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Global Expertise in Neural Engineering

Cleveland FES Center

Report to the Community 2019

Robert Kirsch, PhD
Executive Director

Ronald Riechers, MD
Medical Director

Cover photo:
Training the Next Generation of Neurosurgeons: The Cleveland Course for Advanced Neuromodulation uses augmented reality technology to bring fundamental concepts to life.

Full story page 37.

Dear Friends and Colleagues

The Cleveland Functional Electrical Stimulation (FES) Center has been making great strides and significant progress expanding the research programs. The Cleveland FES Center has grown in consortium partners, research collaborations, and industry partnerships. We are extremely excited to continue driving FES research forward on all fronts.

The Cleveland FES Center is a global leader in neurostimulation and neuromodulation research addressing unmet rehabilitation needs of individuals with spinal cord injuries and neurological disorders. The Cleveland FES Center is made up of individuals who perform and support cutting-edge research focusing on the development and clinical translation of rehabilitation interventions.

I AM HUMAN is a documentary that explores what it means to be human by following the incredible research journey of Cleveland Veteran Bill Kochevar and the cutting-edge work of the Cleveland FES Center at the Louis Stokes VA Medical Center, Case Western Reserve University, and University Hospitals Cleveland Medical Center. The Cleveland Premiere & Panel discussion took place on Thursday, January 30, 2020 at the Hanna Theatre in Playhouse Square.

Advocates come in all shapes and sizes! Individuals including participants and families, sponsors, community and industry partnerships and institutions continue to drive our success. It is due to these relationships and their support along with the commitment of so many that we are closer to realizing our goal!

We encourage you to share our research and stories by connecting with us on social media through Facebook and Twitter. Together, we can continue to drive the research forward and share our successes on the journey!

Sincerely,

Robert Kirsch, PhD
Executive Director

Ronald Riechers, MD
Medical Director

Who We Are

A trans-disciplinary **alliance** of active, passionate and committed professionals, in science and medicine, specializing in the fields of biomedical and neural research, engineering, medicine and rehabilitation. We embrace an open-door, collaborative, compassionate, and inquisitive engagement.

Together, we translate academic knowledge, neural technology, and clinical practice into ***hope and progress.***

Redefining FES

Functional electrical stimulation (FES) is the use of small, artificially generated electrical currents that are safely and selectively applied to the central or peripheral nervous system to replace the actions of neurons that have been damaged by injury or disease. When applied appropriately, FES can “speak the language of the nervous system” and evoke desired actions by both activation and inactivation of various elements of the nervous system (e.g., peripheral nerves, spinal cord, brain). Because virtually all body functions are directly controlled or indirectly influenced by the nervous system, FES is thus a powerful, broadly applicable technique for evoking functional muscle contractions, reducing pain, and restoring balance in autonomic, spinal, and brain circuits. The FES Center is the most comprehensive and cohesive program in the world performing FES investigation that spans from basic to applied, and our investigators work on many different applications.

Investigators

Ajiboye, A Bolu, PhD
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Alberts, Jay, PhD
Cleveland Clinic

Anderson, Kimberly, PhD
MetroHealth Medical Center
Case Western Reserve University

Alexopoulos, Andreas, MD, MPH
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Baker, Kenneth, PhD
Cleveland Clinic
Case Western Reserve University

Bhadra, Narendra, MD, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Bhadra, Niloy, MD, PhD
MetroHealth Medical Center
Case Western Reserve University

Bodner, Donald, MD
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center
University Hospitals

Bourbeau, Dennis, PhD
Louis Stokes Cleveland VA Medical Center
MetroHealth Medical Center
Case Western Reserve University

Bryden, Anne, MA, OTR/L
MetroHealth Medical Center
Case Western Reserve University

Calabrese, Joseph, MD
University Hospitals
Case Western Reserve University

Capadona, Jeffrey, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Chae, John, MD
MetroHealth Medical Center
Case Western Reserve University

Chen, Peijun, MD
Louis Stokes Cleveland VA Medical Center
University Hospitals
Case Western Reserve University

Cornwell, Andrew, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Crago, Patrick, PhD
Case Western Reserve University

DiMarco, Anthony F, MD
MetroHealth Medical Center
Case Western Reserve University

Dunning, Allison Hess, PhD
Louis Stokes Cleveland VA Medical Center

Durand, Dominique, PhD
Case Western Reserve University

Foldvary-Schaefer, Nancy, DO, MS
Cleveland Clinic
Case Western Reserve University

Ford, Paul, PhD
Cleveland Clinic
Case Western Reserve University

Fu, Michael, PhD
MetroHealth Medical Center
Case Western Reserve University
Cleveland Clinic

Furlan, Anthony J, MD
University Hospitals
Case Western Reserve University

Geertman, Robert, MD, PhD
MetroHealth Medical Center
Case Western Reserve University

Ghasia, Fatema, MD
Cleveland Clinic
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Gonzalez, Jorge, MD, PhD
Cleveland Clinic

Gopalakrishnan, Raghavan, PhD, MBA
Cleveland Clinic

Graczyk, Emily, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Gustafson, Kenneth, PhD
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Hardin, Elizabeth, PhD
Louis Stokes Cleveland VA Medical Center

Hdeib, Alia, MD
University Hospitals
Louis Stokes Cleveland VA Medical Center

Hoyen, Harry, MD
MetroHealth Medical Center
Case Western Reserve University

Jacono, Frank, MD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Jenkins, Michael, PhD
Case Western Reserve University

Jurjus, George, MD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Keith, Michael, MD
MetroHealth Medical Center
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Kilgore, Kevin, PhD
MetroHealth Medical Center
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Kirsch, Robert, PhD
Executive Director, Cleveland FES Center
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center
MetroHealth Medical Center
Cleveland Clinic

Knutson, Jayme, PhD
MetroHealth Medical Center
Case Western Reserve University

Kowalski, Krzysztof, PhD
MetroHealth Medical Center
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Lewandowski, John, PhD
Case Western Reserve University

Lewis, Stephen J, PhD
Case Western Reserve University

Lhatoo, Samden, MD, FRCP
University Hospitals
Case Western Reserve University

Machado, Andre, MD, PhD
Cleveland Clinic

Madabhushi, Anant, PhD
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Makowski, Nathan, PhD
MetroHealth Medical Center
Case Western Reserve University

Marsolais, E Byron, MD, PhD
University Hospitals
Case Western Reserve University
Louis Stokes Cleveland VA Medical Center

Mchaourab, Ali, MD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

McIntyre, Cameron, PhD
University Hospitals
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Megerian, Cliff, MD
University Hospitals
Case Western Reserve University

Mehra, Reena, MD
Cleveland Clinic
Case Western Reserve University

Mei, Lin, MD, PhD
Case Western Reserve University

Miller, Jonathan, MD
University Hospitals
Case Western Reserve University

Moynahan, Megan, MS
Case Western Reserve University

Nagel, Sean, MD
Cleveland Clinic
Case Western Reserve University

Nair, Dileep, MD
Cleveland Clinic

Najm, Imad, MD
Cleveland Clinic
Case Western Reserve University

Nemunaitis, Gregory, MD
MetroHealth Medical Center
Case Western Reserve University

Onders, Raymond, MD
University Hospitals
Case Western Reserve University

Peckham, P Hunter, PhD
Case Western Reserve University
MetroHealth Medical Center
Louis Stokes Cleveland VA Medical Center

Plow, Ela, PhD
Cleveland Clinic
Louis Stokes Cleveland VA Medical Center
Cleveland State University

Pundik, Svetlana, MD, MSc
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Rhee, Douglas, MD
Case Western Reserve University
University Hospitals

Richmond, Mary Ann, MD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Riechers, Ronald, MD
Medical Director, Cleveland FES Center
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Ronis, Robert, MD
Case Western Reserve University
University Hospitals

Salameh, Alham, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Schearer, Eric, PhD
Cleveland State University

Selkirk, Stephen, MD, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Selman, Warren, MD
University Hospitals
Case Western Reserve University

Shaikh, Aasef, MD, PhD
Louis Stokes Cleveland VA Medical Center
University Hospitals
Case Western Reserve University

Strohl, Kingman, MD
University Hospitals
Case Western Reserve University

Sweet, Jennifer, MD
University Hospitals
Case Western Reserve University

Tabbaa, Kutaiba, MD
MetroHealth Medical Center
Case Western Reserve University

Taylor, Dawn, PhD
Cleveland Clinic
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University
MetroHealth Medical Center

Tyler, Dustin, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University
MetroHealth Medical Center

Vaidya, Punit, MD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Van Acker, Gustaf, MD, PhD
MetroHealth Medical Center
Case Western Reserve University

Veizi, Elias, MD, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Vrabec, Tina, PhD
Case Western Reserve University
MetroHealth Medical Center
Louis Stokes Cleveland VA Medical Center

Walker, Mark, MD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Walter, Benjamin, MD
Case Western Reserve University
University Hospitals

Whitehair, Victoria, MD
MetroHealth Medical Center
Case Western Reserve University

Williams, Matthew, PhD
Louis Stokes Cleveland VA Medical Center
Case Western Reserve University

Wilson, Richard, MD
MetroHealth Medical Center
Case Western Reserve University

Wilson, Robert, DO
Cleveland Clinic

Research Thrusts

The scope of the Cleveland FES Center and applications of "functional electrical stimulation" have grown notably over the past several years. It has been a significant engine of this expansion. The scope of research has correspondingly evolved and expanded into five research thrusts:

BRAIN HEALTH

Brain stimulation for movement disorders, stroke and traumatic brain injuries, epilepsy and neuropsychiatric disorders

PAIN

Pain mitigation through stimulation of peripheral nerves and the spinal cord

MOVEMENT RESTORATION

Restoring limb and other body movements

AUTONOMIC SYSTEM

Autonomic nervous system stimulation for restoration and/or regulation of internal body and visceral functions

TOOLS & TECHNOLOGY

Development of implantable systems and electrodes, modeling & simulation tools and other rehabilitation approaches complementary to FES

Brain Health

To increase upper limb function, Myomo Inc. recently combined powered elbow with powered grasp to create the MyoPro Motion-G myoelectric elbow-wrist-hand orthosis. This commercially-available device is a non-invasive, powered orthosis that is worn on a partially paralyzed arm to help initiate movement and enhance function. It is designed to be used by persons with various neurological problems, including Traumatic Brain Injuries.

Program Overview

Neurological disorders related to brain mechanisms, such as stroke, TBI, epilepsy, parkinson's disease, and some psychiatric conditions, may be mitigated through the use of electrical stimulation. Rehabilitation techniques can employ brain plasticity to retrain neural mechanisms to mitigate the chronic impact of stroke, TBI, and other brain disorders. Computational modeling of brain circuits can now be used to understand the mechanisms of various brain disorders to develop tools that accurately and selectively target structures, and to devise stimulation patterns improving efficacy. While FES Center investigators have developed FES-based stroke rehabilitation techniques and Deep Brain Stimulation (DBS) for motor disorders for many years, we have more recently established a major human Brain-Computer Interface (BCI) activity.

Pediatric Hand Grasp

A pediatric patient participates in a new therapy for improving hand function in children with hemiplegic cerebral palsy. It utilizes an innovative neuromuscular electrical stimulation therapy that incorporates several rehabilitation techniques shown to improve recovery. Contralaterally Controlled Functional Electrical Stimulation (CCFES) activates paretic muscles to open the affected hand in direct proportion to the degree of opening of the unimpaired hand, as detected by a sensor glove. CCFES is used in combination with hand therapy video games to retrain the brain on hand function.

Investigational Device | Limited by Federal Law to Investigational Use

Gaining a Better Understanding of Parkinson's Disease

One investigator leads three research projects using deep brain stimulation to study gait and balance impairment

During his training as a neuroscientist, Aasef Shaikh, MD, PhD, studied eye movement and the vestibular system – the sensory system that contributes to balance and spatial orientation. Afterward, Shaikh wanted to apply what he learned to complex movement disorders. He decided to focus his research on Parkinson's disease, a neurodegenerative disorder that causes gait and balance impairment. An estimated 1 million people in the U.S. have Parkinson's disease, with an additional 50,000 people diagnosed each year.

As an investigator at the FES Center, Shaikh is currently involved in three research projects related to Parkinson's disease. In broad strokes, they examine how Parkinson's patients perceive the environment in which they walk, how they perceive their own motion through an environment and how they navigate any given environment.

All three projects utilize high-frequency deep brain stimulation (DBS). In 2016, Shaikh teamed with Cameron McIntyre, PhD, a fellow investigator and associate director of industry relations at the FES Center. Shaikh's experience as a vestibular and eye movement scientist, combined with McIntyre's expertise in DBS provided "the perfect model" to study gait impairments in patients with Parkinson's disease, says Shaikh.

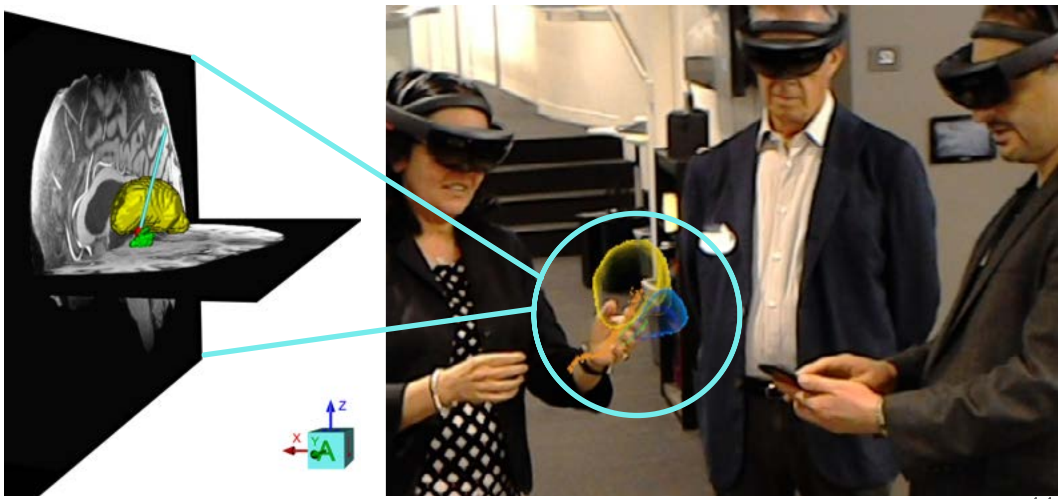
"Through our research, we are beginning to understand more and more about which particular pathways and structures are responsible for perception of motion and heading perception in humans," says Shaikh, who is a neurologist at both the Louis Stokes Cleveland VA Medical Center and University Hospitals Cleveland Medical Center. "In the future, we hope the much broader application of our work beyond Parkinson's will be to use similar concepts and strategies to treat balance function or navigational problems in patients with any condition."

Take a look at the three research projects...

Project One
Motion Perception

“We are studying how patients with Parkinson’s perceive their own directional heading – whether they are going straight ahead or veering to the side,” says Shaikh. “In addition, we’re also interested in understanding why they veer and which particular neural pathways are involved in perception of their self-motion.” Using that information, the researchers hope to discover how to tweak those pathways with DBS to eliminate veering.

Shaikh’s team is conducting behavioral experiments in the lab with motion simulators similar to those used by NASA to train astronauts. In the pilot study, Parkinson’s patients with DBS implantations are placed in the simulator, where experiments are performed with the DBS turned on and off to determine if it makes a difference in perception of motion. That information is then combined with MRI images of the patients’ brains and bioelectric field stimulation models created by McIntyre.



“Together, this gives us a sort of 3D picture of everything involved in the process,” says Shaikh. “That allows us to understand how patients with Parkinson’s perceive their own directional heading.”

Project Two

Gait Dysfunctions

The second project utilizes resources in the Virtual Reality Human Performance Laboratory at the Louis Stokes Cleveland VA Medical Center. Shaikh and McIntyre are teaming with Elizabeth Hardin, PhD, a fellow investigator at the FES Center with research interests in human walking performance and stability, to understand the physiological underpinnings of gait deficits in Parkinson's disease.

One common walking problem is freezing of gait, where patients stop walking and their feet seem stuck to the floor. "Unfortunately, we don't know why it happens," says Shaikh. "It's a context-dependent phenomenon." The researchers postulate that freezing of gait may occur when patients with Parkinson's move from a normal environment to one with a higher optic flow, where spatial landmarks around them seem to be moving at a higher speed.

"Parkinson's patients might experience this in their daily environment, for example, when they go from the lobby of a hospital into a hallway, where it's a narrower space and the landmarks are much closer to their vision," says Hardin.

"We are collecting data in the Virtual Reality Human Performance Laboratory to see if optic flow changes trigger patients to stop walking."

Patients in the lab walk on a treadmill at a specific speed. Then, the researchers create a mismatch between the treadmill speed and the images – the spatial landmarks – in the virtual reality system. "All of a sudden the walls in virtual reality are moving at a much higher speed than the treadmill," says Shaikh. "We have found that people freeze right then and there."

Now that Shaikh's team has discovered how to create freezing of gait on demand, they are studying how DBS can modulate the phenomenon. "We are interested in seeing how DBS affects freezing of gait when optic flow changes in a patient's environment," says Hardin. Ultimately, they hope to determine if patients have a propensity to freeze in certain environments and develop a biomarker for the propensity of gait freezing based on optic flow.

Project Three

Environmental Navigation

In his most recent research project, Shaikh is working alongside Fatema Ghasia, MD, a pediatric ophthalmologist and adult strabismus surgeon at Cleveland Clinic. She studies the role of abnormal neural circuits in strabismus (eye misalignment) and amblyopia (lazy eye).

“Parkinson’s disease is a particularly interesting area because up to 20 percent of patients develop diplopia [double vision], and that occurs because of strabismus and impaired vergence,” she says. Ghasia explains vergence as eye movements that people make routinely while viewing objects at different distances and depths.

Together, she and Shaikh will examine how Parkinson’s patients navigate their environment – how they use their eyes to “search and scan” their surroundings. Ghasia’s role is to assess eye movements in patients before the DBS implementation, while DBS is on and while it is off. “We have the capability to record the eye, head and limb movement simultaneously,” she says. “This allows us to independently assess the abnormalities of the eye movements and tease apart the eye movement abnormalities from the head oscillations and tremor that are frequently seen in Parkinson’s patients.”

The team approach is to investigate the use of DBS to see its effect on vergence and eye movements, in particular binocular coordination of eye movements, says Ghasia. “From the clinical perspective, the studies would provide valuable guidance to understand what the optimal stimulation parameters are for better motor outcomes in Parkinson’s disease patients.”

The collective effort of Shaikh’s research projects has great potential. The same patients who participate in the motion simulator experiments will also partake in the virtual reality experiment with Hardin and the search and scan pattern assessments with Ghasia. “Now we will have three separate pieces of information, and in the future we will be able to fuse them to get the big picture about a patient,” says Shaikh. “That is very important.”

Pain

Program Overview

Effective treatment of pain is a high priority across all areas of clinical practice. Although pharmaceuticals have historically been the primary treatment option for pain, the use of neuromodulation and neurostimulation techniques has increased significantly over the past few decades. Research on the use of neuromodulation for the treatment of pain has also grown rapidly within the FES Center because of the world-class expertise of its investigators regarding the effects of electrical current on neural structures, collaborations with top clinical partners and the clear clinical imperative.

A Tool for Pain Relief

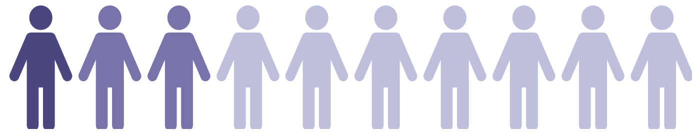
Investigators at the FES Center are studying a variety of electrical nerve block systems for acute and chronic pain

Acute and chronic pain affect at least 100 million U.S. adults and cost the nation up to $630 billion in medical treatment and lost productivity annually, according to the National Academy of Medicine. There are many treatment options for pain management, including medication, neuromodulation, local anesthetics and surgery. Researchers at the Cleveland FES Center are developing innovative solutions focused on electrical nerve blocks – essentially targeting nerves that send the pain signal to the brain and blocking the nerves from sending that signal.

“Pain is one of the largest disease groups in the U.S. It’s larger than heart disease and cancer combined,” says Tina Vrabec, PhD, an investigator at the Cleveland FES Center. “Part of what drives us forward in our research is thinking about the sheer size of the population we can benefit and what our impact can be.”

For the past two years, Vrabec and Niloy Bhadra, MD, PhD, an investigator at the Cleveland FES Center, have partnered with medical technology company Halyard Health to create cutting-edge electrical nerve block solutions. Most recently, the work has focused on minimally-invasive direct current nerve blocks, typically delivered percutaneously via a small catheter containing a conductive fluid that delivers the stimulation.

Pain is one of the **most common** reasons people seek medical care in the U.S.



20% of adults have chronic pain

8% of adults have high-impact chronic pain (limits at least one major life activity)

$560 Billion

estimated medical costs due to chronic pain

Chronic pain is **linked** to...

restricted mobility

opioid dependency

anxiety & depression

Center for Disease Control and Prevention, 2016

"Products based on our electrical nerve block would fit well within Halyard Health's existing products for pain after surgery and chronic pain relief," says Kevin Kilgore, PhD, an investigator at the FES Center. "The overarching goal is to move our ideas into clinical testing and eventually onto the market for treatment of pain."

Moving from High-Frequency to Direct Current Blocks

The project with Halyard Health is the latest in nearly two decades of research on pain management conducted by Bhadra and Kilgore, who began studying electrical nerve blocks to get spastic muscles – such as those in stroke or multiple sclerosis – to relax and improve function. "As our research into nerve block started showing promise, it became apparent that our technique might be used to block any nerve, including pain fibers," says Kilgore.

The researchers initially concentrated on delivery of high-frequency alternating current waveforms to produce reversible nerve blocks. Neuros Medical Inc., a Cleveland-based company, licensed the FES Center's patent for chronic amputation pain. With the company's Altius® System, an electrode is placed around a peripheral nerve, then a small implanted generator sends a high-frequency signal to the electrode to block the pain signal.

The basic difference between high-frequency (HF) blocks and the newer direct current (DC) blocks is in the frequency of the waveform. With HF blocks, the current cycles positive and negative approximately 10,000 times per second. That cycle occurs about once per minute for DC blocks. "We refer to it as 'direct current' because the cycle time is so slow that the body reacts to it as if it were unchanging," says Kilgore.

Customizing Pain Solutions for Specific Applications

Vrabec and Bhadra lead a team of 10 researchers on the collaborative pain management project funded by Halyard Health. The interdisciplinary team includes people with expertise in biomedical, chemical and electrode engineering. They have conducted a lot of basic research for the past two years, studying various kinds of blocks as well as different electrodes.

The basic research involves bench testing – "lots of nuts-and-bolts engineering on electrochemistry, device building and mechanical challenges," says Vrabec. Once the devices are evaluated, then the team tests them in biologic studies to determine the block's effectiveness and get parameters for each of the interventions.

The researchers are pursuing a wide array of solutions because pain varies depending, for example, on where it's located in the body and whether it's acute or chronic. "One of the big pushes in medical care right now is for customization and patient-specific interventions," says Vrabec. "We have a wide toolbox at our disposal – a bunch of different types of electrodes, from implantable to surface electrodes, and different waveforms that may work for some applications better than others. Our systems need to be specific to the requirements [the medical community] is trying to address."

Tapping into the Benefits of Direct Current Blocks

DC blocks have several advantages over other pain management options, such as medication and local anesthetics. One of the biggest benefits is their rapid onset and reversal. "The problem with using drugs is the time needed to control the pain can be anywhere from 30 minutes to six hours," says Bhadra. "In addition, drugs are non-specific, so they will not only kill the pain, but also have many side effects. Then, when the pain stops,

From left: Kevin Kilgore, PhD, Niloy Bhadra, MD, PhD, Tina Vrabec, PhD perform bench testing to study electrochemistry, device building and mechanical challenges.

it takes time to come down from effects of the drug. With DC blocks, we can reverse the effects almost immediately."

DC blocks also can be graded, offering a total block, 90 percent block, 80 percent block and so on. For acute pain, you probably want a complete block. "But when you are tackling pain with peripheral nerve, you also affect motor systems," says Bhadra. "So you can grade the DC block and still allow the muscle to function."

Think about novocaine use for dental work: Patients have to wait until their mouths are numb to begin the procedure, then when it's over, the novocaine often takes hours to wear off. "Imagine how great it would be to have an option that only takes the pain away without losing functionality of your mouth," says Vrabec.

Transferring Solutions from the Lab to the Market

Investigators at the FES Center are excited at the prospects for direct current nerve blocks, some of which are undergoing in vivo biologic studies in tandem with Halyard Health. "The bottom line is that no one else has ever done this," says Bhadra. "We are the first group to show you can safely perform DC blocks without killing the nerve."

Recently, the group has begun testing combinations of surface electrodes and implantable systems, as well as solutions that utilize both HF and DC nerve blocks. It's all part of the extensive toolbox that Vrabec referenced. And while the tools may vary, the primary goal of all electrical nerve blocks is the same – to relieve pain.

"Imagine that you could have a local anesthetic like lidocaine, but it came with a switch that would allow you to turn it on or off whenever you wanted," says Kilgore. "That is the innovation we are working on. If we can make this technique reliable and safe, it will have a lot of different applications."

Movement Restoration

Program Overview

The original motivation for the establishment of the FES Center was the restoration of limb, respiratory, and other body movements to individuals with spinal cord injury, stroke, and several other patient populations through the use of electrical stimulation. Work in this area over the past 25 years has been prolific, with major scientific and clinical impacts. Early work has motivated additional research that has developed into greater research programs within the FES Center. Movement Restoration research continues to be highly innovative, and the FES Center continues to be a leader in translating laboratory discoveries into commercial products and clinical adoption.

Being able to hold a cup so that nobody else has to hold it for you, that's wonderful.

Hand Grasp Participant

New Research Seeks to Restore Functional Control of Arm and Hand for Those With Quadriplegia

Grant for $3 million from the U.S. Department of Defense supports the work being done at University Hospitals, Case Western Reserve University and the Cleveland FES Center.

In science, an N of 1 is rarely enough to support any big conclusions-no matter how significant the results.

That even applies to the story of Bill Kochevar, the Cleveland man who became the first person with quadriplegia in the world to regain functional control of his arm and hand using technology implanted in his brain and limb.

Kochevar, who had been paralyzed from the shoulders down in a bicycling accident in 2006, participated in a study at the Cleveland FES Center and Case Western Reserve University, where researchers implanted two micro-electrode arrays in his motor cortex to capture his brain activity and electrodes in the muscles of his upper and lower arm to stimulate his arm and fingers. A computer interface using mathematical algorithms translated his thoughts into electrical impulses that controlled his muscles.

“We had a lot of success with Bill,” says Robert Kirsch, executive director of the Cleveland FES Center and chair of Case Western Reserve University’s department

ReHAB

Reconnecting the Hand and Arm to the Brain

Bolu Ajiboye, PhD, associate professor of biomedical engineering at Case Western Reserve and Cleveland FES Center research scientist at the Louis Stokes Cleveland VA Medical Center.

Jonathan Miller, MD, director of Functional Neurosurgery at University Hospitals, associate director of clinical affairs at the Cleveland FES Center, and professor of neurological surgery at Case Western Reserve School of Medicine.

Robert Kirsch, PhD, executive director of the Cleveland FES Center and chair of Case Western Reserve University's department of biomedical engineering.

of biomedical engineering. "We learned that we could do this. We learned a lot of other things as well, including about better ways to do [this research] in the future."

When Kochevar died in December 2017, just a few months after the research was published in The Lancet and featured worldwide by the BBC, CBS News, NPR and more, it caused Kirsch and the other researchers to pause and evaluate where to go next. After more than a year of reflecting on the best ways forward, they are poised to launch a feasibility study of the Reconnecting the Hand and Arm to the Brain (ReHAB) System, a greatly enhanced version of the technology used with Kochevar.

The research, which builds upon six years worth of work, is being funded with a $3 million grant from the United States Department of Defense. With Food and Drug Administration approval for up to 12 participants for initial 13-month trials, the first individual is expected to begin the trial in early 2020 followed by additional subjects every nine months or so. "It's time to start doing this with more people and looking at variations across people," says Kirsch.

Here is how ReHAB builds upon previous lines of research and hopes to break new ground:

Wrap Beats

In Kochevar's case, researchers implanted electrodes through the skin into neuromuscular junctions using hypodermic needles. This allowed the electrodes to be easily removed, but they were also somewhat imprecise in their placement. "He was able, by the end, to control his hand and his forearm very precisely," says Jonathan Miller, director of Functional Neurosurgery at University Hospitals, associate director of clinical affairs at the Cleveland FES Center, and professor of neurological surgery at Case Western Reserve School of Medicine. Yet, because the electrodes were inserted directly into the muscle, there were issues controlling the strength of the contractions and limitations on what muscles were able to be activated.

The ReHAB study employs specialized nerve cuffs, developed by Cleveland FES Center investigator Dustin Tyler at Case Western Reserve, which fold around the nerve and offer much greater precision in the placement and intensity of the stimulation. “That leverages the body’s own natural organization,” says Miller. “By stimulating nerves, we’re able to activate muscles the way that the body normally activates them.”

Six Pack

Researchers working with Kochevar implanted two 96-electrode arrays in the motor cortex to capture brain activity associated with hand and arm movement. The ReHAB system includes six, smaller 64-electrode micro-arrays placed in both the motor and sensory cortex, and areas associated with intended movement. “The brain doesn’t think in one straight line. It’s not like information starts one place and then jumps to another place,” says Miller. “It happens all at once and in a lot of different places. Everything that happens in the brain is distributed over a widespread area that works together and along these networks.”

Feedback Loop

By collecting information over a larger area of the brain and tapping into a variety of neural nodes, researchers hope to collect much more detailed information than ever before. In addition, ReHAB won’t just gather information from the brain, but will also return information about touch and spatial alignment back to the brain from the hand and arm.

“That’s been a major problem with a lot of these prosthetic technologies,” says Miller. “There’s not adequate feedback to tell exactly how much force is being applied. We’re hoping to stimulate the brain to mimic sensation, so participants will be able to feel again and, ideally, even recognize where the arm is in space.”

Deeper Pool

Expanding the number of participants brings its own opportunities and challenges. Work with Kochevar could be individualized, while ReHAB will need to be more consistent in its methods. “Obviously, when you scale a project up, it becomes more complicated,” says Miller. Yet, working across individual differences should provide a broader understanding of brain and neural function. Eventually, that knowledge could speed up the pace of development. “We’re hoping we can find some more general organizing principles that aren’t so sensitive to small differences in where the electrodes are placed or the person’s history,” says Kirsch. “If we can figure that out, then we can at least have a broad algorithm that we start with.”

Broader Reach

Researchers hope to expand the ReHAB study beyond individuals with spinal cord injuries, which impacts approximately 291,000 people in the United States. So they’re recruiting participants beyond that population to possibly include those affected by stroke, multiple sclerosis, or spinal cord disfunction due to tumors or radiation damage. “You need to be able to show that this isn’t just something working for one person,” says Miller. “There are things that are translatable and potentially generalizable across many people, because eventually our goal is to make this clinical tool.”

Researchers Restore Complete Respiratory Muscle Function in Participants with SCI

From left: Anthony DiMarco, MD, and Krzysztof Kowalski, PhD explain the system to a Veteran research participant.

Anthony DiMarco, MD, Principal Investigator, and Krzysztof Kowalski, PhD, Co-Investigator, are among a team of researchers at the Cleveland FES Center that is combining two systems to offer complete restoration of respiratory muscle function to participants with spinal cord injury (SCI). Results of an interventional clinical trial demonstrate that a spinal cord stimulation system to restore cough can be used safely and effectively in conjunction with a diaphragm pacing system to restore breathing.

Many individuals with SCI develop respiratory compromise and require mechanical ventilatory support. However, individuals with ventilator-dependent tetraplegia can often be offered an alternative method of ventilatory support through diaphragm pacing, which provides a more natural form of breathing. “We have also demonstrated that diaphragm pacing could be achieved via a less invasive method i.e. laparoscopically placed intramuscular diaphragm electrodes. This method has been successful in liberating thousands of individuals from mechanical ventilation,” says Dr. DiMarco.

A second system has been developed at MetroHealth Medical Center to restore an effective cough to individuals with SCI, thereby helping to reduce the risk of aspiration and the development of respiratory tract infections including pneumonia. “We developed the first method in the world by which we can activate expiratory muscles – abdominal and lower rib cage muscles, using minimally invasive techniques– to produce an effective cough," says Dr. Kowalski. The initial system was implanted surgically, with disc electrodes placed on the dorsal surface of the spinal cord via laminectomy. Drs. DiMarco and Kowalski have subsequently developed a minimally invasive method using wire electrodes that are inserted percutaneously through needles, then advanced to the dorsal spinal cord under fluoroscopic guidance. Research participants utilize a stimulator to produce several different cough efforts ranging from light to strong.

An interventional clinical trial conducted by the research team shows the efficacy of using the two systems in tandem. "Participants can employ diaphragm pacing to restore breathing and also generate an effective cough by simply pushing a button. The project has been very rewarding. We see so many participants who are very pleased with the system and have achieved significant clinical benefit." says Dr. DiMarco.

Among those working alongside Drs. DiMarco and Kowalski at the Cleveland FES Center are Robert Geertman, MD, PhD; and Kutaiba Tabbaa, MD.

Investigational Device | Limited by Federal Law to Investigational Use

For more information on respiratory research programs:
info@FEScenter.org | (216) 231-3257

Autonomic System

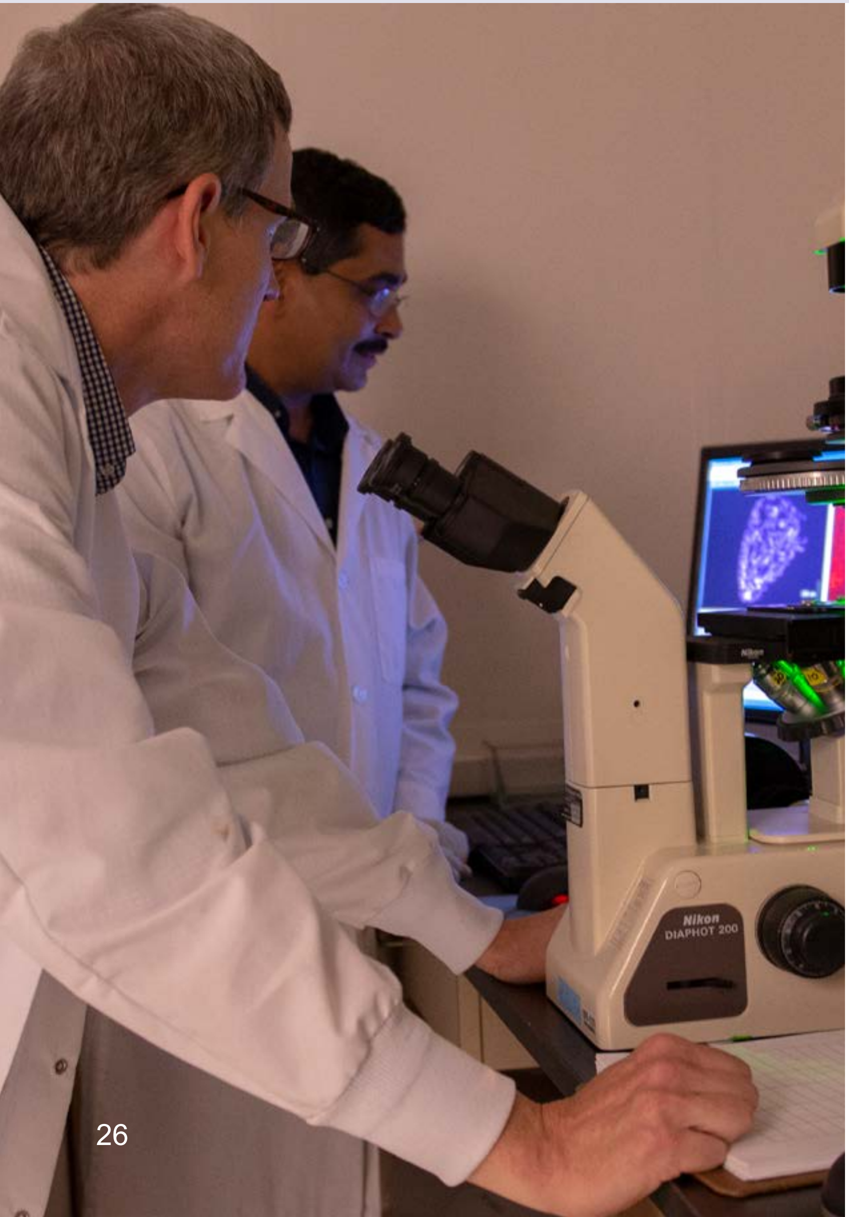
Program Overview

The autonomic nervous system is involved in the control/regulation of almost all internal body functions, including glucose and electrolyte concentrations, blood pressure, inflammatory responses, appetite, bladder and bowel function, autonomic dysreflexia, and many others. The use of electrical stimulation, particularly of the vagus nerve and sensory nerve pathways, has become a popular approach for treating disorders associated with these functions. These approaches are termed “electroceuticals” and “bioelectric medicine” because they avoid systemic drug applications, can be quite selective for specific fascicles (or nerve branches) of the vagus nerve, and can be easily modulated (or even turned off). This is an exciting and rapidly growing area for the use of FES.

A hallmark of our research activities has been collaboration. We've always had teams of whatever the mix of expertise was needed in order to address the clinical problem at hand.

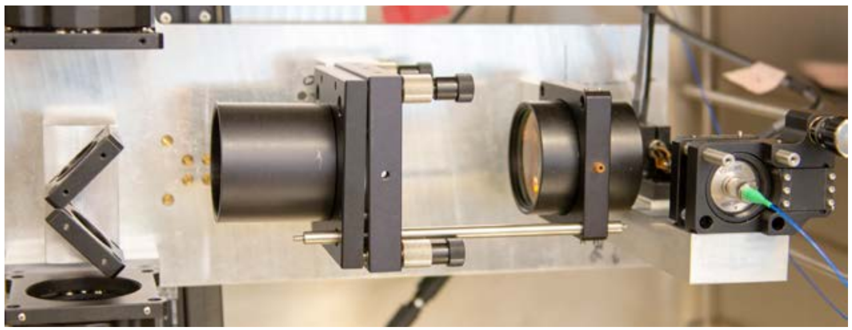
Robert Kirsch, PhD

Shedding Light on the Nervous System



Researchers are harnessing infrared light to modulate, block and excite electrical signals that control organ function

The first line of treatment for many diseases today, ranging from asthma to cardiac arrhythmias, is prescription drugs. But what if there was a better option?



"Drugs are pretty good at treating diseases, but they typically have lots of side effects," says Michael Jenkins, PhD assistant professor of pediatrics and biomedical engineering at Case Western Reserve University School of Medicine. "Recently, it's been shown that we may be able to treat diseases by modulating the electrical signals that control your organs and your autonomic responses."

Last spring, a multidisciplinary team of researchers led by Jenkins received a four-year, $9 million grant from the National Institutes of Health (NIH) to develop enhanced infrared light technology for potentially treating a variety of diseases, including cardiac arrhythmias, high and low blood pressure, asthma and sleep apnea. Researchers from the Jenkins Lab, Vanderbilt University and the University of Pittsburgh have partnered to create new technologies to precisely send infrared light to nerves and ganglia in animals, watch the ensuing activity and map the molecular components in 3-D with high resolution.

Targeting Sensory Fibers

Modulation of the nervous system often utilizes electrodes for stimulation of large fibers. Jenkins' group uses infrared neuromodulation (IRN) applied to peripheral structures, such as the nodose ganglion in the first cervical vertebra, to induce unique patterns of physiological responses that can't be elicited by electrical current or drugs.

"Our infrared light targets small-diameter fibers preferentially, whereas electrical stimulation tends to target the large fibers," says Jenkins. "Electrical currents are decent for eliciting movement – your arms and legs, for instance. But a lot of sensory fibers that control organs are actually small fibers, so there's an advantage to being able to more easily get at those fibers."

Recent work conducted by Jenkins and his peers indicates that IFN can affect collections of nerve cells that control autonomic function, such as heart rate, respiration, digestion and other visceral functions. "Essentially, we take infrared light, shine it into the tissue and try to specifically target regions of the nodose ganglia," says Jenkins. "We've discovered we can do things like lower blood pressure and affect the breathing rate. At this point, we are just starting to build tools to more accurately map what's going on. But it's exciting to get these different types of responses."

Deciphering how the Technology Works

"The ganglion is like a little brain in the periphery structures, controlling certain autonomic functions," says Jenkins. "If we can control those functions, it could be very valuable both as a tool for learning how the circuitry works, but also as a therapeutic tool."

The goal of the NIH grant is four-fold:

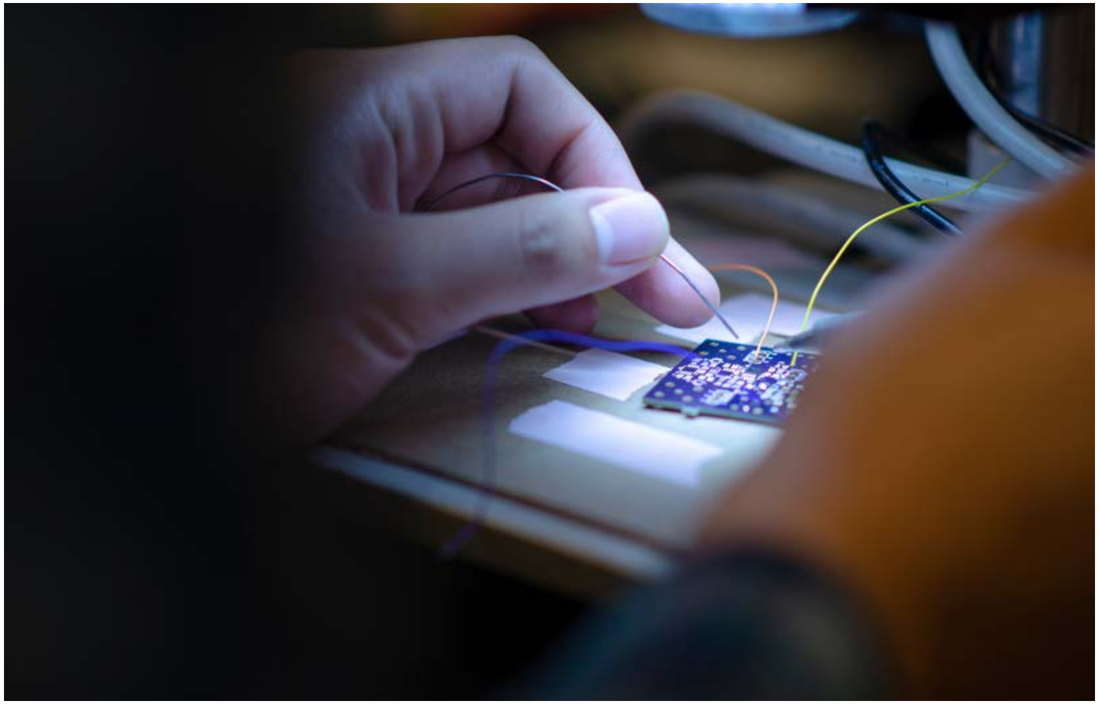
- To create new devices that efficiently and precisely deliver infrared light to nerves and ganglia.

> "Overall, we have a real chance to learn something new about how the biology of sensory fibers work and create therapeutic interventions for treating diseases."
>
> — Michael Jenkins, PhD

- To assess the safety, selectivity and repeatability of IRN.
- To map the spatial organization of the ganglionic function.
- To develop a deeper understanding of how IRN works.

Because the work is in its infancy, the group will spend time studying exactly how IRN affects autonomic functions. "The electromagnetic spectrum includes visible light and infrared light, which has longer wavelengths than visible light," says Jenkins. "We have chosen to use wavelengths that have higher water absorption properties, and we think some of the responses we're getting are due to transiently heating the tissues."

One of the interesting things about the project, says Jenkins, is that the team has gotten different effects when stimulating the nodose ganglion depending upon the parameters they use. Electrode stimulation typically provokes one response no matter where the electrode is placed on the fiber. "But when we use the light, we actually get different responses depending upon where we place our optical fiber," says Jenkins. "The idea is that perhaps we can get more spatial precision with this technique and target certain types of cells."



The collaborators also will study how long you need to shine infrared light on sensory fibers to achieve results. Some effects occur only when the laser is on, while other responses last for hours after applying IRN for only a few seconds.

Working Toward Real-World Applications

Discovering what IRN is capable of doing, creating models for how it works and developing advanced optical systems to facilitate the technology requires a multidisciplinary approach. The research team includes collaborators in seven labs across three universities. The primary biomedical engineers are Jenkins, who earned his PhD in biomedical engineering from Case Western Reserve University in 2008, and E. Duco Jansen, professor of biomedical engineering at Vanderbilt University and one of the inventors of IRN. Other researchers include Hillel Chiel, a biology professor at Case Western Reserve University with a secondary appointment in biomedical engineering, and Stephen Lewis, professor of pediatrics at Case Western Reserve University's School of Medicine.

"One of the exciting things about working in larger groups to solve problems is that you bring together expertise from a number of different areas," says Jenkins. "It's imperative to get a lot of viewpoints if you want to move your science along quickly." And advancing the science of IRN has the potential of helping millions of people with an array of conditions. Consider just two possibilities:

- Diarrheal diseases account for one in nine child deaths worldwide, making diarrhea the second leading cause of death among children under the age of five, according to the Centers for Disease Control and Prevention. Using IRN, clinicians may be able to target the part of the nodose ganglion that controls peristalsis, which pushes ingested food through the digestive tract toward its release at the anus. "By slowing peristalsis down, we can stop diarrhea from taking a fatal tool on people, especially young children in less developed countries, who are particularly susceptible to death from dehydration," says Lewis.

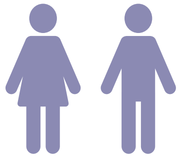
- More than 4 million Americans suffer from recurrent arrhythmias, according to the American Heart Association. Some undergo cardiac ablation to prevent abnormal electrical signals from entering the heart, thereby stopping the arrhythmia. However, there can be unwanted side effects. "Ablation can lead to other problems because no ganglion control just one thing. So people may develop a droopy half of their face or other significant side effects," says Jenkins. "What if you could modulate the signal with infrared light instead of ablating it?"

Michael Jenkins, PhD studies images created using infrared neuromodulation.

While these real-life applications remain on the horizon, Jenkins is excited by the potential for IRN. "With this grant, we'll learn how it works and map the types of responses we are getting. In the future, we'll move toward better ways to deliver the light to the tissue," he says. "Overall, we have a real chance to learn something new about how the biology [of sensory fibers] work and create therapeutic interventions for treating diseases."

Improving the Lives of People with SCI

Researcher tackles everyday bodily processes – bladder and bowel function *– to enhance quality of life*



When Dennis Bourbeau, PhD, contemplated what issues he would like to focus on with his training in neural and electrical engineering, he had one overarching goal – to make a difference in people's lives. "I was compelled in my career to go into something where I would have a big impact," says Bourbeau, an investigator at the FES Center. His research focuses on developing approaches using electrical stimulation to restore pelvic autonomic functions – such as bladder, bowel and sexual function – lost to spinal cord injury (SCI) and other neurological disorders.

"Reading anecdotes and literature reports on the consequences of bladder, bowel and sexual dysfunction was very motivating and inspiring," recalls Bourbeau. "I realized that there was not a lot of work in that area, but at the same time it was a top priority for people with SCI. It became a natural call to action for me."

Moving the Needle of Pelvic Autonomic Functions

While many researchers are making important scientific discoveries in the area of pelvic dysfunction, such as understanding what happens to the bladder after SCI, Bourbeau hopes to make a clinical impact through translational research. Working predominantly with electrical stimulation devices, Bourbeau's aim is improve the quality of life, independence and dignity of patients with SCI and other neurological disorders.

Bourbeau's team currently has four active studies related to bladder and bowel function.

Project One – Improving Bladder Incontinence

After SCI, patients have neurogenic destrusor overactivity: The bladder muscle involuntarily contracts, which increases bladder pressure and decreases the amount of urine the bladder can hold. This, in turn, leads to feelings of bladder urgency and urinary incontinence. In this study, the researchers are stimulating the genital nerve branch of the pudendal nerve to inhibit bladder activity and improve urinary incontinence.

"If you hit the right nerve with the right electrical pattern, you can modulate an inhibitory reflex to turn the muscle off," says Bourbeau. Using automated closed loop stimulation with a sophisticated algorithm developed by a collaborator, Bourbeau's team is examining bladder pressure to answer several key questions: Do they need to use one sensor or two? Can the system determine in real-time if there is a bladder contraction to inhibit before incontinence occurs? If the system works, what would an implanted sensor look like?

Project Two – Improving Bladder Emptying

Patients with SCI may also experience detrusor-sphincter dyssenergia – essentially mixed signals between the bladder and urethral sphincters. This causes pressure to build in the bladder, leading to urine backup in the kidneys. The team is researching whether they can turn off the signal going to the urethral sphincters so patients don't require catheters, while simultaneously activating the bladder.

In a new study, Bourbeau's group is implanting electrodes at the sacral spinal cord to inhibit bladder activity. "If there is an action potential coming down that neuron and we apply the right electrical pattern in a certain spot, the action potential will be blocked," says Bourbeau. "We think of it as an electrical version of a chemical block, like dental anesthetic injections. With electrical stimulation, the block is only there as needed, then it goes away." The team is currently working on approval from the U.S. Food and Drug Administration to test the pattern to inhibit or block nerve activity.

Project Three – Improving Bowel Function

A third study involves testing functional electrical stimulation to increase colonic motility and improve control of bowel function. The movement of stool within the colon is significantly slowed after SCI, which can cause constipation and a host of complications associated with constipation. The aim of Bourbeau's research in this area is to understand where to apply electrical stimulation to achieve bowel motility, what nerves to target, what electrical patterns work best, and why this approach to improve bowel function is effective or not.

The team is currently testing a minimally-invasive approach in human subjects, inserting an electrode into the rectum to ascertain whether or not it stimulates the bowels to move. "It's a safe way to see if the system has potential, and, if so, what would an implanted version look like?" says Bourbeau. "This project is getting us onto the map with bowel function."

Study Four – Developing Wireless Systems

Partnering with Dr. Margot Damaser and her team, Bourbeau's team is developing wireless bladder and pressure sensors to understand what's happening in the bladder and bowel. "Right now, we are developing them as research tools, but the logical next step once they are working is to then develop them to the point of clinical translation," says Bourbeau.

Getting Input from the Real Stakeholders

Although Bourbeau breaks down his research projects into different functions – bladder and bowel – he frames his work around the whole person and what would improve overall quality of life. "The hard work at this point is not the scientific discovery; it's the translation," says Bourbeau. "What's actually going to work for a person with SCI? What is feasible and effective?"

Bourbeau partners with a host of researchers and clinicians to answer these questions, including fellow FES investigator Ken Gustafson, PhD; MetroHealth physicians Robert Geertman, MD, PhD, and Carvell Nyugen, MD; and Margot Damaser, PhD from Cleveland Clinic. He also teams with several members of the Veteran's Administration across the country, including Steven Brose, DO, Graham Creasey, MD, Steve Majerus, PhD, and James Wilson, DO

While clinical and research expertise are critical, input from the patients themselves is equally important to Bourbeau's endeavors. "One of the things we are trying to improve in our lab – and in the field in general – is bringing in these other stakeholders and being smart about how we conduct translational research," he says. "We want good relationships between the PhDs and the MDs, but we also want to hear from people with SCI."

For instance, if a research project shows that stimulation causes increased bladder pressure during contractions, what does that mean to the patient? "If I'm living with SCI, I probably don't care about that. I care about whether I still need a catheter and if I'm still having incontinence," says Bourbeau. "What is the lived experience going to be?"

During the summer of 2018, Bourbeau and his peers conducted a survey of people with SCI asking about how they currently manage bladder and bowel functions and what their priorities are for regaining function. They also asked about attitudes toward nerve stimulation devices. "We want to make sure that if we're developing a host of devices, pharmalogics and biologics for improving function that they will be acceptable," says Bourbeau. "I can tell you if they are effective, but people with SCI need to tell me if they are willing to use them."

In the end, he says, it's all about the patient's lifestyle and values. That's what propelled Bourbeau into the field years ago and what continues to motivate his research today.

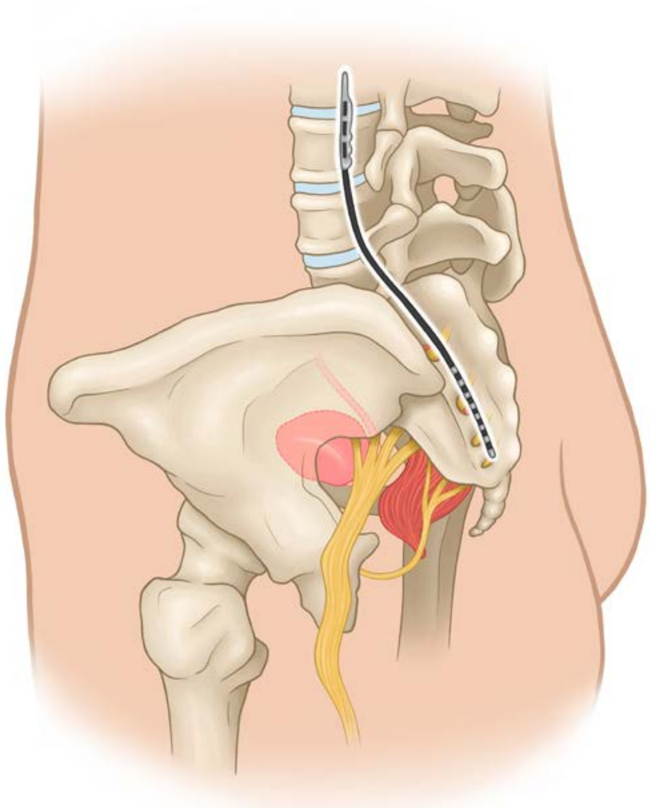


Illustration by Cleveland FES Center

Tools & Technology

Technology Vision

The Cleveland FES Center has the ability to conceive, fabricate, test, and produce advanced technologies addressing clinical applications. Our technological capabilities are divided into two segments; **innovation** and **technical**.

The innovation group is charged with identifying the cutting edge techniques, materials and concepts from across the industry for possible inclusion into neural applications.

The technical production group is charged with fabricating small quantities of implantable and external devices to a quality level fit for clinical use.

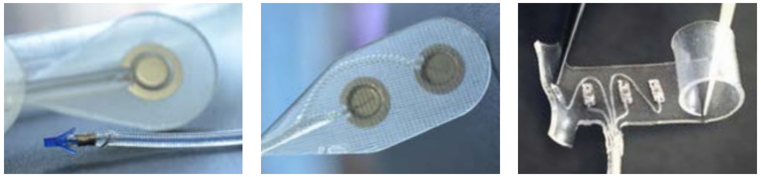
It's been a long road, it's a lot of work to get from the point of things scribbled on napkins to an FDA approved device that can be put into humans.

— Kevin Kilgore, PhD

Networked Neuroprosthesis (NNP) System

A modular, implanted technology designed to provide multiple functions to the same individual with Spinal Cord Injury (SCI). The styles of electrode (below) are chosen by the biomedical engineers and surgeons to customize the system for each patient.

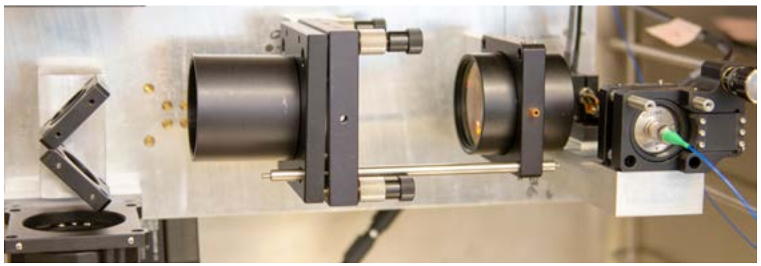
(More information on page 42)



From left: *Epimysial & Intramuscular Electrodes* stimulate movement in the muscle. *Myoelectric Signal (MES) Electrodes* record muscle activity as a control. *Nerve Cuff Electrodes* stimulate or inhibit neural signals.

To place an order on electrodes or for more information contact
Ardiem Medical | info@ardiemmedical.com | ardiemmedical.com

Infrared Light Neuromodulation

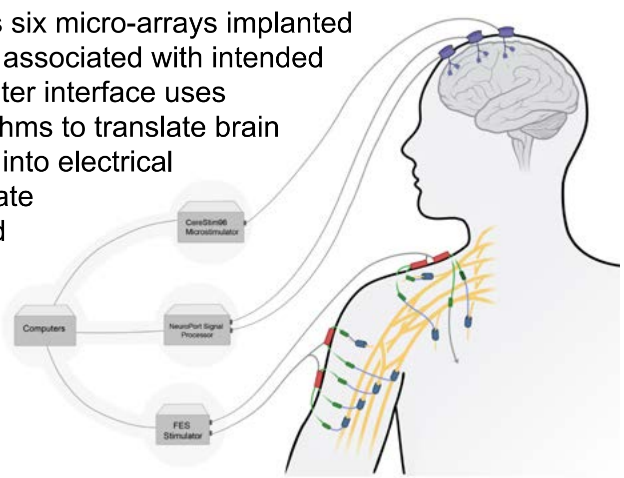


Researchers are harnessing infrared light to modulate, block and excite electrical signals that control organ function.

(More information on page 26)

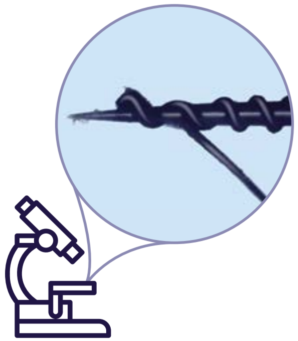
Reconnecting the Hand and Arm to the Brain (ReHAB)

The system includes six micro-arrays implanted in areas of the brain associated with intended movement. A computer interface uses mathematical algorithms to translate brain activity, or thoughts, into electrical impulses that stimulate electrodes implanted in arm muscles to stimulate arm and finger movement.



(More information on page 19)

Carbon Nanotube (CNT) Yarn Electrode



CNT yarn is a new chronic nerve interface that uses highly flexible materials with axon-like dimensions to record neural activity. The results demonstrate the possibility of regulating internal organ function, leading to new bioelectronic therapies and patient health monitoring.

Left: CNT yarn electrode prepared for peripheral nerve implantation by being secured to the tip of a microneurography needle.

Simulation and Modeling

Computer-aided design offers several particular advantages over traditional approaches to the development of neurostimulation technology.

(More information on page 36)


sagittal view

Training the Next Generation of Neurosurgeons

The Cleveland Course for Advanced Neuromodulation uses augmented reality technology to bring fundamental concepts to life

In September, a dozen of the country's top neurosurgeons who specialize in deep brain stimulation (DBS) headed to Case Western Reserve University for two days to beta test the new Cleveland Course for Advanced Neuromodulation. The training course is designed to teach neuromodulation clinicians in fellowships the fundamentals of science, electrochemistry, electrical stimulation and neuroresponse. What makes this course different, aside from its focus on the elementals of how electric fields interact with neurons, is that it utilizes augmented reality.

The course toggles between hour-long lectures, followed by demonstrations using the Microsoft HoloLens to reinforce the material and bring it alive. The HoloLens is a self-contained, holographic computer that allows users to interact with digital content and holograms in the environment around them.

"You see holographic objects in the context of the real world as opposed to virtual reality, where you are 100 percent immersed in a digital environment," says Cameron McIntyre, PhD, a professor of biomedical engineering at Case Western Reserve University, an investigator and associate director of industry relations at the Cleveland FES Center and co-creator of the Cleveland Course for Advanced Neuromodulation. "When you are able to still see the real world, you can see people's faces and communicate with people around you." This makes HoloLens technology an ideal teaching tool, particularly for understanding something as intricate as the human brain and its exquisite network of interconnected neurons.

When McIntyre invited the neurosurgeons to preview the course, he sought confirmation of its value from these key industry leaders. "The big question was 'Is this just a dog-and-pony show, or is this something real?'" says McIntyre, who developed the course in conjunction with Andy Cornwell, PhD, director of strategic and industrial collaborations at the Cleveland FES Center. "The resounding answer was that this has gigantic value."

A Convergence of Ideas

The incorporation of HoloLens technology into the Cleveland Course for Advanced Neuromodulation was serendipitous. Several years ago, McIntyre began envisioning a course for neuromodulation clinicians that would tap into the expertise of neuroengineers at Case Western Reserve University and the Cleveland FES Center. Clinical neuromodulation encompasses DBS, spinal cord stimulation and sacral nerve stimulation to treat a host of conditions, ranging from spinal injury to Parkinson's disease.

"This is probably a $5 billion a year medical device industry," says McIntyre. "Unfortunately, the vast majority of clinical users of those technologies have no real classical training in many of the basic science components related to the devices they use.” So McIntyre, Cornwell and Tom Mortimer, emeritus professor at Case Western Reserve University who is credited with inventing the field of neuromodulation, began to develop content for the advanced modulation course for clinicians.

Around the same time, Case Western Reserve University forged a relationship with Microsoft to become one of the first educational content developers of its HoloLens device. Housed in the university’s 4,500-square-foot Interactive Commons facility, the HoloLens was originally used to create a HoloAnatomy program to teach medical students about the systems and functions of tissues and organs in the human body. During development of the HoloAnatomy course, McIntyre was invited by the faculty director of the Interactive Commons to participate in a demonstration of the HoloLens.

“I only needed to see if for five seconds, and I knew exactly how we could use it for neurosurgical applications,” says McIntyre. “The HoloLens provides a different way to think about connections in the brain. You can see more of a volume-based visualization as opposed to a 2D computer screen. And you can see how things wrap around each other in ways that are hard to do on computer screens.”

In particular, McIntyre recognized the benefits for stereotactic and functional neurosurgery, a subspecialty of neurosurgery that uses a stereotactical frame – a device attached the participant’s head – and a three-dimensional coordinate system to locate very precise targets within the brain during image-guided and physiologically-guided surgeries to treat neurological disorders. That’s when the advanced modulation course and the HoloLens technology converged.

“We started to think about how we could put everything into this holographic environment and use it to train new neurosurgeons on how to use frame systems, brain anatomy visualization and surgical trajectory planning – all the things neurosurgeons have to take into account when they plan a trajectory through someone’s brain,” says McIntyre.

Creation of the Course

One of the challenges in creating the advanced neuromodulation course was condensing the material taught in a neural interfacing course for biomedical engineering students at Case Western Reserve University into a two-day class relevant to clinicians. In addition, McIntyre and Cornwell had to divide the material among didactic lectures and interactive applications using the HoloLens.

They created three hour-long lectures, each one immediately followed by a HoloLens demonstration related to the material. For instance, the first lecture covers targeted release of neurotransmitters, sodium channel control and electrochemistry. Afterward, the class breaks into groups of approximately five people to apply the scientific fundamentals they learned in the context of deep brain stimulation on a human patient brain example.

The course is designed for first-year stereotactic and functional fellows, who have already completed medical school and their neurosurgery residency. Before rolling out the class to fellows, McIntyre opted to receive feedback from experienced neurosurgeons – what he calls the industry’s “key opinion leaders.” The beta test course in September was “a crazy success,” says McIntyre. “It reinforced that there is a huge desire and need for the material.”

The inclusion of augmented reality was a hit. In fact, it was so well received that the neurosurgeons suggested opening up the course to senior clinicians, too. They would like for tertiary clinics with DBS clinical programs to have the opportunity to send teams including neurologists and neurosurgeons to the course to train together, then those teams could go back to their home institutions and disseminate the knowledge they learned. “That would provide an integrated conceptual understanding of the material among colleagues and allow for seamless transition of information into clinical practice, which would benefit the patient,” says McIntyre.

FES Investigators, Aasef Shaikh, MD, PhD and Cameron McIntyre, PhD collaborate with Camilla Kilbane, MD looking through the Hololens at the angle of a DBS electrode implanted in a patient's brain.

At this point, McIntyre and his collaborators are fine tuning the course based on suggestions from the neurosurgeons and deciding on the best way to proceed with the course, which they would like to offer twice a year to 10 to 12 participants. No matter what the final version of the Cleveland Course for Advanced Neuromodulation looks like, it will capitalize on augmented reality technology and the know-how of local neuroengineers.

"We have the expertise and background on how neuromodulation procedures are done, and we know there's an opportunity to fill an educational niche," says McIntyre. "With the HoloLens, we can offer a completely different way of interfacing with data and a much better way of training clinicians."

Industrial Relations

Industrial Relations & Partnerships

The Cleveland FES Center works to translate research technologies to clinical practice through partnerships with industrial collaborations or the formation of new companies. The FES Center can de-risk the technology transfer process by designing solutions addressing regulatory, documentation, and reimbursement hurdles.

The FES Center leverages years of device expertise and neural technology research to de-risk early stage research. These explorations combine industrial development, academic research, and federal funding opportunities to answer specific questions relevant to the academic investigator and industrial partner.

These types of collaborations have proven enormously successful representing a new model for rapid advances and transfers of research to industry.

Strategic Collaborations

The FES Center believes strongly in collaborative research, and works closely with many groups across the country on a wide variety of research projects centered around neuromodulation, neural rehabilitation, neural prostheses, brain-computer interfaces, deep brain stimulation, and more. We strive to stay at the front of new fields of neural stimulation research and frequently partner with other groups where our collective expertise might dovetail.

FES Center investigators regularly compete successfully for major funding initiatives from federal sources, such as NIH and DARPA, as well as industrial and philanthropic agencies. The most successful of these projects are those with content experts from worldwide institutions, and we actively seek– and are responsive to– outside collaborations.

For more information and to discuss strategic collaborations or industrial partnerships:

Andrew Cornwell, PhD
Director of Industrial and Strategic Collaborations
info@FEScenter.org | (216) 231-3257 | Twitter: @andy_cornwell

We are right on the edge of making that connection between basic science, to scientific research, to clinical deployment and then finally commercialization.

Cameron McIntyre, PhD

Associate Director, Industrial Collaborations
Cleveland FES Center

We do research along the whole continuum from bench to bedside, which means we have to have effective collaborations with the neuromodulation industry to bring research ideas to clinical settings.

Andrew Cornwell, PhD

Director, Industrial and Strategic Collaborations
Cleveland FES Center

Collaborative Partners

FES System on Commercialization Path

Restored hand function is one of the top priorities of people living with cervical level spinal cord injury, affecting nearly 100,000 people in the U.S.

An effort by FES Center investigators to commercialize a neuroprosthesis that restores upper extremity function has received the first year of funding by the NIH's National Institute for Neurological Disorders and Stroke, for what will ultimately be a five-year, $7M effort focused on expanding the use of the neuroprosthesis to two other centers. "We've always been driven to get our FES systems out to more people and have greater impact," said P. Hunter Peckham PhD, principal investigator on the grant. "This funding brings us much closer to our goal." Now completing their first year of the project, co-investigators P. Hunter Peckham PhD, Kevin Kilgore PhD, Megan Moynahan, MS, and their team of engineers and clinicians are focused on readying the technology for commercial production and identifying candidate trials sites.

The upper extremity FES system is built upon the Networked Neuroprosthesis (NNP) platform, a modular, implanted technology designed to provide multiple functions to the same individual. Since its conception in 2001, the NNP has been designed, prototyped, and evaluated on the bench, and is currently implanted in five participants with cervical level spinal cord injury, providing both upper extremity function and trunk stability. "In this study, we're focused on restoring upper extremity function only, " said Kevin Kilgore, PhD, co-investigator on the project. "But the NNP is designed to be much more flexible and versatile, and we have plans to expand to other areas. Participants in this study may well be eligible to join other NNP-based studies in the future." One of the team's goals is to make the NNP available to other investigators interested in studying FES-based solutions to movement disorders, pain management, spasticity and autonomic functions.

The five-year project essentially creates a bridge to the completion of a multi-center pivotal clinical trial, although it will not fund the complete trial. Rather, it allows the team to test the final configuration of the technology, recruit and train two additional clinical trial sites, evaluate study outcomes, file the necessary regulatory submissions, and purchase implants for up to 13 participants. Funding from additional sources such as foundation awards and philanthropy will be necessary to complete the full study needed for FDA approval.

The effort to commercialize the system is being driven by the Institute for Functional Restoration (IFR), the mission of which is to create a sustainable commercial pathway for technologies

intended for small markets. “Normally, a technology that’s been demonstrated to work this well in a small feasibility trial would be snapped up by an interested industry partner,” said Megan Moynahan, the IFR’s Executive Director. “But for products intended for a small market, we have to de-risk more of the commercial pathway before a partner might be willing to license it.” The IFR is working to smooth the pathway to commercialization for the NNP upper extremity system. Its prior successes include securing a manufacturing partner for the NNP technology (Synapse Biomedical, Oberlin, OH), obtaining FDA approval to start studying the system in people, and negotiating with the FDA for a Class II (moderate risk) designation. In 2016, the project was accepted into FDA’s “Breakthrough Medical Devices” program.

Making FES systems available to the SCI community has been a longstanding goal of Peckham’s, whose research in this area has spanned decades, and who has facilitated numerous successful commercial endeavors. “While we’ve got a ways to go before we can claim success,” said Peckham, “I am confident we can deliver on our promise to people with spinal cord injury who have been waiting a long time for solutions.”

FES research participant, Kim Anderson, PhD uses the NNP System to drink a cup of tea.

Education


Social Media & Web Presence
VA
>35,000 views
>30 Waiting Rooms
across the US
1.5 M viewers


FES
center

Spreading the Word

Developing technology and advanced science is most valuable if it is communicated effectively. The Cleveland FES Center is dedicated to the dissemination of information related to our work through hosting cutting edge scientific and community-based conferences, participation in presentations, professional publications, popular media features and community programs. Widespread deployment of new technologies is achieved through professional, educational and commercial partnerships.

From Research to Recovery: New Approaches to the Opioid Crisis

July 19th and 20th, 2019
Case Western Reserve University | Linsalata Alumni Center

Featuring speakers from a broad array of disciplines and institutions across the country, 'From Research to Recovery: New Approaches to the Opioid Crisis' provided a platform for the exchange of ideas and information between researchers, clinicians, and providers. They shared innovative ideas, treatment protocols, and discussed new lines of research inquiry to address the opioid crisis.

Michael Jenkins, PhD chairs the session, "Novel Insights into the Mechanisms of Action of Opioids" while Stephen J. Lewis, PhD, conference host and chair, listens to questions from the audience.

CASE WESTERN RESERVE UNIVERSITY | CLINICAL AND TRANSLATIONAL SCIENCE COLLABORATIVE

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2019 Neural Prosthesis
Live Webinar Series

The Neural Prosthesis Seminar Series debuted in 1988. Since its debut, this series has sponsored numerous distinguished clinicians and scientists, working in areas that include functional neuromuscular and electrical stimulation, neuromodulation, brain computer interfaces (BCI), pain mechanisms and blocking, simulation & modeling, autonomic system, traumatic brain injury (TBI), and other related areas.

The Neural Prosthesis Seminar Series is a public educational forum with prominent presenters active in all areas of research. The series brings together researchers, scientists, clinicians and students in the Northeast Ohio Research Community to encourage the exchange of scientific information on global emerging neuromodulation and neurostimulation topics.

The Neural Prosthesis Seminar Series is sponsored by the Cleveland FES Center in partnership with our co-hosts.

Marom Biksom, PhD

Cameron McIntyre, PhD

Jeffrey Ardell, PhD

Cori Bargmann, PhD

Dejan Marković, PhD

Kenneth Baker, PhD

Tim Bruns, PhD

Christos Davatzikos, PhD

Live stream, interaction, and archives available at
FEScenterWebinar.org

Live Webinar: >100 views

Online post-webinar: >800 views


VA Medical Center
UH
University Hospitals
University Hospitals Case

Consortium Partners

The Cleveland FES Center is a consortium of five nationally recognized institutions: Louis Stokes Cleveland VA Medical Center, Case Western Reserve University, MetroHealth Medical Center, University Hospitals of Cleveland, and Cleveland Clinic Neurological Institute. With the support of these partners, the Cleveland FES Center is able to be at the forefront of academic and clinical research, furthering the advancement of neural technology into clinical standards of care. The Cleveland FES Center strives to create an inquisitive and collaborative environment from which researchers, engineers and clinicians work in a unique alliance to develop innovative, patient-centric solutions that improve the quality of life of individuals with neurological or other muscular skeletal impairments. Through the use of neurostimulation and neuromodulation research and applications, the Cleveland FES Center leads the translation of this technology into clinical deployment.

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development

The Louis Stokes Cleveland VA Medical Center provides clinical care to veterans with complications due to spinal cord injuries, head injuries, or stroke, among other illnesses. Along with significant support of individual research projects, the Cleveland VA provides the core infrastructure to further this veteran relevant mission.

CASE WESTERN RESERVE UNIVERSITY EST. 1826

The Cleveland FES Center's inclusion at Case Western Reserve University in the Schools of Engineering and Medicine enables access to leading academic, clinical and engineering expertise, facilities and a rich learning environment all resulting in a dynamic element for FES research and development.

MetroHealth

Integration into the accomplished Rehabilitation Services of MetroHealth Medical Center enables valuable access to patient care and clinical expertise in Orthopaedics & Orthopaedic Surgery, Neurosciences & Neurosurgery, and Physical Medicine and Rehabilitation.

UH University Hospitals

University Hospitals of Cleveland Medical Center joined the FES Center as a consortium member in 2015. It is the primary medical affiliate of CWRU, and has strong clinical interactions with the LSCVAMC. The UHC Neurological Institute has major capabilities in neurosurgery, neurology, epilepsy, and psychiatry that complement and expand the expertise available from the Cleveland VA and MetroHealth Medical Center.

Cleveland Clinic

Cleveland Clinic's Neurological Institute includes more than 300 medical, surgical and research specialists dedicated to the treatment of adult and pediatric patients with neurological and psychiatric disorders. The multidisciplinary institute offers a disease-specific, patient-focused approach to care. U.S. News & World Report's "America's Best Hospitals" survey consistently has ranked the neurology and neurosurgery programs among the top 10 in the nation and best in Ohio.

2019 By the Numbers

25M Funding

Full portfolio on page 68

154 Scientific Publications

1 Book Cover

14 Book Chapters

154 Presentations

Full list of publications on page 52

PEOPLE

86	Principal Investigators
12	Post-Docs
48	Technical/Clinical Support Staff
64	PhD/MS Trainees
5	Operations

SOCIAL MEDIA

Reaching over 7,000 people each week

1,500+ Followers

TECH TRANSFER

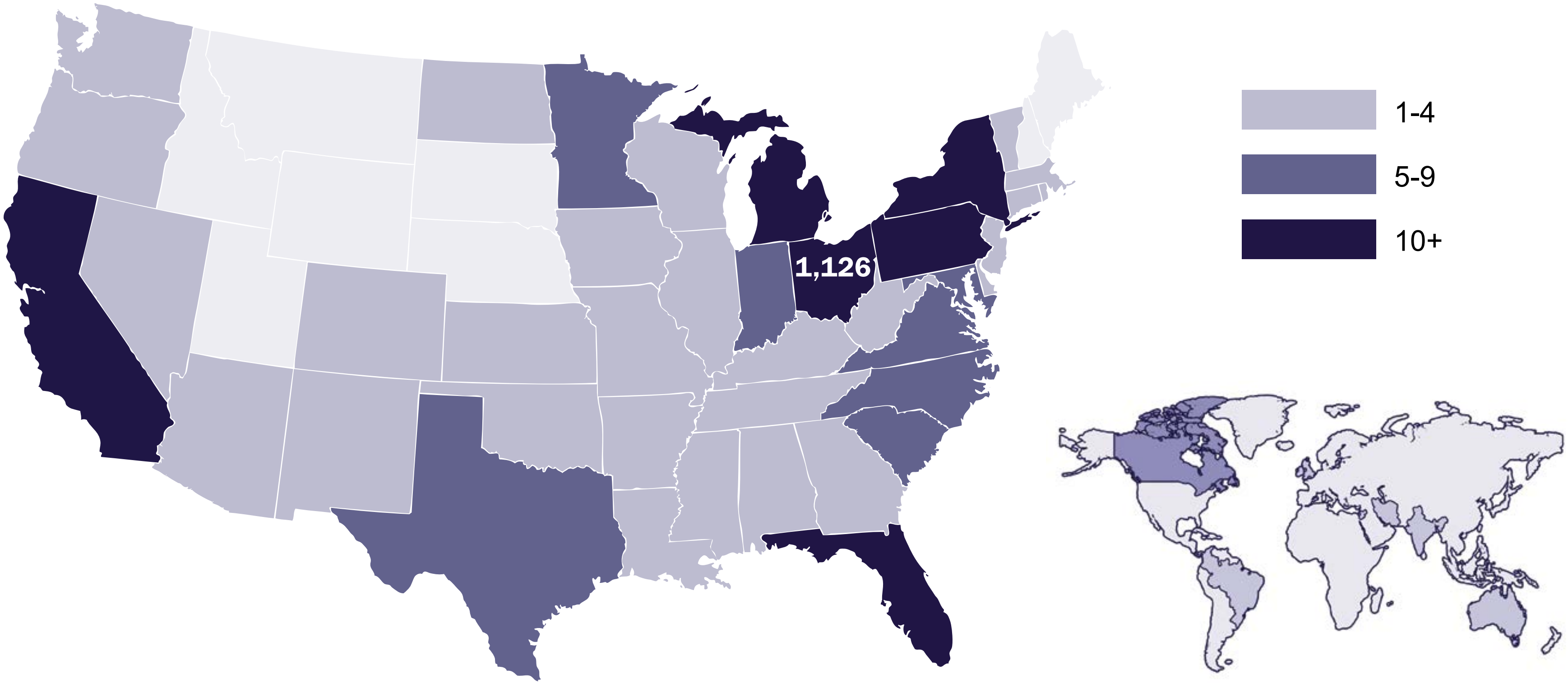
74 Patent Applications

16 Patents Issued

26 Invention Disclosures

1,300 Research Participants

1986-2019



Alabama 4	Delaware 1	Kansas 1	Minnesota 6	New York 16	Pennsylvania 16	Virginia 7	Australia 2	Isreal 1
Arizona 3	Florida 14	Kentucky 1	Mississippi 2	N Carolina 6	Rhode Island 2	Washington 4	Brazil 1	Jordan 1
Arkansas 1	Georgia 3	Louisiana 2	Missouri 4	N Dakota 1	S Carolina 6	W Virginia 1	Canada 6	Persia 1
California 13	Illinois 2	Maryland 5	Nevada 1	Ohio 1,126	Tennessee 2	Wisconsin 2	Columbia 1	Republic of Panama 1
Colorado 3	Indiana 8	Massachusetts 2	New Jersey 2	Oklahoma 4	Texas 6		India 2	United Kingdom 1
Connecticut 3	Iowa 1	Michigan 13	New Mexico 1	Oregon 1	Vermont 1		Ireland 1	

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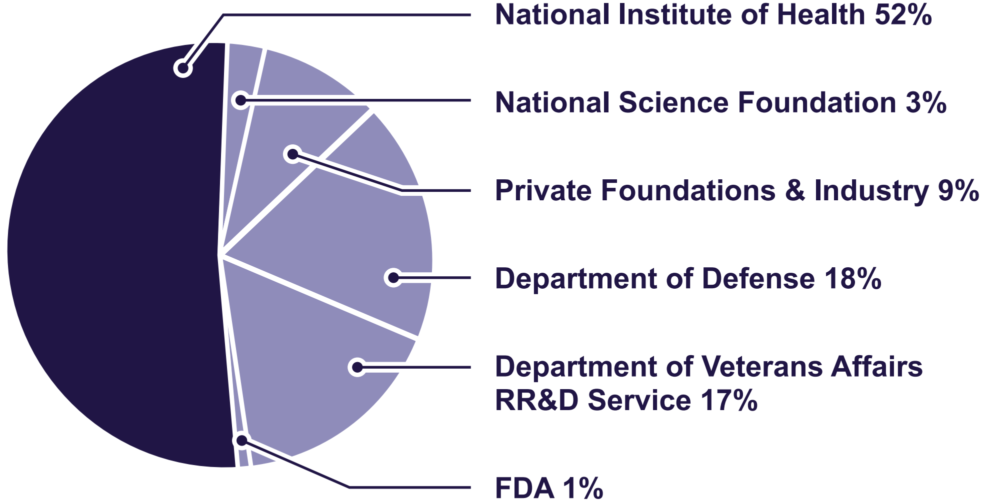
2019 Funding Portfolio

$25 Million



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