

**Advanced Platform Technology Center (APTC)
Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC)**



A VA Research Center

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**ANNUAL REPORT
For Activities during the period: October 1, 2016 – September 30, 2017**

NARRATIVE SUMMARY

KEY IMPACTS

1. Gold medal win at first Cybathlon brings international attention to VA technology.



In front of a sold-out arena, research participant Mark Muhn (*right*) pedaled his way to victory in a record time of 2:58, beating his opponent by an incredible 1:10, in the functional electrical stimulation bike race at the first international Cybathlon (“Cyborg Olympics”) in October 2016 in Zurich, Switzerland. Dr. Ronald Triolo (*right*) and team pioneered applications of this technology to help individuals with leg paralysis to exercise, stand and take steps, and even maintain their balance while standing or sitting. For the competition, a Catrike® was customized with special sensors that relayed the position of the rotating pedals to a small wearable computer that coordinated delivery of electrical pulses that caused the cyclist’s legs to extend and retract to approximate a cycling pattern. The enabling technology applies small electrical currents to the nerves in the trunk, hips and legs to cause the otherwise paralyzed muscles to contract. This Gold medal win garnered over 40 news articles and interviews, and brought news reporters, including the **Emmy-winning HBO VICE**, to Cleveland to learn more about this technological breakthrough. The episode of VICE, titled “Black and Blue & Our Bionic Future,” aired on March 24, 2017.

2. VA technology designed to reactivate the sense of touch featured on the cover of Science Translational Medicine and an episode of CNN’s Great Big Story.



APTC Director of Engineering, Quality and Regulatory Affairs and Core Investigator, Dustin Tyler, Ph.D., published an article titled “The neural basis of perceived intensity in natural and artificial touch” on the cover of Science Translational Medicine (STM). The article has been highlighted in 65 popular press articles and viewed over 14,000 times on the STM website. This article focused on direct stimulation of nerves via implanted electrodes in two amputees to help understand how levels of intensity are perceived and how tactile sensory feedback is transmitted. By modulating the number of nerve fibers stimulated and the frequency of stimulation, sensory information was transmitted in such a way that the amputees could distinguish distinct levels of physical touch intensity.

Results suggest that prostheses outfitted with sensory capabilities can provide a more natural feel to artificial touch through distinctive sensory feedback. **CNN’s Great Big Story** also featured this technology in an episode titled “For Amputees, Reactivating the Sense of Touch.” This episode was released in January and has over 20,500 views. <https://youtu.be/lrn5HbQjkm8>

3. New blood clotting sensor technology licensed and clinical trials started at LSCVAMC.

The ClotChip, a portable sensor that can assess the clotting ability of a person’s blood 95 times faster than existing methods, was licensed to Cleveland-based company XaTek in December 2016 with a goal of bringing it to market within the next three years. Developed by APTC Investigators Drs. Pedram Mohseni, Evi Stavrou, Michael Suster and Umut Gurkan, this point-of-care (POC) device provides a rapid assessment of the integrity of clotting factors and platelet activity.



Graphic by Grace Gongaware

Currently, such results are obtainable only with specialized laboratory testing that can take > 24 hours for results. Because the device works so quickly, emergency responders could use it at the POC to determine whether a patient in trauma is on a blood thinner medication. Dr. Stavrou presented the technology at the American Society of Hematology annual meeting and is leading clinical trials for a pilot study, funded by the American Heart Association and XaTek Innovative Diagnostic Solutions. If the device proves effective in that initial evaluation, XaTek plans to launch a full clinical trial within the following two years, and then seek FDA approval. Funding for the research was provided by the Case-Coulter Translational Research Partnership, the APTC at LSCVAMC and the Case School of Engineering's San Diego-based wireless health program.

4. Long-term evaluation of implanted medical device shows lasting benefits for spinal cord injured participants.



APTC Core Investigators Rudi Kobetic and Drs. Gilles Pinault and Ronald Triolo along with APTC staff published the article, “Long-Term Performance and User Satisfaction with Implanted Neuroprostheses for Upright Mobility After Paraplegia: 2- to 14-Year Follow-Up” in the *Archives of Physical Medicine and Rehabilitation*. This article quantifies the long-term (6.2 ± 2.7 years) effects and functionality of lower extremity (LE) neuroprostheses (NPs) for standing (*right*), transfers, stepping, and seated stability after spinal cord injury in 22 participants. Approximately 60% of the participants maintained usage of their implanted NPs for exercise and daily functioning for more than 10 minutes per day on nearly 50% or more of the days monitored. Ninety percent of the first-generation and 98% of the second-generation implanted NPs still functioned after six years. Almost all participants reporting being very or moderately satisfied with their system. Overall,

the technical and clinical performance of implanted LE NPs generally remained consistent for 22 participants after an average of 6 years of at-home use, suggesting that implanted LE NPs can provide lasting benefits to the spinal cord injury community.

5. APTC Investigators secure multiple medical inventions important to Veteran's health.

APTC continues to be highly productive in the intellectual property arena. Investigators Drs. Hess-Dunning, Schiefer, Triolo, Tyler, and Zorman were awarded a total of four new patents this fiscal year for: 1) an assembly for stimulating motor units, 2) delaying muscle fatigue via stimulation, 3) modular interconnect system for implantable devices, and 4) implantable cuff that delivers stimulation and records neural activity. APTC's collaborative partner CWRU submitted 34 patent applications for APTC Investigators (including 3 Continuation, 1 Divisional, 2 European, 1 China, 2 US, 5 PCT, 15 Provisional, and 5 Utility). APTC Investigators continue their technology transfer productivity with 23 invention disclosures.

6. VA Innovator's Network awards APTC Investigators and staff grants; leads to partnering with leading product and innovation firm.



APTC investigators and staff received five VA Innovator's Network awards. Two "Spark Grants" were awarded to Dr. Frank Jacono to develop a wearable health prototype for continuous blood pressure estimation and a wearable sensor to dynamically estimate body position and automatic fall detection. Dr. M. Kristi Henzel and Kevin Foglyano were awarded "Seed Grants" to, respectively, further develop a sensor suite to warn power wheelchair users of improper foot position on their footplate, and to expand the overground biking program by adding the option for surface stimulation that any disabled Veteran with a spinal cord injury can take advantage of it. A "Spread Grant" was awarded to Dr. Ronald Triolo to finalize the design and fabricate self-leveling walkers (*right*) that automatically adjust the lengths of the front and rear legs for stability on steps and slopes. With these awards, 1) Dr. Jacono's team has collected data and is still in the test and development phase of their projects, 2) Dr. Henzel's team has

started circuit design for different type of footplates, calibrating the pressure sensors, and will use their pilot data in a grant proposal to CDMRP SCIRP, 3) Mr. Foglyano's team purchased more bikes and equipment, made modifications to the biking technology, submitted for IRB approval, and will be submitting a proposal to the Innovator's Network in the fall to sustain the program, and 4) Dr. Triolo's team and product innovation partner Nottingham-Spirk redesigned and fabricated two prototypes of the walker and plan to submit a proposal to the Innovator's Network to fabricate more walkers and conduct a clinical evaluation at LSCVAMC and up to four other VA sites. At the VA Innovation Demo Day in August, the progress of all five projects was presented and Dr. Triolo's was **voted the Audience Favorite** out of over 90 innovations nationwide.

KEY SERVICES

1. LSCVAMC designated a National VA Parkinson's Disease Consortium Center, with Dr. Aasef Shaikh as the Director.

The LSCVAMC has been designated a National VA Parkinson's Disease Consortium Center due to the tremendous clinical research and clinics related to Parkinson's Disease and movement disorders being conducted by Core Investigators and Physicians, Drs. Aasef Shaikh and Mark Walker, along with the many Neurologists that offer specialized treatment. The 51 established Consortium Centers ensure accessibility and continuity of specialized care for Veterans afflicted by parkinsonism, regardless of locality. Dr. Shaikh is the Director of the LSCVAMC Center.

2. VA Healthcare Robotics Roundtable with Dr. David Shulkin in Washington D.C. selected Dr. Ronald Triolo for the invitation-only event.

An invitation-only VA Healthcare Robotics Roundtable was held on June 27, 2017 by Secretary of Veterans Affairs Dr. David Shulkin. Dr. Ronald Triolo, Executive Director of the APTC, was among a select group of subject matter experts in the healthcare robotics field across industry and academia. The purpose of the event was to understand the current robotics landscape, the pipeline of developing capabilities, and the trends driving new inventions and market development to enhance foundational services for Veterans. The goal was to create a short and long term strategy,

outlining future directions to support Veterans and next steps in developing a robust robotics practice in VA.

3. APTC Summer Internship Program inaugural year yields productive outcomes for both interns and mentors.

The summer of 2017 was the inaugural year for the APT-Summer Internship Program (APT-SIP). APT-SIP is for undergraduate science, technology, engineering, and math students who have completed at least their sophomore year of college. The 10-week program allows students to participate in cutting-edge biomedical research projects under the mentorship of our world-class investigators. APTC received 16 applications for 4 slots into the labs of Drs. Jeffrey Capadona, Evon Erefej, Matthew Schiefer, and Ronald Triolo. Dr. Schiefer led the program by coordinating opportunities and activities for the interns. They attended regular Neural Engineering Center Seminars and SOURCE Tuesday Lunch & Learn Sessions as CWRU. They also had the opportunity to present posters and attend conferences. All interns have continued working in their respective mentor's lab. Three are now co-authors on APTC publications and another had an abstract accepted to the Biomedical Engineering Society 2017 conference.

4. New inductions to AIMBE College of Fellows of Core Investigators.

Core Investigators Drs. Jeffrey Capadona and Dustin Tyler were inducted into the prestigious College of Fellows of the American Institute for Medical and Biological Engineering (AIMBE) during the Induction Ceremony at the National Academy of Sciences in Washington, D.C. in March. Dr. Capadona was selected for outstanding contributions in neural interface technology, while Dr. Tyler was selected for outstanding contributions to the design, implementation, and assessment of neuroprostheses and assistive technologies that enhance mobility after neuromuscular disability.

5. APTC co-sponsors the Cleveland Neural Engineering Workshop.

The APTC co-sponsored the 4th Cleveland Neural Engineering Workshop (NEW), a biennial workshop that brings together leaders committed to providing a collaborative multi-disciplinary platform for neural based solutions to prosper. Core Investigator and Associate Director, Dr. Dustin Tyler, continued to provide pivotal leadership in structuring and leading the workshop. APTC staff provided support for the event. Participants in attendance represented the federal government, academia, industry and non-profit sectors. ClevelandNEW supports the mission of the APTC by promoting the adoption of new technologies to serve the clinical needs of Veterans with motor, sensory and cognitive deficits and limb loss. A strategic "roadmap" of the event, which seeks to address the key barriers to progress in the neuromodulation field and identify strategies and actions that will coordinate activity to overcome those barriers, is expected in early 2018.

6. APTC Distinguished Lecture Series brings in speakers from around the country.

In late 2016, APTC began the "APT Center Distinguished Lecture Series" to bring in experienced researchers focusing on research and rehabilitation efforts nationally. Presentations included 1) control mechanisms of human locomotion and applications to robotics and powered prostheses and orthoses, 2) devices to improve gait by exploiting biomechanical workarounds for lost function, and 3) neural culture platform that can be used to screen biologically-active surface coatings and mechanical properties in 3D.

7. APTC participates in outreach and education activities at LSCVAMC and in the community.

Dr. Matthew Schiefer lent his expertise working with amputees during a focus group for local college students' Adaptive Manufacturing Certification capstone projects. The students were required to design a tool that attaches to the body or an inanimate object to allow easier access for disabled individuals. At the meeting, they presented and discussed their ideas with potential users (and developers) of the product.

Kiley Armstrong, a trainee of Dr. Ronald Triolo, was invited to present at St. Ursula Academy's Women in Health Science Professions program, where students meet each month with women in the health science field. Kiley described her experiences in biomedical engineering, neuromuscular stimulation, and prosthetics and orthotics, and gave college advice. The students were unaware of the research being conducted at APTC and very excited to see a new aspect of the health science field.

APTC Investigators and staff hosted VIP tour groups, including family members of Congressman Louis Stokes (VAMC namesake) and staff representatives/congressional aides from many of the Congressional Offices throughout NEO, as well as representatives from some Veteran Service Organizations. LSCVAMC's Take Our Daughters and Sons to Work Day visited APTC for interactive demos and a talk with 7-12 grade students about engineering careers.

8. APTC Core Investigators contribute to journals and conferences in varying roles.

APTC Core Investigators contribute their time and expertise as editors (8) and on editorial boards (9) for 15 journals, and to 7 conferences as chair (1), co-chair (1), committee co-/chairs (2), abstract reviewers (3), and on the conference editorial board (1).

9. APTC Core Investigators serve on VA Grant and Career Award Review Panels.

Drs. Bogie, Capadona, Marasco, McDaniel, Shire, and Triolo contribute their time and expertise to review applications for VA RR&D Merit Reviews, SPIRE and other VA funding mechanisms. Drs. Bogie, Marasco, Shaikh, Stavrou, Triolo, Tyler, and Walker served as grant reviewers for NIH, NSF (Swiss), DoD, and other international and local organizations.

Summary

The APTC continues to advance the state of rehabilitation technology, fulfill our mission and improve the lives of Veterans and the general population through important discoveries, contributions to community outreach, and cutting-edge intellectual property that lead to active industry conversations and licensing opportunities. This past year, the APTC has received international recognition through research projects used in competition and high profile DoD programs, demonstrating that core research programs of the APTC are impactful and vital to Veterans, other federal agencies, and the general public. Of great pride to the APTC is the success and development of our young investigators and interns who further our mission in new areas. As we enter FY18, APTC will continue to pursue innovative and translational work in **Prosthetics/Orthotics, Health Monitoring & Maintenance, Neural Interfacing, and Enabling Technologies**. Our investigators, engineering, quality and regulatory staff continue to extend the capabilities of VA researchers and health care professionals at the local, regional, and national levels.