg
ESR
ART
PWR
Control
DP (°)
25
20
15
10
5
0
10.7
10.7
14.3
6.6
6.8
6.6
5.6
K3
K4
Control
K Level

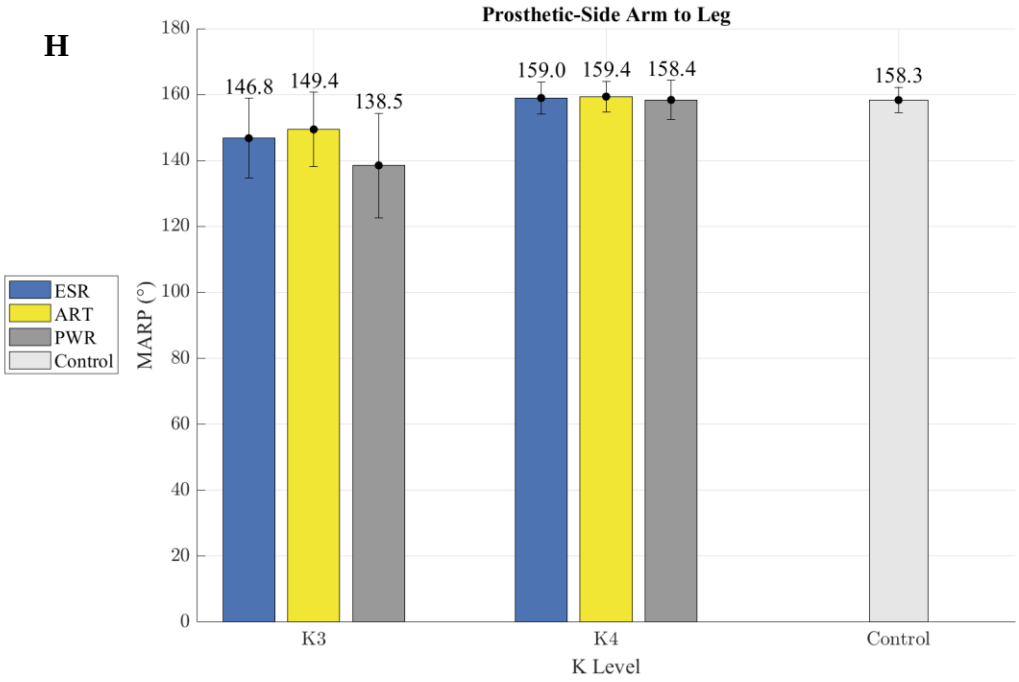
F


Intact-Side Arm to Leg
ESR
ART
PWR
Control
MARP (°)
180
160
140
120
100
80
60
40
20
0
149.9
152.0
151.2
152.7
154.0
153.4
153.3
K3
K4
Control
K Level

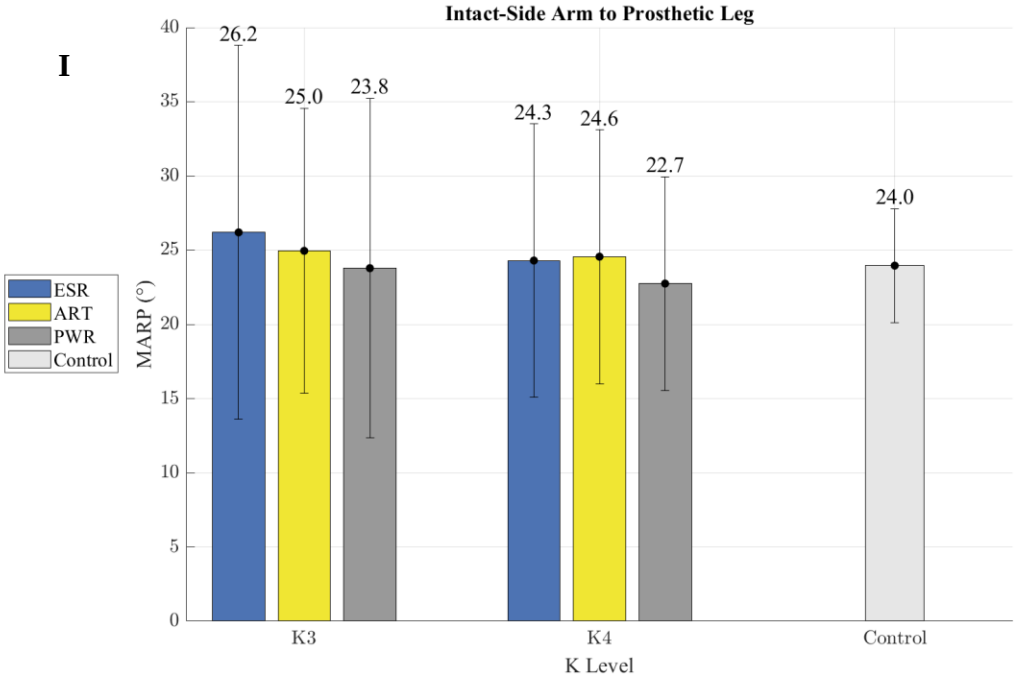
G


Prosthetic Leg to Intact-Side Leg
ESR
ART
PWR
Control
MARP (°)
180
160
140
120
100
80
60
40
20
0
157.5
158.2
157.8
158.0
158.1
158.4
157.6
K3
K4
Control
K Level

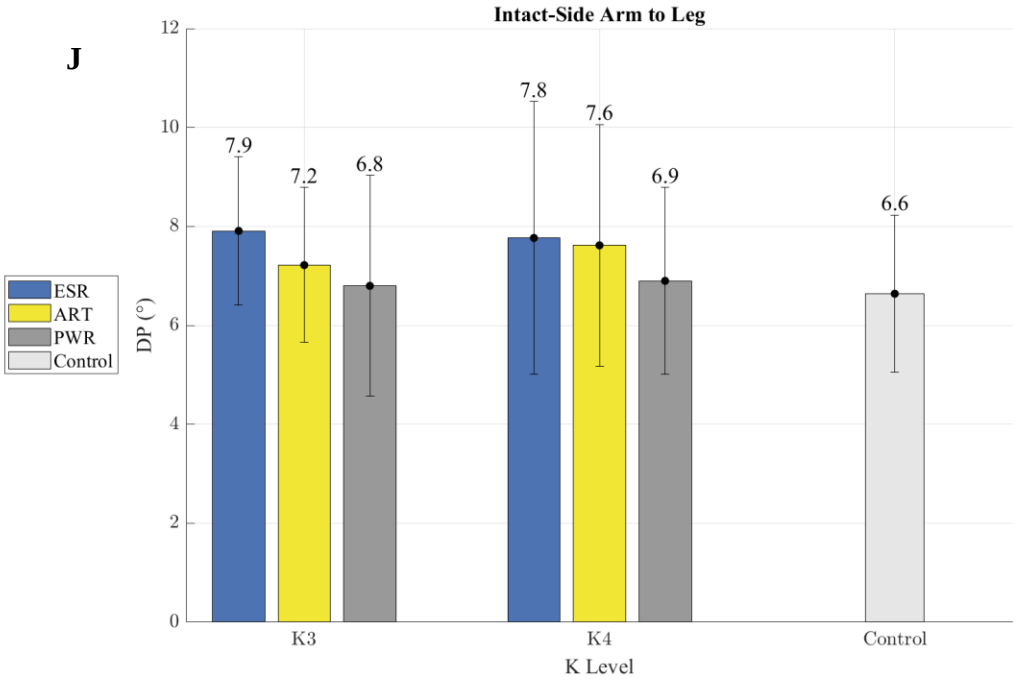
H


Prosthetic-Side Arm to Leg
ESR
ART
PWR
Control
MARP (°)
180
160
140
120
100
80
60
40
20
0
146.8
149.4
138.5
159.0
159.4
158.4
158.3
K3
K4
Control
K Level

I



J



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

While this project was not intended to provide official training and development opportunities, professional development associated with this project included scheduling and hosting quarterly meetings between research sites, submitting quarterly reports to the funding source, managing a Research Coordinator and Research Engineer, and presenting preliminary

research findings to members of the VISN 2 Biomechanics Research for the Advancement of Veteran Outcomes (BRAVO) Laboratory. Participation in quarterly meetings between NY Harbor Healthcare System and WRNMMC research sites provided the development of presentation and leadership skills. These meetings required logistical coordination between members of each site and creation of a research presentation to effectively share updated information and study results with the study team. Presentations necessitate preparation of the data, appropriate statistical analyses, illustrating the data and results in a clear and concise manner, and the ability to plan for future work to enable successful completion of the study. Further, the meetings provided an open forum for discussion, of which the Principal Investigator must guide and mediate between all participants.

Submission of complete and accurate quarterly reports to the funding source is also a part of the professional development associated with this study. Quarterly reports require the Principal Investigator to concisely report pertinent study information related to regulatory updates, study timelines and progress, and study staff involvement. Proper submission of these reports requires the development of time management skills in addition to advancing the skills required for appropriate scientific writing.

Management of a Research Coordinator and Research Engineer contribute to the professional skill development included while acting as Principal Investigator of this study. Weekly meetings occurred between the Principal Investigator and the Research Engineer to enable successful completion of data processing via guidance on specific methodology, data review, and time management. Further, working closely with the Research Coordinator was crucial in the administrative review process to obtain the approval of IRB and HRPO, given the circumstances of this retrospective study.

Presentation of research findings during VISN 2 BRAVO laboratory meetings also provided an opportunity to develop professional skills. While all members are the laboratory are familiar with ongoing research studies within the lab, presentations to all lab members provide an opportunity to discuss the details of the project with other scientists who may provide a different perspective on the results of the study. These meetings also provide a platform for determining the most effective way to discuss the complicated methodology and analysis associated with this study. Creating professional presentations and participating in scientific discussions regarding the findings of this study with the members of the VISN 2 BRAVO laboratory help to sharpen the skills required to present this research to other professional scientists in related fields.

How were the results disseminated to communities of interest?

Preliminary results were disseminated via the Gait and Clinical Movement Analysis Society (GCMAS) 2022 conference in June. This conference is focused on clinical application of biomechanical data and provided a platform to present the study data directly to clinicians. A poster presentation, in addition to a video presentation, were accepted and presented to participants of the conference. Further, results of this study were also presented via poster format for the Department of Veteran Affairs Research Week 2022. The information was made available to all Department of Veteran Affairs researchers to view and ask questions directly to me as the Principal Investigator.

Preliminary results will also be disseminated via the Military Health System Research Symposium (MHSRS) hosted by the Department of Defense in September 2022. A poster presentation entitled "Continuous Inter-Limb Coordination and Stability in Veterans and Service Members with Transtibial Amputation: A Preliminary Analysis" will be included in the Advancements in Prosthetics and Orthotic Technologies that Facilitate Return to Duty Following Neuromusculoskeletal Injuries research topic of the symposium. This professional conference will provide a platform to share and discuss the complex methodology and preliminary findings with other scientists in related fields of study. Following more data processing and analysis, the Principal Investigator will continue to submit abstracts to participate in other professional conferences to continue to disseminate the results of this research study to other scientists and clinicians who may benefit from this novel information.

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

To accomplish the goals and objectives in year 2, completion of data processing and analysis will occur as the remaining participant data are collected. Continued quarterly meeting to discuss the final results of this study will continue, as will meetings with the Research Engineer to ensure data quality and accurate processing. Once all data has been processed, statistical analysis of the data will be used to answer the research questions of this study. At this point, the statistician consultant will become involved in the analysis and support more complex statistics.

4. IMPACT:

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

Implementation of relative phase analysis, the novel methodology utilized in this study, has shown to be sensitive to detecting differences in movement patterns in individuals with transtibial limb loss and those without amputation. These preliminary findings suggest that this methodology can be used in future studies that aim to analyze cyclical movement patterns, like gait. The differences between individuals with and without amputation observed in the preliminary data analysis also highlight the need for intervention to increase the levels of inter-limb coordination and stability in this population. Further, this analysis has provided preliminary evidence of differences in coordination associated with different prosthetic ankle-foot devices, as the PWR device indicates greater coordination compared to the ESR device in one of the limb pairs. This information may provide guidance for the optimal prescription of prosthetic devices that offer the highest levels of coordination and stability for our Veterans and Service Members with transtibial amputation.

What was the impact on other disciplines?

Findings from this study may impact physical intervention and the rehabilitation offered to Veterans and Service Members. The knowledge gained from this study can directly influence the Clinical Practice Guidelines utilized in the prosthetic prescription process and potentially impact the care provided by physical therapists after the patient has been prescribed an appropriate device. Further, illustrating the importance of inter-limb coordination and stability in the daily activities

of individuals with lower limb loss can support the initiative to place greater emphasis on the rehabilitation care team to address these deficits. Improvement in these parameters can directly impact the independence and quality of life of Veterans and Service Members with transtibial amputation, which bolsters the need to prioritize enhancing the coordination and stability abilities of this population.

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 changed based on the outcomes of this research study. Due to the importance of continuous inter-limb coordination and stability in the activities of daily living of this population, it is necessary for clinicians to prescribe the most appropriate ankle-foot device to enhance these parameters. 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 and implementation of specific physical interventions to improve the movement abilities of Veterans and Service Members with transtibial amputation. Information gained from this study will allow the VA and DoD to more adequately address the healthcare needs of Veterans and Service Members with lower limb loss, helping them to independently live high quality, active lives.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report.

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

The data analyzed in this study is dependent upon data collected in an ongoing DoD study (W81XWH-17-2-0014), which was placed on an administrative hold from March 2020 until January 2021 due to the global pandemic. Thus far, data from 27 experimental and 10 control (complete) participants have been collected in the ongoing study. Since the date of regulatory approval for this study, the data that has been collected is being processed and analyzed. Remaining data from the ongoing DoD study will continue to be processed and analyzed as it is collected.

Changes that had a significant impact on expenditures

The expenditures reported are lower than anticipated for this period due to circumstances created by the COVID-19 pandemic. Factors that impacted this change include a reallocation of

staff percent effort to support studies ending during the administrative hold. All required tasks (administrative, data processing, and analysis) were performed for this investigation as outlined in the statement of work for this time period. It is expected that the budget expenses will increase in year 3 to match the originally proposed budget for this study.

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

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**
  - **Journal publications.**

    Poster presentation for the Gait and Clinical Movement Analysis Society (GCMAS) 2022 Annual Conference

    Poster presentation for the Department of Veteran Affairs Research Week 2022

    Upcoming poster presentation for the Military Health Systems Research Symposium

    See appendices for full abstracts.

  - **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

Name:	Alexis Sidiropoulos, PhD
Project Role:	Principal Investigator
Researcher Identifier:	
Nearest person month worked:	2
Contribution to Project:	Oversees overall integrity of the study
Funding Support:	

Name:	Jason Maikos, PhD
Project Role:	Co-Investigator at NYHHS
Researcher Identifier:	
Nearest person month worked:	2
Contribution to Project:	Consults on data analysis and interpretation
Funding Support:	

Name:	Michael Hyre, MS
Project Role:	Study Coordinator at NYHHS
Researcher Identifier:	
Nearest person month worked:	1
Contribution to Project:	Oversees all regulatory activities at NYHHS
Funding Support:	CDMRP award number W81XWH-19-OPORP-CRA

Name:	Bradford Hendershot, PhD
Project Role:	Co-I at WRNMMC
Researcher Identifier:	
Nearest person month worked:	2
Contribution to Project:	Consults on data interpretation
Funding Support:	

Name:	David Herlihy, BS
Project Role:	Research Engineer at NYHHS
Researcher Identifier:	
Nearest person month worked:	1
Contribution to Project:	Performs data processing
Funding Support:	CDMRP award number W81XWH-19-OPORP-CRA

- **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?**

  - **Organization Name:** Walter Reed National Military Medical Center (WRNMMC)
  - **Location of Organization:** Bethesda, MD
  - **Partner's contribution to the project**
    - Collaboration

8. SPECIAL REPORTNG REQUIREMENTS

- **COLLABORATIVE AWARDS: N/A**
- **QUAD CHART: See attached**

9. APPENDICES

MHSRS Abstract

Introduction: The number of Veterans and Service Members (SMs) living with transtibial amputation (TTA) is growing due to the aging population living with dysvascular disease and diabetes, as well as from U.S. military involvements abroad[1,2]. With high costs of healthcare associated with such injuries[3], it is expected that conclusive research is available to clinicians for proper prosthetic prescription. However, most research is noncommittal and lacks the guidance required for clinical practice[4]. Metabolic and biomechanical factors are the primary outcomes used to evaluate the effectiveness of prosthetic devices during walking, but results in the literature are mixed, limiting evidentiary support for optimal prescription guidelines[5]. Conversely, continuous measures of coordination and stability, evaluated using Relative Phase (RP) analysis, provide superior sensitivity over traditional spatiotemporal measures and detect changes at a greater resolution[6]. To date, only one study has investigated continuous gait coordination and stability in individuals with lower limb loss, which showed that this population experiences deficits in both parameters[7]. However, this study included a limited sample size (n=7) of individuals with transfemoral amputation, all of which were grouped together regardless of prosthetic device type. Therefore, the knowledge of which device type provides optimal coordination and stability for individuals with TTA is still unknown. The first aim of this study is to determine the continuous gait inter-limb coordination and stability levels of Veterans and SMs with TTA. It is hypothesized that individuals with TTA will indicate lower levels of gait inter-limb coordination and stability

compared to individuals without TTA. The second aim of this study is to determine the extent to which continuous gait inter-limb coordination and stability of Veterans and SMs with TTA are influenced by different Energy Storing and Returning (ESR) ankle-foot devices (i.e., ESR, articulating ESR, and powered ESR). It is hypothesized that the powered ESR (PWR) device will allow individuals with TTA to achieve greater levels of coordination and stability compared to the articulating (ART) and non-articulating (ESR) devices.

Methods: Participants with TTA (n=16) randomly received 3 prosthetic devices (ESR, ART, and PWR) with duplicate sockets. After device training, participants separately utilized each prosthetic foot for 1 week of home-use. Following each week, participants underwent biomechanical gait analysis using 3-D motion capture with each device type. During gait analysis sessions, participants walked at 1.3 m/s across a 10-meter instrumented walkway until at least 15 cycles (i.e., steps) per foot were recorded. A control group of intact participants (n=10) also took part in a single gait analysis session.

RP analysis was used to calculate the outcome measures of Mean Absolute Relative Phase (MARP), a continuous measure of coordination, and Deviation Phase (DP), a continuous measure of stability. A low MARP value (closer to 0°) indicates an in-phase relationship between two oscillating segments (i.e., arm and leg), while a high MARP value (closer to 180°) indicates an anti-phase relationship between two segments. A low DP value (closer to 0°) indicates greater stability in the organization of the neuromuscular system, while a high DP value (closer to 180°) indicates less stability in the system.

Non-normal data distribution, shown by Shaprio Wilk tests, required non-parametric analyses. MARP and DP were analyzed using Wilcoxon Signed Rank Tests to determine group differences between the ESR, ART, PWR, and Control groups. Phasing relationships between the arms, legs, ipsilateral prosthetic-side arm and leg, ipsilateral intact-side arm and leg, contralateral prosthetic-side arm and intact-side leg, and contralateral intact-side arm and prosthetic-side leg were evaluated. Significance was set at $p<0.05$.

Results: Significant differences between limb pairs observed in preliminary data are presented below for median MARP and DP values. Non-significant results are not presented ($p>0.05$ in all cases).

Aim 1:

MARP:

Arms: The Control (165.63°) group indicated *better* coordination compared to the ESR (157.57°) group ($p=0.03$).

Ipsilateral Intact-Side Arm and Leg: The Control (158.52°) group indicated *better* coordination compared to the ESR (153.20°) group ($p=0.03$).

DP:

Arms: The Control (7.52°) group indicated *greater* stability compared to the ART (8.55°) group ($p=0.04$) and the ESR (11.26°) group ($p=0.03$).

Legs: The Control (2.77°) group indicated *greater* stability compared to the ART (3.64°) group ($p=0.04$).

Ipsilateral Intact-Side Arm and Leg: The Control (6.09°) group indicated *greater* stability compared to the ART (7.17°) group ($p=0.03$).

Contralateral Intact-Side Arm and Prosthetic-Side Leg: The Control (6.48°) group indicated *greater* stability compared to the ESR (8.80°) group ($p=0.01$).

Contralateral Prosthetic-Side Arm and Intact-Side Leg: The Control (5.13°) group indicated *greater* stability compared to the ESR (9.45°) group ($p=0.03$).

Aim 2:

MARP:

Contralateral Intact-Side Arm and Prosthetic-Side Leg: The ESR (22.47°) group indicated *lower* levels of coordination compared to the PWR (17.62°) group (p=0.02).

DP:

Arms: The ESR (11.26°) group indicated *lesser* stability compared to the ART (8.55°) group (p=0.03).

Ipsilateral Intact-Side Arm and Prosthetic-Side Leg: The ESR (8.92°) group indicated *lesser* stability compared to the PWR (7.32°) group (p=0.02).

Contralateral Intact-Side Arm and Prosthetic-Side Leg: The ESR (8.80°) group indicated *lesser* stability compared to the PWR (7.29°) group (p<0.001).

Discussion: Preliminary analysis of this dataset indicated that RP analysis is sensitive enough to identify differences between groups. This analysis highlighted deficits in the coordination and stability between the limbs of Veterans and SMs with TTA and individuals with TTA. Further, the ESR device was associated with lower levels of coordination and stability compared to the PWR group. Interestingly, all limb pairs involving the intact-side arm were associated with lower levels of coordination and stability for the ESR device. These initial findings may illustrate a compensatory effect of the intact-side arm swing during gait. However, additional data may potentially impact these initial findings. These deficits may directly impact activity restriction, creating a lack of physical activity and ultimately producing a negative influence on the lives of Veterans and SMs. Further investigation is warranted, as continued analysis may show greater differences between the coordination and stability levels of individuals with and without TTA and differences between device types. Importantly, findings can directly influence prescription guidelines to optimize healthcare for all Veterans and SMs with TTA.

Conclusions: Different prosthetic device types influence the inter-limb coordination and stability of Veterans and SMs with TTA during gait. While all devices utilized in this study provide independence for this population, certain device types may promote better coordination and stability leading to a higher quality of life for this population.

References

1. Ziegler-Graham, K., et al. (2008). Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehab, 89,* 422-429.

2. Krueger, C., et al. (2012). Ten years at war: Comprehensive analysis of amputation trends. *J Trauma Acute Care Surg, 73,* 438-444.

3. Blough, D., et al. (2010). Prosthetic cost projections for service members with major limb loss from Vietnam and OIF/OEF. *J Rehab Res Dev, 47,* 387-402.

4. Highsmith, M., et al. (2016). Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews. *J Rehab Res Dev, 53,* 157-184.

5. Healy, A., et al. (2018). A systematic review of randomised controlled trials assessing effectiveness of prosthetic and orthotic interventions. *PLoS ONE, 13*(3), 1-42.

6. Haddad, J., et al. (2010). Relative phase coordination analysis in the assessment of dynamic gait symmetry. *J App Biomech, 26*(1), 109-113.

7. Donker, S., et al. (2002). Interlimb coordination in prosthetic walking: Effects of asymmetry and walking velocity. *Acta Psych, 110,* 265-288.

Research Week Poster

Gait Coordination and Stability of Individuals Living with Transtibial Limb Loss

[1]Alexis Sidiropoulos, PhD[1], David Herlihy, BS[1,2], Jason Maikos, PhD[1]
[1]Department of Veteran Affairs, New York Harbor Healthcare System, New York, NY, USA
[2]Narrows Institute of Biomedical Research and Education, Inc., Brooklyn, NY, USA

INTRODUCTION

- The number of Veterans and Service Members (SMs) with transtibial amputation (TTA) is growing due to increasing rates of dysvascular disease and military involvements abroad[1,2]
- Conclusive research for proper prosthetic prescription is not available for clinicians[3]
- Metabolic and biomechanical outcomes indicate mixed results[4]
- *Continuous measures* of **coordination** and **stability** evaluated using Relative Phase (RP) Analysis provide superior sensitivity compared to traditional measures[5]
- Only one previous study: limited sample size, no differentiation between devices[6]

This study aimed to:

1. Determine the continuous gait inter-limb coordination and stability levels in Veterans and SMs with TTA
2. Determine the extent to which coordination and stability are influenced by different Energy Storing and Returning (ESR) ankle-foot devices
   1. ESR
   2. Articulating ESR
   3. Powered ESR

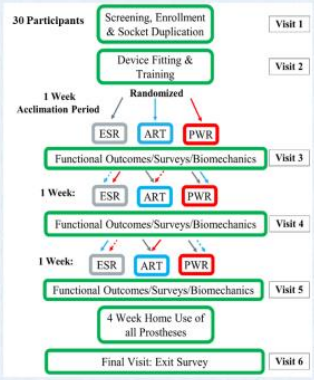
METHODS

Participants

Participants of this study are of a convenience sample from an ongoing Department of Defense funded study (W81XWH-17-2-0014).

- 16 Veterans and SMs with TTA, 10 control participants without TTA
- Prosthetic user for minimum 1 month
- Functional Independence Measure: Level-6 – Modified Independence
- No active wounds/ulcers
- Over 18 years old

Figure 1. Study Design



Biomechanical Gait Analysis

- Full body marker set – prosthetic limb matched intact limb
- Participants walked across 10-meter walkway at comfortable speed (1.3 m/s)
- Collected ≤15 cycles (i.e., steps) per trial

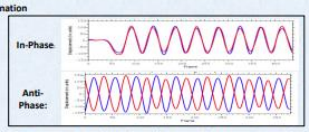
Outcome Measures

Mean Absolute Relative Phase (MARP): measure of **coordination**

- In-phase: ↓ MARP = better coordination
- Anti-phase: ↑ MARP = better coordination

Deviation Phase: measure of **stability**

- In-phase, anti-phase: ↓ DP = better stability



Data Analysis

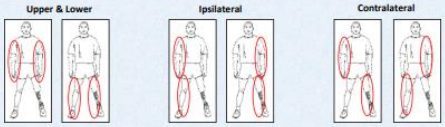
$$MARP = \Sigma(|\phi relative\ phase|/N)$$

where Φrelative is the relative phasing relationship between the two segments and N is the # of points in the RP mean ensemble curve.

$$DP = (\Sigma|SDi|)/N$$

where N is the # of points in the RP mean ensemble curve and SD is the SD of the mean ensemble curve at the *i*th point.

Limb Comparisons:



Statistical Methods

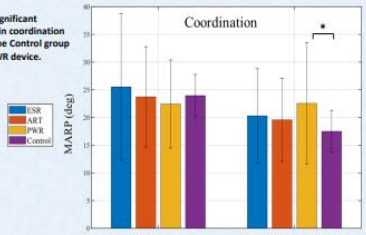
- Repeated measures ANOVA determined differences between devices
- T-tests determined differences between the experimental and control groups
- Significance was set at $p<0.05$ (only significant results presented)

RESULTS

MARP:

Prosthetic-Side Arm to Intact-Side Leg: Control group (158.3°) = better coordination than PWR group (153.0°)

Figure 2. Significant difference in coordination between the Control group and the PWR device.



DP:

Legs: Control group (2.97°) = greater stability than ESR (3.39°) group, ART (3.77°) group, PWR (3.71°) group

Ipsilateral Intact-Side Arm and Leg: Control (6.64°) and PWR (6.85°) groups = greater stability than ESR group (7.95°)

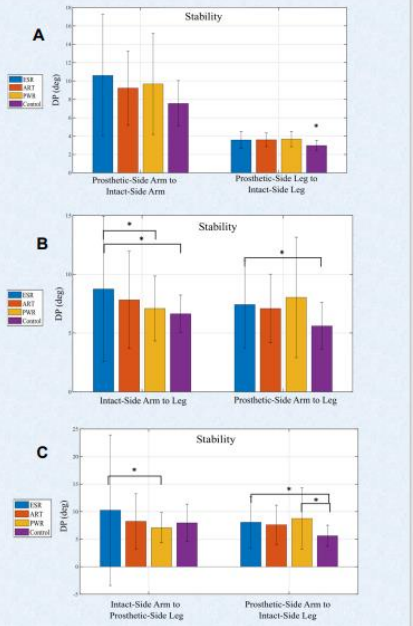
Ipsilateral Prosthetic-Side Arm and Leg: Control group (5.60°) group = greater stability than ESR group (7.60)

Contralateral Intact-Side Arm to Prosthetic-Side Leg: PWR group (6.88°) = greater stability than ESR group (7.93°)

Contralateral Prosthetic-Side Arm and Intact-Side Leg: Control (5.61°) and PWR (8.36°) groups = greater stability than ESR group (8.38°)

Acknowledgments: DoD for funding this study (W81XWH-19-OPORP-CRA) and the ongoing study on which this research builds (W81XWH-17-2-0014).

Figure 3. Significant differences in stability of the (A) legs, ipsilateral limb pairs (B), and contralateral limb pairs (C) between the Control and Experimental groups.



CONCLUSIONS

- RP analysis is sensitive enough to identify significant differences in coordination and stability between individuals with and without TTA
- PWR is only device that indicates deficits in coordination compared to the Control group
- No differences in coordination between devices
- ESR device indicates greatest number of deficits in stability from Control group
- PWR device is more stable than the ESR device
- Additional data may impact the initial findings

REFERENCES

1. Ziegler-Graham, K., et al. (2008). Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil, 89*, 422-429.
2. Krueger, C., et al. (2012). Ten years at war: Comprehensive analysis of amputation trends. *J Trauma Acute Care Surg, 73*, 438-444.
3. Highsmith, M., et al. (2016). Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews. *J Rehab Res Dev, 53*, 157-184.
4. Healy, A., et al. (2018). A systematic review of randomised controlled trials assessing effectiveness of prosthetic and orthotic interventions. *PLoS ONE, 13*(3), 1-42.
5. Haddad, J., et al. (2010). Relative phase coordination analysis in the assessment of dynamic gait symmetry. *J App Biomech, 26*(1), 109-112.
6. Dorsch, S., et al. (2002). Inhibitory coordination in prosthetic walking: Effects of asymmetry and walking velocity. *Acta Psych, 110*, 265-286.

GCMAS Abstract

CONTINUOUS INTER-LIMB COORDINATION AND STABILITY IN VETERANS AND SERVICE MEMBERS WITH TRANSTIBIAL AMPUTATION

Alexis Sidiropoulos, PhD[1], David Herlihy, BS[1,2], Jason Maikos, PhD[1]
[1] Department of Veteran Affairs New York Harbor Healthcare System, New York, NY
[2]Narrows Institute for Biomedical Research and Education, Inc., Brooklyn, NY
E-mail: alexis.sidiropoulos@va.gov

INTRODUCTION

The number of Veterans and Service Members (SMs) with transtibial amputation (TTA) is growing due to the aging population with dysvascular disease and diabetes, as well as from U.S. military involvements abroad [1,2]. With high associated healthcare costs [3], it is expected that conclusive research is available to clinicians for proper prosthetic prescription. However, most research is noncommittal and lacks guidance for clinical practice [4]. Traditional biomechanical parameters indicate mixed results, limiting evidentiary support for optimal prescription guidelines [5]. Conversely, continuous measures of coordination (the movement relationship between limbs) and stability (the ability to offset a perturbation) derived from Relative Phase (RP) analysis provide superior sensitivity and detect changes at a greater resolution [6]. The aims of this study were to determine (1) continuous gait inter-limb coordination and stability levels of Veterans and SMs with TTA, and (2) the extent to which these levels are influenced by different Energy Storing and Returning (ESR) ankle-foot devices (i.e., ESR, articulating ESR (ART), and powered ESR (PWR)). It was hypothesized that individuals with vs. without TTA will indicate lower levels of coordination and stability, and that the PWR device will be associated with greater levels of coordination and stability compared to the ESR and ART device types.

Table 1: Deficits in coordination and stability in Veterans and SMs with TTA compared to individuals without TTA.

	DP	**Z**	**p-value**
Arms			
Control	7.52(3.30)	-1.99	**0.04**
ART	8.55(6.47)		
Control	7.52(3.30)	-2.19	**0.03**
ESR	11.26(6.49)		
Legs			
Control	2.77(0.58)	-1.99	**0.04**
ART	3.64(0.68)		
Intact-Side Arm and Leg			
Control	6.09(2.52)	-2.09	**0.03**
ART	7.17(3.60)		
Intact-Side Arm and Prosthetic-Side Leg			
Control	6.48(3.62)	-2.45	**0.01**
ESR	8.80(4.08)		
Prosthetic-Side Arm and Intact-Side Leg			
Control	5.13(2.94)	-2.19	**0.03**
ESR	9.45(5.90)		
	MARP	**Z**	**p-value**
Arms			
Control	165.63(7.30)	-2.19	**0.03**
ESR	157.57(16.97)		
Intact-Side Arm and Leg			
Control	158.52(6.01)	-2.09	**0.03**
ESR	153.20(10.83)		

Note: Median(Interquartile Range). Significant values are shown in bold.

CLINICAL SIGNIFICANCE

Improved coordination and stability due to a specific ankle-foot device will support evidence based guidelines for prosthetic prescription.

METHODS

Thirty individuals with unilateral TTA (55.3±13 years, 15 males, 1 female) were fit and evaluated with 3 different prosthetic ankle-foot devices: ESR, ART, and PWR. Participants were randomly assigned and separately utilized each prosthetic foot for 1 week at home. After each 1-week trial, participants with TTA and 10 age-matched individuals without TTA (control) participants underwent full-body biomechanical gait analysis. All participants walked at 1.3 m/s across a 10-meter instrumented walkway until at least 15 steps per foot were recorded. RP analysis calculated continuous measures of coordination, Mean Absolute Relative Phase (MARP), and stability, Deviation Phase (DP), between limbs (i.e., arms, legs, ipsilateral arms and legs, and contralateral arms and legs). A low MARP value (closer to 0°) indicates a more in-phase relationship, while a high MARP value (closer to 180°) indicates a more anti-phase relationship. A low DP value (closer to 0°) indicates a more stable organization of the neuromuscular system and a high DP value (closer to 180°) indicates less stability. Due to non-normal distribution, Wilcoxon Signed Rank tests were used to determine significance at $p<0.05$.

RESULTS

Aim 1: Veterans and SMs with TTA experience deficits in coordination and stability compared to individuals without limb loss (Table 1).

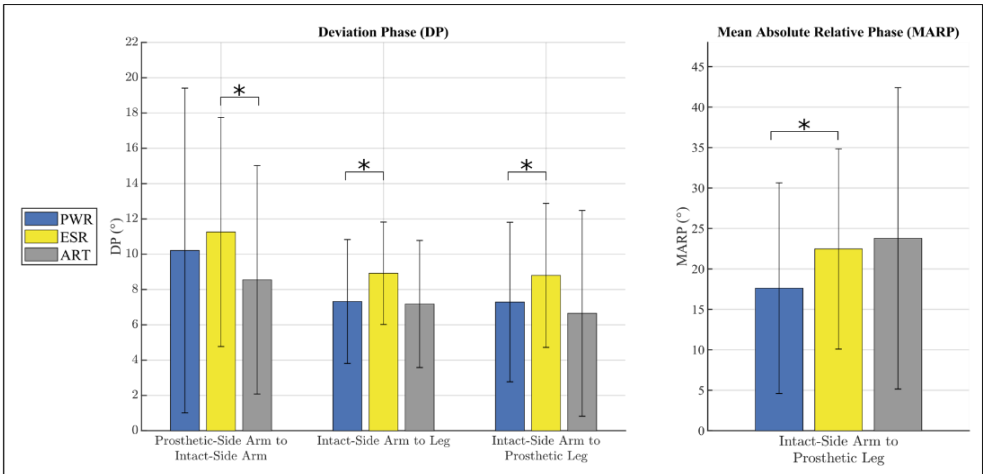


Figure 1: Significant differences in coordination and stability between devices.

Aim 2: Veterans and SM with TTA had lower levels of coordination and stability with the ESR compared to the PWR and ART devices (Figure 1).

DISCUSSION

Preliminary analysis of this dataset indicates that RP analysis is sensitive enough to identify differences between the experimental and control groups and device types. In contrast of our hypothesis, lower levels of coordination and stability observed with the ESR device were associated with the intact-side arm. This may highlight a compensatory effect of the intact-side arm swing during gait. However, further investigation is warranted, as continued analysis may indicate additional differences in coordination and stability between individuals with and without TTA and between device types. Importantly, due to the positive impact of coordination and stability on functional mobility and gait, findings from this study can directly influence prescription guidelines to optimize healthcare for all Veterans and SMs with TTA.

REFERENCES

1. Ziegler-Graham, K., et al. (2008) Arch Phys Med Rehab, 89: 422-429.
2. Farrokhi, S. (2018). MSMR, 25(7): 10-16.
3. Blough, D., et al. (2010) J Rehab Res Dev, 47: 387-402. 10.1682/JRRD.2009.04.0037
4. Highsmith, M., et al. (2016) J Rehab Res Dev, 53: 157-184. 10.1682/JRRD.2015.03.0046
5. Healy, A., et al. (2018) PLoS ONE, 13(3): 1-42. 10.1371/journal.pone.0192094
6. Haddad, J., et al. (2010) J App Biomech, 26(1): 109-113.

ACKNOWLEDGMENTS

We thank the Veterans and SMs who participated in this study.

DISCLOSURE STATEMENT

This investigation is funded by the DoD Orthotics and Prosthetics Outcomes Research Program (OPORP) (award number W81XWH-20-1-0409) and expands upon a funded, ongoing study (DoD OPORP, award number W81XWH-17-2-0014). The views expressed in this abstract are those of the authors and do not reflect the official policy of the Departments of Veterans Affairs.