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TITLE: Multiaxis Prosthesis Control Through an Osseointegrated Neural Interface

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

CONTRACTING ORGANIZATION: University of Wisconsin System, Madison, WI

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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.

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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?

<u>Specific Aims:</u>
(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	1-30	40%
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.	18-30	25%
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	18-48	10%

What was accomplished under these goals?

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	90%
Subtask 4: Test TADA revision: mechanical tests, pilot tests of walking in 2 participants.	9-18	0%
Repeat Subtasks 1-4 to finalize design of TADA v3. 2 more participants	15-24	20%
Subtask 5: Test TADA performance and human biomechanics in uneven locomotion: speeds, ramps, side slopes, curves. Test 10 human subjects	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	20%
Manuscript on design principles.	30	0%
Manuscript on human trial results.	36	0%

Comments:

Task 1 Subtasks 1-3: We built the TADA v2 (see Figures) and worked hard to control the motors. That was harder than anticipated for the embedded system, but it is working well. The system is highly adjustable, so we are finalizing the adjustments and moving to a planning phase for human testing. The control software architecture was revamped to use ROS (Robot Operating System) to coordinate multiple computer processes.

The new TADA v2 is much, much faster than the original, bordering on “too fast” in the sense that it has more power, and therefore height and weight, than intended. Plans for TADA v3 will focus on minimizing size and weight again and achieving performance between that of the v1 and v2.

Human subjects testing is expected to begin in Y3Q2 – first testing for functionality of the various control modes, then advancing to testing effects on persons with amputation.

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	100%
Subtask 2: Design and manufacture of Sheep TADA	18-24	90%
Subtask 3: Design and manufacture uninstrumented passive prostheses	18-24	100%
Subtask 4: Ovine TADA bench testing	18-24	20%
Subtask 5: Programming communications of STADA with implantable ONI.	21-30	5%
Subtask 6: Design and manufacture instrumented passive prostheses	21-30	100%
Milestone(s) Achieved:		
Production of preliminary ovine TADA schematics	18-20	100%
Production of the first ovine TADA prototype	24	90%
Full bidirectional integration (sensory and control)	30	5%

Comments:
Task 2 Subtask 1: Team from U. Utah has successfully delivered prosthesis implants. There were some challenges with tooling and adapting the design, but they have been delivered and two surgeries have been performed. See figures.

Task 2 Subtask 2: Sheep TADA (STADA) has been prototyped in several preliminary versions, with effort spent on minimizing height. The available build height is less than we anticipated in the proposal, so squeezing in the wedge-cam mechanism proved impractical in that space. At the same time, we spent some effort and discussion pondering whether a true 2-DOF ankle was appropriate for a sheep, which has no inversion/eversion at an "ankle" but does have two toes in its hoof. Therefore, we used closely-related principles to design a different style of cam-drive mechanism to give the sheep separate control of two toes. Multiple prototypes have been built, shrinking the form factor to match the available space – an effort that will be concluded in the succeeding quarter. Rather than the original force/moment sensor intended to be used for neural force feedback to the animal, this design will include both thin membrane potentiometers for contact force sensing and hoof angle sensors for kinematic feedback as an alternative option.

Task 2 Subtask 3 and 6: Both uninstrumented ("dummy") and instrumented passive prostheses were built as planned – see Figures. The fundamental size constraint was determined by the Europa+ instrumented pyramid, and the dummy prosthesis was built to approximate the same footprint. We ran into some issues with data from the Europa+ pyramids, in that one of the channels (axial Force, unfortunately) is distorted; this appears to be a known-but-not-publicized issue with the device. Fortunately, there are still two clean Moment channels that will be satisfactory for usage with the neural feedback device.

Task 2 Subtask 5: Programming of STADA with ONI: no practical progress yet; but we have been planning initial aspects of where to get different signals and what they will accomplish.

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	50%
Subtask 3: Open loop electrophysiology (3 sheep)	19-45	5%
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	100%
First implementation of the STADA prosthesis	24	60%
Testing complete	45	0%
Paper on ovine ONI	48	0%
Paper on closed-loop control of STADA in sheep	48	0%

Comments:
Task 3 Subtask 1: behavioral testing has taken a back seat to the more urgent tasks related to implants and surgery. Basic testing is ongoing to generate force/loading signals from the sheep and train it to walk over force plates.
Subtask 2: Two surgeries have been performed. The first (February 2022) was successful implantation of the osseointegrated prosthesis abutment and a dummy/placeholder electronics package (no neural interface). This sheep is healthy and ambulatory with the dummy prosthesis, and will be the first to try out the STADA. The second surgery (August 2022) included the neural interface and was initially successful, with early open-loop electrophysiology testing showing signal recording and stimulation. Unfortunately, an unknown incident with the animal led to loosening of the abutment and associated complications that could not be resolved. Ultimately the animal was euthanized. The surgical team has been spending time debriefing this event and replanning for an improved surgery on the next animal, in October or November.
Subtask 3: The first open-loop electrophysiology tests were performed during the brief time the second animal had the implants. See Figures for simple results showing recording and stimulation. This task will be reset for the next animal.

Figure 1: TADA v2, incorporating two brushless DC motors to control a double wedge-cam system to reorient the ankle in dorsi/plantarflexion and in/eversion. It achieves +/-10 deg of motion in any combination of directions. The system is much faster than the original (can complete a full cycle of plantarflexion to dorsiflexion and back in one swing phase). It needs some wiring clean-up, but is operable. At right, it is shown on a bypass orthosis, used to test it for strength and function. Future revisions will aim to shrink the size and weight while integrating more of the control hardware (currently mounted in a waist-pack).

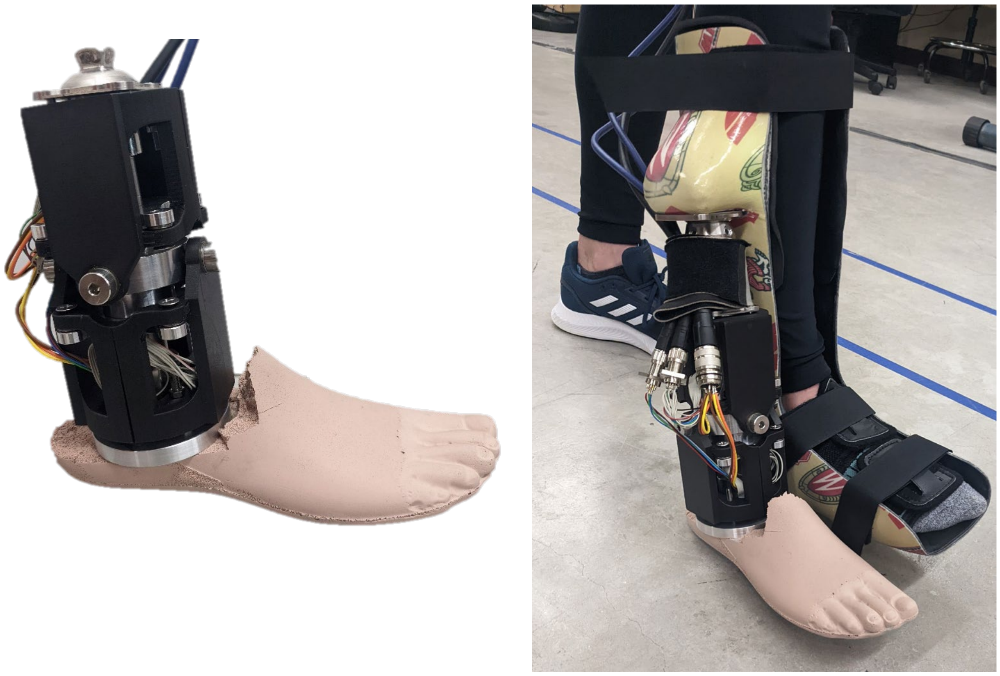
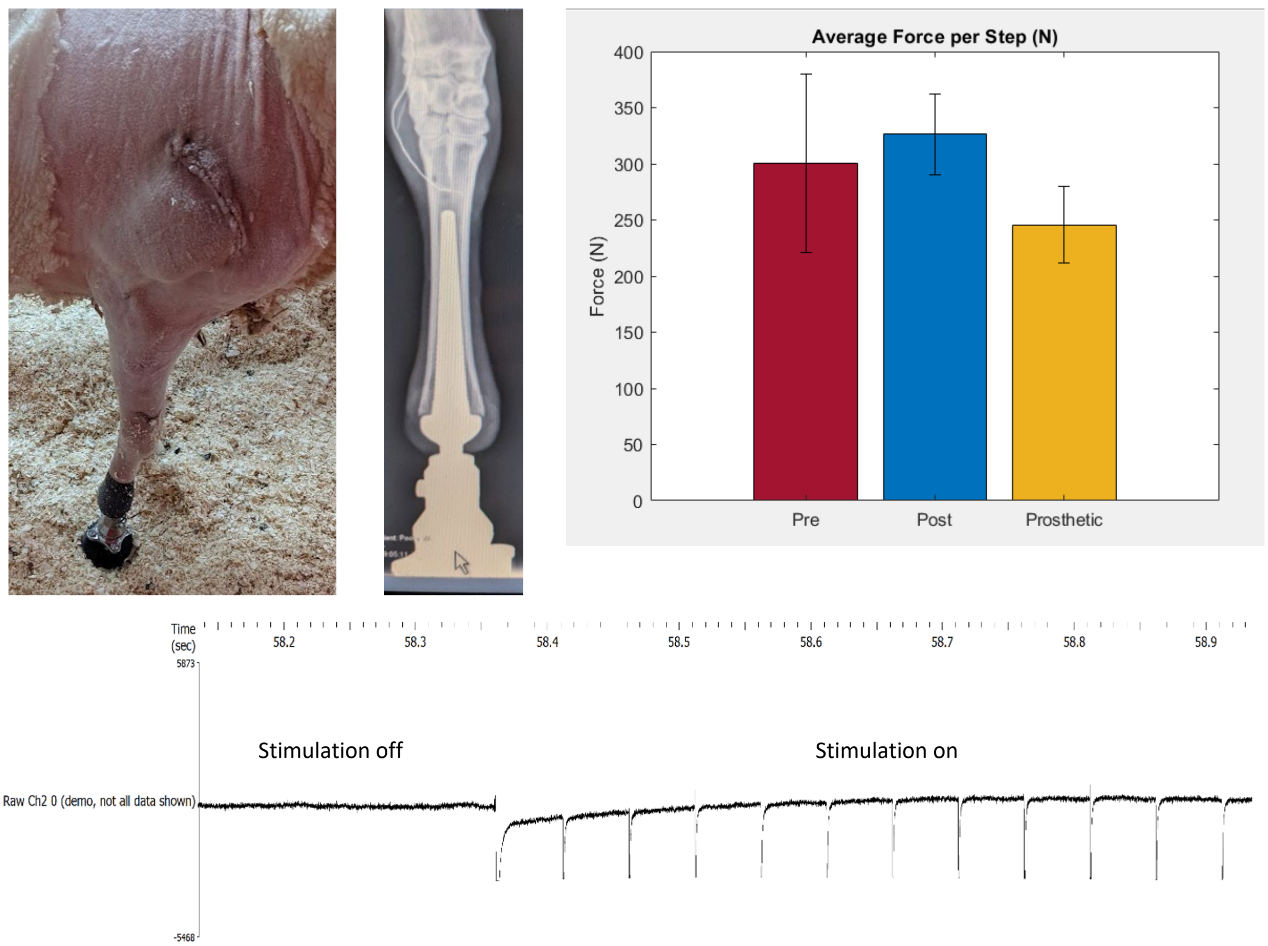


Figure 2: STADA (Sheep TADA) prototype, showing +/-10 deg articulation capability of two "toes" in the approximate shape of the sheep hoof. This design concept was selected for compactness after the available build height proved much less than hoped following the sheep's amputation/osseointegration surgery. The internal mechanics use the same principles as TADA, but a different style of cam.

Figure 3: “Dummy” (top) and Instrumented (bottom) prostheses for the sheep. The “dummy” prosthesis includes a 3D-printed metal plate for structure, a polyurethane tread molded over it, and a nylon 3D-printed spacer with pressed-in inserts for strength and to match weight. The Instrumented prosthesis uses the Europa+ Smart Pyramid and a matching polyurethane tread. The prosthesis adapter on top attaches to the osseointegrated prosthesis abutment.

Figure 4: Results of recent surgery on the sheep. (Left) The second sheep that underwent surgery had an electronics pack and wires implanted in the shoulder and leg, and is shown here with the "dummy" prosthesis attached for everyday use. (Center) The osseointegrated abutment was inserted in the tibia, as were the wire leads and the amputated nerves. (Right) Forces recorded before and after surgery. (Bottom) Recorded traces from Channel 2 of the electronics module, when stimulation was introduced on a separate channel. The signal can be regarded as an "artifact", but does indicate that the recording system was operational. Unfortunately this sheep did not fully heal and had to be euthanized; replanning for the next surgery is ongoing in the surgical team.



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. Mr. Nichols did a deep dive to create software to control the motors and the pose of the TADA. Ms. Roembke finalized the TADA v2 and built the various STADA prototypes.

Another graduate student, Lucas Sears, worked in the UW Department of Surgery on the surgical techniques and data processing for the sheep.

One undergraduate student, Sofya Akhetova, has been training and working to set up a software architecture and multiple nodes that will coordinate sensors, control and decision making in the TADA and STADA software.

Professional Development:
Ms. Roembke and Mr. Nichols participated as attendees in the Dynamic Walking conference, which was hosted by our group in Madison, WI. Ms. Akhetova assisted and also attended. This conference provided opportunities for all these students to interact extensively with other leading researchers working on wearable robots, prostheses, exoskeletons, walking robots, and more.

How were the results disseminated to communities of interest?

Mr. Nichols and Ms. Roembke both delivered presentations at Dynamic Walking.

PI Peter Adamczyk and UW Surgery Co-I Aaron Dingle presented the project status at the MOMRP in-progress review in September 2022.

See *6. Products* for details.

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

In Year 3 we plan the following steps:

- Testing TADA V2 and its controller
- Testing with the first cohort of human users
- Surgery on the next sheep to establish a functional ONI.
- Testing/revising the first STADA for survivability and function in use by a sheep.
- Integrating the STADA with the neural interface: first via recording (to control the STADA) and then by stimulation (to feed back force or position information to the animal).
- Dissemination – manuscripts as outlined in the goals.

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

The STADA design was switched from a two-axis wedge-cam design ("TADA-mini") to a two-toed hoof-like design. This change was made due to space constraints, but is also more appropriate for the needs of a sheep.

Actual or anticipated problems or delays and actions or plans to resolve them

Control of the motors in TADA v2 has been much more challenging than anticipated. This has slowed the movement toward human testing, but the fundamental challenges have now been resolved and we are advancing toward such testing in Y3.

Surgery with undesirable outcome on the 2nd sheep has necessitated replanning. We expect the next surgery to go better.

Changes that had a significant impact on expenditures

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.

Nothing to report.

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

Nothing to report.

Other publications, conference papers and presentations.

Roembke RA, Nichols KN, **Adamczyk PG** (2022) TADA Design. *Dynamic Walking 2022*. June 13-16, 2022. Madison, WI, USA. Oral presentation and Poster.

Nichols KN, Roembke RA, **Adamczyk PG** (2022) Exploration of semi-active control laws for the Two Axis aDaptable Ankle (TADA). *Dynamic Walking 2022*. June 13-16, 2022. Madison, WI, USA. Oral presentation and Poster.

Adamczyk PG, Dingle A, et al (2022) Multi-Axis Prosthesis Control Through an Osseointegrated Neural Interface. *Military Operational Medicine Research Program (MOMRP)* update meeting. September 9, 2022. Online. Oral presentation.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

- **Inventions, patent applications, and/or licenses**

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

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 prosthesis control. Mr. Nichols has led the others as a team. He also completed a manuscript on a prior data set.*

Name: *Rebecca Roembke*
Project Role: *Graduate Student*
Researcher Identifier (ORCID): *none*
Nearest person month worked: *6*
Contribution to Project: *Ms. Roembke finalized TADA v2 and near-finalized STADA v1.*

Name: *Lucas Sears*
Project Role: *Graduate Student*
Researcher Identifier (ORCID): *unknown*
Nearest person month worked: *2*
Contribution to Project: *Mr. Sears worked to develop surgical techniques and to test the first sheep and the Europa+ prosthesis load sensors.*

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.*

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.

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 one other active grant, but this has not affected the availability of time to dedicate to this project.

FW-HTF-P: Collaborative Research: Exoskeleton-Assisted Worker Performance Augmentation in Construction

Capacity:	Co- PI (with Zhenhua Zhu (UW), Fei Dai (West Virginia U.))
Sponsor:	NSF (Future of Work at the Human-Technology Frontier-
Amount:	Planning) UW Portion:
Period Covered:	2021-2022

What other organizations were involved as partners?

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: