

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



**A VA Research Center**

<http://www.aptccenter.research.va.gov>

**ANNUAL REPORT**

**For activities during the period: October 1, 2018 – September 30, 2019**

## **NARRATIVE SUMMARY**

### **KEY IMPACTS**

#### **1. VETERANS OUTREACH: Improving quality of life one Veteran at a time**



APTC staff, students, and research participants were involved in two Challenge America: Makers for Veterans (CAMVETS) events to develop innovative technical solutions for the unmet needs or challenges faced by individual Veterans with physical disabilities. Each event was a 3 day make-a-thon to create an innovate solution for a specific Veteran. APTC was instrumental in organizing and bringing the first ever CAMVETS in the United States to the LSCVAMC in Spring 2019. APTC staff worked with a wheelchair-dependent Army Veteran who has adult onset adreno leukodystrophy with ataxia to create a device that could transition him easily from his wheelchair to his

recumbent bike, tractor, and four-wheeler. All 10 teams developed a working prototype solution for their individual Veteran and filed provisional patents, 2 of which are being further pursued by the VA Technology Transfer Program. APTC “makers” in the event included Drs. Clay Kelly and Steve Majerus, and biomedical engineer Aiden Friederich. For the Fall 2019 CAMVETS, APTC makers Frank Zitko, Will Rasper, Kevin Foglyano, Kristen Gelenitis, Dr. Steve Majerus, Lisa Lombardo, Cody Dulaney, and two other employees from LSCVAMC formed a team for a wheelchair-dependent Air Force Veteran with a central nervous system disorder to more effectively use his overhead ceiling lift to perform independent squats and leg stretch exercises. Through our efforts, the Veteran re-engaged with healthcare providers at LSCVAMC and reconnected with the clinical services and other resources that he needed. The APTC team was awarded the Community Choice Award. The impact of CAMVETS is immeasurable due to the personalized treatment of each Veteran, and the APTC plans to play an increasingly expanded role in future events.

#### **2. ARCHITECTURAL ACCESS FOR VETERANS: Leveling the world with the press of a button**



The Self-Leveling Walker (SLW), an innovation conceived by Dr. Ronald Triolo, patented by the VA Technology Transfer Program (US 9,119,757B2), and prototyped/field tested by APTC staff Frank Zitko and Stephanie Bailey, meets an unmet market need for a new rehabilitation tool and mobility aid that can continuously adjust to meet the demands of independently negotiating inclined surfaces or stairs. The SLW is potentially a more affordable solution for stair navigation compared to the purchase and installation costs of bilateral handrails, ramps, or stair lifts. It also has the potential to accelerate the return to an unadapted home by reducing the time and cost of extended rehabilitation stays to safely master stairs. The legs of the SLW are coupled such that, with the press of a button, the front legs retract and the rear legs lengthen (and vice versa) with the application of gentle downward pressure from bodyweight. Releasing the button locks the legs in position until the next change in surface. When the legs are locked at the same length, the device performs exactly like a standard walker on level surfaces, making

it the only walker a user will ever need regardless of the environment. The device was successfully field-tested in two other VA Medical Centers (Cincinnati and Seattle) on almost 50 disabled veterans. The extensive interviews our team conducted with 100 rehabilitation professionals and potential consumers confirmed the value that the device would have to clinicians and patients alike. In 2018 at LSCVAMC alone, over 3,100 various types of walkers and 566 stair gliders (cost=\$3,000+ each) were issued by the Prosthetics & Sensory Aids Service to Veterans who might benefit from the new intervention. The next steps are to remove the remaining barriers to commercialization by optimizing the design for manufacturability and testing it to applicable standards. Licensing negotiations are underway for eventual commercial translation.

### 3. EXERCISE FOR PARALYZED VETERANS: Improving the health through biking and rowing



The health and fitness of paralyzed Veterans is being improved via novel exercise interventions that combine surface neural stimulation with commercially available exercise equipment. Recumbent tricycles and stationary rowing machines are adapted for Veterans with spinal cord injury or disorder (SCI/D), stroke, and other paralyzing neurological conditions to communicate with a new, easy-to-use, tablet-based interface that works with a user-friendly surface stimulation system developed by the APTC. We have transferred the system outside of the laboratory to the SCI/D Service at the medical center for physical and recreational therapists to apply

clinically with their Veteran clients. Dr. John McDaniel and Ms. Lisa Lombardo, exercise physiologist and research physical therapist with the Center, are taking advantage of the new platforms to examine the physiological effects of exercise and optimize treatment paradigms for maximal benefit. Nine participants have enrolled and show positive changes in muscle strength and cardiovascular fitness, as well as feelings of improved well-being and overall better health. Dr. McDaniel recently received funding from the Nielsen Foundation to translate this work to other VA Medical Centers, Kent State University, a local adapted fitness center (Buckeye Wellness, Valley View OH), and Craig Rehabilitation Hospital in Colorado.

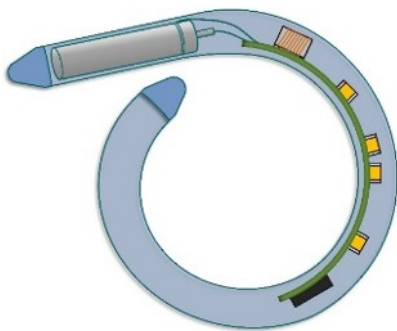
### 4. MOBILITY FOR VETERANS WITH SCI: Exoskeletal-Assisted Walking



The use of a motorized exoskeleton can enable wheelchair-dependent Veterans with spinal cord injury (SCI) to stand and walk in the community alongside their peers. It provides weight-bearing exercise and the ability to interact with others at eye level. This Cooperative Studies Project (CSP), which originated at the Bronx VA and is being led by Dr. Kristi Henzel the site PI at the LSCVAMC, aims to enroll 160 Veterans assigned to either a standard of care group, who continue their usual activities in their wheelchairs, or an Exoskeletal-Assisted Walking (EAW) group, who are trained to safely operate and are issued an EAW device for four months of use in their homes and communities. The impact on quality of life (QOL) and overall health are being monitored and compared to the standard of care of wheelchair use alone. Increased QOL is anticipated along with improvements in reported bladder, bowel, and pain issues, cholesterol profiles, fasting plasma glucose, and

insulin levels, as well as decrease in total body fat mass and sleep disturbance, and increases in physical functioning and social and emotional health. *Currently, we are not able to share results or enrollment numbers due to CSP restrictions.*

### 5. TREATING INCONTINENCE: Addressing a major concern of aging or paralyzed Veterans



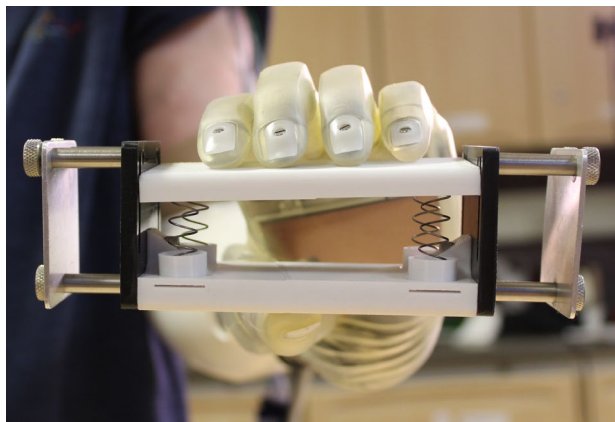
The global prevalence of urinary incontinence is enormous, with approximately 60% of men and women over age 60 experiencing stigmatizing symptoms of urine leakage. Furthermore, 80% of individuals with SCI/D have lower urinary tract dysfunction and limited sensation of bladder fullness. Uncontrolled urine leakage can be especially problematic in this group, since it sharply increases the risk of pressure ulcer infection and can set off a cascade of negative health events. Veterans are disproportionately affected by urinary incontinence, who consistently rank better treatment options among their most important health concerns. Led by Dr. Margot Damaser, our Incontinence Technologies program approaches this critical health issue from three complementary directions: 1)

Developing new sensors for improved diagnosis and personalized medicine, 2) Integrating them into new neurostimulation treatments for Veterans with SCI/D, and 3) Providing clinicians with new tools to better understand how the nervous system and bladder interact, thereby enabling the discovery of new interventions. We are currently negotiating a Joint Development Agreement with a major manufacturing company for



manufacturing the Incontinence Technologies, as well as negotiating a license of our issued patent, US #10,478,113B2. We have also executed an Evaluation Agreement with Hologic, Inc. to enable market research of one technology, the UroMonitor.

## 6. SENSATION FOR VETERANS WITH LIMB LOSS: Prosthetic hands and feet that feel



APTC Core Investigators are the world leaders in restoring useful and naturalistic sensation to Veterans with upper and lower limb loss. Drs. Paul Marasco, Ronald Triolo, and Dustin Tyler are advancing the field of prosthetics and implanted sensory neuroprostheses that allow amputees to feel the interactions of their prostheses with the environment as if their limbs were intact. Forty-one Veterans have been enrolled to their studies and five have taken their sensory-enabled upper limb prostheses for long-term at-home testing. The projects are moving beyond sensory mapping to 1) Determining how amputees transition to and interact with their new sensory prostheses, 2) Understanding how the subjects choose to use

their devices, and 3) Identifying when the device is perceived to be most useful. The goal is to have users think of their prostheses as parts of their bodies, instead of inanimate tools connected to their residual limbs. In August, Dr. Tyler published an account of the overwhelmingly positive results of a four month at-home trial of the implanted upper limb sensory neuroprosthesis in *Frontiers of Neuroscience*, which has already garnered 1,900+ views and almost 400 downloads. Drs. Marasco and Triolo were both published in *Nature Scientific Reports* and have accumulated 360+ and 670+ article views, respectively. Plans include initiating a VA-sponsored 15 subject clinical trial of the completely implanted upper limb sensory neuroprosthesis in preparation for pre-market approval via the Humanitarian Device Exemption, extending the lower limb program from trans-tibial to trans-femoral amputees, and pursuing applications in limb loss due to diabetes.

## KEY SERVICES

### 1. APTC Investigators organize IEEE BioCAS conference & NeuroCAS workshop

The IEEE Biomedical Circuits & Systems (BioCAS) 2018 Conference, a premier international forum for interdisciplinary research and development activities at the crossroads of medicine, life sciences, physical sciences, and engineering that shape tomorrow's medical devices and healthcare systems, was Co-Chaired by APTC Investigators Drs. Pedram Mohseni and Dustin Tyler. Drs. Steve Majerus and Michael Suster from the APTC served as BioCAS Demo Session Co-Chairs. This conference brought together 265 members of our communities to broaden their knowledge in emerging areas of research at the interface of the life sciences and the circuits and systems engineering. Immediately after the conference was a 1.5-day collaborative workshop, NeuroCAS 2018, which was Co-Chaired by APTC Investigator Dr. Matt Schiefer to explore challenges from across the areas of central and peripheral/autonomic nervous system interfaces through a mixture of structured discussions followed by brainstorming and informal networking.

### 2. APTC engages LSCVAMC in workshop for nonprofit *RePlay for Kids*

Participation more than doubled at this year's *RePlay for Kids* toy adaptation and repair workshop with 52 staff and Veterans volunteering to modify about 75 mainstream, battery-powered toys with external switches so that children with disabilities can use them. *RePlay for Kids* is a nonprofit organization for the repair of therapeutic toys and assistive technologies for children with disabilities. At the workshop, Veterans and volunteers were shown how to adapt mainstream, battery-powered toys with external switches so that children with physical and developmental disabilities could enjoy them. Fox 8 Cleveland covered the event, interviewing some of the volunteers. APTC Executive Director Dr. Ronald Triolo has been on the Board of Directors for *RePlay* since May 2001 and was elected Board Chair in 2018.

### 3. APTC participates in outreach and education activities in the community

In addition to conducting approximately 30 tours of our facilities at LSCVAMC this fiscal year, APTC investigators, staff, and trainees were a part of numerous outreach activities in the community and the medical center. Below are a few examples.

The Mean Green STEM Machine is a program designed to expose Cleveland students in grades 2-7 to a variety of Science, Technology, Engineering and Math (STEM) topics, build awareness of career opportunities in STEM, and introduce them to diverse STEM practitioners. APTC graduate students Breanne Christie, Aidan Friederich, and Nabeel Chowdhury hosted a hands-on neuroscience session that highlighted information important to Veterans health, including brain anatomy and function and how it might be compromised by trauma or disease.

Summer Research Experiences for high school students were provided by the APTC, in conjunction with the Cleveland FES Center. The two-week observational experience enabled 12 participants to sit in on patient visits with Dr. Clay Kelly in the Prosthetics Clinic, learn about creating prosthetic limbs in the Prosthetic Fabrication Laboratory, and visit with investigators and staff at 22 different labs to learn more about the research projects, career opportunities, and rehabilitative services in the VA.

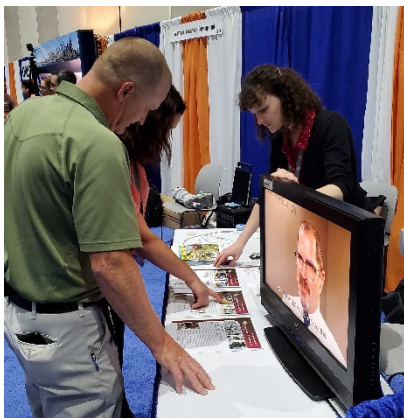
### 4. New appointments for APTC Investigators

Dr. Jonathan Baskin, APTC Associate Director for Translation, was recently appointed to the Office of Translation and Innovation (OTI) at CWRU, where he will represent the interests of LSCVAMC in general and APTC in particular. Dr. Baskin will fully utilize this opportunity to gain access to the University's substantial translational resources, which can extend and complement those of the VA, and apply them to accelerate the dissemination and eventual commercialization of Center developments to maximize their impact to Veterans.

Dr. Kath Bogie was elected to the Board of Directors for the Wound Healing Society (WHS) where she has served on the Education Committee since 2011. The mission of WHS is to improve wound healing outcomes through science, professional education, and communication. Dr. Bogie is serving a three-year term (2018-2021) and attends regular meetings.

Dr. Mark Weidenbecher was appointed to the Otolaryngology Veteran Affairs Committee, an Academic/Foundation committee of the American Academy of Otolaryngology – Head and Neck Surgery/Foundation (AAO-HNS/F). Committee members voluntarily apply to serve two-year terms which will afford Dr. Weidenbecher the opportunity to help advance the science and art of medicine related to otolaryngology, specifically as it is related to Veterans healthcare. He joins Dr. Jonathan Baskin, who has been a member since 2017, in providing this service to Veterans.

### 5. APTC participates in the VA RR&D Roadshow at AOPA in San Diego



Investigators and research participants with upper or lower limb loss in the sensory restoration projects of Drs. Dustin Tyler and Ronald Triolo, including one Navy Veteran, demonstrated their systems at the American Orthotic and Prosthetic Association (AOPA) National Assembly at the San Diego Convention Center as part of the Rehab Roadshow organized by VA Office of Rehabilitation Research & Development (RR&D). This activity highlighted the impact of the technologies developed by RR&D, and the Center's commitment to translating it to disabled Veterans. During the meeting, Dr. Tyler moderated a special symposium entitled *Prostheses that Feel: Clinical and Technical Considerations for Restoring Sensation to Upper and Lower Limb Amputees* organized by APTC investigators and staff Drs. Hamid Charkhkar, Emily Graczyk, and Courtney Shell to present our recent advances in restoring naturalistic sensation after limb loss. There were over 2,000 attendees at this year's AOPA, which provided an opportunity for us to help RR&D disseminate information to orthotic, prosthetic, and pedorthic professionals.

## 6. APTC Summer Internship Program yields productive outcomes for interns and mentors

The Center's Wen H. Ko Summer Internship Program had a very productive 3rd year. We received 28 applications and accepted 5 undergraduate students into the labs of Drs. Hamid Charkhkar, Allison Hess-Dunning, Steve Majerus, Andrew Shoffstall, and Dustin Tyler. Dr. Hess-Dunning led the program by coordinating opportunities and activities for the interns. They attended regular Neural Engineering Center Seminars and SOURCE Tuesday Lunch & Learn Sessions at CWRU and had the opportunity to interact with Veterans during the course of active VA research projects and present posters summarizing their experiences. Four interns have continued working with their mentors on VA studies. Many commented on how much hands-on experience they were given by their mentors, and how they appreciated being trusted to work out their individual pieces of their projects.

## 7. APTC helps senior leadership understand the translational value of pre-clinical research to Veterans



APTC Investigators Drs. Margot Damaser (IACUC Chair), Ronald Triolo, and Dustin Tyler participated in a two-day site visit to LSCVAMC by Drs. Carolyn Clancy, Deputy Under Secretary for Discovery, Education and Affiliate Networks, Rachel Ramoni, Chief R&D Officer, and Michael Fallon, Chief VMO to learn more about the results of our pre-clinical research studies involving canine models translation into new treatments for disabled Veterans. Specific examples of how pre-clinical trials of prototypes of the Uromonitor, peripheral nerve cuff electrodes, and other APTC technologies led to devices that are now approved for human use deployed in Veterans

were highlighted. The group toured our laboratories and met Veterans who demonstrated the systems developed and validated in animal models, including a Navy Veteran with lower limb loss participating in our sensory neuroprosthesis project, and an Army Veteran taking advantage of our rowing exercise program. Speaking with our researchers and subjects gave VA Senior Leadership a better understanding and appreciation for the positive outcomes that have been derived from pre-clinical research that will be helpful in crafting future VA policy.

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

APTC Core Investigators contribute their time and expertise as editors (1) and on editorial boards (8) for 9 journals, and to 12 conferences as co-chairs (3), abstract reviewers (2), session chairs (3), and on conference editorial boards (1), organizing committees (4), and program committee (3).

## 9. Core Investigators serve on grant review panels

Drs. Capadona, Erefej, Shire, and Tyler contribute their time and expertise to review applications for VA RR&D funding mechanisms. Drs. Bogie, Damaser, Marasco, and Tyler served as grant reviewers for NIH, DoD, NSF and other non-federal 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 made important advancements in their projects, increased mentoring capabilities, and engaged Veterans through research projects and conference chairing, 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 FY20, APTC will continue to pursue innovative and translational work in the clinical application areas of **Prosthetics/Orthotics, Health Monitoring & Maintenance, Neural Interfaces**, as well as developing and disseminating new **Enabling Technologies**. Our investigators, staff, and trainees continue to extend the capabilities of VA researchers and health care professionals at the local, regional, and national levels.