AWARD NUMBER: W81XWH-19-1-0447

TITLE: Optimal Selection of Prosthetic Knee and Foot Combination for Improving Walking and Standing Performance in Transfemoral Prosthesis Users

PRINCIPAL INVESTIGATOR: Steven A. Gard, PhD

CONTRACTING ORGANIZATION: Northwestern University, Evanston, IL

REPORT DATE: October 2021

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**
October 2021	Annual	01Sep2020-31Aug2021

4. TITLE AND SUBTITLE
2021
Optimal Selection of Prosthetic Knee and Foot Combination for Improving Walking and Standing Performance in Transfemoral Prosthesis Users

5a. CONTRACT NUMBER
W81XWH-19-1-0447

5b. GRANT NUMBER
OP180013

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Steven A. Gard, PhD

E-Mail: sgard@northwestern.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

Northwestern University
633 Clark Street
Evanston, IL 60208

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 purpose of this study is to systematically compare different combinations of mechanical prosthetic knee joint and foot-ankle components to determine how walking and standing performance are affected in transfemoral prosthesis users. This project will involve a collaborative effort between Northwestern University and the Jesse Brown VA Medical Center. For the first aim, we will perform computer simulations of the transfemoral prosthesis configurations with the different combinations of prosthetic knee and ankle components to determine how swing phase foot clearance is affected and stance phase stability of the prosthetic knee joint is influenced. For the second aim, we will perform quantitative gait analyses on subjects walking on level ground, stairs and slopes with polycentric and single-axis knees, and hydraulic and solid foot-ankle components. Finally, for the third aim, the standing balance of subjects will be evaluated using a series of tests that measure upright balance during quiet standing and stability following balance perturbation.

15. SUBJECT TERMS
Prosthesis, prosthetic knee, prosthetic foot, transfemoral, amputee, gait, standing

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	13	**19b. TELEPHONE NUMBER** *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION

Numerous studies involving human subjects testing, mechanical characterizations and computer simulations have been conducted to compare different types of prosthetic components in order to better understand their impact on prosthesis users' activities of daily living. However, to date there have been no systematic investigations to determine how to best combine a prosthetic knee and foot for improving walking and standing performance in transfemoral prosthesis users. The purpose of this study is to systematically compare different combinations of mechanical prosthetic knee joint and foot-ankle components to determine how walking and standing performance are affected in transfemoral prosthesis users. The goal is to identify those prosthetic knee and foot combinations that impart greater benefits to the user than others. This project will involve a collaborative effort between Northwestern University and the Jesse Brown VA Medical Center. For the first aim, we will perform computer simulations of the transfemoral prosthesis configurations with the different combinations of prosthetic knee and ankle components to determine how swing phase foot clearance is affected and stance phase stability of the prosthetic knee joint is influenced. For the second aim, we will perform quantitative gait analyses on subjects walking on level ground, stairs and slopes with polycentric and single-axis knees, and hydraulic and solid foot-ankle components. Finally, for the third aim, the standing balance of subjects will be evaluated using a series of tests that measure upright balance during quiet standing and stability following balance perturbation. This project will require four years to complete. This work is directly applicable to the Veteran Health Administration's Patient Care Mission because the results may improve the gait and quality of life of veterans with lower limb amputations. The results from this study will contribute directly to the VA/DoD Clinical Practice Guideline (CPG) for the rehabilitation of individuals with lower limb amputation. This CPG is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with lower limb amputation (LLA), thereby leading to improved clinical outcomes. The overall goal of this study is to generate evidence that physicians and prosthetists can use when determining the suitability of prosthetic knee and foot components for a particular patient, for justifying their prosthetic prescription, and for ultimately providing the highest quality of care for individuals with lower-limb amputation.

2. KEYWORDS

Prosthesis
Prosthetic knee
Prosthetic ankle
Prosthetic foot
Transfemoral
Amputee
Gait
Standing

3. ACCOMPLISHMENTS

- **What were the major goals of the project?**

Aim 1: To perform kinematic computer simulations of the transfemoral prosthesis with the different mechanical prosthetic knee and foot components.
Hypothesis 1.1—The polycentric knee will improve stance phase stability and increase swing phase foot clearance compared to a single-axis knee unit.
Hypothesis 1.2—A hydraulic foot-ankle component with increased ankle motion will provide a more optimal roll-over shape (i.e., prosthetic foot-ankle rocker radius) during stance and increase swing phase foot clearance compared with a non-articulated prosthetic foot.

Aim 2: To systematically evaluate the walking performance of unilateral, transfemoral amputees using different combinations of mechanical prosthetic knees and feet.
Hypothesis 2.1—We hypothesize that walking performance will be superior with the combination of the polycentric knee and hydraulic foot-ankle components.

Aim 3: To systematically evaluate the standing balance performance of unilateral, transfemoral amputees using different combinations of mechanical prosthetic knees and feet.
Hypothesis 3.1—We hypothesize that subjects will have better performance on the balance assessments while wearing the polycentric knee and hydraulic foot-ankle components.

- **What was accomplished under these goals?**

Work on Aim 1 was initiated in 2019. Specifically, we completed an initial model and analysis of the stance-phase of gait with a single-axis knee, which was subsequently written up as a manuscript and submitted for publication:

Pace A, Howard D, Gard SA, Major MJ (2020). Using a Simple Walking Model to Optimize Transfemoral Prostheses for Prosthetic Limb Stability—A Preliminary Study. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 28(12), 3005-3012. doi: 10.1109/TNSRE.2020.3042626.

Work on the stance-phase of gait model will continue, with simulations being run for the polycentric knee mechanism.

During this reporting period we also initiated work on the swing-phase model of the transfemoral prosthesis (Aim 1). Mr. Miguel Vaca Moran, MS, a PhD student in the Biomedical Engineering Dept. at Northwestern University, is being mentored by Dr. Steven Gard, PI on this project. During this reporting period, Miguel developed a preliminary Lagrangian model of the swing leg prosthesis having a single-axis knee that is driven by the swing leg hip. The model will allow for either constant or variable damping in the knee unit, and will output the toe clearance and effective leg length as a function of the knee flexion angle. The next step is to incorporate more accurate data for the masses and moments of inertia of the prosthetic components, then we will need to model the complex rotational behavior of the polycentric knee mechanisms. The model will be used to better understand the prosthetic components that are being analyzed in this project, but can also be generalized to analyze other types of prosthetic knees and feet.

Recruitment for Aims 2 & 3 of this study was abruptly halted in March of 2020 due to the COVID pandemic, and administrative holds were placed on this project by Northwestern University and the Department of Veterans Affairs. The administrative holds were lifted in late 2020, but research subjects were still hesitant to participate in our study at that time due to ongoing COVID concerns. Therefore, the project focus during the first half of this reporting period was shifted from the human subject's research portion of the project (Aims 2 & 3) to the modelling aspect (Aim 1). Recruitment efforts of human subjects for this study were initiated in the latter half of this reporting period. Two subjects were successfully recruited and enrolled, and testing is expected to begin during the month of September. (NOTE: Data collection for the first subject began during the week of September 20th. Specifically, subject 1 came in for two testing sessions and completed the testing for 2 of the 4 prosthetic configurations. Testing for this subject will be completed during the month of October, 2021.) Accelerated recruitment of research subjects has already started and is expected to continue over the next reporting period.

NOTE: See included SOW for indication of specific progress on each task.

- **What opportunities for training and professional development has the project provided?**
  Dr. Anna Pace completed an internship with us in 2019 while she was finishing up her Ph.D. degree in the School of Science, Engineering and Environment at the University of Salford, UK. Specifically, she completed some simulation work to determine the effect of a single-axis knee on stance-phase stability of a transfemoral prosthesis user, contributing to Aim 1 of this project. Her results produced a presentation at a scientific conference and an article that was published in a peer-reviewed scientific journal.

  Mr. Miguel Vaca Moran, M.S. is currently working on his Ph.D. in Biomedical Engineering at Northwestern University and is being advised by Dr. Steven Gard, PI on this grant. Miguel will finish up Aim 1 and complete Aims 2 & 3 to satisfy the research component of his Ph.D. degree.

- **How were the results disseminated to communities of interest?**
  Results from Aim 1 were presented at the 2020 American Society of Biomechanics Annual Meeting and published as an article in the *IEEE Transactions on Neural Systems and Rehabilitation Engineering.*

- **What do you plan to do during the next reporting period to accomplish these goals?**
  We will continue to develop the swing-phase model (Aim 1) that will be used for the computer simulations of the transfemoral prosthesis.

  We will also enroll an additional 6-8 human subjects in the study, fit them with the different combinations of prosthetic components, and perform standing and walking evaluations (Aims 2 & 3).

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**
  Nothing to report.

- **What was the impact on other disciplines?**
  Nothing to report.

- **What was the impact on technology transfer?**
  Nothing to report.

- **How was the impact on society beyond science and technology?**
  Nothing to report.

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**
  Recruitment for this study was abruptly halted in March of 2020 due to the COVID pandemic, which was prospectively reported to the HRPO Human Subjects Protection Administrative Support, Mrs. Lynell West. Additionally, administrative holds were placed on this project by Northwestern University and the Department of Veterans Affairs, which were lifted at the end of 2020. However, research subjects were still hesitant to participate in our study early in 2021 due to ongoing COVID concerns. Nonetheless, we have since recruited and enrolled two subjects in the study and are aggressively recruiting additional subjects in an effort to get our study back on schedule.

- **Changes that had a significant impact on expenditures**
  Due to the lengthy administrative hold placed on this project, we reduced some personnel efforts and did not purchase prosthetic components that would have been required for the human subjects testing. Therefore, we have considerably more carryover funds from Y2 into Y3 than originally anticipated. We do anticipate spending these carryover funds as more subjects are enrolled in the study and research personnel get caught up on project effort commitments.

- **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**
  Not applicable.

- **Significant changes in use or care of biohazards and/or select agents**
  Not applicable.

6. PRODUCTS

- **Publications, conference papers, and presentations**
  - **Journal publications**
    Pace A, Howard D, Gard SA, Major MJ (2020). Using a Simple Walking Model to Optimize Transfemoral Prostheses for Prosthetic Limb Stability—A Preliminary Study. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 28(12), 3005-3012. doi: 10.1109/TNSRE.2020.3042626.

  - **Books or other non-periodical, one-time publications**
    Nothing to report.

  - **Other publications, conference papers, and presentations**
    Pace A, Howard D, Gard S, Major M (2020). A Simple Walking Model to Optimize Prosthetic Knee and Foot Combinations for Prosthetic Limb Stability. *Virtual 44th Meeting of the American Society of Biomechanics*, August 4-7.

- **Website(s) or other Internet site(s)**
  We created an informational Website for this project to help disseminate information and assist with recruitment of research subjects:
  https://www.nupoc.northwestern.edu/research/projects/lowerlimb/optimal_selection_pxknee.html

- **Technologies or techniques**
  Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Nothing to report.

- **Other Products**
  Nothing to report.

7. PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Steven Gard, PhD
Project Role:	PI
Researcher Identifier:	0000-0002-4251-2464
Nearest person month worked:	2.2
Contribution to Project:	Oversight, protocol development, recruitment, modeling
Funding Support:	NA

Name:	Matthew Major, PhD
Project Role:	Co-Inv
Researcher Identifier:	0000-0002-2330-4619
Nearest person month worked:	0.4
Contribution to Project:	Protocol development, modeling
Funding Support:	NA

Name:	Michael Cavanaugh, CPO
Project Role:	Research Prosthetist
Researcher Identifier:	
Nearest person month worked:	0.6
Contribution to Project:	Recruitment, protocol development
Funding Support:	NA

Name:	Miguel Vaca Moran, MS
Project Role:	Graduate Student
Researcher Identifier:	
Nearest person month worked:	9.0
Contribution to Project:	Protocol development, modeling
Funding Support:	NA

Name:	Rebecca Stine, MS
Project Role:	Co-Inv
Researcher Identifier:	
Nearest person month worked:	2.4
Contribution to Project:	Protocol development, recruitment
Funding Support:	NA

Name:	Paul Hammond II, MS
Project Role:	Research Engineer
Researcher Identifier:	
Nearest person month worked:	3.6
Contribution to Project:	Modeling
Funding Support:	NA

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  No.

- **What other organizations were involved as partners?**
  Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

- **Quad Chart**
  Updated quad chart has been included as a separate attachment.

9. APPENDICES

Nothing to report.