

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: Department of Veteran Affairs
New York Harbor Healthcare System
423 East 23rd Street, New York, NY 10010

REPORT DATE: July 2021

TYPE OF REPORT: ANNUAL

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

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE July 2021	2. REPORT TYPE ANNUAL	3. DATES COVERED June 1, 2020-May 31, 2021
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) Department of Veteran Affairs New York Harbor Healthcare System 423 East 23 rd Street, New York, NY 10010		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 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). However, only the Powered ESR device shows significant differences in coordination from intact individuals. Further, the Powered ESR device also indicates poor coordination values compared to the other two devices. These findings imply that the Powered ESR device is not advantageous in the optimization of coordination and stability in this population.		

15. SUBJECT TERMS

Prosthetics, Coordination, Stability, Transtibial Amputation, Gait

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 18	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER <i>(include area code)</i>

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

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	5
2. Keywords	5
3. Accomplishments	5
4. Impact	11
5. Changes/Problems	13
6. Products	14
7. Participants & Other Collaborating Organizations	14
8. Special Reporting Requirements	16
9. Appendices	16

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 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 disadvantages associated with the use of a 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).

Major Task 1: IRB Submission and Team Meetings	% Completion	Completion/Expected Completion Date
Subtask 1: Prepare and Submit IRB Documents		
IRB protocol Submission: <i>Requesting Exemption from IRB Review</i>	<i>100%</i>	Completed: 6/20/2020

<i>Milestone Achieved: IRB Approval/Exemption from Review R&D Committee Review and Approval</i>	100%	Completed: 9/14/2020
<i>Milestone Achieved: HRPO Approval/Concurrence</i>	100%	Completed: 3/1/2021
Subtask 2: Team Meetings		
Kick-Off Meeting	100%	Completed: 6/24/2020
Y1Q1 Meeting	100%	Completed: 9/2/2020
Y1Q2 Meeting	100%	Completed: 12/9/2020
Y1Q3 Meeting	100%	Completed: 3/17/2021
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)	100%	Completed: 9/15/2020
Implement relative phase analysis to experimental data	33%	Expected: 10/1/2021
Implement relative phase analysis to control data	80%	Expected: 7/15/2021
Perform statistical analysis to compare output from two groups	0%	Expected: 10/15/2021
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	0%	Expected: 10/30/2021
<i>Milestone Achieved: 100% of analysis complete</i>	0%	Expected: 10/30/2021
<i>Milestone Achieved: Identified which prosthetic device is associated with the highest levels of coordination and stability</i>	0%	Expected: 10/30/2021
Major Task 4: Data Interpretation and Dissemination		
Subtask 1: Interpret data and share findings		
Meetings to discuss the interpretation of the data associated with specific aims 1 and 2	0%	Expected: 11/30/2021
Subtask 2: Manuscript Preparation/Conference Presentation		
Roles for dissemination of findings (abstracts, scientific presentations, and manuscripts) assigned	0%	Expected: 12/15/2021
Plan for subsequent studies submitted	0%	Expected: 12/30/2021

<i>Milestone Achieved: Report findings from study</i>	<i>0%</i>	Expected: 4/30/2021
<i>Milestone Achieved: Manuscript preparation</i>	<i>0%</i>	Expected: 4/30/2021

What was accomplished under these goals?

Major Activities

Administrative Approval

IRB and HRPO submission and approval were obtained prior to the start of data analysis for this project. A classification of Exemption status from local IRB Committee Review as well as the approval memo from the local Research and Development Committee were received. The Principal Investigator was prompted to address the HRPO requirements for the VA New York Harbor IRB approval memo and therefore clarifications were sent to the HRPO reviewer pertaining to the initial submission on 01/08/2021. The Associated Chief of Staff for Research from VA New York Harbor confirmed the exemption category on 01/22/2021 and the research team met with HRPO reviewers to resolve pending questions about the IRB review process on 02/08/2021. On 03/01/2021, the ORP HRPO sent a memorandum indicating concurrence with the exemption determination made by the VA New York Harbor. As of that date, the project was granted permission to proceed with no further requirement for review by the HRPO. The annual Project Status Report is due to the local VA New York Harbor R&D by 07/26/2021.

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. In addition to a study kick-off meeting on 06/24/2020, quarterly meetings have occurred on 09/02/2020, 12/09/2020, and 03/17/2021. The annual meeting is scheduled to occur on 06/23/2021. Please see the agenda below:

Date: June 23rd, 2021

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

Wednesday, June 23rd, 2021

Item	Presenter
Study Overview	AS
Presentation (Status, Preliminary Data Analysis, Future Work)	AS
Data Processing Updates	MP
Schedule Quarterly Call (Y2Q1)	All
Open Forum	All
Closing Remarks, Questions, Concerns	All

Data Processing

Before IRB and HRPO approval were obtained, the MatLab pipelines were created and completed in preparation for data processing. Therefore, data were ready for processing once administrative approval was granted. The MatLab coding system has been used to analyze 10 (33% complete) individuals with transtibial limb loss and 8 (80% complete) individuals without amputation. Data processing continues as more data becomes available from the ongoing DoD study (W81XWH-17-2-0014) on which this study builds. Currently, data from an additional 11 participants with lower limb loss and 1 participant without amputation have been collected and will be processed, leaving a total of 9 participants with transtibial amputation and 1 participant without amputation to be collected to complete the ongoing study. Though minimally delayed due to the COVID-19 pandemic, data processing and analysis is expected to be completed by October 2021.

Significant Results and Key Outcomes

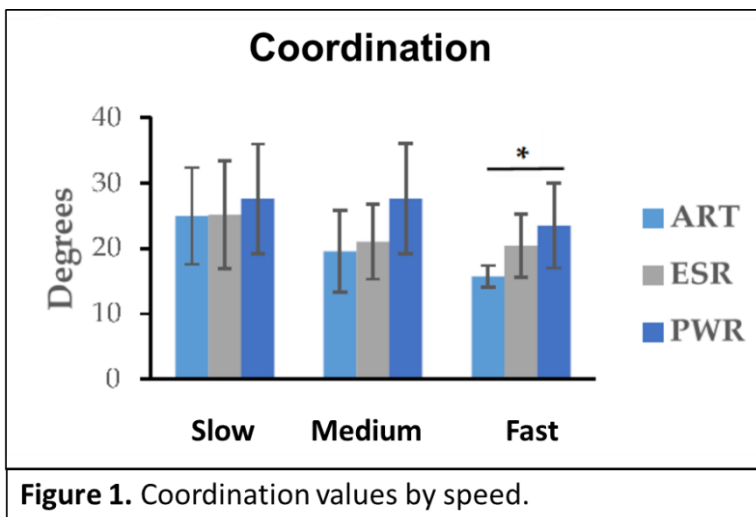
Preliminary Data Analysis

Relative Phase Analysis has been implemented on the available data using the customized MatLab code. Further, a statistical software (SPSS Version 25) has been used to identify any statistically significant findings in the preliminary data. These data indicate statistically significant differences in both coordination and stability between Veterans and Service Member with transtibial amputation and individuals without lower limb loss (Table 1). The findings highlight the disadvantages associated with the Powered Energy Storing and Returning (ESR) device (PWR) compared to the ESR and Articulating ESR (ART) devices, as there are a greater number of differences observed between individuals wearing the PWR device and those without lower limb loss compared to when individuals with transtibial amputation wear either the ESR or ART devices. Further, only the PWR device indicates differences between the control group (individuals without amputation) and Veterans and Service Members with transtibial limb loss.

Stability		
Limb Pair	t-stat	p-value
<u>Control vs ART</u>		
Arms	0.78	0.05
Legs	2.60	0.02
<u>Control vs ESR</u>		
Arms	0.71	0.05
Legs	0.04	0.03
<u>Control vs PWR</u>		
Arms	2.13	0.05
Legs	2.20	0.04
Prosthetic-Side Arm and Leg	2.26	0.04
Prosthetic-Side Arm and Intact-Side Leg	2.35	0.03
Coordination		
Limb Pair	t-stat	p-value
<u>Control vs PWR</u>		
Prosthetic-Side Arm and Intact-Side Leg	2.26	0.04

Table 1. Statistically significant differences between Veterans and Service Members with Transtibial amputation and individuals without lower limb loss (Control).

While differences between prosthetic devices have not yet been observed, the addition of more data may lead to significant differences between the ESR, ART, and PWR devices. However, while this study intends to include analysis of a single, “medium” walking speed, exploratory data analysis of additional data collected during the ongoing DoD-funded study at a “slow” and “fast” speed indicate that the PWR device produces lower levels of coordination between the prosthetic-side arm and intact-side leg compared to the ART device, as a lower degree represents better coordination between this pair of limbs (Figure 1). This result highlights the disadvantages associated with the PWR device as it illustrates the poor level of coordination individuals with transtibial amputation can achieve while wearing this device compared to another device type.



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 of 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 will be disseminated via the Military Health System Research Symposium (MHSRS) hosted by the Department of Defense. 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 poster is scheduled to be presented at the August 2021 MHSRS meeting. 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, data processing and analysis will continue as more data becomes available. This will also be associated with continued 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. Continued quarterly meetings will be scheduled and the Principal Investigator will provide the entire research team with study progress reports and update the study timeline as needed.

4. IMPACT:

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

While data analysis is ongoing, 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, similar to 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 and stability associated with different prosthetic ankle-foot devices. Preliminary data indicates that the PWR device has the most deficits in stability and coordination for Veterans and Service Members with transtibial amputation. 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 21 experimental and 9 control 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. Further, the administrative hold on enrollment associated with the ongoing DoD study have now been lifted and collection of both experimental and control participants has been restarted. Data from the ongoing DoD study will continue to be processed and analyzed as it is collected.

It should also be noted that the Principal Investigator, Dr. Alexis Sidiropoulos, will be making use of the Family Medical Leave Act with an estimated timeline of June 24th-September 19th. During this time, all responsibilities will be transitioned to Co-Investigator Dr. Jason Maikos. For any required communication associated with this grant, either Dr. Jason Maikos or Mr. Michael Hyre should be contacted, as both study team members have been working closely on this project from the start.

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 2 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.**

- Nothing to Report.

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

- Nothing to Report.

- **Other publications, conference papers, and presentations.**

- Preliminary results of this study have been submitted to the Military Health Systems Research Symposium hosted by the DoD via an abstract and accepted as a poster presentation. This poster entitled “Continuous Inter-Limb Coordination and Stability in Veterans and Service Members with Transtibial Amputation: A Preliminary Analysis” will be presented in August at the 2021 symposium. See appendix for full abstract.

- **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:	5
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:	Ashley Knight, PhD
Project Role:	Co-I at WRNMMS
Researcher Identifier:	
Nearest person month worked:	2
Contribution to Project:	Consults on data interpretation
Funding Support:	

Name:	Michael Poppo, MS
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 REPORTING 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 injuries³, 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 practice⁴. 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 guidelines⁵. 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 resolution⁶. 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 parameters⁷. 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=6) 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=6) 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 Shapiro Wilk tests, required non-parametric analyses. MARP and DP were analyzed using Mann-Whitney U-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).

MARP:

Contralateral Intact-Side Arm and Prosthetic-Side Leg: The Control (23.06°) group differed from the ESR (16.86°) group ($U=6$, $p=0.05$) and ART (16.67°) group ($U=6$, $p=0.05$).

Contralateral Prosthetic-Side Arm and Intact-Side Leg: The Control (16.11°) group differed from the PWR (26.14°) group ($U=4$, $p=0.03$).

DP:

Arms: The Control (9.08°) group differed from the ESR (11.66°) group ($U=5$, $p=0.04$) and the PWR (16.53°) group ($U=1$, $p=0.01$).

Legs: The Control (2.99°) group differed from all three prosthetic device types: ESR (4.35°) group ($U=3$, $p=0.02$); ART (4.10°) group ($U=3$, $p=0.02$); PWR (4.35°) group ($U=3$, $p=0.02$).

Ipsilateral Prosthetic-Side Arm and Leg: The Control (5.71°) group differed from all three prosthetic device types: ESR (9.87°) group ($U=5$, $p=0.05$); ART (9.99°) group ($U=6$, $p=0.04$); PWR (16.79°) group ($U=3$, $p=0.02$).

Contralateral Prosthetic-Side Arm and Intact-Side Leg: The Control (5.39°) group differed from all three prosthetic device types: ESR (10.56°) group ($U=5$, $p=0.04$); ART (12.46°) group ($U=5$, $p=0.04$); PWR (18.88°) group ($U=4$, $p=0.03$).

Discussion: RP analysis of this preliminary dataset indicated significant differences in the coordination and stability between the limbs of individuals without TTA and those with TTA; however, there were no differences in either measure between the different prosthetic device types. Additional data may potentially impact this initial finding. Interestingly, both the ipsilateral and the contralateral limb pairs involving the prosthetic-side arm (i.e., Prosthetic-side arm and prosthetic-side leg, and prosthetic-side arm and intact-side leg) indicated deficits in stability for all three device types. This may highlight a compensatory effect of the prosthetic-side arm swing during gait. Additionally, all device types indicated stability deficits between the legs. This instability can 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.