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CONTRACTING ORGANIZATION: Narrows Institute of Biomedical Research, Inc.
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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					
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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 2022-June 2023 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	*93%*	Expected: 7/15/2023
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	*93%*	Expected: 8/15/2023
Milestone Achieved: 100% of analysis complete	*93%*	Expected: 8/15/2023
Milestone Achieved: Identified which prosthetic device is associated with the highest levels of coordination and stability	*ongoing*	Expected: 9/15/2023

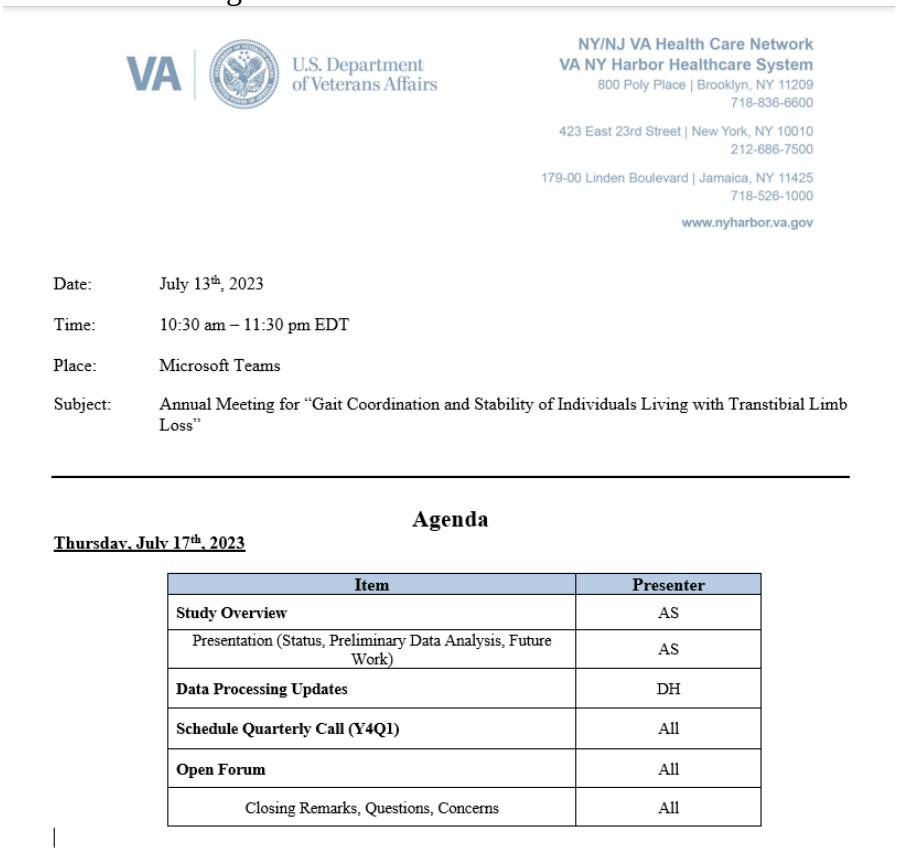
What was accomplished under these goals?

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 07/13/2023. Please see the agenda below:



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718-526-1000

www.nyharbor.va.gov

Date: July 13th, 2023

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, July 17th, 2023

Item	Presenter
Study Overview	AS
Presentation (Status, Preliminary Data Analysis, Future Work)	AS
Data Processing Updates	DH
Schedule Quarterly Call (Y4Q1)	All
Open Forum	All
Closing Remarks, Questions, Concerns	All

Data Processing

Data for 28 (93% complete) individuals with transtibial limb loss and 10 (100% complete) individuals without amputation have been processed, leaving 2 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 2023.

	Individuals with TTA		**Individuals without TTA**	
	Completed	Remaining	Completed	Remaining
Collected	28	2	10	0
Processed	26	2	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 that the PWR device provides less coordination, but greater stability to individuals with transtibial limb loss. However, this may change once outlier are removed. Further, data will be re-evaluated using specific demographic information, such as age, as a covariate.

Significant differences in coordination observed between the Control group and the experimental groups includes the Control group indicated greater coordination between the legs compared to the ART group, and better coordination between the contralateral prosthetic-side arm to intact-side leg compared to the PWR group. Between groups, the PWR group indicated less coordination between the ipsilateral prosthetic-side arm to leg compared to both the ART and ESR groups, and less coordination between the contralateral prosthetic-side arm to intact-side leg compared to both groups. No other significant differences between groups were observed.

For stability, significant differences in DP included the Control group indicated greater stability between the contralateral prosthetic-side arm to intact-side leg compared to both the PWR and ART groups. Between prosthetic devices, the PWR group indicates greater stability between the ipsilateral intact-side arm to leg compared to the ESR group, and greater stability between the contralateral intact-side arm to prosthetic-side leg compared to both the ART and ESR groups. No other significant differences between groups were observed.

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) 2023 conference in June during a podium presentation. This conference is focused on clinical application of biomechanical data and provided a platform to present the study data directly to clinicians. Further, results of this study were also presented via podium presentation for the Summer Biomechanics, Bioengineering, and Biotransport Conference in June 2023. The theme of this conference was “Building Interfaces Across Tissues, Disciplines, and Communities”.

Preliminary results will also be disseminated via the Military Health System Research Symposium (MHSRS) hosted by the Department of Defense in August 2023. A poster presentation entitled “Continuous Inter-Limb Gait Coordination and Stability in Veterans and Service Members with Transtibial Amputation: Influences of Prosthetic Ankle-Foot Devices” will be included in the “From Laboratory to Clinic: Progress of Orthotic and Prosthetic Technologies and Outcomes” 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 3, 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 lower levels of coordination and greater levels of stability compared to the ESR and ART devices. 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 28 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.**

    See appendices for full abstracts.

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

    Nothing to Report.

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

    Podium presentation for the Gait and Clinical Movement Analysis Society (GCMAS) 2023 Annual Conference, June 2023

    Podium presentation for the Summer Biomechanics, Bioengineering, Biotransport (SB3C) 2023 Annual Conference, June 2023

    Upcoming poster presentation for the Military Health Systems Research Symposium, August 2023

    Sidiropoulos, A.N., Herlihy, D., & Maikos, J.T. (2023). Implementation of relative phase analysis to evaluate continuous inter-limb coordination and stability in individuals with lower limb loss – Design and protocol for a retrospective analysis. *Under Review.*

- **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

SB3C Abstract:

CONTINUOUS INTER-LIMB GAIT COORDINATION AND STABILITY IN VETERANS AND SERVICE MEMBERS WITH TRANSTIBIAL LIMB LOSS: INFLUENCES OF PROSTHETIC ANKLE-FOOT DEVICES

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INTRODUCTION

The number of Veterans and Service members (SMs) with transtibial limb loss (TLL) 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]. Metabolic and biomechanical parameters, the primary outcomes traditionally used to determine effectiveness of prosthetic devices, indicate mixed results, 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]. The first aim of this study was to quantify levels of continuous

inter-limb gait coordination and stability among Veterans and SMs with TLL. It was hypothesized that individuals with vs. without TLL will walk with lower levels of inter-limb coordination and stability. The second aim was to determine the extent to which gait coordination and stability of Veterans and SMs with TLL 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 the PWR device will indicate greater levels of coordination and stability compared to the other devices.

METHODS

Thirty individuals with unilateral TLL were fit and evaluated with 3 different prosthetic ankle-foot devices: ESR, ART, and PWR. Participants separately utilized each prosthetic foot for 1 week at home. After each 1-week trial, participants with TLL underwent biomechanical gait analysis. Ten individuals without TLL performed a single gait analysis session. 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.

MARP is calculated using the following equation:

$$\mathrm{MARP} = \Sigma(|\phi_{\mathrm{Rel.}}|/\mathrm{N}) \qquad (1)$$

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

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.

DP is calculated using the following equation:

$$\mathrm{DP} = (\Sigma|\mathrm{SDi}|)/\mathrm{N} \qquad (2)$$

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

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.

Two sample T-tests determined differences between the Control participants and each device (PWR, ESR, ART) for MARP and DP separately. Linear mixed effect models compared MARP and DP between devices, while accounting for repeated observations. Pairwise comparisons were conducted using estimated marginal means. Significance was set at $p<0.05$.

RESULTS

Aim 1: Veterans and SMs with vs. without TLL experience deficits in coordination and stability (Table 1).

Table 1. Differences in coordination (MARP) and stability (DP) in Veterans and SMs with TLL compared to intact individuals.

	MARP	t-value	p-value
Arm to Arm			
Control	157.6	-3.1	0.004
ART	162.6		
Prosthetic-side Arm to Intact-Side Ankle			
Control	17.3	-2.1	0.03
ART	22.8		
	DP	**t-value**	**p-value**
Leg to Leg			
Control	2.9	-2.2	0.03
PWR	3.6		
Control	2.9	-2.3	0.03
ART	3.5		
Prosthetic-Side Wrist to Intact-Side Ankle			
Control	5.5	-2.0	0.04
PWR	7.8		
Control	5.5	-2.1	0.04
ART	7.4		

Aim 2: The PWR device indicates a less coordinated gait pattern than the ART device between the prosthetic-side arm and leg, and lesser coordination than both the ESR and ART devices between the prosthetic-side arm and intact-side leg (Figure 1). However, the PWR device indicates a more stable gait pattern than the ESR device between the intact-side arm and leg and is more stable than the ART and ESR devices between the intact-side arm and prosthetic-side leg (Figure 2).

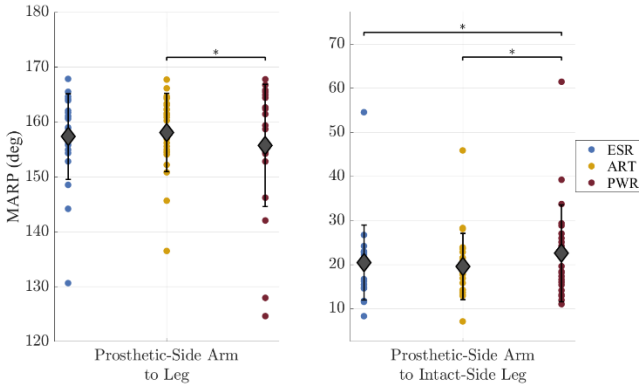

Figure 1. Inter-limb coordination as Mean Absolute Relative Phase (MARP) between groups and devices (only significant differences illustrated).

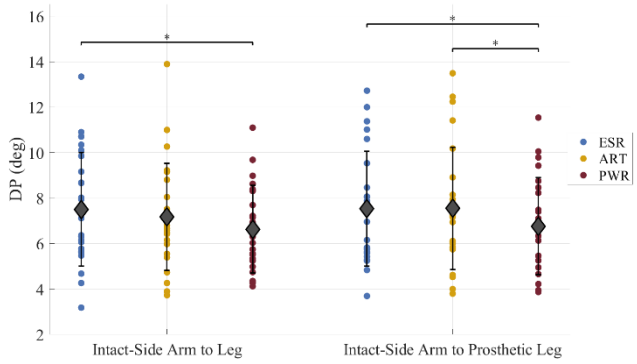

Figure 2. Inter-limb stability as Deviation Phase (DP) between groups and devices (only significant differences illustrated).

DISCUSSION

Preliminary analysis of this dataset indicates that RP analysis is sensitive enough to identify differences between individuals with vs. without TLL and between the PWR, ART, and ESR devices. As expected, individuals with vs. without TLL experience deficits in both coordination and stability.

Interestingly, the PWR device was associated with both greater levels of stability and lower levels of coordination compared to the ESR and ART devices. This discrepancy may be due to the novelty of the device for some individuals with TLL (notwithstanding the 1-week acclimation). It is possible that the active push-off provided by the PWR device disrupts the coordinative pattern the individual is accustomed to with a non-powered device, while the new pattern associated with the device allows for greater consistency of the motor pattern compared to the other devices. However, it should be noted that this device is also associated with large outliers in the coordination measure. It is possible that removal of such outliers may eliminate the significant coordination deficits observed between the PWR device and both the Control group and the other devices. If so, a clear advantage of the PWR device would become evident, as it provides the greatest stability advantage to individuals with TLL. Though, device acclimation is an important consideration for future work.

Given the identified deficits in gait coordination and stability among Veteran and SMs with TLL, particularly across different types of prosthetic ankle-foot devices, such findings can help support development of rehabilitation programs focused on improving these parameters. Importantly, findings can directly influence prescription guidelines to optimize healthcare for all Veterans and SMs with TLL, helping them to live high quality, active lives.

ACKNOWLEDGMENTS

We thank Dr. Timothy Moore for his statistical support, the VISN 2 BRAVO lab and Walter Reed National Military Medical Center for data collection contributions, and the Narrows Institute for their support. The views expressed herein are those of the authors, and do not necessarily reflect the official policies of the U.S. Departments of the Army, Navy, or Air Force, nor the U.S. Government. The identification of specific products or instrumentation is considered

an integral part of the scientific endeavor and does not constitute endorsement or implied endorsement on the part of the authors nor by the U.S. Government. This investigation is funded by the DoD Orthotics and Prosthetics Outcomes Research Program (OPORP) (W81XWH2-1-0409) and expands upon an ongoing study (DoD OPORP, W81XWH-17-2-0014).

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MHSRS Abstract

Introduction: With high healthcare costs associated with transtibial limb loss (TLL)[1], 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[2]. Metabolic and biomechanical parameters, the primary outcomes traditionally used to determine effectiveness of prosthetic devices, indicate mixed results in the literature, limiting evidentiary support for optimal prescription guidelines[3]. 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[4]. The first aim of this study was to quantify levels of continuous inter-limb gait coordination and stability among Veterans and Service Members (SM) with TLL. It was hypothesized that individuals with vs. without TLL will walk with lower levels of inter-limb coordination and stability. The second aim was to determine the extent to which gait coordination and stability of Veterans and SMs with TLL 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 the PWR device will indicate greater levels of coordination and stability compared to the other devices.

Methods: Twenty-five individuals with unilateral TLL were fit and evaluated with 3 different prosthetic ankle-foot devices: ESR, ART, and PWR. Participants separately utilized each prosthetic foot for 1 week at home. After each 1-week trial, participants with TLL underwent biomechanical gait analysis. Ten individuals without TLL performed a single gait analysis session. 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 was utilized to calculate continuous measures of coordination, Mean Absolute Relative Phase (MARP), and stability, Deviation Phase (DP), between limbs. 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.

Two sample T-tests determined differences between the Control participants and each device (PWR, ESR, ART) for MARP and DP separately. Linear mixed effect models compared MARP and DP between devices,

while accounting for repeated observations. Pairwise comparisons were conducted using estimated marginal means. 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: Veterans and SMs with vs. without TTL experience deficits in coordination and stability.

Arms: The **Control** (157.6°) group indicated *better* coordination compared to the **ART** (162.6°) group (p=0.004).

Prosthetic-Side Arm to Intact-Side Leg: The **Control** (17.3°) group indicated *better* coordination compared to the **ART** (22.8°) group (p=0.03).

Prosthetic-Side Arm to Intact-Side Leg: The **Control** (5.5°) group indicated *better* stability compared to the **PWR** (7.8°) (p=0.04) and the **ART** (7.4°) (p=0.04) groups.

Legs: The **Control** (2.9°) group indicated *better* stability compared to the **PWR** (3.6°) (p=0.03) and **ART** (3.5°) (p=0.03) groups.

Aim 2: Differences between prosthetic device-types were observed.

MARP:

Prosthetic-Side Arm and Leg: The **PWR** (155.6°) group indicated *lesser* coordination than the **ART** (157.9°) (p=0.04) group.

Prosthetic-Side Arm and Intact-Side Leg: The **PWR** (22.6°) group indicated *lesser* coordination than the **ESR** (20.4°) (p=0.04) and **ART** (22.4°) (p=0.04) devices.

DP:

Intact-Side Arm and Leg: The **PWR** (7.0°) group indicated *greater* stability than the **ESR** (9.1°) (p=0.01) group.

Intact-Side Arm and Prosthetic-Side Leg: The **PWR** (6.6°) group indicated *greater* stability than the **ART** (7.5°) (p=0.03) and **ESR** (7.6°) (p=0.01) groups.

Discussion: Preliminary analysis of this dataset indicates that RP analysis is sensitive enough to identify differences between individuals with vs. without TLL and between the PWR, ART, and ESR devices. As expected, individuals with vs. without TLL experience deficits in both coordination and stability.

Interestingly, the PWR device was associated with both greater levels of stability and lower levels of coordination compared to the ESR and ART devices. This discrepancy may be due to the novelty of the device for some individuals with TLL (notwithstanding the 1-week acclimation). It is possible that the active push-off provided by the PWR device disrupts the coordinative pattern the individual is accustomed to with a non-powered device, while the new pattern associated with the device allows for greater consistency of the motor pattern compared to the other devices. However, it should be noted that this device is also associated with large outliers in the coordination measure. It is possible that removal of such outliers may eliminate the significant coordination deficits observed between the PWR device and both the Control group and the other devices. If so, a clear advantage of the PWR device would become evident, as it provides the greatest stability advantage to individuals with TLL. Though, device acclimation is an important consideration for future work.

Conclusions: Given the identified deficits in gait coordination and stability among Veteran and SMs with TLL, particularly across different types of prosthetic ankle-foot devices, such findings can help support development of rehabilitation programs focused on improving these parameters. Importantly, findings can directly influence prescription guidelines to optimize healthcare for all Veterans and SMs with TLL, helping them to live high quality, active lives.

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GCMAS Abstract:

CONTINUOUS INTER-LIMB GAIT COORDINATION AND STABILITY IN VETERANS AND SERVICE MEMBERS WITH TRANSTIBIAL LIMB LOSS: INFLUENCES OF PROSTHETIC ANKLE-FOOT DEVICES

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INTRODUCTION

With high healthcare costs associated with transtibial limb loss (TLL) [1], 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 [2]. Metabolic and biomechanical parameters, the primary outcomes traditionally used to determine effectiveness of prosthetic devices, indicate mixed results, limiting evidentiary support for optimal prescription guidelines [3]. 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 [4]. The first aim of this study was to quantify levels of continuous inter-limb gait coordination and stability among Veterans and Service Members (SM) with TLL. It was hypothesized that individuals with vs. without TLL will walk with lower levels of inter-limb coordination and stability. The second aim was to determine the extent to which gait coordination and stability of Veterans and SMs with TLL 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 the PWR device will indicate greater levels of coordination and stability compared to the other devices.

CLINICAL SIGNIFICANCE

Understanding continuous coordination and stability for individuals with TLL and the effect of prosthetic devices will support evidence-based guidelines for prosthetic prescription.

METHODS

Twenty-five individuals with unilateral TLL were fit and evaluated with 3 different prosthetic ankle-foot devices: ESR, ART, and PWR. Participants separately utilized each prosthetic foot for 1 week at home. After each 1-week trial, participants with TLL underwent biomechanical gait analysis. Ten individuals without TLL performed a single gait analysis session. 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.

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.

Two sample T-tests determined differences between the Control participants and each device (PWR, ESR, ART) for MARP and DP separately. Linear mixed effect models compared MARP and DP between devices, while accounting for repeated observations. Pairwise comparisons were conducted using estimated marginal means. Significance was set at $p<0.05$.

Table 1. Differences in coordination (MARP) and stability (DP) in Veterans and SMs with TLL compared to intact individuals.

	MARP	t-value	p-value
Arm to Arm			
Control	157.6	-3.1	0.004
ART	162.6		
Prosthetic-side Arm to Intact-Side Ankle			
Control	17.3	-2.1	0.03
ART	22.8		
	DP	**t-value**	**p-value**
Leg to Leg			
Control	2.9	-2.2	0.03
PWR	3.6		
Control	2.9	-2.3	0.03
ART	3.5		
Prosthetic-Side Wrist to Intact-Side Ankle			
Control	5.5	-2.0	0.04
PWR	7.8		
Control	5.5	-2.1	0.04
ART	7.4		

RESULTS

Aim 1: Veterans and SMs with vs. without TLL experience deficits in coordination and stability (Table 1).

Aim 2: The PWR device indicates a less coordinated gait pattern than the ART device between the prosthetic-side arm and leg, and lesser coordination than both the ESR and ART devices between the prosthetic-side arm and intact-side leg (Figure 1). However, the PWR device indicates a more stable gait pattern than the ESR device between the intact-side arm and leg and is more stable than the ART and ESR devices between the intact-side arm and prosthetic-side leg (Figure 2).

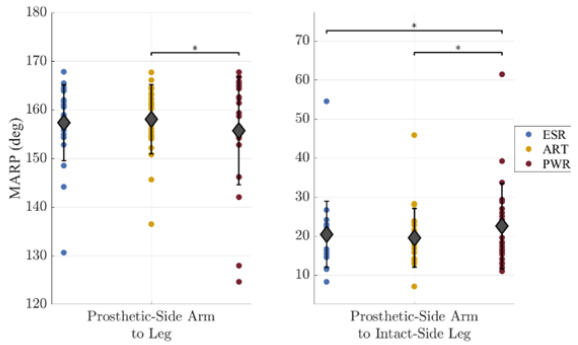

Figure 1. Inter-limb coordination as Mean Absolute Relative Phase (MARP) between groups and devices (only significant differences illustrated).

DISCUSSION

Preliminary analysis of this dataset indicates that RP analysis is sensitive enough to identify differences between individuals with vs. without TLL and between the PWR, ART, and ESR devices. As expected, individuals with vs. without TLL experience deficits in both coordination and stability.

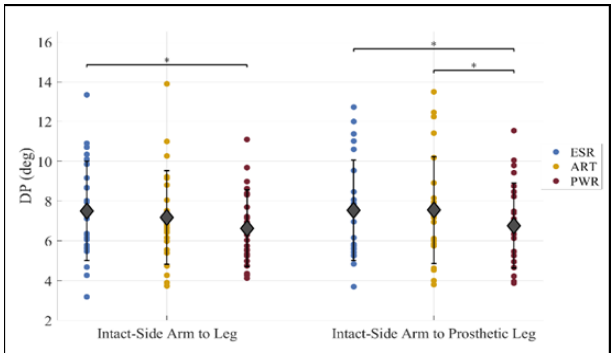

Figure 2. Inter-limb stability as Deviation Phase (DP) between groups and devices (only significant differences illustrated).

Interestingly, the PWR device was associated with both greater levels of stability and lower levels of coordination compared to the ESR and ART devices. This discrepancy may be due to the novelty of the device for some individuals with TLL (notwithstanding the 1-week acclimation). It is possible that the active push-off provided by the PWR device disrupts the coordinative pattern the individual is accustomed to with a non-powered device, while the new pattern associated with the device allows for greater consistency of the motor pattern compared to the other devices. However, it should be noted that this device is also associated with large outliers in the coordination measure. It is possible that removal of such outliers may eliminate the significant coordination deficits observed between the PWR device and both the Control group and the other devices. If so, a clear advantage of the PWR device would become evident, as it provides the greatest stability advantage to individuals with TLL. Though, device acclimation is an important consideration for future work.

Given the identified deficits in gait coordination and stability among Veteran and SMs with TLL, particularly across different types of prosthetic ankle-foot devices, such findings can help support development of rehabilitation programs focused on improving these parameters. Importantly, findings can directly influence prescription guidelines to optimize healthcare for all Veterans and SMs with TLL, helping them to live high quality, active lives.

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4. Haddad, J., et al., *J App Biomech*, 26(1): 109-113, 201.

CMAS Abstract

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

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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).

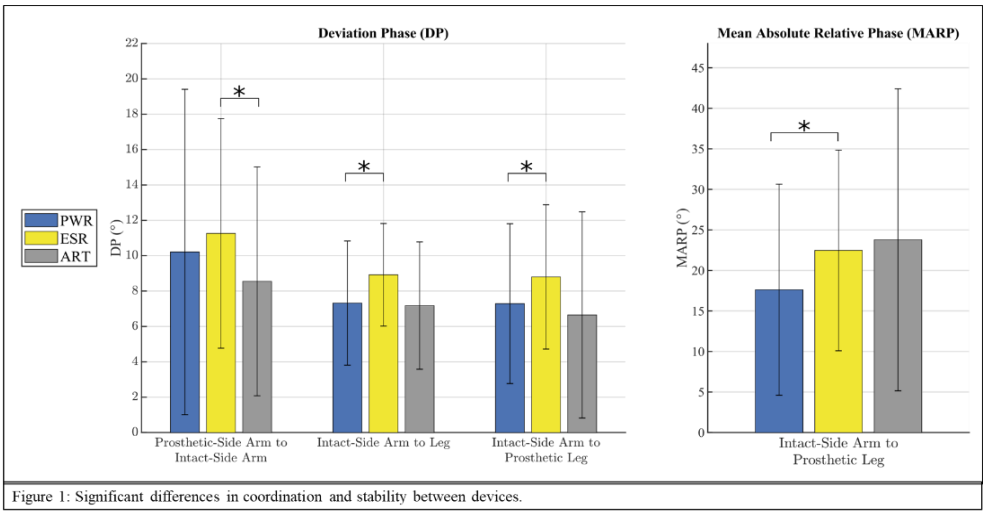

Figure 1: Significant differences in coordination and stability between devices.

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.

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DISCLOSURE STATEMENT

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