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

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

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**6. AUTHOR(S)**

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**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

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

University of Nebraska at
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6001 Dodge St EAB 209
Omaha, NE 68182-2000

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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.

**15. SUBJECT TERMS**
None listed.

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
|---|---|---|---|---|---|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | USAMRDC |
| Unclassified | Unclassified | Unclassified | Unclassified | 12 | 19b. TELEPHONE NUMBER *(include area code)* |

## TABLE OF CONTENTS

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, 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.

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:** 95%

**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 (NMCSD)
**Target date**: 04/31/2024
**Completion**: 0%

**Subtask 2.3**: Data collections at Northwestern University (NU)/VA
**Target date**: 04/31/2024
**Completion**: 10%

**Subtask 2.4**: Data analyses
**Target date**: 07/31/2024
**Completion**: 10%

**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**: 50%

**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:** 0%

**Subtask 4.2:** Manuscript preparations
**Target date**: 07/31/2024
**Completion**: 0%

**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).

**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

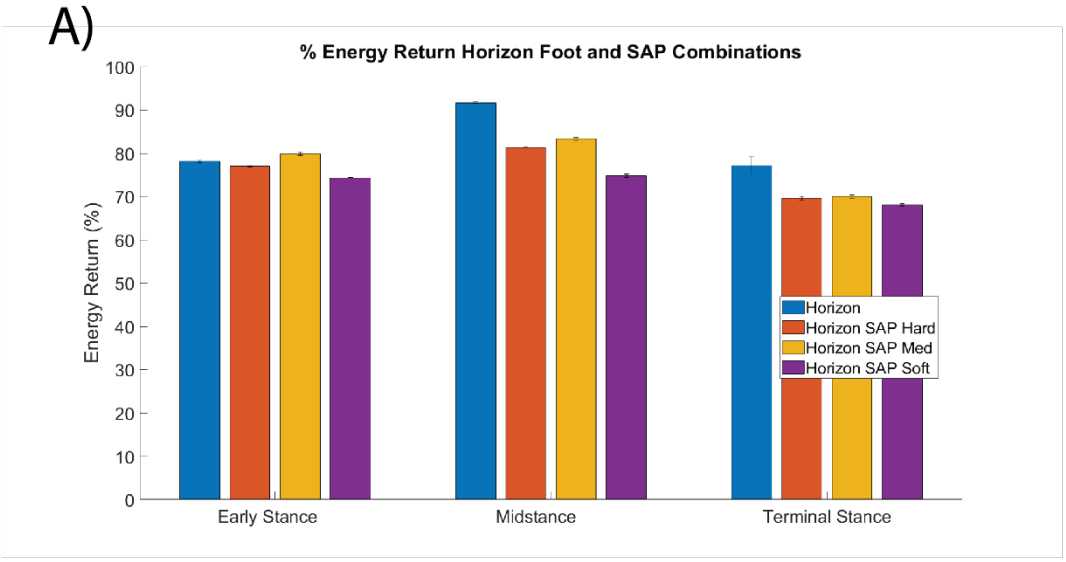
**Subtask 2.2**: Data collections at Naval Medical Center San Diego (NMCSD)

**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

**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).

**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).



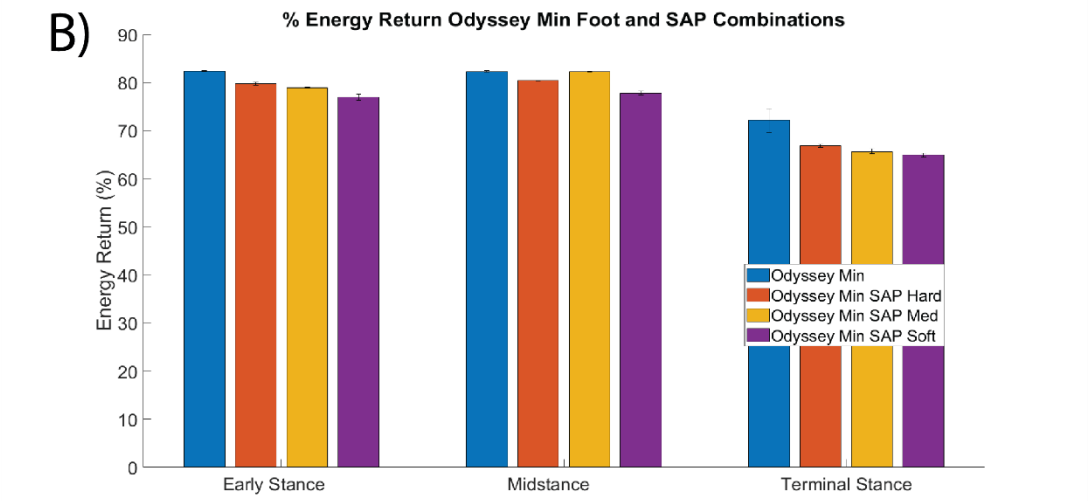




**Figure 2:** using the bench testing method (from Figure 1), the magnitude of energy return was quantified across two different commercially available prostheses: A) Horizon, College Park and B) Odyssey, College Park across three different hardness levels (Hard, Medium, Soft) of shock-absorbing pylon (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).

**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

**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).

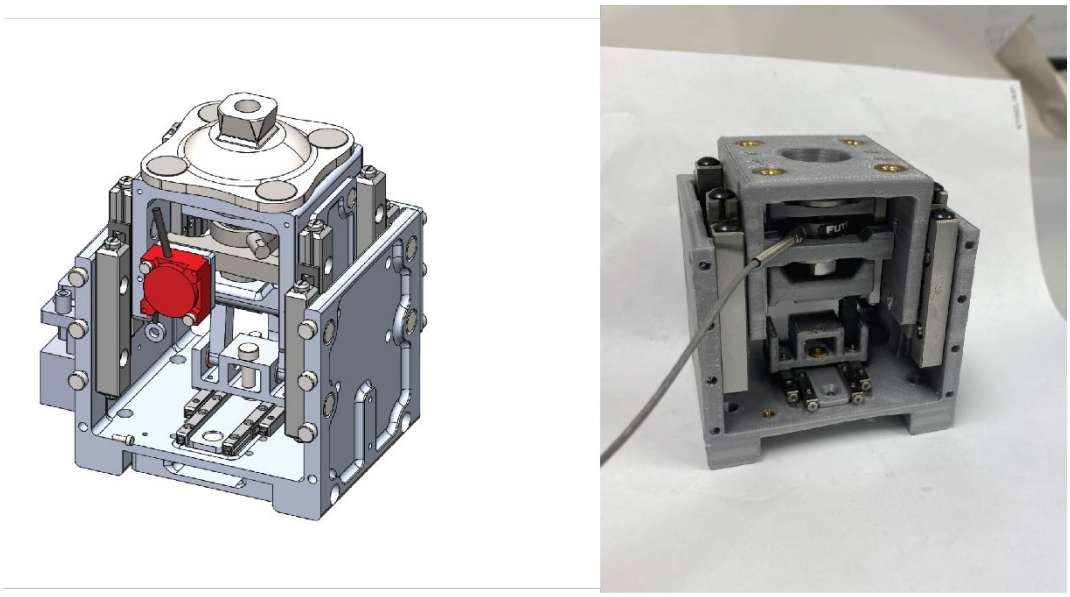


**Figure 3**: Humotech has developed a novel pylon emulator, which is the company's latest addition to the prosthesis product line. The pylon emulator can be programmed to vary in stiffness and damping dynamically, which sets it apart substantially from other commercially available shock-absorbing pylons. 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.

**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

**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

**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

**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

**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

**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

**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

- **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?**

  Nothing to report.

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

  For the next reporting period, our major goal is to prioritize recruitment of human subjects (Major Tasks 2 and 3). With the recent approval from the Office of Human Research Oversight (OHRO), all sites will prioritize data collections.

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. This problem has now been resolved. PI Kota Takahashi has accepted a new position at the University of Utah. The request to transfer the grant to the University of Utah is currently under review. We anticipate delays with the project until the grant transfers to the new institution.

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

     Nothing to report.

   - **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**

     Nothing to report.

     - **Journal publications.**

       Nothing to report.

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

       Nothing to report.

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

Nothing to report.

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

| | |
|---|---|
| Name: | *Matthew Major* |
| Project Role: | *Co-PI* |
| Researcher Identifier (e.g. ORCID ID): | *0000-0002-2330-4619* |
| Nearest person month worked: | *1* |
| Contribution to Project: | *Dr. Major has worked on getting the Single IRB approval, the Jesse Brown VA IRB approval.* |
| Funding Support: | |

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

| | |
|---|---|
| Name: | *Seth Donahue* |
| Project Role: | *Postdoc* |
| Researcher Identifier (e.g. ORCID ID): | *0000-0002-8387-9887* |
| Nearest person month worked: | *2.5* |
| Contribution to Project: | *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.* |
| 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?**

  Nothing to report.

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

  Nothing to report.

8. **SPECIAL REPORTING REQUIREMENTS**
   - **COLLABORATIVE AWARDS:**
   - **QUAD CHARTS:**
9. **APPENDICES:**