

AWARD NUMBER: W81XWH-21-2-0007

TITLE: Optimizing Prosthetic Shock Absorption for High-Demand Mobility of Service Members with Leg Amputation

PRINCIPAL INVESTIGATOR: Kota Takahashi

CONTRACTING ORGANIZATION: University of Nebraska, Omaha, NE

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14. ABSTRACT Shock-absorbing prosthetic legs are designed for high-impact activities that are relevant to active duty service members. These prostheses act to soften the impact forces as the leg collides with the ground. While there are numerous commercially-available shock-absorbing prostheses, there are currently no objective guidelines for prescribing such devices. The goal of this proposal is to study the effects of various modular shock-absorbing prosthetic components (feet, ankles, to pylons) on user performance during a wide range of high-demand activities such as walking on slopes, stairs, during pivot maneuvers, and load carriage. To do this, we will employ novel experimental platforms and analytical techniques to test Service Members and Veterans using various combinations of shock-absorbing prostheses, while we obtain estimates of musculoskeletal health-related outcomes (forces, motion, and energy of the legs) and qualitative surveys on mobility and comfort.					
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1. INTRODUCTION:

Shock-absorbing prosthetic legs are designed for high-impact activities that are relevant to active duty Service Members. These prostheses act to soften the impact forces as the leg collides with the ground. While there are numerous commercially-available shock-absorbing prostheses, there are currently no objective guidelines for prescribing such devices. The goal of this proposal is to study the effects of various modular shock-absorbing prosthetic components (feet, ankles, and pylons) on user performance during a wide range of high-demand activities such as walking on slopes, stairs, during pivot maneuvers, and load carriage. To do this, we will employ novel experimental platforms and analytical techniques to test Service Members and Veterans using various combinations of shock-absorbing prostheses, while we obtain estimates of musculoskeletal health-related outcomes (forces, motion, and energy of the legs) and qualitative surveys on mobility and comfort.

2. KEYWORDS:

Amputation, prosthetics, walking, musculoskeletal, health, biomechanics, optimization, rehabilitation

3. ACCOMPLISHMENTS:

- What were the major goals of the project?

Major Task 1: Regulatory reviews and cooperative agreements

Subtask 1.1: Regulatory review and approval for all experiments

Target date: 10/31/2021

Completion: 100%

Subtask 1.2: Cooperative Research and Development Agreement (CRADA)

Target date: 10/31/2021

Completion: 100%

Major Task 2 - Aim 1: Evaluate the independent and combined effects of clinically available shock-absorbing pylons and ankles on musculoskeletal health outcomes

Subtask 2.1: Recruit patients with transtibial amputation

Target date: 04/31/2024

Completion: 0%

Subtask 2.2: Data collections at Naval Medical Center San Diego (NMCS D)

Target date: 04/31/2024

Completion: 0%

Subtask 2.3: Data collections at Northwestern University (NU)/VA

Target date: 04/31/2024

Completion: 15%

Subtask 2.4: Data analyses

Target date: 07/31/2024

Completion: 15%

Major Task 3 - Aim 2: Systematically characterize and predict the effects of a range of prosthetic linear and rotational stiffness on musculoskeletal health outcomes (36 months)

Subtask 3.1: Software/hardware development for pylon emulator

Target date: 12/31/2021

Completion: 75%

Subtask 3.2: Recruit patients with transtibial amputation

Target date: 04/31/2024

Completion: 0%

Subtask 3.3: Data collections at University of Nebraska at Omaha (UNO)/VA

Target date: 04/31/2024
Completion: 0%

Subtask 3.4: Data analyses
Target date: 07/31/2024
Completion: 0%

Major Task 4: Dissemination of Results

Subtask 4.1: Conference presentations at professional societies
Target date: 07/31/2024
Completion: 20%

Subtask 4.2: Manuscript preparations
Target date: 07/31/2024
Completion: 10%

Subtask 4.3: Dissemination at Military Treatment Facility (MTF) and VA
Target date: 07/31/2024
Completion: 0%

Subtask 4.4: Education modules at Northwestern University Prosthetics and Orthotics Center (NUPOC)
Target date: 07/31/2024
Completion 0%.

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

Major Task 1: Regulator reviews and cooperative agreements

Subtask 1.1: Regulatory review and approval for all experiments

Year 1, Quarter 1: We have received Single IRB approval from the institutional IRB of the PI. The two VA sites (Omaha VA and Jesse Brown VA Medical Center in Chicago) have received approvals for exceptions to the Single IRB. A separate IRB application to the Omaha VA has been approved. An IRB approval from the Jesse Brown VA Medical Center is currently pending. Hiring for research personnel (postdoctoral research associate, graduate student assistant) is in progress.

Year 1, Quarter 2: We submitted an abstract to the Military Health System Research Symposium (MHSRS) 2022 conference. A purchase order to Humotech for a customized prosthetic pylon component was executed. An IRB approval from the Jesse Brown VA Medical Center is currently pending. Mr. Seth Donahue was hired at Jesse Brown VA Medical Center in Chicago to assist with data collection/analyses at that site. Mr. Donahue's starting date is March 21, 2022. Ms. Wendy Beattie (CPO) was hired at Jesse Brown VA Medical Center to serve as the research prosthetist.

Year 1, Quarter 3: An IRB approval from the Jesse Brown VA Medical Center was approved on April 13, 2022. Final approval from the Office of Human Research Oversight (OHRO) is pending.

Year 1, Quarter 4: An approval from the Office of Human Research Oversight (OHRO) was obtained for the Single IRB protocol (which covers the sites at University of Nebraska, Naval Medical Center San Diego, and Humotech) on July 27, 2022. Approvals from OHRO for the two VA sites exempt from the Single IRB requirement (Omaha VA, Jesse Brown VA) were obtained on July 27, 2022. OHRO requested Northwestern University to be reliant on the Single IRB at University of Nebraska. The reliance request was submitted to the University of Nebraska IRB on August 8, 2022 (approval is pending).

Year 2, Quarter 1: Approval to add Northwestern University to the Single IRB at University of Nebraska IRB was obtained on November 18, 2022.

(Subtask 1.1 is complete)

Subtask 1.2: Cooperative Research and Development Agreement (CRADA)

Year 1, Quarter 1: The Cooperative Research and Development Agreement (CRADA) between the sites is currently in progress

Year 1, Quarter 2: Nothing to report

Year 1, Quarter 3: The Cooperative Research and Development Agreement (CRADA) was approved on April 7, 2022.

(subtask 1.2 is complete)

Major Task 2 - Aim 1: Evaluate the independent and combined effects of clinically available shock-absorbing pylons and ankles on musculoskeletal health outcomes

Subtask 2.1: Recruit patients with transtibial amputation

Year 1, Quarter 1: Nothing to report

Year 1, Quarter 2: Nothing to report

Year 1, Quarter 3: Nothing to report

Year 1, Quarter 4: Nothing to report

Year 2, Quarter 1: Nothing to report

Year 2, Quarter 2: Nothing to report

Year 2, Quarter 3: Nothing to report

Year 2, Quarter 4: Nothing to report

Subtask 2.2: Data collections at Naval Medical Center San Diego (NMCS D)

Year 1, Quarter 1: Nothing to report

Year 1, Quarter 2: Nothing to report

Year 1, Quarter 3: Nothing to report

Year 1, Quarter 4: Nothing to report

Year 2, Quarter 1: Nothing to report

Year 2, Quarter 2: Nothing to report

Year 2, Quarter 3: Nothing to report

Year 2, Quarter 4: Nothing to report

Subtask 2.3: Data collections at Northwestern University (NU)/VA

Year 1, Quarter 1: Nothing to report

Year 1, Quarter 2: Nothing to report

Year 1, Quarter 3: Nothing to report

Year 1, Quarter 4: Mechanical bench testing data were collected and analyzed (see Figures 1-2 below).

Year 2, Quarter 1: Nothing to report

Year 2, Quarter 2: Nothing to report

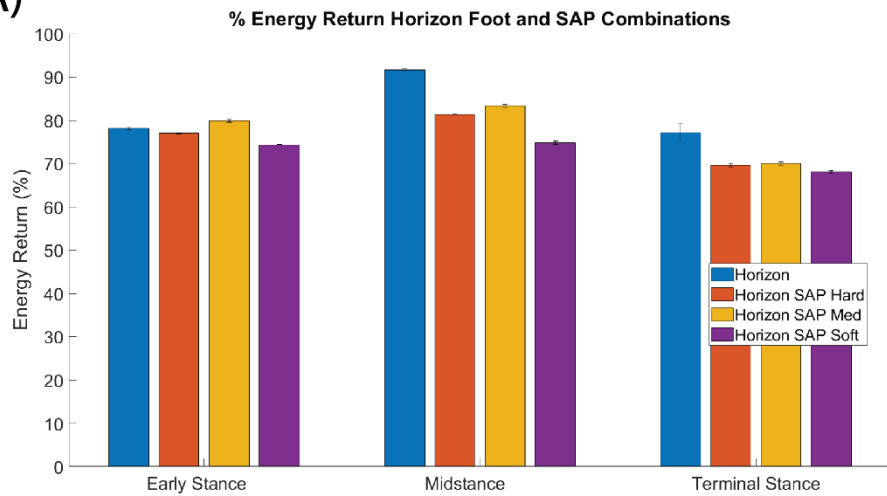
Year 2, Quarter 3: Nothing to report

Year 2, Quarter 4: Nothing to report



Figure 1: the research team at Northwestern University/Jesse Brown VA Medical Center has previously validated a bench testing method to quantify mechanical characteristics of prosthetic components (e.g., stiffness, energy return or dissipation), representative of unique loading patterns encountered during different phases of walking (e.g., early stance, midstance, and terminal stance). In this project, the bench testing method was applied to quantify the properties of two different prosthetic foot/ankle components, with and without shock-absorbing pylons of varying levels of hardness (see Figure 2).

A)



B)

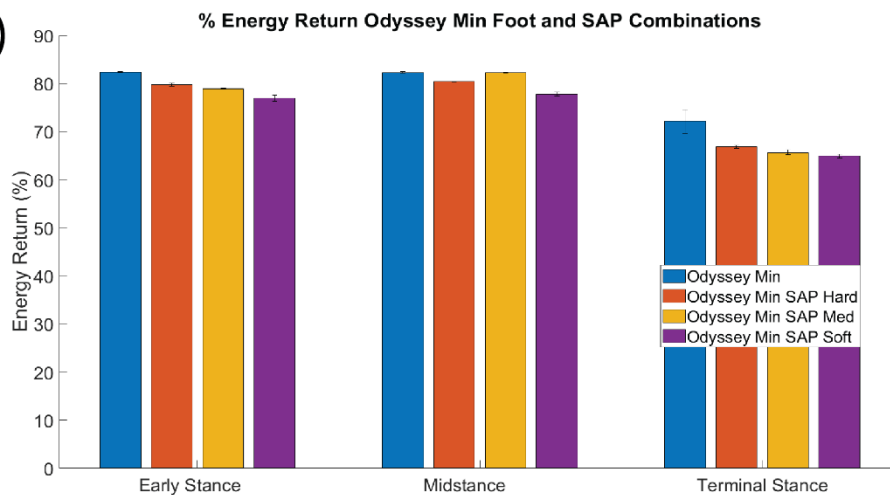


Figure 2: using the bench testing method (from Figure 1), the magnitude of energy return was quantified across two different commercially available prostheses: A) Horizon, College Park and B) Odyssey, College Park across three different hardness levels (Hard, Medium, Soft) of shock-absorbing pylon (SAP) (DuraShock, Fillauer). The prosthetic feet and the levels of SAP hardness directly affected the magnitude of energy return across three different simulated loading patterns, signifying early stance, midstance and terminal stance. We are currently recruiting participants with a below-knee amputation to determine the effects of prosthetic feet and SAP on musculoskeletal health outcomes (e.g., forces and motion of legs, patient-reported comfort) during military-relevant high-demand walking tasks (e.g., walking on slopes, stair ascent/descent, load carriage, pivoting, etc). Data were presented at MHSRS 2023.

Subtask 2.4: Data analyses

Year 1, Quarter 1: Nothing to report

Year 1, Quarter 2: Nothing to report

Year 1, Quarter 3: Nothing to report

Year 1, Quarter 4: Nothing to report

Year 2, Quarter 1: A conference abstract was submitted to the International Society of Prosthetics and Orthotics on October 10, 2022, for data involving mechanical bench testing of prosthetic components (see Figures 1-2).

Year 2, Quarter 2: A conference abstract was submitted to the Military Health System Research Symposium (MHSRS) on February 21, 2023, for data involving mechanical bench testing of prosthetic components (i.e., sub-aim of Major Task 2). A manuscript related to this project was submitted to the Journal of Mechanisms and Robots, on December 22, 2022.

Year 2, Quarter 3: Nothing to report

Year 2, Quarter 4: Nothing to report

Major Task 3 - Aim 2: Systematically characterize and predict the effects of a range of prosthetic linear and rotational stiffness on musculoskeletal health outcomes (36 months)

Subtask 3.1: Software/hardware development for pylon emulator

Year 1, Quarter 1: Nothing to report

Year 1, Quarter 2: Purchase order to Humotech for a customized prosthetic pylon emulator component was executed.

Year 1, Quarter 3: Software/hardware development for pylon emulator is in progress at Humotech.

Year 1, Quarter 4: Humotech has developed software and hardware for a customized prosthetic pylon emulator (see Figure 3 below).

Year 2, Quarter 1: Nothing to report

Year 2, Quarter 2: A conference abstract was submitted to the Military Health System Research Symposium (MHSRS) on February 21, 2023, related to the pylon emulator (see Figure 3).

Year 2, Quarter 3: Nothing to report

Year 2, Quarter 4: Nothing to report

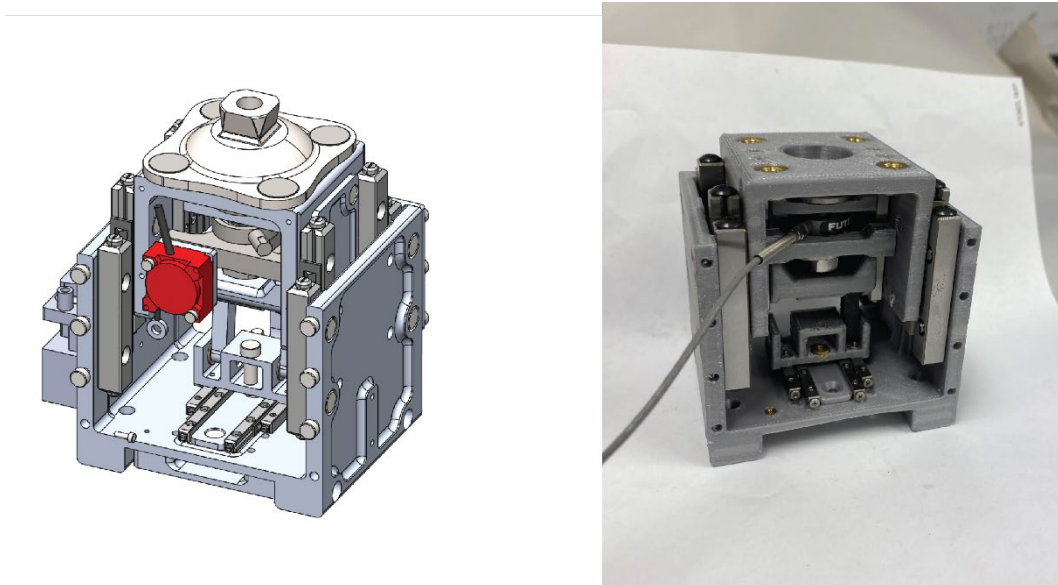


Figure 3: Humotech has developed a novel pylon emulator, which is the company's latest addition to the prosthesis product line. The pylon emulator can be programmed to vary in stiffness and damping dynamically, which sets it apart substantially from other commercially available shock-absorbing pylons. The pylon emulator includes a load cell and spring potentiometer sensors which measure the load and position of the device, respectively. End users of up to 263 lbs can use the device at walking speeds to understand their preference in pylon stiffness. The pylon emulator will be delivered to PI Takahashi's laboratory for experiments involving individuals with below-knee amputation.

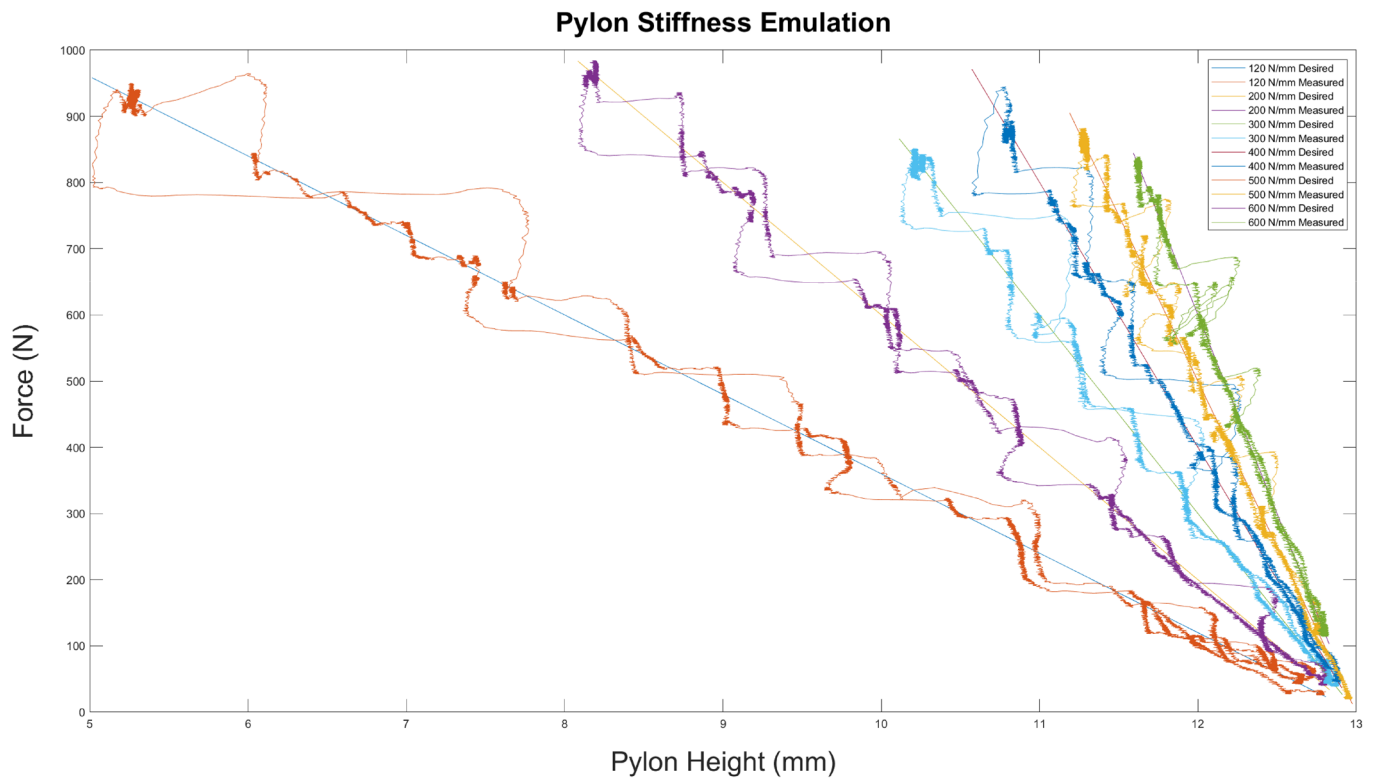


Figure 4: The novel pylon emulator (described in Figure 3) can simulate a wide range of linear stiffness in the axial direction (i.e., ratio of force and pylon compression) comparable to commercially available pylons. Ongoing work is to improve the accuracy of force-displacement trajectories to improve precision of the axial stiffness control. Future experiments involving participants with leg amputation walking with the pylon emulator will be conducted in PI Takahashi's lab. (data presented at MHSRS 2023)

Subtask 3.2: Recruit patients with transtibial amputation

Year 1, Quarter 1: Nothing to report
 Year 1, Quarter 2: Nothing to report
 Year 1, Quarter 3: Nothing to report
 Year 1, Quarter 4: Nothing to report
 Year 2, Quarter 1: Nothing to report
 Year 2, Quarter 2: Nothing to report
 Year 2, Quarter 3: Nothing to report
 Year 2, Quarter 4: Nothing to report

Subtask 3.3: Data collections at University of Nebraska at Omaha (UNO)/VA

Year 1, Quarter 1: Nothing to report
 Year 1, Quarter 2: Nothing to report
 Year 1, Quarter 3: Nothing to report
 Year 1, Quarter 4: Nothing to report
 Year 2, Quarter 1: Nothing to report
 Year 2, Quarter 2: Nothing to report
 Year 2, Quarter 3: Nothing to report
 Year 2, Quarter 4: Nothing to report

Subtask 3.4: Data analyses

Year 1, Quarter 1: Nothing to report
 Year 1, Quarter 2: Nothing to report

Year 1, Quarter 3: Nothing to report
Year 1, Quarter 4: Nothing to report
Year 2, Quarter 1: Nothing to report
Year 2, Quarter 2: Nothing to report
Year 2, Quarter 3: Nothing to report
Year 2, Quarter 4: Nothing to report

Major Task 4: Dissemination of Results

Subtask 4.1: Conference presentations at professional societies

Year 1, Quarter 1: Nothing to report
Year 1, Quarter 2: We submitted an abstract to the Military Health System Research Symposium (MHSRS) 2022.
Year 1, Quarter 3: Abstract to MHSRS was rejected.
Year 1, Quarter 4: Nothing to report
Year 2, Quarter 1: Nothing to report
Year 2, Quarter 2: Nothing to report
Year 2, Quarter 3: An oral presentation at the International Society of Prosthetics and Orthotics was completed.
Year 2, Quarter 4: Two MHSRS abstracts (one poster, one oral) were accepted. The team will be presenting at the 2023 MHSRS conference.

Subtask 4.2: Manuscript preparations

Year 1, Quarter 1: Nothing to report
Year 1, Quarter 2: Nothing to report
Year 1, Quarter 3: Nothing to report
Year 1, Quarter 4: Nothing to report
Year 2, Quarter 1: Nothing to report
Year 2, Quarter 2: A manuscript was submitted to the Journal of Mechanisms and Robots, on December 22, 2022 (under review)
Year 2, Quarter 3: Nothing to report
Year 2, Quarter 4: A manuscript was submitted to Prosthetics and Orthotics International, on July 25, 2023.

Subtask 4.3: Dissemination at Military Treatment Facility (MTF) and VA

Year 1, Quarter 1: Nothing to report
Year 1, Quarter 2: Nothing to report
Year 1, Quarter 3: Nothing to report
Year 1, Quarter 4: Nothing to report
Year 2, Quarter 1: Nothing to report
Year 2, Quarter 2: Nothing to report
Year 2, Quarter 3: Nothing to report
Year 2, Quarter 4: Nothing to report

Subtask 4.4: Education modules at Northwestern University Prosthetics and Orthotics Center (NUPOC)

Year 1, Quarter 1: Nothing to report
Year 1, Quarter 2: Nothing to report
Year 1, Quarter 3: Nothing to report
Year 1, Quarter 4: Nothing to report
Year 2, Quarter 1: Nothing to report
Year 2, Quarter 2: Nothing to report
Year 2, Quarter 3: Nothing to report
Year 2, Quarter 4: Nothing to report

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

This project has provided a postdoctoral scholar, Dr. Seth Donahue, with training in musculoskeletal modelling, biomechanics and clinically-driven research in prosthetics and rehabilitation. Dr. Donahue gained experience in data collection and analysis generated from mechanical bench testing of prosthetic components, physics-based numerical modelling to simulate and predict prosthesis mechanical behavior, and managing a clinical research project.

- **How were the results disseminated to communities of interest?**

We have presented our results at the 2023 International Society of Prosthetics and Orthotics conference and the 2023 Military Health System Research Symposium (MHSRS).

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

We are waiting for the approval of our transfer request (submitted on August 3, 2022 – Year 1, Quarter 4). Once our transfer request is approved, our goal is to prioritize the recruitment of human subjects (Major Tasks 2 and 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.

- **What 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**

There were delays in getting IRB approval, which has been resolved.

PI Kota Takahashi accepted a new position at the University of Utah. On August 3, 2022 (Year 1, Quarter 4), the sponsored programs office from the PI's former institution (University of Nebraska at Omaha) requested the DOD grants manager to transfer the grant to the University of Utah. The request is currently pending approval.

We anticipate delays with the project until the grant transfers to the new institution. We anticipate that the continued uncertainty of this grant would directly affect the personnel hired from this grant – keeping the personnel intact through other funding mechanisms will become a challenge in the near future. We are also facing difficulties in hiring new personnel at PI Takahashi's site at University of Utah, since the grant transfer has not been confirmed. In order to resolve this problem, we will continue to reach out to the science officer and grants managers for status updates regarding the transfer request.

- **Changes that had a significant impact on expenditures**

We have not had any new expenditures since Year 1, Quarter 4, since the transfer request was submitted at that time, and we are awaiting approval.
- **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.**
 - Donahue S, Kingsbury T, Takahashi K, Major MJ. "Data-driven modelling of the non-linear dynamics of passive lower-limb prosthetic systems." *Journal of Mechanisms and Robots* (under review)
 - Donahue S, Vaca Moran M, Beattie W, Kingsbury T, Takahashi K, Major MJ. "Characterizing the interaction effects of modular components on transtibial prosthesis stance-phase mechanical behavior." *Prosthetics and Orthotics International* (under review)
 - **Books or other non-periodical, one-time publications.**

Nothing to report.
 - **Other publications, conference papers, and presentations.**
 - Donahue S, Kingsbury T, Takahashi K, Major MJ. "A data-driven approach to prosthetic system mechanical characterization using sparse identification of nonlinear dynamics." *International Society of Prosthetics and Orthotics World Congress, April 2023, Guadalajara, Mexico.*

- Donahue SR, Kingsbury T, Takahashi KZ, Major MJ. “Novel implementation of a data-driven model of nonlinear dynamics to better characterize prosthetic leg mechanical behavior for prosthesis classification, prescription, and design.” Military Health System Research Symposium, August 2023, Kissimmee, FL, USA.
 - Takahashi KZ, Caputo JM, Curran CS, Kingsbury TD, Major MJ. “Emulating prosthetic pylon properties to systematically evaluate effects on locomotion performance.” Military Health System Research Symposium, August 2023, Kissimmee, FL, USA.
 - Donahue SR, Stine R, Beattie W, Kingsbury T, Takahashi KZ, Major MJ. “The effects of damping componentry on stance phase prosthetic work”. American Society of Biomechanics, August 2023, Knoxville, TN, USA.
- **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

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

Name:	<i>Kota Takahashi</i>
Project Role:	<i>PI</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0002-8943-9639</i>
Nearest person month worked:	<i>1</i>
Contribution to Project:	<i>Dr. Takahashi has worked on getting the Single IRB approval, the Omaha VA IRB approval, and initiated the CRADA approval</i>
Funding Support:	

Name:	<i>Matthew Major</i>
Project Role:	<i>Co-PI</i>

Researcher Identifier (e.g. ORCID ID):	0000-0002-2330-4619
Nearest person month worked:	1
Contribution to Project:	<i>Dr. Major has worked on getting the Single IRB approval, the Jesse Brown VA IRB approval.</i>
Funding Support:	

Name:	<i>Trevor Kingsbury</i>
Project Role:	<i>Co-PI</i>
Researcher Identifier (e.g. ORCID ID):	0000-0001-5298-8725
Nearest person month worked:	1
Contribution to Project:	<i>Mr. Kingsbury has worked on getting the Single IRB approval and initiated the CRADA approval.</i>
Funding Support:	

Name:	<i>Seth Donahue</i>
Project Role:	<i>Postdoc</i>
Researcher Identifier (e.g. ORCID ID):	0000-0002-8387-9887
Nearest person month worked:	2.5
Contribution to Project:	<i>Dr. Donahue has performed data collection and analysis generated from mechanical bench testing of prosthetic components, physics-based numerical modelling to simulate and predict prosthesis mechanical behavior, and managing a clinical research project.</i>
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

PI Takahashi has received two new active funding. These new projects do not change the percent effort on this DOD-funded project.

NIH R01 HD106911

Role: PI

08/26/22-07/31/27

Thermoregulation in individuals with a leg amputation: mechanics and vascular physiology factors to understand risks for tissue complications

NIH R01 AR081287

Role: Co-PI

09/15/22-08/31/27

A framework for feasible translation to enhance foot and ankle function in aging and mobility

Co-PI Major has received three new active funding. These new projects do not change the percent effort on this DOD-funded project.

W81XWH-22-C-0102

Role: PI

Adaptive technology to optimize rehabilitation of lower extremity musculoskeletal injuries throughout recovery

OR220159

Role: Co-I

Development and Validation of SUPPORT (Sprayable Universal Polyurethane Orthosis for Rapid Treatment) for More Severe Injuries

HT9425-23-1-0474

Role: Co-I

Improving Mobility and Function Following Transfemoral Amputation: A Novel Approach to Reverse Volumetric Muscle Loss

Co-PI Kingsbury has no changes to report.

- **What other organizations were involved as partners?**

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

- **COLLABORATIVE AWARDS:**
- **QUAD CHARTS:**

9. APPENDICES: