

AWARD NUMBER: W81XWH-20-1-0884

TITLE: Multiaxis Prosthesis Control Through an Osseointegrated Neural Interface

PRINCIPAL INVESTIGATOR: Peter G. Adamczyk, Ph.D.

CONTRACTING ORGANIZATION: University of Wisconsin System, Madison, WI

REPORT DATE: October 2021

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for public release; distribution is unlimited.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE October 2021		2. REPORT TYPE Annual		3. DATES COVERED 30Sep2020-29Sep2021	
4. TITLE Multiaxis Prosthesis Control Through an Osseointegrated Neural Interface				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-20-1-0884	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Peter Adamczyk E-Mail: peter.adamczyk@wisc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Wisconsin System 21 N. Park St. Ste 6401 Madison, WI 53706-1534				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 Persons with lower-limb amputation lose both the structure of a limb and control over its functions. This research will contribute to solving problems of prosthesis function, attachment, and sensorimotor interfacing. We will refine a two-axis prosthetic ankle to improve balance and reduce discomfort by adapting to terrain and different movement behaviors. We will test this prosthesis to determine its benefits in activities including sloped walking and walking on curved paths or turns. We will also advance the science of osseointegration and neural interfaces using sheep as a model of human amputation, implanting a mechanical anchor in the bone and a two-way neural recording and stimulation system with nerves in both muscle and bone. The mechanical anchor will support the prosthesis, whereas the neural interface will transfer neural signals from the sheep to control the prosthesis and from the prosthesis to give sensation to the sheep. We will test the ability of the sheep to control the prosthesis and to sense ground forces using this two-way neural interface.					
15. SUBJECT TERMS None listed					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 14	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	5
4. Impact	9
5. Changes/Problems	10
6. Products	11
7. Participants & Other Collaborating Organizations	12
8. Special Reporting Requirements	14
9. Appendices	14

1. INTRODUCTION:

This research addresses lower-limb prosthesis technology, osseointegration of a prosthesis with the skeleton, and neural interfaces for control of prostheses and restoration of sensation. First, the research will advance the development of a two-axis prosthetic ankle for terrain and activity adaptation. Development will include human testing and multiple revisions. Second, the research will adapt osseointegration technology and techniques (bone-implanted, percutaneous prosthesis attachment) to a sheep model of amputation, adding special abutment features for in-bone implantation of electrodes for a neural interface. Third, the research will test bidirectional neural interfacing, recording signals from residual limb muscles to command prosthesis movement and delivering information from external force measurements as neural stimulation to peripheral nerves implanted in the bone canal. Three sheep will be tested for their ability to learn to control the prosthesis and respond to external forces indicated through stimulation.

2. KEYWORDS:

Limb loss; mobility; prosthesis; multiaxis; sheep model; amputation; neural interface; bidirectional; osseointegration

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aims:

- (1) Refine a Two-Axis ‘Daptable Ankle (TADA) prosthesis and test its effects on human biomechanics without neural control.
- (2) Develop a Sheep TADA (STADA) prosthesis and integrate with bidirectional neural interface.
- (3) Evaluate the STADA prosthesis controlled by an ONI in a chronic sheep model of amputation with bidirectional osseointegrated neural interface.

Abbreviations: UW= University of Wisconsin - Madison; UU= University of Utah; DU= Duke University; TADA= Two-Axis ‘Daptable Ankle (prosthesis); STADA= Sheep TADA; EMG= electromyography

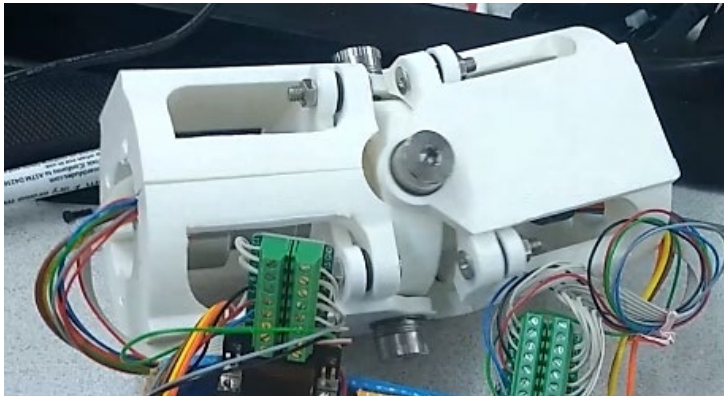
Aim/Task	Timeline (Months)	Progress (%)
Specific Aim 1: Refine the TADA prosthetic ankle and test its effects on human biomechanics without neural control.		
Major Task 1: Refine and Test TADA v2 and v3		
Subtask 1: Test variations of mechanism geometry, materials, and sizing. Codify design rules. Select an improved design.	1-6	90%
Subtask 2: Upgrade motors and transmission. Optimize sensors for control and evaluation. Select new design.	1-6	100%
Subtask 3: Build TADA with a protective housing and embedded electronics. Assemble with foot prosthesis. Tune control algorithms.	6-12	50%
Subtask 4: Test TADA revision: mechanical tests, pilot tests of walking in <u>2</u> participants.	9-18	0%
<u>Repeat Subtasks 1-4 to finalize design of TADA v3. 2 more participants</u>	15-24	5%
Subtask 5: Test TADA performance and human biomechanics in uneven locomotion: speeds, ramps, side slopes, curves. <u>Test 10 human subjects</u>	18-27	0%
Subtask 6: Dissemination Publish design paper (mechanism considerations). Publish human testing paper (nonlevel terrain with TADA).	21-30	0%

Milestone(s)		
HRPO/ACURO Approval	5	100%
TADA v3 suitable for scaled-up human trial.	21	0%
Design principles for TADA mechanism of any load capacity.	21	10%
Manuscript on design principles.	30	0%
Manuscript on human trial results.	36	0%
Specific Aim 2: Develop a Sheep TADA (STADA) prosthesis and integrate with bidirectional neural interface.		
Major Task 2: Sheep TADA (STADA) prosthesis with bidirectional communication with neural interface.		
Subtask 1: Manufacture of osseointegrated implants	18-24	5%
Subtask 2: Design and manufacture of Sheep TADA	18-24	5%
Subtask 3: Design and manufacture instrumented passive prostheses	18-24	0%
Subtask 4: Ovine TADA bench testing	18-24	0%
Subtask 5: Programming communications of STADA with implantable ONI.	21-30	5%
Subtask 6: Design and manufacture instrumented passive prostheses	21-30	0%
Milestone(s) Achieved:		
Production of preliminary ovine TADA schematics	18-20	0%
Production of the first ovine TADA prototype	24	0%
Full bidirectional integration (sensory and control)	30	5%
Specific Aim 3: Evaluation of the TADA prosthetic controlled by an ONI in a chronic ovine model.		
Major Task 3: Closed loop control of a TADA prosthesis		
Subtask 1: Pre-surgical behavioral assessment in sheep - free ambulation, standing, structured tests (3 sheep)	18-24	0%
Subtask 2: Surgical procedure (3 sheep)	18-24	0%
Subtask 3: Open loop electrophysiology (3 sheep)	19-45	0%
Subtask 4: Closed loop TADA control (3 sheep)	24-45	0%
Subtask 5: Behavioral assessment during free ambulation (3 sheep)	18-24	0%
Milestone(s) Achieved:		
First surgery	18-24	0%
First implementation of the STADA prosthesis	24	0%
Testing complete	45	0%
Paper on ovine ONI	48	0%
Paper on closed-loop control of STADA in sheep	48	0%

What was accomplished under these goals?

During the Year 1 reporting period, the team focused on the following activities:

- Regulatory approval
 - IRB and HRPO approvals are fully complete
- Team onboarding
 - Graduate students Rebecca Roembke and Kieran Nichols were assigned to the project.
 - Temporary additional support was provided by graduate student Ryan Moreno.
- Design of the TADA.
 - An extensive motor selection process was carried out. Multiple preliminary prototypes were built to test motor and parts layout concepts.
 - We investigated control interface hardware and strategies to drive the motors.
 - The first full revision of TADA was designed and prototyped with 3D-printed plastic parts. An image of the partially-functional plastic prototype is shown below, excluding the prosthetic foot.



-
-
- Carbon fiber and metal parts are being manufactured.
- A second concept with additional design revisions is also underway. The concept is to reduce height and weight by incorporating multiple smaller actuators (motors) in parallel. This concept will also represent a step toward the STADA (sheep TADA).
- Software refactoring
 - Students worked to convert the original self-contained program into a modular and more versatile version.

- Sheep/Surgery portion of the work

The UW team have slowly been receiving equipment and technology from both **Utah and Duke Teams**. Since receiving preliminary hardware from the **Duke Team (01/27/2021)** we have been focused on interfacing the various hardware with the Europa+ force sensor (Orthocare Innovations, WA 2015). This sensor will eventually be connected to the endoprosthesis supplied by the **Utah Team**, as part of the ONI, delivering wireless force data from each animal, which will then be relayed back to the wireless stimulation devices provided by the **Duke Team**, to deliver stimulation to the residual nerves, allowing the animal to “feel” it’s “hoof”. We recently received the first osseointegrated implant from the **Utah Team** (delivered 08/04/2021), along with all the required materials to perform implantation. A virtual meeting discussing the surgical implantation of osseointegrated implants was conducted on 08/23/2021, involving all with all relevant team members. Cadaver practice was performed 09/13/2021 at which mechanical failures in the unique surgical tools required to implant the osseointegrated implant were discovered. Following these cadaver surgeries, tools were returned to the Utah team and a resolution is still being devised as we have encountered roadblocks in the manufacturing pipeline. After initial delivery and testing of hardware and software from the Duke team, all equipment has been returned to make minor adjustments and modifications, which are currently taking place on schedule.

Duke Team:

- Built and tested benchtop system for wireless stimulation implant
- Assembled and tested wireless 16 channel recording benchtop prototype

Utah Team:

- Received the delayed manufacture and shipment of endoprosthesis from Avalign Thortex (Portland, Oregon)
 - Associated surgical tools were insufficient and have been returned for repair or replacement
- Endoprosthesis designed and manufactured to include Europa+ and dummy Europa+ for everyday wear
- Endoprosthesis mechanically tested

UW Team:

- Performed osseointegrated implant surgery in cadavers semi-successfully.
 - Modifications to surgical tools required and underway
- Successful establishment of the external trigger to generate force based impulses from Europa+ via Raspberry Pi

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

Training:

Two graduate students – Rebecca Roembke and Kieran Nichols – had substantial one-on-one mentoring with Prof. Adamczyk on all the research as they developed the hardware for the TADA. Another graduate student, Ryan Moreno, helped to refactor the control software, and received training in the movement reconstruction algorithms and modular software architecture we intend to use.

Professional Development:

Ms. Roembke and Mr. Nichols participated as attendees (virtual) in summer conferences including Dynamic Walking and American Society of Biomechanics. Mr. Nichols also participated in the International Society of Biomechanics virtual meeting.

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?

In Year 2 we plan the following steps:

- Completion of the current TADA and its controller
- Testing with users
- Completion of the next revision for more compact design
- Codifying design guidelines
- Designing and building the first STADA (Sheep TADA)
- Beginning work to integrate the STADA with the neural interface.

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?

The underlying TADA technology is patented, so advancements in the technology will gradually improve the prospects for commercial transfer. No concrete steps were taken toward transfer in this period, however.

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

COVID has caused supply chain problems with some parts of the work – e.g. a months-long delay in motor shipment, problems acquiring tools for the osseointegrated prosthesis abutments, and difficulty getting tech support. This is gradually resolving. Construction of a walkable prosthesis is a bit behind schedule, but rapid prototyping in-house enabled us to iterate quickly on preliminary versions.

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

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.

Nothing to report.

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

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report. Conference deadlines for 2021 followed too rapidly the beginning of the project in Fall 2020.

- **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: Peter Adamczyk
Project Role: PI
Researcher Identifier (ORCID): 0000-0001-5374-7691
Nearest person month worked: 1
Contribution to Project: Dr. Adamczyk worked to direct the training of both graduate students and their development of the Two-Axis 'Daptable Ankle (TADA).

Name: Kieran Nichols
Project Role: Graduate Student
Researcher Identifier (ORCID): none
Nearest person month worked: 6
Contribution to Project: Mr. Nichols worked on motor and amplifier selection and control software refactoring. Mr. Nichols has led the others as a team. He also worked to write a manuscript on analysis of a prior data set that may inform control of the TADA ankle.

Name: Rebecca Roembke
Project Role: Graduate Student
Researcher Identifier (ORCID): none
Nearest person month worked: 6
Contribution to Project: Ms. Roembke was the main system designer for the TADA prosthesis. She developed a range of concepts, of which two were designed in moderate detail and one was finalized and chosen for manufacture.

Name: Ryan Moreno
Project Role: Graduate Student
Researcher Identifier (ORCID): none
Nearest person month worked: 2
Contribution to Project: Mr. Moreno completed refactoring of the controller software to use Robot Operating System, and polished up a foot motion reconstruction algorithm used previously.

Name: Jonah Mudge
Project Role: Graduate Student
Researcher Identifier (ORCID): unknown
Nearest person month worked: 2
Contribution to Project: Mr. Mudge worked to integrate Europa+ prosthesis load sensors with a wearable computer, in preparation for triggering neural stimulation.

Name: Samuel Poore
Project Role: Senior Personnel
Researcher Identifier (ORCID): unknown
Nearest person month worked: 1
Contribution to Project: Dr. Poore worked to develop and practice the implantation procedure for the ovine model.

Name: Aaron Dingle
Project Role: Co-Investigator
Researcher Identifier (ORCID): unknown
Nearest person month worked: 1
Contribution to Project: Dr. Dingle worked to develop and practice the implantation procedure for the ovine model, and coordinated efforts across the surgical, implant, and neural interface teams.

Name: Aaron Suminski
Project Role: Senior Personnel
Researcher Identifier (ORCID): unknown
Nearest person month worked: 1
Contribution to Project: Dr. Suminski advised on neural interface development and implementation.

Name: Weifeng Zeng
Project Role: Senior Personnel
Researcher Identifier (ORCID): unknown
Nearest person month worked: 1
Contribution to Project: Dr. Zeng is part of the surgical team working on implantation techniques.

Name: Yan Lu
Project Role: Senior Personnel
Researcher Identifier (ORCID): unknown
Nearest person month worked: 1
Contribution to Project: Dr. Lu is part of the surgical team working on implantation techniques.

Name: Brett Nemke
Project Role: Research Manager
Researcher Identifier (ORCID): unknown
Nearest person month worked: 2
Contribution to Project: Mr. Nemke helped organize the many moving parts of the surgery side of the project.

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 has acquired two other active grants, but these have not affected the availability of time to dedicate to this project.

Wearable Shear Wave Tensiometry for Tracking Tendon Load During Dynamic Movement

Capacity: Contact PI (Co-PI: D. Thelen)
Sponsor: NIH Phase II STTR, R42AR07489
Dates: 2020-2022

DOD RESTORE: Objective Assessment of Functional Muscle-Tendon Behavior for Enhancing the Diagnosis and Treatment of Tendon Pathologies

Capacity: Co-Investigator (PI: D. Thelen)
Sponsor: US Department of Defense, W81XWH-21-2-0006

What other organizations were involved as partners?

Organization: Duke University

Location: Durham, NC, USA

Contribution: Work on neural interface system for the Sheep portion of the project.

Organization: University of Utah

Location: Salt Lake City, UT, USA

Contribution: Work on osseointegration implants for the Sheep portion of the project.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: