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**TITLE:** Optimizing Warfighter Performance with Neurally Integrated Robotic Lower Limb Prostheses

**PRINCIPAL INVESTIGATOR:** Ronald Triolo, PhD

**CONTRACTING ORGANIZATION:** Case Western Reserve University, Cleveland, OH

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**14. ABSTRACT**
Majority of limb loss incidents (~75%) among US Military Service members is in the lower limb. However, restoring sensorimotor function with advanced active prostheses that communicate directly with the intact nervous system falls far behind development of robotic prostheses for individuals with upper limb loss. The objective of this project is to develop and deploy a fully implantable, self-contained, neurally integrated bidirectional lower limb neuroprosthesis that can be readily incorporated into the body schema and utilized without cumbersome external components. In this project, a total of six subjects (three with trans-tibial and three with trans-femoral limb loss) will be enrolled. Electrical stimulation through nerve cuff electrodes directly excites the sensory nerves remaining in the residual limb while electromyography (EMG) signals from intramuscular electrodes are interpreted to intuitively control the actions of advanced robotic lower limb prosthesis. We examine the impact of integrating sensory feedback with EMG-controlled robotic prostheses on balance, gait, and performance during complex mobility tasks in laboratory and during use at home and in community.

**15. SUBJECT TERMS**
None listed.

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## 1. INTRODUCTION:

The majority of limb loss incidents (~75%) among US Military Service members is in the lower limb. However, restoring sensorimotor function with advanced active prostheses that communicate directly with the intact nervous system falls far behind development of robotic prostheses for individuals with upper limb loss. The objective of this project is to develop and deploy a fully implantable, self-contained, neurally integrated bidirectional lower limb neuroprosthesis that can be readily incorporated into the body schema and utilized without cumbersome external components. Although state-of-the-art prosthetic technologies, such as microprocessor-controlled knees and powered ankles, restore some level of function to lower limb amputees, such wearable robotic devices still cannot provide natural somatosensory feedback related to the lost limb or respond seamlessly to the intent of the user in unexpected situations. Our bidirectional neuroprosthesis will allow users to directly control their prostheses by sensing and interpreting the activities of the intact muscles formerly associated with the desired movement, while simultaneously eliciting useful sensations that correspond to joint movements and limb loading to provide seamless sensory feedback about the motorized ankle/knee motion and foot-ground interactions. This project addresses a limitation in the current technology and will lay the foundation for a new generation of prosthetic devices that are fully integrated with the intact nervous system. A total of six subjects (three with trans-tibial and three with trans-femoral limb loss) will receive surgically implanted non-penetrating, high contact density peripheral nerve cuff electrodes on the sciatic and/or tibial nerves above the knee. Bipolar intramuscular recording electrodes will be implanted in the residual and intact upper thigh or gluteal muscles. Electrical stimulation delivered via the nerve cuff electrodes directly excites the sensory nerves remaining in the residual limb while electromyographic (EMG) signals from the implanted intramuscular electrodes are interpreted to intuitively control the actions of advanced robotic lower limb prosthesis. We examine the impact of integrating sensory feedback with EMG-controlled robotic prostheses on balance, gait, and performance during complex mobility tasks in the laboratory and during use at home and in community.

## 2. KEYWORDS:

Bidirectional neuroprosthesis, lower-limb amputees, peripheral nerve stimulation, gait, balance, myoelectric control, robotic prosthesis, neurally integrated prosthesis

## 3. ACCOMPLISHMENTS:

**What were the major goals of the project?**

During this project we aim to:
1) Amend the IRB study protocol at the Louis Stokes Cleveland VA Medical Center (LSCVAMC) to include EMG control and a fully implantable system and amend the IDE that currently regulates the fully implantable system for upper limb amputees to lower limb applications (35% Completed).
2) Procure critical components required for the implant surgery (40% Completed)

3) Identify six lower-limb amputees and complete the implant procedure with temporary percutaneous interface (30% Completed).
4) Design, prototype, verify, and produce electronic hardware and system software to access and control internal circuitry of robotic prostheses (Genium and Proprio) (15% Completed).
5) Determine the effects of bidirectional neuroprosthesis on static and dynamic measures of posture, balance, and gait mechanics (10% Completed).
6) Determine the effects of bidirectional neuroprosthesis during complex mobility tasks such as ascending/descending inclines or stairs, negotiating difficult changing terrain, dual tasks, and horizontal ladder walking task (5% Completed).
7) Install fully implantable bidirectional neuroprosthesis in two bidirectional neuroprosthesis recipients and establish reliable communications with INC and Hub (Not started yet).
8) Evaluate subjective perceptions of balance confidence, utility, comfort, satisfaction and ease of use of the neuroprosthesis and measure its impact on overall mobility, incidence/severity of falls and phantom pain episodes during homegoing trials. (Not started yet).

**What was accomplished under these goals?**

**Clinical Accomplishments**

We successfully completed our first implant surgery for this project on March 31, 2021, with a 56-year-old Navy Veteran with right trans-tibial limb loss resulting from a motor vehicle accident 14 years prior. The participant is an experienced regular user of an Ottobock Empower robotic ankle. During implant surgery he received two high-density nerve cuff electrodes on the sciatic and the tibial nerves in the popliteal fossa on the affected side. In addition, eight bipolar intramuscular (IM) recording electrodes were implanted in the lateral and medial gastrocnemius and peroneus longus muscles of the residual limb and the rectus femoris, vastus lateralis, and long head of bicep femoris in the thigh of the affected side. All the contacts of the IM and cuff electrodes are accessed through percutaneous leads existing the body at the upper thigh. The participant resumed use of his prosthesis two weeks after the surgery. To this date, he has not experienced any medical complications or adverse events because of the implanted system and has resumed all pre-surgical activities. The participant lives in Florida and visits our laboratory on monthly basis to perform the planned tests to achieve the stated project milestones.

The sensory thresholds for the nerve cuff contacts are all within the expected range (below 50 $\mu C/cm^2$) and are consistent with the previously published reports from traumatic trans-tibial amputees who previously received nerve cuff electrode technology for sensory restoration in our laboratory. Recordings from all IM electrodes show EMG activity with expected physiological features e.g., the signal magnitude increases as the subject is instructed to perform maximal voluntary contractions of the muscles of interest. The electrical impedances of all cuff and IM electrode contacts are below 5 kΩ suggesting that electrical continuity of the system is intact. So far, the participant has visited the laboratory for four full-day test sessions since receiving the system. We have performed series of experiments including thorough thresholding and perceptual mapping, speed matching during split-belt treadmill walking, determining reflex responses during and after sensory stimulation, and characterizing EMG patterns during over ground walking as well as stair navigation and ramp ascent/descent. The data collection is still ongoing, and the participant is expected to return to our laboratory on October 23, 2021 and monthly thereafter.

We recently identified and enrolled our second participant in this project, a 50-year-old Army Veteran with a left knee disarticulation due to trauma approximately three years ago who is a daily user of an ALUX Microprocessor Knee. We have completed all the screening assessments, thoroughly examined his residual limb, and examined pressure points on the socket to determine suitable incision sites for the implanted system. He signed the consent form for the implant surgery on September 9, 2021. We have also devised a surgical plan and discussed it with the vascular surgeon on the team (Co-Investigator Dr. Gilles Pinault) who will perform the implantation. The pre-op testing is scheduled for October 21, 2021, and we are actively working with the surgeon and the clinical staff at the LSCVAMC to secure an OR date. We anticipate that the implant surgery will be completed before the end of 2021.

Our physical therapist identified a Navy Veteran with unilateral transtibial amputation who lives in Minnesota and is very interested in enrolling in the study. He is 59 years old who lost his left foot in a motorcycle accident about a year ago. We have been communicating with him via phone and are in the process of scheduling a screening visit to Cleveland. He has also signed a release of his medical records, and we have reviewed his medical history. Although his current BMI is over 35 (the threshold in the eligibility criteria for our study), he has started to lose weight through exercise and diet and is working hard to lower his BMI to acceptable levels within a few months. If he meets our eligibility criteria, we intend to enroll him as our third participant.

During every in-person visit and all the tests with human subjects, our team and participants strictly follow policies recommended by the federal government and local officials to increase safety for subjects and our staff. Our team has worked closely with Research Service the LSCVAMC and VA Northeast Ohio Healthcare System leadership to compile a plan such that research activities with human subjects could be performed without interruption while adhering to social distancing or other COVID 19 precautions.

To further expedite subject recruitment efforts, we have produced high-quality prints of our IRB approved flyer, which is distributed to local prosthetists, physical therapists, and amputee support groups. Moreover, we have worked with a professional medical illustrator at the Advanced Platform Technology Center (APTC) at Cleveland VA to create an illustration which will be published in the *Amputee Coalition* magazine as an advertisement to inform readers about the study and serve as another source of recruitment. This advertisement will be published after IRB approval (pending). We have also been in regular contact with the National Director of Amputee Health (Dr. Joseph Webster), Walter Reed National Military Medical Center (Dr. Paul Pasquina), the Tampa VA Medical Center (Dr. Heckman), and OrthoCarolina (a private medical practice specializing in limb loss) to identify potential implant candidates.

**Technical Accomplishments**

We developed and implemented new firmware for our external stimulator unit. This firmware ensures operational stability of the stimulation system and includes the data logging capabilities required for home and community use of the bidirectional prosthesis. In addition, we have designed and are testing a new cellphone-based user interface to facilitate intuitive use of the neuroprosthesis outside of the laboratory. These software updates provide much easier and more reliable communication between the stimulator and the instrumented prosthesis. The smartphone app allows users to adjust the stimulation intensity and length of stimulation within a previously specified safe range. The benchtop testing of the new firmware and the app was completed in early Summer 2021. We have also compiled the required documents for regulatory approval from the local IRB and the FDA. Upon completion of pending electromagnetic compatibility and electrical safety tests, we will submit an amendment to our existing IDE to incorporate these technical advances into our project.

We devised a method of wirelessly accessing the sensors for knee angle rate, axial load, and knee moment from the Genium microprocessor-controlled knee. The initial data collection was accomplished via a custom routine in MATLAB and a PC equipped with a Bluetooth receiver. Bluetooth receiver. Using this platform and custom microcontroller programming, we were able to successfully connect to the Genium device, initiate the data transmission, receive sensor data, and document characteristics such as range, noise level, and packet loss rate in the wireless communication. To integrate the data stream with our external stimulator, we developed an embedded solution using a Teensy 3.6 board equipped with a 180 MHz ARM Cortex-M4 processor and real-time performance capabilities. The Teensy board was interfaced with a in real time. The received data were examined for integrity and were processed to make them suitable for the stimulator control module which will modulate the pulse parameters based on the sensor signals. Similarly, we have worked with Ossur, the company which manufactures the Proprio powered ankle prosthesis, to gain access to internal sensors of their device. We have been able to read the ankle angle sensor consistently via Bluetooth and are currently working to feed the data stream into our stimulator unit following the same procedure described for the Genium device.

Our technical team has partnered with a small engineering firm in southeast Ohio to develop a small, portable biopotential module to collect and process EMG signal from the IM electrodes. The engineering firm, Carroll Biomedical, has a long history of developing miniature neurotechnology for rehabilitation. The biopotential module will be integrated into the existing controller unit currently utilized for the sensory stimulation. The final product will allow us to perform onboard processing of the EMG signal in real-time and generate suitable motor commands to the prosthesis. This stand-alone system will serve as the main controller unit for the bidirectional prosthesis during ambulatory tasks and at home.

**Administrative Accomplishments**

We added three new members to our team during the reporting period to accelerate the progression of this project: Dr. Daekyoo Kim (postdoctoral scholar, 100%), Mr. Evan Vesper (MS student in Biomedical Engineering, 100%) and Ms. Alexandra Hutchison (Research Nurse & Coordinator, 30%). Dr. Kim is an expert in biomechanics and will perform gait and balance assessments with the bidirectional neuroprosthesis. Mr. Vesper received his BSc in electrical and biomedical engineering and will design and test the EMG controller that interfaces with the commercially available robotic prostheses. Ms. Hutchison is a licensed practical nurse and will assist with clinical follow ups with participants. She will also help with regulatory submissions and maintaining records.

**Dissemination Accomplishments**

Our team organized and moderated a session titled, "Sensorimotor Neuroprosthetics: Are We Ready for Widespread Clinical Application?" at the *Neural Interfaces Conference* on June 25, 2021. Leading researchers in the field presented latest scientific findings, shared some of the challenges in sensory restoration techniques, and discussed future directions. Furthermore, Co-Investigator Dr. Hamid Charkhkar co-moderated a mini-symposium titled "Technologies to Restore Sensory Feedback after Lower-Limb Amputation" at the *10th International IEEE/EMBS Conference on Neural Engineering (NER'21)*. This special session consisted of six speakers and was jointly organized by Dr. Charkhkar and Dr. Lee Fisher from the University of Pittsburg. In addition, our work was featured on *The PBS NewsHour* on September 1, 2021. This coverage was part of the report entitled "How Sensors, Rewiring Nerves Could Help Prosthetics Feel and Function Like Real Limbs" produced by renowned reporter, Miles O'Brian.

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

All team members completed their laboratory safety training and *VA Human Subjects Protection* and *Good Clinical Practices* through The Collaborative Institutional Training Initiative.

We have procured and installed a state-of-the-art real-time control rapid prototyping system (Speedgoat) in our laboratory that facilitates model-based design using MATLAB and Simulink. Students and technical staff have learned how to use this new system and can develop the code to control delivery of electrical stimulation to cuff electrodes, collect EMG signals, and implement control algorithms in real time.

With support from a special equipment grant from the Rehabilitation R&D Service of the VA, we purchased a Computerized Dynamic Posturagrpahy device equipped with immersive virtual reality (Bertec Inc.). This device enables us to characterize static and dynamic balance while ascertaining contribution of different sensory inputs such as vision and vestibular system. Drs. Charkhkar and Sheehan attended a training course to learn how to operate the device and have instructed other members of the staff in its use.

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

We publish all our scientific findings in professional clinical/scientific venues that are Open Access to disseminate results and progress free of charge to the public. On February 2, 2021, we published an article in *Frontiers in Neuroscience* which described the results of manipulating plantar sensation in lower-limb amputees on adjusting quiet stance.

On August 3, 2021, we volunteered for the Virtual Internship Fireside Chats event which was hosted by Case-Coulter Translational Research Partnership (CCTRP). During this event more than 100 attendees, mainly undergraduate students in biomedical engineering from across the country, learned about our project through a dynamic presentation and a follow up Q&A session.

To increase our outreach, we have worked with the medical illustrator at APTC to design a new illustration to inform public about our study. This illustration will be published as an advertisement in Amputee Coalition magazine, *inMotion*. This magazine is published bimonthly for amputees, caregivers and healthcare professionals, providing information related to limb loss.

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

- Complete the implant surgery for the second and third participants
- Conduct threshold/mapping and functional experiments with our second and third participants
- Continue our efforts to identify, recruit, screen, and enroll subsequent candidates into the study
- Characterize EMG signals during ambulatory tasks from all enrolled participants
- Conduct gait and balance tests with all enrolled participants
- Develop a prosthesis controller based on the EMG signal and complete benchtop testing
- Control delivery of sensory stimulation based on sensor data from the Genium or Proprio prostheses
- Complete development of the portable biopotential recording module for ambulatory EMG collection
- Acquire approval from IRB and FDA for our new stimulator controller and the smartphone app
- Procure all the components necessary for the third and fourth implant surgeries

## *4.* IMPACT:

**What was the impact on the development of the principal discipline(s) of the project?**

Our article published in *Frontiers of Neuroscience* examines how electrically elicited tactile input is incorporated into the body's sensorimotor system. Results from this work expands the base of knowledge on how foot-sole tactile information is integrated with other sensory modalities to control postural adjustments during internal perturbations.

**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:

Nothing to Report

**Changes in approach and reasons for change**

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

We are still encountering delays in scheduling OR time for our implant surgery due to a backlog of elective procedures due to the ongoing pandemic. However, our team has been successfully advancing the required technology for the study, productively working with existing participants to collect data, identifying a waiting list of future implant recipients. Therefore, any delays in the OR schedule should not affect overall progress.

The technical development for the biopotential module might be delayed due to the shortage of electronic chips. This should not affect our laboratory testing, but may delay our plan for the eventual homegoing trial.

**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.**

Shell, C. E., Christie, B. P., Marasco, P. D., Charkhkar, H., & Triolo, R. J. (2021). Lower-Limb Amputees Adjust Quiet Stance in Response to Manipulations of Plantar Sensation. *Frontiers in Neuroscience*, 15, 118. (Published). The federal support through this award was acknowledged.

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

Nothing to Report.

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

Our team member, Dr. Charkhkar, moderated and presented in the following sessions:
1) "Sensorimotor Neuroprosthetics: Are We Ready for Widespread Clinical Application?", *Neural Interfaces 2021: The NANS-NIC Joint Meeting*, Jun. 25-26, 2021
2) "Technologies to Restore Sensory Feedback after Lower-Limb Amputation", *10th International IEEE/EMBS Conference on Neural Engineering (NER'21)*, May 4-6, 2021

- **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**

| |
|---|
| The link to the PBS NewsHour video:<br><br>https://www.youtube.com/watch?v=9vtcmZai3yI&ab_channel=PBSNewsHour |

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Name: Ronald Triolo
Project Role: PI
Researcher Identifier (e.g. ORCID ID): 0000-0003-0984-5803
Nearest person month worked: 1
Contribution to Project: Programmatic, administrative and scientific oversight of all aspects of the project

Name: Hamid Charkhkar
Project Role: Co-investigator (Technical)
Researcher Identifier (e.g. ORCID ID): 0000-0001-5485-5969
Nearest person month worked: 2
Contribution to Project: Conducting sensory stimulation tests, including stimulus calibration and parameter setting, psychometric testing, system integration and outcome measurement

Name: Suzhou Li
Project Role: PhD Student (Technical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Designing and performing experiments to characterize effects of sensory neuroprosthesis in responding to slips and trips

Name: Daekyoo Kim
Project Role: Postdoctoral Fellow (Technical)
Researcher Identifier (e.g. ORCID ID): 0000-0002-6123-2900
Nearest person month worked: 2
Contribution to Project: Designing and conducting balance and gait assessments and analyzing biomechanical data from participants using sensory neuroprosthesis

Name: Evan Vesper
Project Role: Graduate student (Technical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Characterizing the EMG recordings from intramuscular electrodes and designing controller algorithm

Name: Melissa Schmitt
Project Role: Nurse Coordinator (Clinical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Regulatory reporting and compliance, medical monitoring and clinical services

Name: Aarika Sheehan
Project Role: Physical Therapist (Clinical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Subject recruiting, candidate screening, functional training and outcome assessment

Name:  John Schnellenberger
Project Role:  Biomedical Engineer (Technical)
Researcher Identifier (e.g. ORCID ID):  N/A
Nearest person month worked:   1
Contribution to Project: Circuit design and software development for biopotential module and the external

Name:  Jeremy Dunning
Project Role:  Electrical Engineer (Technical)
Researcher Identifier (e.g. ORCID ID):   N/A
Nearest person month worked:   1
Contribution to Project: Circuit design and software development for interfacing with Genium and Proprio prostheses

Name: Jillian Vala
Project Role:  Biomedical Engineer (Technical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked:   1
Contribution to Project: Develop computer code for experiments. Assist in conducting experiments to assess effects of sensory feedback in lower limb amputees

**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?**

Organization Name: Ottobock
Location of Organization: Vienna, Austria
Partner's contribution to the project: Industrial partner and collaborator. Ottobock provided us with a Genium Knee prosthesis on loan without charge and will lend technical assistance with accessing internal circuitry of the device.

Organization Name: Ossur
Location of Organization: Reykjavik, Iceland
Partner's contribution to the project: Industrial partner and collaborator. Ossure provided us with a two Proprio powered ankles on loan without charge and will lend technical assistance with accessing internal sensor data of the device.

Organization Name: Case Western Reserve University
Location of Organization: Cleveland, OH
Partner's contribution to the project: Access to microfabrication, electronic design and circuit testing facilities, and technical support required for external stimulator design modifications and fabrication.

Organization Name: Carroll Biomedical
Location of Organization: Jewett, OH
Partner's contribution to the project: Carroll Biomedical will design and fabricate a portable biopotential module which will be utilized to collect EMG from IM electrodes, perform onboard processing, and generate suitable commands to control the prosthesis.

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:**

## 9. APPENDICES: