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TITLE: Natural Sensation of Foot-Floor Interactions for Transfemoral Amputees via Neural Stimulation

PRINCIPAL INVESTIGATOR: Ronald Triolo, PhD

CONTRACTING ORGANIZATION: Louis Stokes Cleveland VA Medical Research & Education Foundation

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14. ABSTRACT The objective of this project is to provide useful sensation of prosthetic foot-floor interactions to transfemoral amputees by directly interfacing with the nervous system in the residuum. Amputees are slow to adapt to loss of lower limb sensation, and fall-related fear and anxiety are all life-long consequences of amputation. Over this reporting period, we have identified and enrolled a 50-year-old Army Veteran with a left knee disarticulation who will be our first implant recipient. Our technical and clinical teams have worked to develop a surgical plan in which the ideal incision locations for the internal connectors and percutaneous exit sites were determined. We anticipate the implant surgery to be completed by the end of 2021. Furthermore, we have accessed and streamed internal sensor data from the Genium prosthesis in real time, and finalized the integration of the signals with our external stimulator controller. This completed the proposed elements of the sensory neuroprosthesis that will provide users with sensations of foot-floor interactions as well as the knee joint angle. We have expanded their outreach and are actively working to identify new potential sources of participant referrals by contacting clinicians and prosthetists both locally and nationally. Psychometric and functional test continues with previously enrolled transtibial participants.					
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Accomplishments	1
4. Impact	5
5. Changes/Problems	6
6. Products	8
7. Participants & Other Collaborating Organizations	11
8. Special Reporting Requirements	13
9. Appendices	

1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The objective of this project is to provide useful sensation of prosthetic foot-floor interactions to trans-femoral amputees by directly interfacing with the nervous system in the residuum. Amputees are slow to adapt to loss of lower limb sensation, and fall-related fear and anxiety are all life-long consequences of amputation. These issues are particularly important for individuals with trans-femoral limb loss who constitute approximately 40% of the entire amputee population. Despite noteworthy advances in robotic prostheses for lower limb amputees, meaningful and direct sensory feedback from the lost limb has not yet been incorporated into currently available prosthetic technologies. This project focuses on restoring useful sensation of prosthetic foot-floor interactions as well as knee joint motion to trans-femoral amputees by directly exciting the upper sciatic nerves remaining in the residual limb with the new, non-penetrating, high contact density Composite Flat Interface Nerve Electrode (C-FINE). We hypothesize that the electrically evoked sensations from C-FINEs implanted on the proximal sciatic nerve in the residuum will be perceived as naturally arising from the missing limb, that their psychometric properties (quality, location, modality and intensity) will be stable, and that they will improve standing balance, gait mechanics and symmetry, and the ability to negotiate unstructured terrain and uneven surfaces. Positive effects on the cognitive attention required for walking in unfamiliar or distracting environments, incidence and fear of falling, balance confidence, and phantom pain are also anticipated and will be reflected in patterns of home and community use.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Sensory restoration, lower-limb amputees, nerve cuff electrodes, peripheral nerve stimulation, gait, balance, sensory neuroprosthesis

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW.

During this project we aim to:

- 1) Design, prototype, verify and produce new hardware and software to extract sensor signals from an advanced microprocessor-controlled knee and utilize them to control neural stimulation. (90% Completed).
- 2) Identify five trans-femoral amputees and install high contact density C-FINEs on their proximal femoral nerves. (40% Completed). Expected implant date for the transfemoral candidate: November 2022.
- 3) Characterize psychometric properties and explore interactions between perceived sensation and all system inputs. (20% completed. Our mitigation plan is to continue to pursue this work with 3 transtibial amputees who previously received identical implanted systems under separate DoD funding.)
- 4) Determine effects of natural sensation on standing balance, gait mechanics, stair/ramp ascent and negotiating difficult terrain under various conditions. (20% completed. Our mitigation plan is to continue to pursue this work with 3 transtibial amputees who previously received identical implanted systems under separate DoD funding.)

5) Explore subjective perceptions of balance confidence, utility, comfort, satisfaction and ease of use of the sensory neuroprosthesis and measure effects on cognitive/attentional burden and incidence/severity of falls and phantom pain episodes. (20% completed. Our mitigation plan is to continue to pursue this work with 3 transtibial amputees who previously received identical implanted systems under separate DoD funding.)

6) Evaluate patterns of usage in the home and community and other objective or subjective outcome measures including any carryover effects. (30% completed, as part of our mitigation plan, we completed a 11-month long homegoing trial with a transtibial amputee participant and are preparing to launch the second homegoing trial with another transtibial participant in the coming year).

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided.

The implant surgery for the transfemoral participant is scheduled and confirmed for November 23rd, 2022. We have worked with the clinical staff at Louis Stoke Cleveland VA Medical Center (LSCVAMC) to secure access to OR. 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 participant's care provider because of other ongoing health issues. According to our surgical plan, the participant will receive two high-density 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 (4 per 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 quarterly report.

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. 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. Moreover, we updated our study listing on ClinicalTrials.gov to include all aspects of the project.

We have pursued the goals stated in this project with our enrolled transtibial amputees. We completed an implant surgery last year on March 31, 2021. He is Navy Veteran with right trans-tibial limb loss who 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 $\mu\text{C}/\text{cm}^2$) 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.

Through a 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.

In a new experiment, we characterized the effects of electrically elicited sensations to the sensorimotor control system of individuals with lower limb loss by probing H-reflex excitability in triceps surae muscles. Our results show that electrically elicited plantar sensation is affecting spinal reflex pathways in a similar manner as natural sensation from an intact foot. Our team is finishing the data processing and a journal manuscript will be submitted to *Frontiers of Neuroscience* in late December 2022 – early January 2023.

Our team presented results from this and other DoD sponsored projects 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 in 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 multiple 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 the LSCVAMC), 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.

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 provide a presentation 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.

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

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 (CITI Training).

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*.

With support from a special equipment grant from the Rehabilitation R&D Service of the US Department of Veterans Affairs, we acquired an instrumented staircase (Berotec, Inc.). The instrumented stairs are equipped with highly accurate forceplates designed to measure ground reaction forces while ascending or descending stairs. This new equipment is now installed and operational at our Motion Study Laboratory and all team members are trained on how to perform the device setup prior to data collection with subjects.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

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?

If this is the final report, state "Nothing to Report." Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Complete the implantation surgery for the enrolled participant with trans-femoral limb loss
- Conduct threshold/mapping and functional experiments with the trans-femoral participant
- Continue efforts to identify, recruit, screen, and enroll subsequent candidates with trans-femoral and trans-tibial limb loss
- Procure all the system components necessary for all planned implant surgeries
- Continue the psychometric and functional tests with previously enrolled participants with transtibial limb loss

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

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*.

Presentations by our team members at the *International Society for Prosthetics and Orthotics (ISPO) 18th World Congress* shared the effects of the prolonged use of the sensory neuroprosthesis in a lower limb amputee. These findings are crucial to identify benefits as well as challenges in transitioning this technology outside the laboratory and into the real life.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*

- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

We experienced significant delays in identifying and enrolling participants during the project period due to the COVID-19 pandemic. Therefore, some of the expected progress outlined in the last year’s report did not materialize. The enrolled participant, a 50-year-old Army Veteran with a left knee disarticulation, is very enthusiastic about the study and we expect to complete the implantation surgery in November 2022. In addition, we have experienced some delays in securing OR time due to a backlog in elective procedures at Louis Stokes Cleveland VA Medical Center. Our team actively coordinates with the medical staff at LSCVAMC and the surgeon on the team to identify a suitable OR date for the implant procedure. Because of these unforeseen circumstances, the experimental schedule anticipated with participants with trans-femoral limb loss had to be adjusted accordingly. We are mitigating the impact of these issues by continuing to collect data from experiments described in our SOW with our trans-tibial participants who previously received the implanted sensory neuroprosthesis. Furthermore, we requested for a no-cost extension (NEC) of this project for another year to complete the tasks outlined in SOW. NEC was approved in October 2022 and our team has continued the work uninterrupted.

To accelerate our recruitment effort, we have developed a plan which could be summarized by a) distributing our IRB approved study flyers electronically and in print locally and nationally to prosthetists, physical therapists, clinicians, and amputee support groups, b) expanding our outreach to the public by producing video reports in local and national TV outlets as well as advertising in magazines targeted at amputee population such as *iMotion*, c) establishing contacts with prominent clinicians and centers involved in providing care to amputees, such as Walter Reed National Military Medical Center (Dr. Paul Pasquina), the Tampa VA Medical Center (Dr. Jeffery Heckmen), and OrthoCarolina (a private medical practice specializing in limb loss), educating them about our inclusion criteria and participation timeline, and distributing our recruitment materials.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

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: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

• **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

- 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 in November 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. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time*

conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

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)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

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/MOv8bpTlg-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?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

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: 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: 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?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

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 load without charge, and will lend technical assistance with accessing internal sensor data of the Genium 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.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

- 9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*