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

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CONTRACTING ORGANIZATION: Cleveland VA Medical Research & Education Foundation, Cleveland, OH

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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.

15. SUBJECT TERMS
None listed.

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1. INTRODUCTION:

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. These issues are particularly important for individuals with transfemoral 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 transfemoral 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:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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. (95% Completed).
2) Identify five transfemoral amputees and install high contact density C-FINEs on their proximal femoral nerves. (40% Completed).
3) Characterize psychometric properties and explore interactions between perceived sensation and all system inputs. (75% completed*)
4) Determine effects of natural sensation on standing balance, gait mechanics, stair/ramp ascent and negotiating difficult terrain under various conditions. (75% completed*)
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. (75% completed*)

6) Evaluate patterns of usage in the home and community and other objective or subjective outcome measures including any carryover effects. (30% completed*)

* Our mitigation plan is to continue pursuing these goals with one transfemoral amputee who received the implanted system under this project, and three transtibial participants with transtibial limb loss who previously received identical implanted systems under separate DoD funding.

What was accomplished under these goals?

Scientific/Technical Accomplishments:

Our team successfully installed the implanted system in a 50-year-old Army veteran who lost his left leg at the knee due to trauma four years prior to enrolling in the study. The surgical procedure took place on November 23, 2022 and involved the installation of two 16-contact compliant flat interface nerve electrodes (C-FINEs) on the sciatic nerve in his residual limb. Additionally, the participant received 12 bipolar intramuscular (IM) recording electrodes in the hamstring, quadricep, and gluteal muscle groups (4 per group) as part of a separate DoD funded project. A percutaneous interface provided access to the C-FINEs and IM electrodes, with lead wires to the implanted components exiting the skin in the lower abdominal area. External connectors were installed on the percutaneous leads to interface with custom sensory stimulation and myoelectric recording circuitry. The surgery spanned about six hours, and the participant was discharged the following day.

Preliminary observations suggest that electrical stimulation through about 70% of the tested C-FINE contacts elicited sensations referred to the missing limb. However, sensory thresholds seem to be higher compared to those obtained from transtibial subjects. This discrepancy might be due to the participant's use of pregabalin, a medication intended to alleviate phantom pain but also known to affect nerve excitability. We presented a summary of these findings, including a comparison of the sensory thresholds between participants with transtibial and transfemoral limb loss, in a poster titled "Eliciting Plantar Sensation via Nerve Cuff Electrodes in Individuals with Transtibial versus Transfemoral Amputation" at the *11th International IEEE EMBS Conference on Neural Engineering (NER'23)* in Baltimore, MD on April 25-27, 2023.

We have pursued the goals stated for this project with this new participant with transfemoral limb loss, as well as existing recipients of the system with transtibial limb loss. Accordingly, we conducted a set of experiments with our previously enrolled subjects with transtibial limb loss involving split-belt treadmill walking. The goal of these experiments was to analyze the impact of elicited plantar sensation on both motor adaptation and speed perception. Our findings indicate that these elicited plantar sensations not only increased stance time and propulsive force on the prosthetic side, but also improved gait symmetry and enhanced the perception of prosthetic leg movement during walking. These outcomes suggest that restoring plantar sensation can make the locomotor adaptation response of lower limb amputees resemble that of able-bodied individuals. Furthermore, they indicate that a peripheral nerve-based approach to elicit plantar sensation directly affects central nervous pathways involved in locomotion and motor adaptation during walking. The results also have important functional implications that highlight the role of plantar sensation in increasing mobility, improving walking dynamics, and possibly reducing fall risk in amputees. Our manuscript, "Restored Plantar Sensations in Individuals with Lower-Limb

Loss Improve Gait Symmetry, Limb Movement Perception, and Locomotor Adaptation," summarizes these results and will be published in *Science Robotics* in October 2023.

A manuscript describing our recent findings titled "Neural Sensory Stimulation Does Not Interfere with the H-Reflex in Individuals with Lower Limb Amputation," is currently in press in *Frontiers in Neuroscience – Neuroprosthetics*. This submission highlights an experiment that characterized the effects of electrically elicited sensations on the sensorimotor control system of individuals with lower limb loss by probing H-reflex excitability in triceps surae muscles. We found that delivering electrically elicited plantar sensations did not interfere with reflex pathways while participants maintained static postures and loading conditions mimicking gait. This means that individuals with lower limb loss can receive the benefits of our neural sensory stimulation technology, such as improved gait symmetry, without the stimulation interfering with reflex pathways that are important for smooth and stable walking.

We have collected data with three participants (two transtibial, one transfemoral) for an experiment that studies how providing neural sensory stimulation can affect an individual's ability to recover from treadmill-induced perturbations. We are actively performing analysis on the data. So far, we have found that providing the neural sensory stimulation appears to reduce the peak trunk flexion angular velocity for two participants during recovery from simulated slips and trips. This means that the sensory neuroprosthesis appears to enable these participants to better control how their bodies move during perturbations to steady state walking. We communicated these findings in a presentation titled "Sensory Neuroprosthesis Improves Recovery from Treadmill Induced Stumbles" at the *11th International IEEE EMBS Conference on Neural Engineering (NER'23)* in Baltimore, MD on April 25-27, 2023.

We continue to make progress on establishing a wireless connection between the Ottobock Genium microprocessor knee and our new external control unit and integrating the commercially available prosthesis with the implanted stimulation and recording system. An algorithm has been developed and tested that uses the Genium's on-board strain gauge sensors to drive neural stimulation to elicit plantar sensation. This will enable us to estimate the plantar pressure profile without the need for external pressure insoles, offering an easier and more practical solution for our participants with transfemoral limb loss. Moreover, we have fostered a working relationship with the newly appointed Director of the Ottobock Salt Lake City Research Hub. The Director granted us access to Ottobock's proprietary software, which will enable us to modify the prosthesis as needed and help service the existing Genium knee in our laboratory. Furthermore, Dr. Charkhkar gave a presentation to Ottobock's Research and Development team in July 2023, where he shared our work on interfacing our neural technology with the Genium prosthesis. The DoD's role in the project was duly acknowledged before the international audience.

We have begun data collection on a new assessment that investigates the impact of Sensory Neuroprosthesis (SNP) activation on stair negotiation. Since individuals with lower limb loss often rely heavily on visual feedback when walking, stairs can pose a unique challenge, especially when their view is obstructed while carrying items. We are utilizing kinetic and kinematic data from a Bertec Instrumented Staircase and a Vicon motion capture system to understand how the SNP influences factors such as safety, toe clearance, and strategy when negotiating stairs with varying levels of visual feedback.

Clinical/Outreach Accomplishments:

To date our participant with transfemoral limb loss has experienced no clinical issues following the surgery. All incision sites healed as expected, and the participant has reported no complications in using his prosthesis. We began delivery of electrical stimulation to the C-FINEs at four weeks post-surgery, as outlined in our IRB protocol. Since then, he has attended regular

laboratory visits where we conduct experiments to characterize sensations elicited by electrical stimulation delivered through the implanted nerve cuff electrodes.

Four members of our team attended the *Annual Meeting of Biomedical Engineering Society (BMES)* held in San Antonio, TX between October 12-15, 2022 to present results from this and other DoD projects. 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 Annual Meeting*. In all these presentations, this DoD effort was acknowledged.

Co-Investigators Drs. Gilles Pinault and Hamid Charkhkar attended the *Advances in Amputation Surgery International Conference* on January 27, 2023, at the Hospital for Special Surgery in New York, NY. Dr. Pinault presented the surgical technique for installing the implantable neural interfaces to restore sensorimotor function by highlighting the recent surgery with our participant with transfemoral limb loss as a case study. Following the talk, both Drs. Pinault and Charkhkar participated actively in the Q&A session. The Department of Defense's contribution to the project was duly acknowledged during the presentation.

Dr. Hamid Charkhkar presented our work across various platforms, reaching audiences from clinicians to researchers. He presented at the *Bioengineering Seminar at George Mason University* in Fairfax, VA, on April 13th, 2023. On May 20th, he gave a presentation at the *Orthotic and Prosthetic Innovative Technologies (OPTech) Conference* in Minneapolis, MN and engaged in a panel discussion with neuroprosthetics experts following the presentation to address the challenges and recent advancements in neuroprosthesis research. The audience at *OPTech* included certified prosthetists, established researchers, industry representatives, and clinicians from across the nation. Additionally, On June 14th, Dr. Charkhkar delivered a lecture in the *Musculskeletal Research Training Program* at Case Western Reserve University School of Medicine to communicate our latest findings. In all presentations, the DoD contribution was acknowledged.

In our ongoing effort to increase awareness, members of our team attended the annual *Veterans Wheelchair Games* in Portland, OR from July 4-9, 2023, where we were an exhibitor. Our participant with transfemoral limb loss competed in the games, attaining medals in multiple events. In addition, we continued our engagement at the *Amputee Coalition* meeting in Orlando, FL, from August 2-5. The same participant was once again in attendance and conducted a live demonstration of the SNP, providing attendees with firsthand experience of its potential.

We routinely distribute our IRB approved flyer to local prosthetists, physical therapists, and amputee support groups. Moreover, we redesigned our ad in the Amputee Coalition's magazine, *inMotion*, which ran during the second half of 2022. We have significantly increased our recruitment efforts locally and nationally by reaching out to clinicians. Accordingly, we created an advertisement that runs daily on the Digital Announcement Network boards throughout the LSCVAMC. Our team also continues to regularly search for any eligible candidates in the Amputee and Endocrine/Diabetic Clinics at the LSCVAMC on a weekly basis, and routinely attend Amputee Clinic at MetroHealth Medical Center.

Additionally, our work at the LSCVAMC on sensory restoration in amputees was featured in a **CBS 60 Minutes** segment titled "Feeling of Feeling." This segment focused on the ongoing developments in prosthetic technology that can potentially restore a sense of touch to persons with limb loss. Interviews were conducted with our implant recipients at LSCVAMC, and showcased the work of Co-Investigator Dustin Tyler, who uses the identical technology to restore sensation in upper limb amputees.

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

All team members are up to date on the safety training and *VA Human Subjects Protection* and *Good Clinical Practices* through The Collaborative Institutional Training Initiative (CITI Training).

Three undergraduate students joined our team during summer 2023 as interns. These students, ranging from sophomore to senior, trained with the Investigators and graduate students on our team. They assisted with technical development, experimental setup, and data collection and analysis while being encouraged to develop their own small undergraduate research projects.

Our graduate and undergraduate students have given presentations at scientific meetings around the country during this reporting period. These included presentations at the *BMES Annual Meeting* and *NER'23.* More details on these are provided below in the presentations section.

How were the results disseminated to communities of interest?

Co-Investigators and students from our team actively disseminated results of our studies by presenting at professional scientific meetings including *BMES*, the *Bioengineering Seminar at George Mason University*, the *Orthotic and Prosthetic Innovative Technologies (OPTech) Conference,* the *Musculoskeletal Research Training Program* at Case Western Reserve University School of Medicine, and the *Advances in Amputation Surgery International Conference*. In addition, our work on sensory restoration in amputees was featured in a **CBS 60 Minutes** segment titled "Feeling of Feeling." The segment focused on the ongoing developments in prosthetic technology that can restore a sense of touch to persons with limb loss and included interviews with our implant recipients at LSCVAMC that showcased the work of Co-Investigator Dustin Tyler, who uses the identical technology to restore sensation in upper limb amputees.

We were an exhibitor at the *Amputee Coalition National Conference* and annual *Veteran's Wheelchair Games.* In addition to our team members, our transfemoral amputee participant attended both of these events and provided a live demonstration of our sensory neuroprosthesis at the *Amputee Coalition National Conference*.

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

- Continue data collection on experiments with participant(s) with transfemoral and transtibial limb loss
- Intensify efforts to identify, recruit, screen, and enroll subsequent candidates with transfemoral and transtibial limb loss
- Conduct human experiments with the system that integrates our SNP with the Ottobock Genium microprocessor knee
- Disseminate results garnered from this and other DoD supported projects at local and national scientific meetings
- Conduct a home-use study of our SNP system with our enrolled participant with transfemoral limb-loss

4. IMPACT:

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

Our findings show that delivering electrically elicited plantar sensations with our implanted cuff electrodes did not interfere with reflex pathways while participants maintained static postures and loads representative of gait. This means that individuals with lower limb loss can receive the benefits of our neural sensory stimulation technology, such as improved gait symmetry, without the stimulation interfering with reflex pathways that are important for smooth and stable walking. A manuscript with these findings is in press in *Frontiers in Neuroscience.*

We have shown that 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 locomotor adaptation, suggesting integration of this new input in the central nervous system. These results will be published in the October 2023 issue of *Science Robotics*.

Our participant with transfemoral limb-loss who underwent implant surgery in November 2022 reported a noticeable decrease in phantom pain since the start of sensory neural stimulation. This observation suggests that sensory input perceived as arising from the amputated limb may affect phantom pain perception.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

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

We experienced some delays in securing OR time due to a backlog in elective procedures at Louis Stokes Cleveland VA Medical Center, which postponed implant surgery for our most recently recruited participant, a 50-year-old Army Veteran with a left knee disarticulation. Nonetheless we coordinated with OR staff and Co-Investigator Dr. Pinault (the surgeon performing the implantation surgery) and the participant successfully received the system during this reporting period. Because of these unforeseen circumstances, the anticipated experimental schedule for this participant with transfemoral limb loss had to be adjusted accordingly. He has been coming to LSCVAMC to participate in experiments regularly since his implantation, allowing us to collect data for many of the experiments described above. We also continue to mitigate the impact of these scheduling and transfemoral limb loss participant enrollment issues by collecting data from experiments described in our SOW with participants with transtibial limb loss who previously received the implanted sensory neuroprosthesis with other support from the DoD. Furthermore, we requested a second no-cost extension (NCE) of this project that will allow us to complete the tasks outlined in the SOW.

To accelerate subject recruitment, we have increased our presence locally and nationally, including a plan to specifically target potential participants in the waiting areas for the Prosthetics Service, in addition to Amputee Clinic. This will provide increased convenience by allowing us to arrange for a study staff member to meet personally with individual prosthesis users who may not have medical issues, provide study materials, and answer questions following their standard appointments. Additionally, our nationwide recruitment efforts have been bolstered by the **CBS 60 Minutes** episode that featured our research and recently re-aired in July. As a result, we are in contact with another candidate, who we will be screening in the near future.

Changes that had a significant impact on expenditures

The COVID-19 pandemic had a significant impact on the progression of this project, particularly during years three and four. Restrictions on elective procedures, mandatory administrative prohibitions on human studies research, and a general reluctance of candidates and study participants to visit the Medical Center for screening or research procedures all posed significant obstacles to the recruitment and enrollment of transfemoral subjects and progress toward the timeliness of achieving the stated milestones. Despite these challenges, we were able to recruit a transtibial participant, surgically install the system, and quantify performance of the SNP while expanding our understanding of the underlying sensory neurophysiology and effects on gait and balance after limb loss. We have since been able to regain and maintain momentum, steadily making progress on and accomplishing the tasks outlined in the SOW. The request for an additional NCE will provide the necessary time to finalize these tasks in a budget neutral way while also enabling the generation of comprehensive results that encompass both the transfemoral and transtibial amputee populations. Currently unexpended funds will be used exclusively for salary support for investigators, staff, and research assistants, as well as for support of study participants, including travel, lodging and acquisition of required implantable and external system components. No additional funds will be necessary to complete the project, which we anticipate will be successfully concluded at the end of the requested NCE.

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) S. Li, R. Triolo, H. Charkhkar. "Neural Sensory Stimulation Does Not Interfere with the H-Reflex in Individuals with Lower Limb Amputation." *Frontiers in Neuroscience - in press.* DoD support is acknowledged in the manuscript.
2) D. Kim, R. Triolo, H. Charkhkar. "Restored Plantar Sensations in Individuals With Lower-Limb Loss Improve Gait Symmetry and Locomotor Adaptation." *Science Robotics - in press.* DoD support is acknowledged in the manuscript.
3) 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,* vol. 16, 2023. 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) H.Morgan, R. Triolo, H. Charkhkar. Quantifying cutaneous vasodilation reflexes in lower limb amputees. *2023 Biomedical Engineering Society (BMES) Annual Meeting*. Seattle, WA, Oct. 2023 (Accepted for podium presentation).
2) L.Hauck, R. Triolo, H. Charkhkar. Quantifying peripheral nerve stimulation sensations through pressure matching. *2023 Biomedical Engineering Society (BMES) Annual Meeting*. Seattle, WA, Oct. 2023 (Accepted for podium presentation).
3) A. Khot, D. Noble, R. Triolo, H. Charkhkar. Advancing bidirectional neuroprosthetics with the Open Source Leg. *2023 Biomedical Engineering Society (BMES) Annual Meeting*. Seattle, WA, Oct. 2023 (Accepted for poster presentation).
4) M. Koishida, S. Li, J. Schnellenberger, R. Triolo, H. Charkhkar. Integrated EMG processing module for bidirectional neuroprosthesis. *2023 Biomedical Engineering Society (BMES) Annual Meeting*. Seattle, WA, Oct. 2023 (Accepted for poster presentation).
5) E. Petros, R. Triolo, H. Charkhkar. Sensory Neuroprosthesis reduces the cognitive load during dual-task walking in individuals with lower limb loss. *11th International IEEE EMBS Conference on Neural Engineering (NER'23).* Baltimore, MD, Apr. 2023. (Poster presentation)
6) L. Hauck, R. Triolo, H. Charkhkar. Eliciting plantar sensation via nerve cuff electrodes in individuals with transtibial versus transfemoral amputation. *11th International IEEE EMBS Conference on Neural Engineering (NER'23).* Baltimore, MD, Apr. 2023. (Poster presentation)
7) S. Li, R. Triolo, H. Charkhkar. Sensory Neuroprosthesis improves recovery from treadmill-induced stumbles. *11th International IEEE EMBS Conference on Neural Engineering (NER'23).* Baltimore, MD, Apr. 2023. (Poster presentation)
8) H. Charkhkar. The Integration of Ottobock Genium and Neural Interface to Restore Sensation to Lower Limb Amputees, *Internal presentation to the Ottobock R&D department*, Jun. 21, 2023. (Invited talk)
9) H. Charkhkar. The Power of Connection: Restoring Neural Pathways in Lower Limb Amputation, *Musculoskeletal Research Program 2023 Seminar Series*, Jun. 14, 2023. (Invited talk)
10) H. Charkhkar. Bidirectional Neuroprosthesis to Restore Sensory and Motor Function in People with Lower Limb Amputation, *Orthotic and Prosthetic Innovative Technologies (OPTech) Conference*, Minneapolis, MN, May 20, 2023. (Invited talk)
11) H. Charkhkar. A bidirectional neuroprosthesis for individuals with lower limb loss: technology development and functional impacts, *Bioengineering Seminar at George Mason University*, Fairfax, VA, Apr. 13, 2023. (Invited talk)

12) H. Charkhkar. Design, development, and deployment of a mobile app user interface for a sensory neuroprosthesis, *Advanced Platform Technology Monthly Town Hall*, Cleveland, OH, Feb. 6, 2023. (Invited talk)
13) G. Pinault, H. Charkhkar. Neural interface technology to restore sensory and motor functions in individuals with lower limb loss, *Advances in Amputation Surgery International Conference*, Hospital for Special Surgery (HSS), New York, NY, Jan. 27, 2023. (Invited talk)
14) Connecting Lower Limb Prostheses to the Nervous System: Benefits, Challenges, and Promises, *MetroHealth Center for Rehabilitation Research Seminar*, Cleveland, OH, Nov. 16, 2022. (Invited talk)
15) 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)
16) 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)
17) 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)
18) 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)

- **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**

- Popular Mechanics Article featuring an interview from Dr. Hamid Charkhkar: Everything You Need to Know About Proprioception, Your Body's 'Silent' Sixth Sense'

- Podcast featuring Dr. Hamid Charkhkar: Biomechanics on our Minds, Episode 55: Proprioceptive Prostheses and Clinical Impact | Hamid Charkhkar and Anna Smith

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: Eileen Petros
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 on cognitive load during ambulation

Name: Lindsey Hauck
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 determine stimulation thresholds

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: Eileen Petros
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 on cognitive load during ambulation

Name: Daekyoo Kim
Project Role: Postdoctoral Fellow (Technical)
Researcher Identifier (e.g. ORCID ID): 0000-0002-6123-2900
Nearest person month worked: 26
Contribution to Project: Designing and conducting balance and gait assessments and analyzing biomechanical data from participants using sensory neuroprosthesis

Name: John Schnellenberger
Project Role: Biomedical Engineer (Technical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Technical Support for hardware required for stimulation, development of external neural stimulator

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: Dakota Noble
Project Role: Biomedical Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2
Contribution to Project: Assisting in Genium Technical Development, project management and report preparation

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: 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: Subject Scheduling, Point of contact with Physicians

Name: Jessica Jarvela
Project Role: Study Coordinator (Clinical)
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: IRB Updates, Regulatory & Training Compliance

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 collaborator. Ottobock provided us with a Genium Knee prosthesis 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.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: