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

VA RR&D Research Center

http://www.aptcenter.research.va.gov

ANNUAL REPORT
For Activities during the period: October 1, 2020 – September 30, 2021

2021 Annual Report for activities during the period October 1, 2020 to September 30, 2021

Advanced Platform Technology Center (APTC)

Louis Stokes Cleveland VA Medical Center (LSCVAMC), Cleveland, OH

RR&D Center

RR&D Center funding number: A1871C

Award Dates: January 1, 2020 to December 31, 2024

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Mission of the APT Center
To advance innovative technologies along the translational pathway that address the health and independence of disabled Veterans.

Vision of the APT Center
To be a national leader and valued partner for the discovery and clinical implementation of medical, rehabilitative or restorative technologies for the well-being of Veterans.

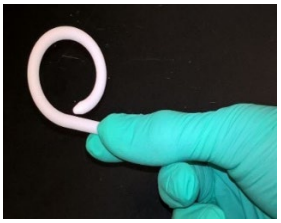
APT Center research sites
The APT Center is located on the premises of the LSCVAMC and operates in partnership with Case Western Reserve University (CWRU) Schools of Engineering and Medicine. In addition, our Core Investigators collaborate with clinicians and researchers located at University Hospitals Cleveland Medical Center (UH), MetroHealth Medical Center (MHMC), and Cleveland Clinic Foundation (CCF) and other institutions nationally. The APT Center capitalizes on significant local expertise in the areas of *microelectronics, micro/nanofabrication, materials science and mechanics* to address unmet needs of disabled Veterans and the broader rehabilitation community. Center research and development activities are focused on four clinical application areas: **Prosthetics & Orthotics, Health Monitoring & Maintenance Neural Interfaces and Activity-Based Neurorehabilitation.**

Narrative Summary
KEY IMPACTS

1. APT Center Breakthrough Point of Care Device Gets Optimized for Trauma Care

APT Center Investigators, Drs. Michael Suster and Pedram Mohseni, were awarded two grants totaling $90,000 in 2021 to advance their patented ClotChip technology for trauma care applications. The device quickly analyzes a patient's bleeding risk using minimal amounts of blood in less than 30 minutes. Clinical studies have shown ClotChip is able to collect blood and platelet measurements for patients in states which cause them to bleed excessively. Current developments include optimizing ClotChip to assess blood coagulation in patients with a tendency toward excessive clotting.

2. Uromonitor Completes First Human Trial and Moves Forward with New Enhancements



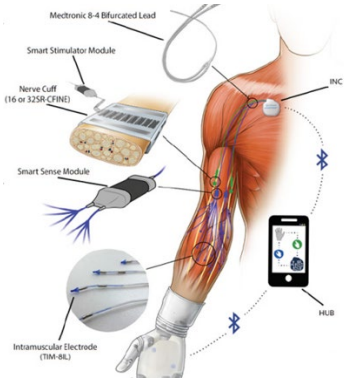
APT Center Investigators Drs. Steve Majerus and Margot Damaser were granted a 3-year, $890,000 VA Merit Award for their project involving the UroMonitor, which helps treat bladder disorders in Veterans with spinal cord injury or neurodegenerative conditions. The device recently finished its first human trial in 11 adult women with refractory overactive bladder disorder. The next phase will look into the feasibility of using a new type of nerve stimulation, called triggered sacral neuromodulation. The UroMonitor sensor is inserted into the bladder and transmits a feedback signal enabling bladder stimulation at critical times during bladder filling to prevent urine leakage.

3. Five APTC Investigators/Staff Awarded Funds Through the VHA Innovation Investment Program

Their innovations include:

- A unique slipcover designed to protect wheelchairs from the elements (Stephanie Baily)
- A tablet for a rowing machine with surface stimulation for spinal cord injury (Lisa Lombardo)
- A point of care ultrasound to determine thrombosis risk in hemodialysis (Dr. Steve Majerus)
- An upper extremity assisted bike to improve exercise for Veterans with lower body impairments (William Rasper)
- An ambulatory eye recording device for diagnosing dizziness at home (Dr. Mark Walker)

4. First iSens System is Implanted into a Veteran Research Participant



For those with limb loss, the iSens system enables the user to move the prosthesis by just thinking about moving their hand and it provides sensation that feels to the patient like the prosthesis is their hand. Dr. Dustin Tyler led a team of more than 60 scientists, clinicians, and engineers for the first-ever implant of the iSens system in a Veteran subject at the Louis Stokes Cleveland VA Medical Center in November. The operation resulted in the successful connection of all 96 communication channels between engineered systems and the patient. The subject was able to make different functional movements of their phantom limb and said they could 'feel their pinky finger for the first time in years.'

5. Technology Transfer Assistance Program to Support VA Inventors

APT Center engineer Stephanie Bailey is leading the Cleveland VA Medical Center's new Technology Transfer Assistance Program (TTAP), funded by the VA Technology Transfer Program. The goal of TTAP is to turn VA inventions from across the country into working, functional prototypes to better prime them for commercialization. The first TTAP project, delivered in 2021, was a shower bench prototype to assist those in wheelchairs with safe transfer into the bathtub.

6. Real Time Blood Pressure Sensing Technology to Address Hypertension

APT Center Investigators Drs. Jonathan Baskin and Dustin Tyler developed an approach that employs an implanted neuromodulatory system to address drug resistant hypertension. The Investigators demonstrated efficacy of the novel stimulation system in an acute human model, however, a vital element in this treatment modality is sensing blood pressure. Drs. Baskin and Tyler are currently running a pre-clinical study of a fully implanted extravascular blood pressure sensing technology that will measure blood pressure and heart rate, thus informing a control algorithm in real time and enable autonomous maintenance of a patient's blood pressure within a physician-defined therapeutic range.

KEY SERVICES

1. APTC Expands External Market Assessment and Veteran Engagement Panels

APTC engaged a new external consultant, Wave Strategy, to assist Investigators with market assessments for their technologies. Wave Strategy has successfully conducted assessments for Dr. Steve Majerus and Dr. Jon Baskin. The Veteran Engagement Panel program assists Investigators in incorporating the voices of Veterans into the design and conduct of their research & development activities. The qualitative researchers at the Cleveland VAMC IIRECC successfully conducted and reported their findings from the initial panel. In addition, they have begun working with Dr. Krisiti Henzel on the next panel.

2. APTC Engages Indigo Anchor to Provide Project Management Training

During the 2020 APTC External Review conducted by Indigo Anchor, project management training was identified as a need by investigators and staff. In 2021, Indigo Anchor kicked off training for the APTC engineering team on scrum project management methodology. Since then, the engineering team has continued weekly sprint sessions and is aligning investigators and staff on project priorities and progress.

3. APT Center Establishes Medical Monitoring Committee

APT Center established a Medical Monitoring Committee (MMC) which provides independent, ongoing quality assurance and evaluation of APT's studies. The MMC reviews human subject activities, adverse events, safety, study procedures and outcomes and factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study. The MMC was also designed to identify potential trends that may indicate previously unanticipated issues, which could affect the risk profile for subjects.

4. Core Investigators Make Significant Contributions to Journals and Committees

APTC Core Investigators contributed their time and expertise as editors / associate editors (10), on editorial boards (9), reviewers (14), committee members (18) and committee/session chairs (5). Of the many publications, Drs. Steve Majerus and Margot Damaser were awarded the first of the two Best Paper Awards of the Engineering and Urology Society (EUS) for their evaluation of their wireless ambulatory cystometry device,

UroMonitor, and Dr. Paul Marasco's work was featured on the cover of Science Robotics highlighting his development of a neural-machine interface for a bionic prosthetic arm that leverages the sense of touch.

5. APTC Acquires Nano-Jet Printer as a Shared Resource for VA Investigators

The Integrated Deposition Systems Desktop Nano-Jet Printer is capable of printing both conductive and insulating materials with extremely high precision, on the scale of microns. It is akin to a "3-D printer," but with greater accuracy for making small features. The printer is currently being used to fabricate the high-density in-line Connectors, printed implantable leads and wirelessly readable printed sensors to support VA Merit, SPiRE and Garverick Incentive awards granted to APT Center Investigators Drs. Doug Shire and Janet Gbur.

6. APT Center Supports Diversity in STEM

Dr. Kath Bogie received a $210,000 supplement from VA ORD to support VA researcher and ORD DEI Research Awardee Dr. Letitia Graves, in her 2-year project to determine how symptom science can be used to help explain, predict, and manage secondary health conditions following SCI. The APT Center also hosted its most diverse cohort yet of undergraduate summer interns from Case Western Reserve, Saint Louis and Youngstown State Universities. The students focused on projects supporting orthodontics materials research, intercortical microelectrode performance and neurostimulation of sensory nerves, among other projects.

7. APTC Integrates New Cleveland VA Technology Transfer Specialist

In August 2021, Dr. Emily Rosenthal joined the Cleveland VA Medical Center as the local VA Technology Transfer Specialist. The APT Center quickly introduced her and featured her at the APTC October 2021 Town Hall. In addition, she has been actively meeting with APTC Leadership team members and assisting Investigators with inventions and new technologies.

8. APTC Facilitates Connection with Robotic Startup

Through the APTC's connection with the VA Innovators Network, RIF Robotics, a startup looking to automate sterile processing, was referred to Dr. Jon Baskin. Dr. Baskin, the APTC Assoc Director for Translation, is now advising them on their technology by providing customer validation and market research feedback.

9. APT Center Expands Social Media Outreach and is Highlighted in Local and National News

APT Center researchers and participants have been featured throughout the year in local and national productions and on the APT Center's YouTube channel. Drs. Hamid Charkhar and Dustin Tyler were both featured on PBS Newshour and Cleveland's local FOX 8 News for their work in restoring movement and sensation to those with limb loss. Investigators and students have also been regularly featured on YouTube talking about the wide variety of research projects being conducted at the APT Center.

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 leads to active industry conversations and licensing opportunities. This past year, APTC investigators made important advancements in their projects, increased mentoring capabilities, and engaged Veterans through research projects, demonstrating that core research programs of the APTC are impactful and vital to Veterans, other federal agencies, and the public.