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

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CONTRACTING ORGANIZATION: Northwestern University, Evanston, IL

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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

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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?**

Aim 1: Work 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 submitted and published in an engineering journal:

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.

For the mathematical simulation portion of the project, we worked during the past year to identify a specific software package to use for performing the swing-phase simulation. After a search of different simulation utilities, we identified two that appeared to offer the necessary capabilities for the project: Working Model 2D and Simscape Multibody from MATLAB. A basic simulation of the system was implemented on each of these packages to identify advantages and disadvantages of each. Based on these evaluations, we decided to proceed with Simscape Multibody because of the flexibility that it provides to work with customized code from MATLAB. For the mathematical simulation itself, we have identified the input and output variables that are required and have determined which of them will be used to perform an optimization process. Currently, we are working on building the simulation using some of the experimental data that we have obtained thus far.

Mechanical characterization of the prosthetic feet and knees are also required so that we can incorporate mechanical properties of the components into the simulation model. Therefore, we have recently determined the stiffness and roll-over shape characteristics of the College Park Horizon and Odyssey feet. The Odyssey foot has a variable hydraulic stiffness for plantarflexion and dorsiflexion, so we performed two characterizations for this foot: one for minimum stiffness and the other one for maximum stiffness. To determine prosthetic foot stiffness, we performed the keel, heel, and single-axis tests according to the “AOPA’s Prosthetic Foot Project” guidelines using an Instron machine that loads the foot while measuring displacement. The data acquired were used to calculate hysteresis and stiffness. The results are presented in Figures 1 and 2. To determine the roll-over shape (ROS) characteristics of each foot, we performed bench testing using a customized roll-over shape testing system in the motion analysis research laboratory. The feet were mounted to an inverted pendulum apparatus and loading was applied as center of pressure under the foot was tracked as the pendulum was rolled forward. The load for the ROS testing was varied from 100 lbs. to 250 lbs. in 50 lbs. increments. The ROS radii were calculated following the Hansen et al. (2000) method, and these results are presented in Figures 3 and 4. We are currently working on a method to determine the rotational stiffness and damping of the two prosthetic knees.

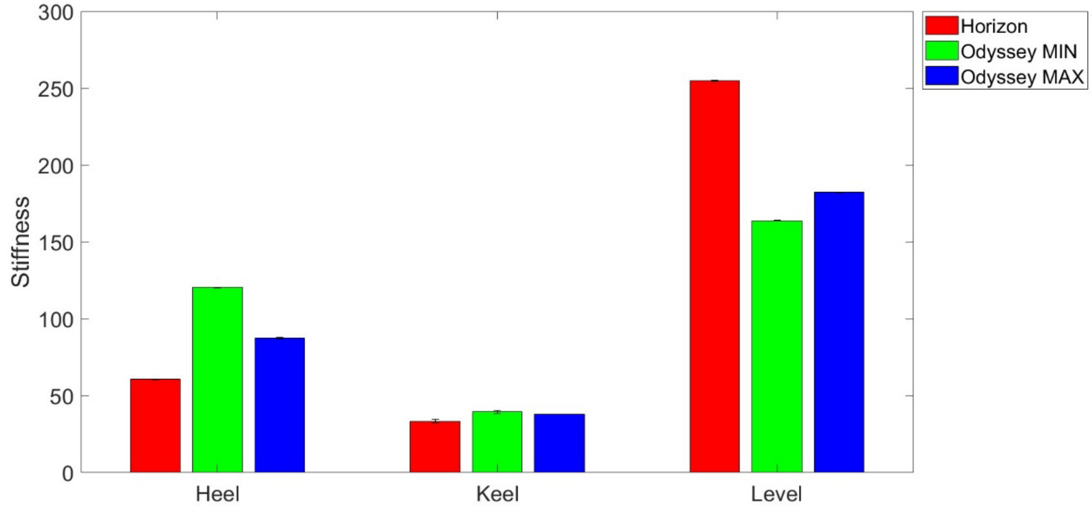

Figure 1—Stiffness (N/m) of the prosthetic feet at specific points under the foot.

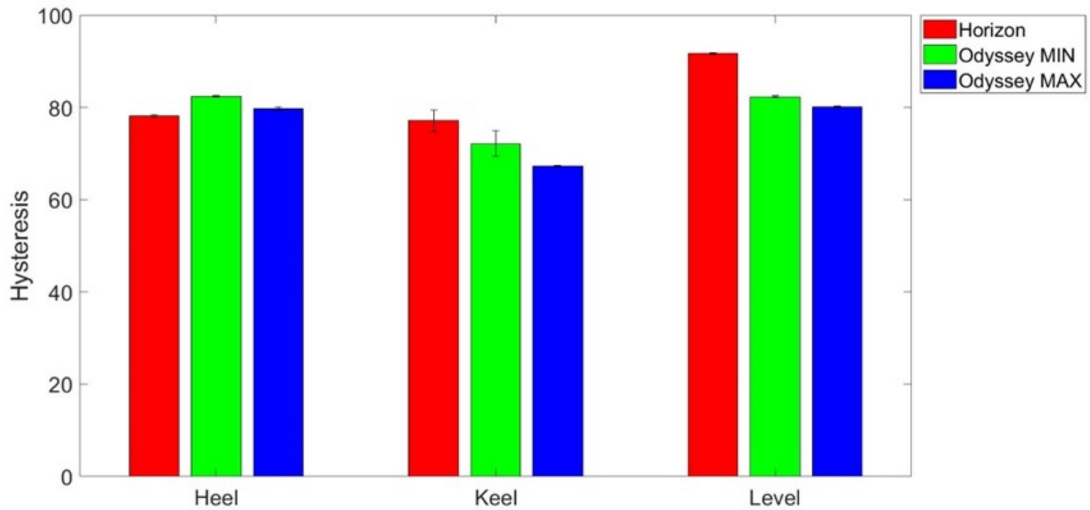

Figure 2—Hysteresis (N•m) of the prosthetic feet as measured from mechanical testing.

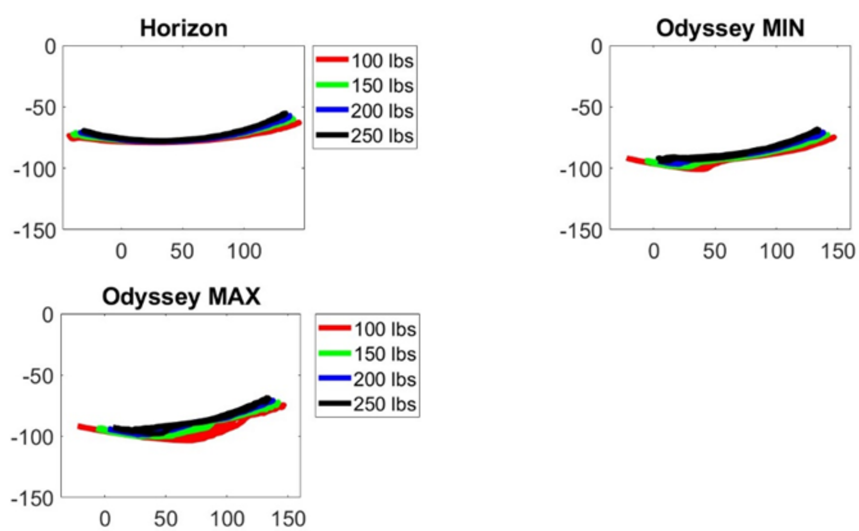

Figure 3—Graphs illustrate the roll-over shape (ROS) characteristics as the prosthetic feet are loaded with different weights.

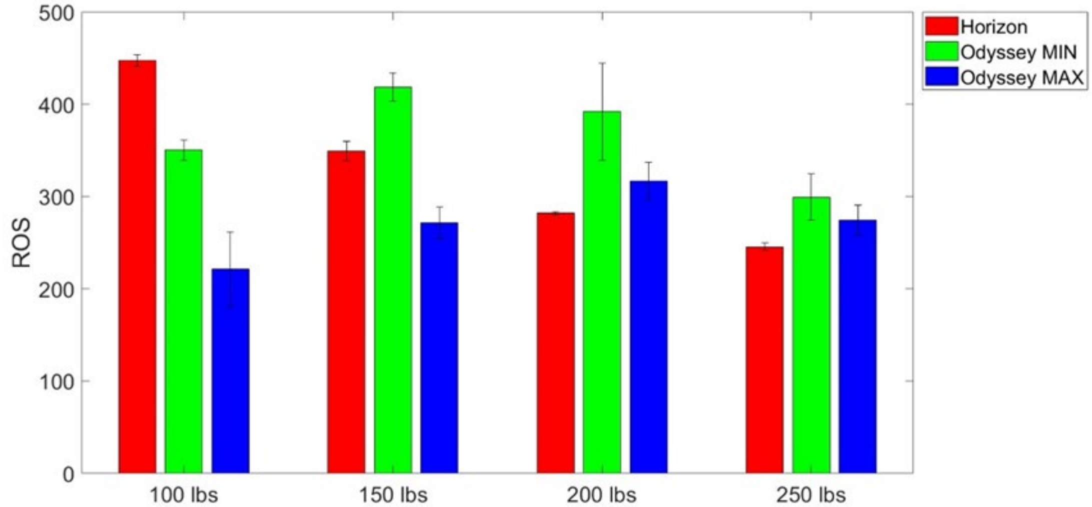

Figure 4—Roll-over shape (ROS) radii (in mm) for each of the feet at different applied loads.

<u>Aims 2 & 3</u>: 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, recruitment efforts of human subjects for this study weren't fully initiated until the latter half of 2021. To date, we have successfully completed experiments for the first 3 participants. This work included the gait evaluations during level walking, ramp ascent and descent, stairs, and standing balance testing using the Biodex system in the motion analysis research laboratory. The gait analysis data (Aim 2) have been processed using Cortex and Visual 3D, and main variables of interest were calculated using customized code in MATLAB. The variables that we are analyzing includes the pre-swing knee moment, knee moment action impulse, knee ankle foot roll-over shape (KAFROS), and toe and heel clearances during swing phase. A summary of these results is presented in Figures 5-9. These data clearly illustrate that there are several notable functional differences between the prosthetic component types, which will help prosthetists in the selection of components for their clients. Data analysis and interpretation are ongoing. We will initiate the processing and analysis of standing data (Aim 3) in the next few weeks.

Finally, we are pleased to report that we have successfully recruited participants 4, 5 and 6, and are currently in the process of scheduling their testing sessions.

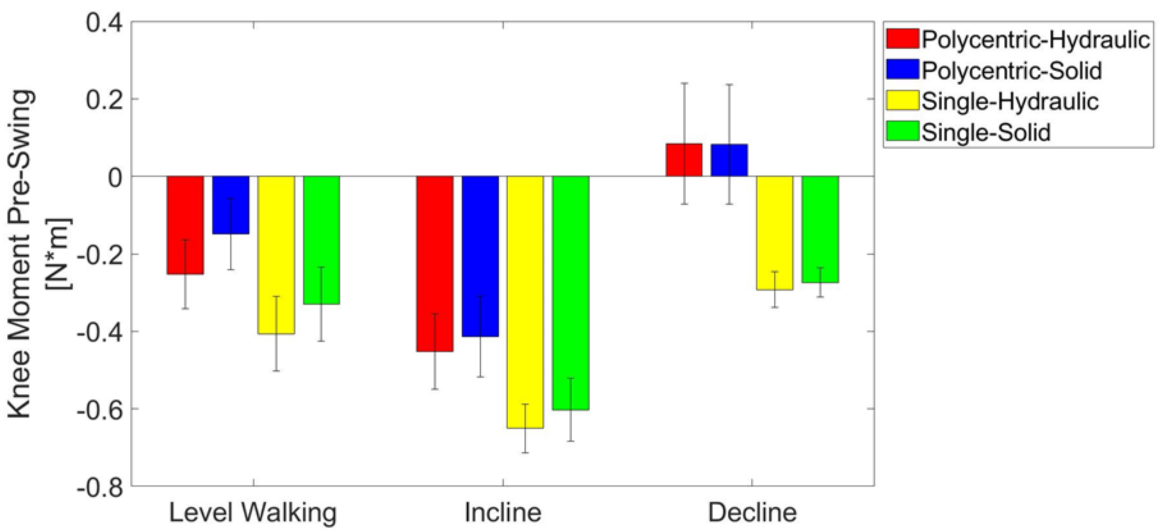

Figure 5—The knee moment during the pre-swing phase of gait for each of the prosthetic knees on different walking surfaces.

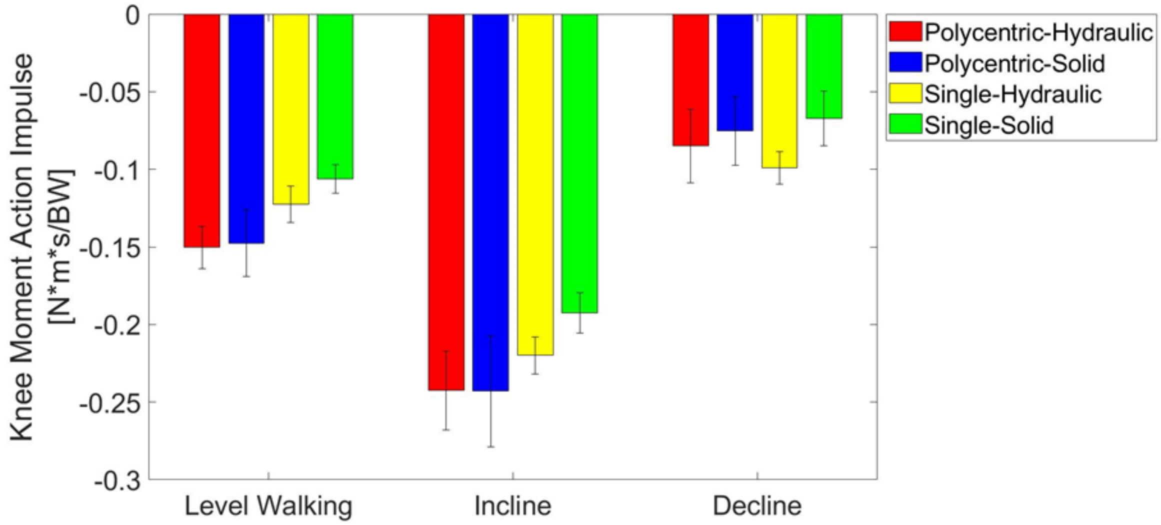

Figure 6—The knee moment action impulse calculated during the pre-swing phase of gait.

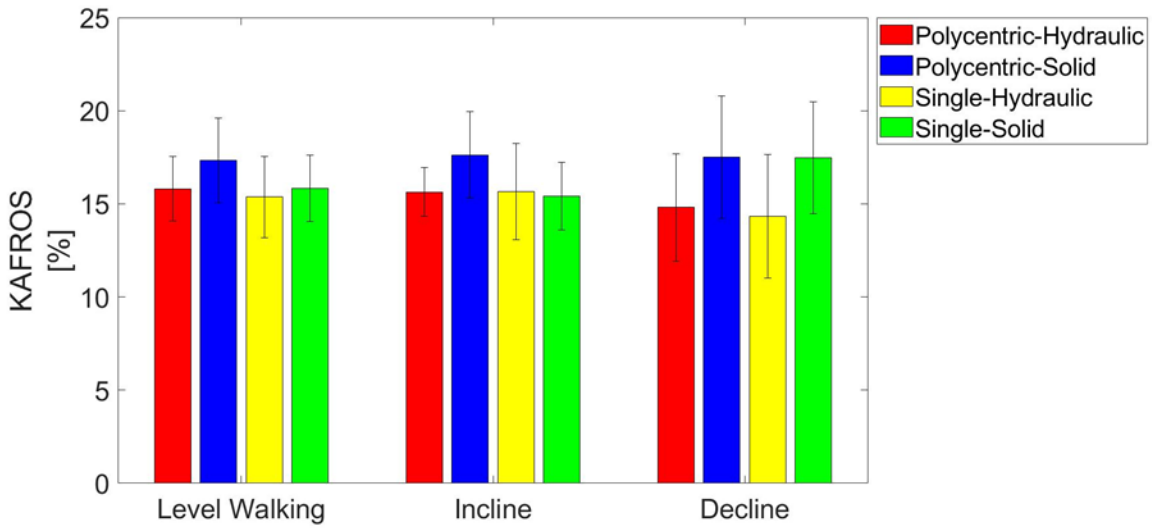

Figure 7—The roll-over shape (ROS) radii expressed as a percentage of body weight for the subjects walking on different surfaces.

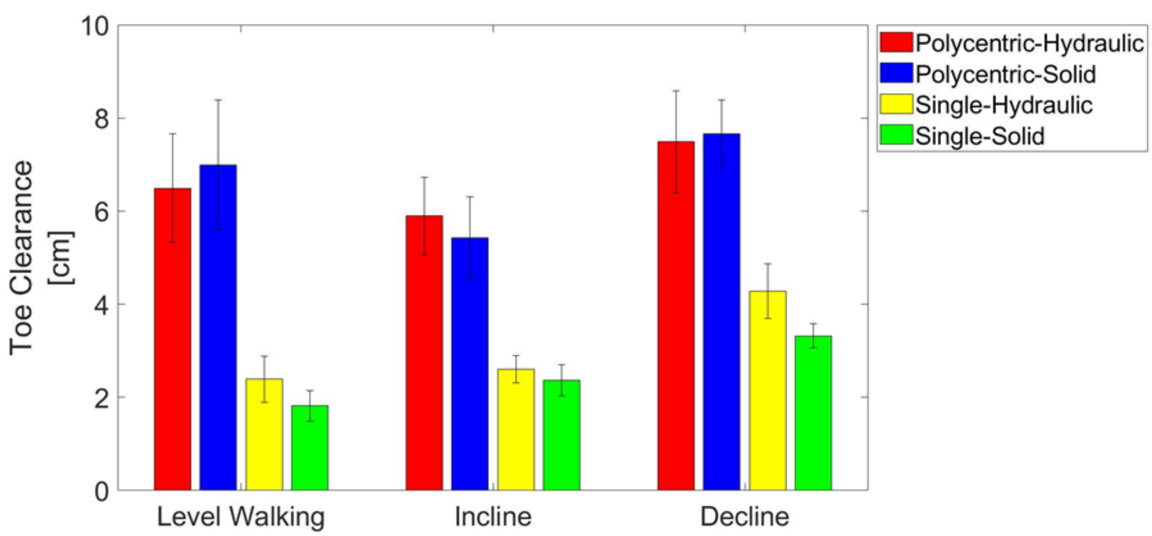

Figure 8—The amount of minimum swing phase toe clearance that subjects achieved for each prosthetic knee-foot combination.

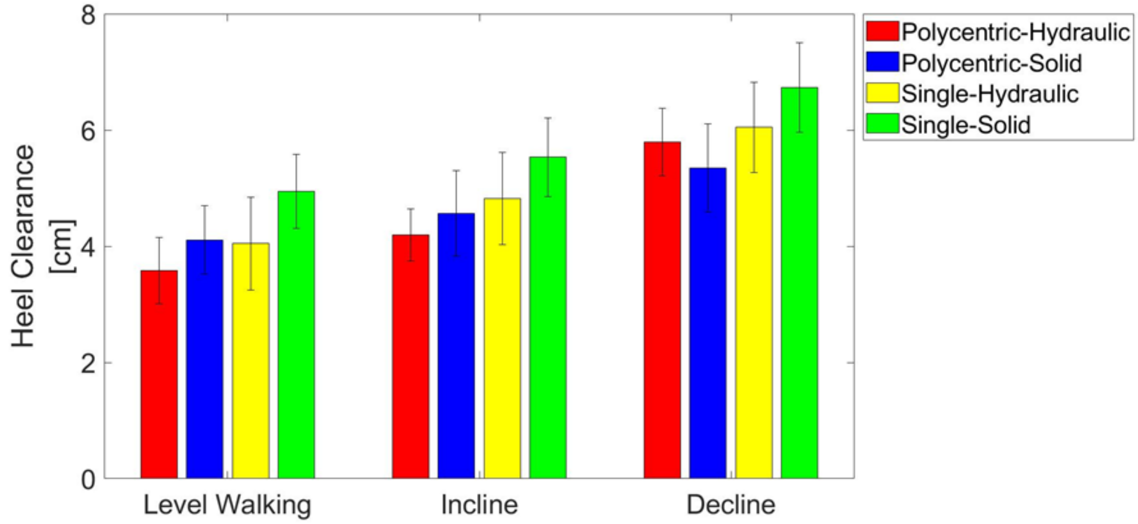

Figure 9—The amount of minimum swing phase heel clearance that subjects achieved for each prosthetic knee-foot combination

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 jointly advised by Dr. Steven Gard, PI on this grant, and Dr. Matthew Major, Co-Investigator. 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 also anticipate that we will 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).

References

Hansen A, Gard S, Childress D. (2000). The determination of foot/ankle roll-over shape: clinical and research applications. Paper presented at: *Pediatric Gait: A New Millennium in Clinical Care and Motion Analysis Technology*; July 22. doi: 10.1109/PG.2000.858888.

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. We have since completed testing on three subjects in the study and have recruited an additional three subjects for testing. Nonetheless, recruitment remains challenging. Therefore, we will continue to aggressively recruit eligible individuals from among previously identified clinics and hospitals in the Chicago area.

- **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. Additionally, recruitment of subjects is still lagging behind what we had originally planned. Therefore, we have considerably more carryover funds from Y3 into Y4 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/areas-of-research/lower-limb-prosthetics.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, data interpretation
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:	1.2
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, data acquisition and analyses
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, data acquisition
Funding Support:	NA

Name:	Paul Hammond II, MS
Project Role:	Research Engineer
Researcher Identifier:	
Nearest person month worked:	3.6
Contribution to Project:	Modeling, data acquisition
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.