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CONTRACTING ORGANIZATION: Case Western Reserve University, Cleveland, OH

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14. ABSTRACT
The vast majority of limb loss incidents (~75%) among US Military Service members occur 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 which are rapidly becoming commercially available to trans-femoral and trans-tibial amputees. 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 intuitively utilized without cumbersome external components. A total of six subjects (three with trans-tibial and three with trans-femoral limb loss) will be enrolled. Neural stimulation delivered via multi-contact cuff electrodes directly excite the sensory nerves remaining in the residual limb while electromyography (EMG) signals from intramuscular electrodes are interpreted to control the actions of advanced robotic lower limb prostheses. We will examine the impact of integrating sensory feedback with EMG-controlled robotic prostheses on subjective measures of user acceptance and objective measures of balance, gait, and performance during complex mobility tasks in laboratory and during use at home and in community.

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None listed.

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1. INTRODUCTION:

The vast majority of limb loss incidents (~75%) among US Military Service members occur 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 which are rapidly becoming commercially available to trans-femoral and trans-tibial amputees. 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 intuitively utilized without cumbersome external components. 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 excite 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 subjective and qualitative indicators of user acceptance, and quantitative measures of 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 (60% Completed)

3) Identify six lower-limb amputees and complete the implant procedure with temporary percutaneous interface (35% Completed).
4) Design, prototype, verify, and produce electronic hardware and system software to access and control internal circuitry of robotic prostheses (Genium and Proprio) (30% Completed).
5) Determine the effects of the bidirectional neuroprosthesis on static and dynamic measures of posture, balance, and gait mechanics (20% Completed).
6) Determine the effects of the bidirectional neuroprosthesis during complex mobility tasks such as ascending/descending inclines or stairs, negotiating difficult changing terrain, dual tasks, and a horizontal ladder walking task (15% Completed).
7) Install fully implantable bidirectional neuroprosthesis in two percutaneous system 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 Activities

We have scheduled our second implant surgery and confirmed the operating room (OR) availability at Louis Stoke Cleveland VA Medical Center (LSCVAMC) for November 23rd, 2022. The participant is a 50-year-old Army Veteran with a left knee disarticulation due to trauma. The limb loss happened approximately four years ago, and the volunteer is a daily user of a RHEO advanced microprocessor knee. We have completed all the screening assessments, thoroughly examined the residual limb, and examined pressure points on the socket to determine suitable incision sites for the implanted system. Although he had signed the consent form for the implant surgery in late 2021, we delayed the implant procedure for about a year based on the feedback from his care provider regarding other ongoing health issues that have since resolved. According to our surgical plan, the participant will receive two high contact density stimulating cuff electrodes (i.e., C-FINEs) on the sciatic and tibial nerves (one cuff electrode on each nerve). In addition, we will implant a total of 12 bipolar intramuscular (IM) recording electrodes in hamstring, quadricep, and gluteal muscle groups, four IM in each muscle group. The access to implanted components will be through a percutaneous interface exiting the body in the lower abdomen. Further details on surgical procedure will be provided in the next report.

Our first participant, a Navy Veteran with right trans-tibial limb loss who underwent the implant surgery last year, still visits our laboratories at LSCVAMC on a monthly basis to complete planned experiments. So far, he has not experienced any medical complications or adverse events because of the implanted system. The sensory thresholds for the nerve cuff contacts are still within the expected range (below 50 $\mu C/cm^2$) and are consistent with the previously published reports from traumatic trans-tibial amputees who had already received nerve cuff electrode technology for sensory restoration in our laboratory. Recordings from 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).

We routinely distribute our IRB approved flyer to local prosthetists, physical therapists, and amputee support groups. Moreover, our study advertisement has been published in the *Amputee Coalition* magazine, *inMotion,* since June 2022. We have received at least half a dozen phone calls from potential candidates. Our study coordinator has been in communication with these individuals and the screening and implant consent forms have been sent for review to those who could potentially qualify for enrollment. To this date, we have identified three interested candidates who will be invited to LSCVAMC for screening. These individuals are traumatic trans-tibial amputees and regular users of lower-limb prostheses.

Furthermore, we have significantly increased our recruitment efforts by reaching out to clinicians at various healthcare centers, locally and nationally. Study brochures were mailed to 13 community-based outpatient clinics in the Cleveland area and the Rocky Mountain VA in Colorado. In addition, our team continues to regularly search for any eligible candidates in Amputee Clinic and Endocrine/Diabetic Clinic at LSCVAMC on a weekly basis, and maintains communications with Walter Reed Military Medicine Center, the Tampa and Minneapolic VA Medical Centers, and the National VA Amputee Care System. Furthermore, we have been in contact with Dr. Susan Lucht (Director of PM&R at the Southern Arizona VA Health Care System) and emailed study materials, sent professionally printed informational brochures, and suggested to arrange a meeting or presentation to review the project. During follow-up conversations with Ian Stephens (Physical Therapist, Cleveland Clinic Foundation), we were informed that he distributed our study brochures at their monthly Rehab Manager Meeting. After reaching out to Dr. Kristin Cornuelle-Marks (Physical Therapist at TriHealth in Cincinnati, OH), we were introduced to the physical therapist that heads their amputee health program. Subsequently, we mailed study brochures to their healthcare center for distribution. Lastly, we updated our study listing on ClinicalTrials.Gov so that updated aspects of the project including the development of a motor controller was explicitly mentioned. Our team is revising the ClinicalTrials.Gov listing with additional details at their request.

Technical Activities

Our technical team has partnered with a small engineering firm, Carroll Biomedical in southeast Ohio, to develop and fabricate an Electromyography Processing Module (EPM) which will be integrated into our existing external neural controller. The EPM will allow us to collect EMG signals from intramuscular electrodes, perform onboard processing and generate suitable motor commands to control a motorized lower limb prosthesis. This integration with the existing neural controller will establish a stand-alone system functioning as the main control unit for the bidirectional prosthesis during ambulatory tasks and outside laboratory testing. The hardware design for EPM was completed in July 2022. Electronic parts were procured, and the circuit boards were fabricated, assembled, and tested in September 2022. The EPM specifications included in the design were as follows:

- 8 channels of differential EMG or 16 channels of single-ended EMG with optional passive reference or weakly-driven bias electrodes.
- Texas Instruments ADS1298 analog front end (AFE) with a common-mode input voltage range of ±2.5V, an analog-to-digital resolution of 24 bits, and a maximum of sample rate of 32 ksps.
- Electrical isolation between the EMG measurement circuitry and the EPM's power circuitry, digital processing, and external controller bus.
- STMicro STM32F423ZHT6 ARM® 32-bit Cortex®-M4 microcontroller for configuring the AFE and processing EMG data, with on-chip memory of 1.5 MB of flash and 320 kB of SRAM.
- Lattice iCE40 FPGA for optional digital filtering and/or processing of the EMG data, including hardware-based fast fourier transform (FFT) analysis.

- U-Blox Nordic Bluetooth 5.0 radio which can be using for streaming incoming data from external sensors or streaming outgoing EMG data to a central hub.
- STMicro LSM6DSO32 inertial measurement unit (IMU) for determining 9-axis orientation of the device.
- Interfaces to connect the EPM to the APT Center's UECU external controller, as well as the ability to run the EPM stand-alone with a power source such as a battery.

The next major design effort will be to develop the firmware for the EPM, which includes drivers for interfacing with the neural controller. EMG onboard processing software will then be added. It is anticipated that the EMG processing software will undergo several rounds of improvements once the EPM is ready for experiments with neuroprosthesis recipients.

Sixteen months post implantation in our first subject, all the intramuscular electrodes except one are functional and can collect EMG signals with high signal-to-noise ratios ranging from 19 dB to 51 dB. During multiple experimental sessions, the participant performed different locomotion modes including level-ground walking and ramp and stair negotiations with and without the sensory neuroprosthesis to restore plantar sensation on the missing foot. An offline supervisory controller has been implemented in MATLAB to distinguish between different locomotion modes on a gait cycle basis. Our team has also developed custom routines in MATLAB to perform pre-processing on the data and extract EMG features associated with certain gait events (e.g., heel strike or initial contact). The dataset is being utilized to train an EMG controller for a powered ankle prosthesis. In addition, our team has devised an experiment to measure the EMG from intramuscular electrodes as the participant is instructed to match the ankle movement on his intact side. This data will be utilized to establish a direct control law which will determine the torque of the prosthetic joint. The direct and supervisory control approaches will be combined to provide a hybrid control strategy in the robotic prosthesis.

Our team has continued the development of a virtual reality (VR) simulator for an ankle prosthesis. The EMG input captured from the implanted intramuscular recording electrodes will be utilized to control a virtual representation of a real-life myoelectric ankle prosthesis. This VR simulator provides a platform to decouple the myoelectric control scheme from the physical prosthesis. Hence, compared to the implementation on a real prosthesis, it will be easier to train users on myoelectric control and will provide a user-friendly and safe environment to test a variety of control algorithms. Previous work established a virtual environment where the user can view and control the dorsi- and plantar-flexion of a virtual ankle prosthesis using real-time surface EMG signals. We have successfully added a Bluetooth-based IMU to track the rotation of the user's knee joint instead of relying on imprecise joystick input from handheld controllers. This method allows for intuitive control of the virtual lower limb where it "follows" the user's natural movement.

Through series of split-belt treadmill walking experiments, we investigated the effects of plantar sensation elicited by our peripheral neural stimulation technique on motor adaptation and speed perception. We found that elicited plantar sensations increased stance time and propulsive force on the prosthetic side, improved gait symmetry, and yielded an enhanced perception of prosthetic leg movement while walking. Most importantly, our results show the response to the locomotor adaptation paradigm among lower limb amputees with the restored plantar sensation became similar to able-bodied individuals. These findings suggest that a peripheral nerve-based approach to elicit plantar sensation directly affects central nervous pathways involved in locomotion and motor adaptation during walking. Our results have important functional implication on highlighting the role of plantar sensation in increasing mobility, improving walking dynamics, and possibly reducing fall risks in amputees. We have prepared a manuscript based on these findings which will be submitted to *Science Robotics* by mid-November 2022.

We developed an ambulatory dual task experiment. The dual task paradigm is based on the notion that maintaining gait symmetry and stability involves high level cognition, specifically executive function, and attention. With compromised somatosensory input, a person concurrently executing a sensorimotor and cognitive task may demonstrate a measurable performance degradation in one or both tasks. Qualitative reports indicate lower limb amputees devote more focus to walking suggesting a higher cognitive load. Prior work has shown individuals with lower limb loss experience significant gait changes during dual tasking compared to able-bodied participants. In our experiment, participants walked on an instrumented treadmill while performing a visual stroop (VStroop) test with and without elicited plantar sensations. The VStroop test consists of color words presented in incongruent colors, with participants responding with the font color of the stimulus. We repeated this experiment with the SNP in active and inactive conditions (randomized order) to examine the effects of elicited plantar sensations on the dual task performance. Metrics of interest are accuracy of responses, and gait symmetry and stability parameters. The data collection has been completed with three transtibial amputees and data processing is underway.

We procured an Open-Source Bionic Leg designed by the University of Michigan and distributed by Human Movement Technologies LLC. The design is state-of-the- art and we will be able to alter the hardware and software of the device without intellectual property constrains often imposed by commercial prosthesis manufacturers. In addition, the Open-Source Leg provides a platform for collaboration with other research groups on developing software control systems without having to consider the hardware in technical discrepancies. The device is customizable and equipped with sensors such as load cells, which allows tracking the loading profile of the prosthesis during ambulation. Furthermore, the software suite is compatible with MATLAB and Simulink, which we use for our laboratory experiments. This Bionic Leg is lighter than the biological leg and has less mass than the prosthetic legs designed by MIT and Vanderbilt according to a 2020 article reviewing the capabilities of this prosthesis. The range of motion for the knee and ankle are 120 and 30 degrees. The delivery of this Bionic Leg is expected on December 1, 2022.

Administrative Activities

We have recruited two new PhD students, Eileen Petros and Lindsey Hauck, who joined our team in late August 2022 and will be directly working on this RESTORE project. Ms. Hauck will be responsible for developing a myoelectric controller for the bidirectional prosthesis and Ms. Petros will utilize VR technology to validate developed controllers prior to hardware implementation. She will also perform dual task experiments to evaluate effects of the neuroprosthesis on cognitive load.

Dr. Ronald Triolo, PI, presented RESTORE project updates during the MOMRP FY22 Musculoskeletal In-Progress Review session on September 9, 2022. Following the session, we have had meetings with two RESTORE participants, Dr. Aaron Dingle from University of Wisconsin-Madison and Dr. Sergiy Yakovenko from West Virginia University who expressed interest in our work. We are exploring potential collaboration opportunities with these teams.

Dissemination Activities

Our team presented results from this project at local and national scientific meetings. Four members of our team attended the *Annual Meeting of Biomedical Engineering Society (BMES)* held in San Antonio, TX between October 12-15, 2022. In this meeting, we had two podium presentations titled, "*Restored plantar sensation in lower-limb amputees improves gait symmetry and perception"* and *"Characterizing effects of electrically elicited sensations on spinal reflex pathways."* In addition, we had two undergraduate poster presentations at the BMES. For more details, see the PRODUCTS section of this report.

Furthermore, we participated in the *Department of Defense Advances in Biomedical Research Symposium* held in Cleveland, OH between August 18-19, 2022. This symposium sponsored by Case Western Reserve University brought together Northeast Ohio's leading biomedical researchers to illustrate and define the most significant future technology areas of Biomedical, Health and Human Performance Sciences for academic and United States government research. Dr. Charkhkar, Co-I, presented a poster on the latest findings from this project. Additionally, our team participated in the *2022 NE Ohio Musculoskeletal Research Summer Symposium* on August 17, 2022, in Cleveland, OH where we presented two posters. Dr. Daekyoo Kim, postdoctoral scholar, won the best poster presentation award in this symposium.

Drs. Charkhkar and Sheehan virtually presented our research at the *Minnesota Grand Rounds seminar* on May 13, 2022, which was approved for continuing education credit. Over 60 individuals from multiples disciplines attended the talk. Prior to the seminar, promotional material was forwarded to all VA prosthetists nationwide. Additionally, emails were sent to Dr. Jeffrey Heckman (Physician and Medical Director at the Regional Amputation Center at the Tampa VA), Jennifer Gutowski and Katie Landwehr (Director and Associate Director of Southern Arizona VA Health Care System), Dr. Clay Kelly (Physician and Chief of PM&R at CLE VAMC), Dr. Noel So (Physician and Regional Amputee Medical Director at Rocky Mountain VA), Dr. Jonathan Todd McVey (Chief of Podiatry at the LSCVAMC), Theo Forosty (Prosthetist at Syracuse VA), and Ian Stephens (Physical Therapist at Cleveland Clinic Foundation) requesting they inform their staff within their healthcare systems about the study.

We were an exhibitor at the *Amputee Coalition National Conference* which took place from August 10-13 in Palm Desert, CA. Over 100 individuals, many living with limb loss, visited our booth to learn more about our research. Of those, approximately 15 people reported interest in participation and provided contact information to follow up. Additionally, we met with various clinicians and businesses who were interested in our research and agreed to help provide referrals. Various groups such as the Dallas Amputee Network and Hanger Prosthetics requested that we present to their groups at a later date so that individuals living with limb loss and clinicians who were not in attendance at the conference could learn about our project and this research opportunity. Our participant who received the implanted system last year attended the conference and was present at the booth answering visitors' questions. He wore the portable neural controller and the instrumented prosthesis while at the conference showcasing the technology.

We are also scheduled to be an exhibitor at the *American Physical Therapy Association Combined Sections Meeting (CSM)* scheduled to take place February 23-25, 2023, in San Diego, CA. CSM attracts over 15,000 participants annually which will enable us to discuss our work with numerous therapists from around the nation serving individuals with limb loss.

Dr. Sheehan provided an in-person presentation about the research project at Summa Rehab Hospital in Akron, Ohio on May 24, 2022. Clinicians and individuals with limb loss were in attendance and study brochures were handed out to all individuals. We have been in correspondence with Ellie Steiger (Physical Therapist Assistant, Summa Health) who helped organize this talk and are planning for another presentation early next year.

We updated our study brochure with new pictures and information that now addresses the bidirectional nature of the neuroprosthesis. The previously approved version only mentioned the sensory feedback aspect of the study, whereas the new version addresses the added goal to develop a motor controller that would provide intuitive control of the prosthesis based on EMG signals from the IM electrodes. This new version was approved by the IRB in July 2022.

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

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

Five undergraduate students joined our team during summer 2022 as interns. These students ranging from freshman to senior trained with the Co-I, postdoctoral scholar, and graduate students in our team. They assisted with data analysis, experiment setup, and were encouraged to develop small undergraduate research projects on their own. Two of these students presented posters on their work at the *BMES*.

How were the results disseminated to communities of interest?

Our team actively participated in professional scientific meetings including *BMES*, *Department of Defense Advances in Biomedical Research Symposium*, and *2022 NE Ohio Musculoskeletal Research Summer Symposium* where we presented results from this project. In addition, we have presented this project to clinicians and prosthetists by participation in Grand Round seminars such as the *Department of Veteran Affairs Employee Education System Seminar* (presented by Drs. Charkhkar and Sheehan on May 13, 2022) and *City-wide Grand Rounds at MetroHealth Rehabilitation Institute* (presented by Dr. Charkhkar on March 7, 2022).

We were an exhibitor at *Amputee Coalition National Conference* in Palm Desert, CA during August 10-13, 2022. Two of our team members including one of our participants showcased the technology. The booth was visited by over 100 individuals, many living with limb loss, and various clinicians and businesses who were interested in our research.

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

- Complete the implant surgery for the second, third and fourth participants
- Conduct threshold/mapping and functional experiments with all 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
- Develop a prosthesis controller based on the EMG signal and complete benchtop testing
- Implement the myoelectric controller in VR environment and subsequently implement it on the Open Source Leg.
- Test the portable EPM for ambulatory EMG collection
- Acquire approval from IRB and FDA for the fully implantable system, *iSens*

4. IMPACT:

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

Our findings show individuals with lower limb amputation achieved higher gait symmetry and stability with the sensory neuroprosthesis. In addition, we demonstrated elicited plantar sensations from the missing foot improved the locomotor adaptation suggesting integration of this new input in the central nervous system. These results will be submitted for publications to *Science Robotics*.

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

In spite of ongoing difficulties in scheduling OR times for our implant procedures due to a backlog of elective case at the LSCVAMC, we have successfully secured a surgery date for our second subject on November 23rd. Our team has been further advancing the goals of the study by productively working with existing participants to collect data, and identify a waiting list of future implant recipients. Therefore, any delays in the OR schedule should not affect overall progress.

Our plans to upgrade two participants to the fully implantable system, *iSens*, will be delayed due to supply chain issues and shortage of system components. Our team is working hard to procure the required components as soon as they become available. This delay will not affect our planned experiments because participants will have the percutaneous interface which provides full access to implanted nerve cuffs and intramuscular electrodes.

Changes that had a significant impact on expenditures

We have adjusted the staff efforts based on the project needs by engaging new graduate research assistants at Case Western Reserve University and decreasing the salary expenditure on the VA personnel accordingly. These changes are budget-neutral and will not affect the dollar amount of the award. The total effort will also be unchanged since we are substituting employees of one institution for another.

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.

1) D. Kim, R. Triolo, H. Charkhkar. Restored plantar sensations in individuals with lower-limb loss improve gait symmetry and locomotor adaptation, *Science Robotics (to be submitted by November 15, 2022).* DoD support is acknowledged in the manuscript.
2) M. Schmitt, J. Wright, R. Triolo, H. Charkhkar, E. Graczyk. The experience of sensorimotor integration of a lower limb sensory neuroprosthesis: A qualitative case study. *Frontiers in Human Neuroscience*, Under Review. DoD support is acknowledged in the manuscript

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

Nothing to Report.

Other publications, conference papers and presentations.

1) D. Kim, R. Triolo, H. Charkhkar. Restored plantar sensation in lower-limb amputees improves gait symmetry and perception. *2022 Biomedical Engineering Society (BMES) Annual Meeting*. San Antonio, TX, Oct. 2022 (podium presentation)
2) S. Li, R. Triolo, H. Charkhkar. Characterizing effects of electrically elicited sensations on spinal reflex pathways. *2022 Biomedical Engineering Society (BMES) Annual Meeting*. San Antonio, TX, Oct. 2022 (podium presentation)
3) A. Sheehan, J. Vala, C. Shell, R. Triolo, H. Charkhkar. Prolonged use of a sensory neuroprosthesis affects performance and strategy in negotiating stairs. *International Society for Prosthetics and Orthotics (ISPO) 18th World Congress*. Nov. 2021 (poster presentation)
4) M. Schmitt, J. Wright, H. Charkhkar, R. Triolo, E. Graczyk. Long-term home use of a lower extremity sensory neuroprosthesis: a qualitative case study. *International Society for Prosthetics and Orthotics (ISPO) 18th World Congress*. Nov. 2021 (poster presentation)
5) M. Person, A. Hall, H. Charkhkar. Prosthetic smart liner for monitoring residual limb health and wound prevention. *2022 Biomedical Engineering Society (BMES) Annual Meeting*. San Antonio, TX, Oct. 2022 (poster presentation)
6) J. Baker, M. Person, H. Charkhkar. Wearable system for estimating energy expenditure in lower-limb amputees. *2022 Biomedical Engineering Society (BMES) Annual Meeting*. San Antonio, TX, Oct. 2022 (poster presentation)
7) H. Charkhkar, D. Kim, R. Triolo. Neurally integrated prostheses for individuals with lower limb loss. *Department of Defense Advances in Biomedical Research Symposium*. Cleveland, OH, Aug. 2022 (poster presentation)
8) D. Kim, R. Triolo, H. Charkhkar. Restored plantar sensation in lower-limb amputees improves gait symmetry and perception. *2022 NE Ohio Musculoskeletal Research Summer Symposium*. Cleveland, OH, Aug. 2022 (poster presentation)
9) S. Li, R. Triolo, H. Charkhkar. Characterizing effects of electrically elicited sensations on spinal reflex pathways. *2022 NE Ohio Musculoskeletal Research Summer Symposium*. Cleveland, OH, Aug. 2022 (poster presentation)
10) H. Charkhkar, A. Sheehan. Restoring the neural connection to the missing lower extremity of individuals with limb loss. Department of Veteran Affairs Employee Education System Seminar, May 13, 2022 (oral presentation)
11) H. Charkhkar. Connecting lower limb prostheses to the nervous system. City-wide Grand Rounds at MetroHealth Rehabilitation Institute, March 7, 2022 (oral presentation)

- **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**

Our team members recorded series of short videos with the support from Advanced Platform Technology Center, a Department of Veterans Affairs Research Center in the Rehabilitation Research and Development Service. The links to these videos are as follows:

- APT Center's Dr. Hamid Charkhkar discusses work on sensorized lower limb prosthetics: https://youtu.be/KQg3QlO3cPE
- APT Center's Suzhou Li on restoring sensation & motor function for those with lower-limb prosthetics: https://youtu.be/MOv8bpTIg-o
- APT Center's Eileen Petros discusses using virtual reality to improve prosthetic devices: https://youtu.be/kkkok04soN4
- APT Center's Evan Vesper discusses improving lower limb prosthesis function: https://youtu.be/Yj_dgqibf0c
- APT Center's Dr. Daekyoo Kim discusses using neurotechnology to improve gait asymmetry: https://youtu.be/_difCLMvE3o

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: 1.8
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: 6
Contribution to Project: Conducting sensory stimulation tests, including stimulus calibration and parameter setting, psychometric testing, system integration and outcome measurement, supervising students and assisting the PI in project management

Name: Suzhou Li
Project Role: PhD Student (Technical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 6
Contribution to Project: Designing and performing experiments to characterize effects of sensory neuroprosthesis in responding to slips and trips

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 EPM and the external neural controller

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: Eileen Petros
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 VR and dual task experiments

Name: Daekyoo Kim
Project Role: Postdoctoral Fellow (Technical)
Researcher Identifier (e.g. ORCID ID): 0000-0002-6123-2900
Nearest person month worked: 6
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: 2
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: 0.6
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: Alexandra Hutchison
Project Role: Study Coordinator (Clinical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3.6
Contribution to Project: Regulatory reporting and compliance, medical monitoring and clinical services

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 EPM 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: