
ClevelandFES
NEURAL RESTORATION THROUGH INNOVATION

Cleveland FES Center

Report to the Community 2024

Robert Kirsch, PhD
Executive Director

Ronald Riechers, MD
Medical Director

Dear Friends and Colleagues

It is a year to celebrate new partnerships and outreach! It is such an exciting time in neurostimulation and neuromodulation (FES) research. The Cleveland FES Center is Transforming Rehabilitation through our research thrusts in Movement Restoration, Pain Mitigation, Brain Health, Autonomic Restoration, and Translation and Clinical Dissemination. FES researchers are pursuing research that focus on spinal cord injuries and neurological disorders.

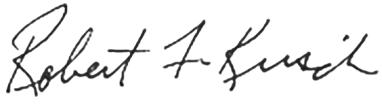
Collaboration is critical. The Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center and the Cleveland FES Center have worked collaboratively on many programs. We are very excited to welcome the Syracuse VA Medical Center - SCI/D Center as consortium member. This alignment is designed to increase shared knowledge and expertise in FES research to better serve Veterans. With the addition of the Syracuse VA Medical Center - SCI/D Center we are positioned to focus on programs that will provide the greatest impact for Veterans and individuals with spinal cord injuries.

Translation continues to be weaved through all FES research. The Summer NeuroTech Talk series debuted linking academic researchers with industry counterparts. The series is designed to share the triumphs and pitfalls along the pathway for research and commercialization.

The “Feeling of Feeling” was featured on CBS News’ 60 Minutes highlighting the work of multiple FES Center researchers and teams. Exploring advancements in artificial prosthetics technology that can now restore a sense of touch. Journalist Scott Pelley came to Cleveland and spoke with volunteers of experimental research who underwent surgery to advance this breakthrough technology.

We encourage you to join us as we work to drive the discovery and development of FES research sooner rather than later. Check out FESCenter.org and follow us on Facebook, LinkedIn, Instagram, and X.

Sincerely,



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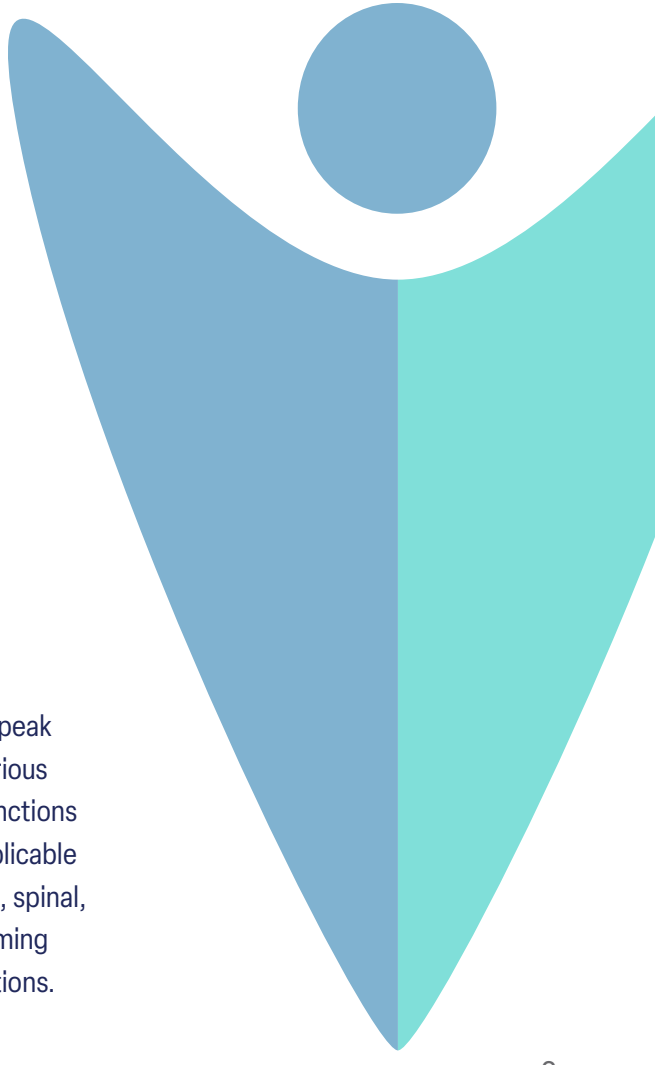
Our Mission

What is Cleveland FES?

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.

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How We Transform

Rehabilitation

The Cleveland FES Center is focused on discovering, implementing, and translating paradigm-shifting rehabilitation interventions. Our research provides a major impact on the daily lives of Veterans, and aims to improve clinical standards of care and make rehabilitation accessible and affordable for all.

FES Center Strategy

Clinical Expertise

Identifying clinical need

Ethics and safety

Implementation in people

Engineering

New tools & technologies

Clinical prototypes

Human interfacing

Collaboration

Science

Physiological mechanisms

New concepts for interventions

Preclinical feasibility of new interventions

Translation & Dissemination

Discoveries into products

Treatments into clinical practice

A Pathway to Innovation

Our Research and Operational Thrusts

The scope of the Cleveland FES Center and the applications of functional electrical stimulation have grown notably over the past several years, leading to additional and expanded research studies. As a result, the neurological systems under study as well as the tangential focus areas have correspondingly evolved and expanded into six research and operational thrusts:

CLINICAL AND BASIC RESEARCH

Brain Health

Targeted activation of neural systems to replace or modulate brain structures

Pain Mitigation

The use of specific neuromodulation and neurostimulation regimens to treat pain

Movement Restoration

Coordinated activation of paralyzed muscles to improve motor functions

Autonomic Restoration

Modulation of autonomic systems to regulate internal body and visceral functions

Translation and Clinical Dissemination

To convert laboratory discoveries in products and clinical practice

Bioethics

Applying a multi-disciplinary approach to solve moral and ethical questions linked to FES research

Brain Health

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. 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. Research in this area has also investigated the use of electrical stimulation to reduce involuntary muscle contractions triggered by neurological conditions.

Restoring Links Between the Brain and the Body

Men and women who have had strokes often find themselves unable to use a hand or arm. That leads to real-life complications on a daily and hourly basis.

The thought of your body not responding to your brain can be a scary one for healthy individuals. But the thought of bringing that ability back to patients is a driving force to investigators for the Cleveland FES Center.

In their varied and collaborative research, investigators Jayme Knutson, PhD; David Cunningham, PhD; Michael Fu, PhD; Aasef Shaikh, MD, PhD, and Ahlam Salameh, PhD, MSc; are focused on using functional electrical stimulation (FES) to restore connections, bringing movement back to a limb, like a hand.

The research is geared toward real-life applications that can provide solutions to complex problems, and is illustrative of the efforts of the FES Center. Together, its scientists, engineers and clinicians are studying how FES can improve the lives of those with neurological or other musculoskeletal impairments.

The Center is a consortium of six nationally recognized institutions: the VA Northeast Ohio Healthcare System (VANEOHS), the Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center, Case Western Reserve University, the MetroHealth System, University Hospitals and the Cleveland Clinic Neurological Institute. Through neurostimulation and neuromodulation research and applications, the Cleveland FES Center vigorously seeks solutions as it fosters a culture of collaboration and support.

“We’re on the cutting edge of where the (electrical stimulation) field is right now,” said FES Associate Medical Director Aasef Shaikh, MD, PhD. “There are thousands of options of how stimulation can be applied and which technologies the stimulation can be paired with.”

Using the Strong Arm to Heal the Weak Arm

Losing hand function on one side of the body is a common result of stroke. It’s a debilitating condition that can make everyday tasks difficult and have a serious impact on a person’s independence.

MetroHealth researchers affiliated with the Cleveland FES Center have been working to develop a remedy with the help of functional electrical stimulation

or directing a flashlight.

"Repeating everyday tasks, with the assistance of CCFES to open the hand may help the person recover neural pathways and restore functional use of the weak hand," said Knutson, a Professor and Staff Scientist in the Department of Physical Medicine and Rehabilitation at Case and the MetroHealth System.

"Our largest study of CCFES to-date showed that CCFES-mediated therapy is more effective than pre-programmed cyclic electrical stimulation, which is the most common method of stimulation currently used in therapy," Knutson says. "The difference is, CCFES allows the participant to control when and how much the hand opens, which makes the device helpful in practicing daily tasks and is important for neuroplasticity."

"We're on the cutting edge of where the (electrical stimulation) field is right now. There are thousands of options of how stimulation can be applied and which technologies the stimulation can be paired with." ***-Aasef Shaikh, MD, PhD***

Back in 2004, Jayme Knutson, PhD, a Principal Investigator at the Center, began developing contralaterally controlled functional electrical stimulation (CCFES) therapy for stroke survivors. Knutson created a device that detects hand opening from the stroke patient's "good" hand and similarly stimulates the weak hand to open, so the patient can practice using their hand in therapy.

The device features a glove wired with sensors and worn on the good hand, which is connected to the stimulation device. On the other side of the device, electrodes stimulate muscles in the forearm, causing the weak hand to open whenever the gloved hand is opened. Once the hand is opened, the person can grasp and release objects and execute a variety of tasks like applying deodorant

Today, these research interests are continuing in the first multi-site clinical trial of CCFES led by Knutson's site in Cleveland (MetroHealth Rehabilitation Institute), with additional sites in New Jersey (The Kessler Foundation), Atlanta (Emory University), and Baltimore (Johns Hopkins University).

"We want to see if our results are repeatable in other locations and with other clinicians who have no prior experience with the regimens," Knutson said. "Ideally, the study will be able to confirm whether using CCFES with occupational therapy is consistently better at helping the brain and body recover hand function than the other protocols."

Combining Muscle Stimulation with Brain Stimulation

Knutson's results with CCFES have also inspired other Cleveland-based studies. FES Center and MetroHealth System investigator David Cunningham, PhD, is now studying the efficacy of a specific type of brain stimulation — transcranial direct current stimulation (tDCS) — administered with CCFES. This noninvasive technology uses a low-level direct electrical current applied to the scalp.

The triple-blinded study investigates three 12-week therapy regimens in stroke survivors who have experienced a loss of hand function: CCFES plus tDCS (two active tDCS montages), and CCFES with sham tDCS.

"This is the first randomized clinical trial of stroke survivors using noninvasive transcranial direct current brain stimulation in combination with CCFES as a form of therapy for restoring hand function after stroke," said Cunningham, who is also Assistant Professor of Physical Medicine and Rehabilitation at Case and the MetroHealth System. "Ideally, the study will help clinicians provide more prescriptive and effective therapy regimens, including the use of functional electrical stimulation, to help stroke patients regain hand function."

To understand how the brain changes, the study also uses another form of stimulation called Transcranial Magnetic Stimulation (TMS). With TMS, a coil is placed on the head that is activated with electromagnetic current, stimulating the brain. The participant's responses are carefully tracked through the resultant muscle activation.

"When the stimulation is applied, there is a muscle response. Depending on how I manipulate the timing and intensity of the simulation, I can make various inferences about different pathways within the brain," Cunningham said.

The goal is to enroll 63 participants who experienced a stroke between six months and two years prior to the study and who now experience chronic hemiplegia resulting from the stroke.

The long-term vision is an effective technology-based treatment that stroke survivors can self-administer at home. The present study is a stepping stone toward that goal.

"This study is building off the positive findings of the CCFES studies," Cunningham said. "There do appear to be limitations in the ceiling of recovery that people can experience. But by adding noninvasive brain stimulation, we might pass through the ceiling or at least accelerate recovery so that it takes less time to get to the ceiling."

Relief from Muscle Spasticity

Still more achievements from the FES Center's stroke rehabilitation researchers at MetroHealth include continued progress on an electrical nerve block to turn off overactive muscles.

Over the past two decades, investigators Kevin Kilgore, PhD, and Niloy Bhadra, PhD, later joined by investigator Tina Vrabec, PhD, have developed, tested and refined a method to block nerve conduction using high frequency stimulation. Dr. Kilgore's original motivation for developing the electrical nerve block was to

treat muscle spasticity in individuals who experienced a stroke or cerebral palsy in hopes of relaxing the spastic muscles so that FES could be used to stimulate other muscles and produce functional movement.

Knutson and his stroke research colleagues at MetroHealth realized that using the technology to treat spasticity in stroke patients was by itself an important pursuit.

"As stroke rehabilitation researchers, we're eager for a technology like this, because we have a lot of stroke patients who suffer from spasticity," Knutson said. "My focus is in developing a device to relieve spasticity for these patients."

Having such a treatment could reduce the pain caused by muscle tightness, prevent joint contracture, or simply make it easier for stroke patients to do things like put their arm through a shirt-sleeve, Knutson explained.

Working toward that goal, Knutson led recent work on a first-in-human intraoperative demonstration of the nerve block to treat spasticity. The team used electrical stimulation to create artificial arm muscle contractions during surgery, then applied the nerve block electrode to effectively turn the muscle contraction off. A case study sharing the work was published in the summer of 2024.

"We demonstrated that the electrical nerve block could work," Knutson said, adding that he is now working to secure funding for a clinical study of the technology in stroke survivors. "The team has been developing and refining the electrical nerve block technique for 20-plus years so that it would be ready for human studies," Knutson shared. "With the demonstration completed, we've reached that point. So we're very excited about moving this technology development forward into clinical trials."

Taking a Closer Look at Brain-Muscle Connections

Salameh's work focuses on the ways the brain communicates with muscles and how muscles respond to the brain. Her study looks at patients with chronic issues with their hand or arm six months after a stroke.

The study flows from her original focus on studying changes in brain activity using a commercially available EEG-NIRS system — Near Infrared Spectroscopy. The goal was to help improve arm function for people after a stroke.

During the research, Salameh realized how much still isn't known about the normal physiology of how the brain controls arm function.

"We were trying to treat something without knowing enough details on the normal physiology and without knowing how the disease or stroke changes the normal physiology," said Salameh, an assistant professor at the Kent State University College of Podiatrist medicine and the director of the university's Neurophysiology and Neuromodulation Lab.

This led to her present study, which uses EMG (electromyography) to measure muscle activity in healthy individuals while simultaneously using EEG (electroencephalogram) and the NIRS system to record brain activity.

"The goal is to answer two questions," Salameh said. "First, how is the brain talking

to the muscles, commanding the muscles to do the activity and how the muscles are responding. And second, how do the muscles performing the task talk to each other."

For the study, information garnered from healthy individuals is being compared to information from those who have had a stroke to see what differences may exist in the brain-muscle signals.

"The timing and the strength of the signals when the brain is talking to the muscles or when the muscles are talking to each other is not the same between somebody who doesn't have a disease compared to somebody who has it," she said.

> *"I'm very hopeful and excited about the work, because we're changing the way we're analyzing the data. By breaking the movement down into small blocks, we found a lot of information that we'd been lacking."* ***-Ahlam Salameh, PhD, MSc***

Salameh said the research is in early stages, but she has accumulated a significant amount of data both from healthy participants as well as those who have experienced a stroke. Analysis illustrates the intricacies and details of brain-muscle communication.

Salameh is now preparing to publish the results of this work.

"I'm very hopeful and excited about the work, because we're changing the way we're analyzing the data," Salameh said. "The traditional method is missing a lot of information because people have traditionally been looking at the movement as one block. By breaking the movement down into small blocks, we found a lot of information that we'd been lacking."

That study may help Salameh apply the findings to therapy protocols, which is a major reason for her excitement.

Studying Neurostimulation as a Treatment for Parkinson's Symptoms

The Center's Associate Medical Director Aasef Shaikh, MD, PhD, is also heavily involved in studying and restoring lost connections in the brain. Shaikh is also a neurologist with both the VA Northeast Ohio Healthcare System and with University Hospitals Cleveland Medical Center.

His research aims to better understand and treat conditions common in people with Parkinson's Disease: specifically balance, involuntary muscle contractions (dystonia), and tremor.

Funded by the U.S. Department of Veterans Affairs, Shaikh's work is oriented to benefit the population of about 3 million Americans – including 100,000 U.S. Veterans — diagnosed with Parkinson's Disease.

“One of the big problems that people with Parkinson’s disease face is a lack of balance, which can lead to falls. They also have issues with eye movement, vision and perception,” Shaikh says.

He explained that many current Parkinson’s treatments focus on correcting movement-related systems. In contrast, his studies center on non-motor symptoms connected with the disease.

“My research is focused on eye movement, vision impairments, balance and perception, which may affect navigation and walking and lead to an increased risk of falls.”

The participants in the study are individuals receiving deep-brain stimulation, already a standard of care to treat Parkinson’s tremors and involuntary movements. DBS uses surgically implanted electrodes to stimulate nerves in the brain, effectively curbing Parkinson’s tremors.

Shaikh is leveraging those electrodes to better understand which regions of the brain are affected by stimulation and how they respond. The goal is to find which areas of the brain control vision and perception, and then stimulate those areas to treat or improve symptoms.

The work has been underway for close to three years and has already shown promising results, Shaikh says.

“We are finding the areas of the brain which, when stimulated, can improve the person’s perception of their own movement and also improves their ability to see or make eye movements.”

Another of Shaikh’s studies is looking at how adaptive exercise might benefit brain health in Parkinson’s patients. Some of the participants in that study have DBS, allowing Shaikh to see how brain activity changes during exercise.

Medical professionals already know that exercise benefits Parkinson’s patients, but Shaikh hopes to learn what happens at a neural level.

“The idea is to understand how can we integrate exercise with deep brain stimulation to help treat Parkinson’s symptoms,” said Shaikh.

The team is using an adaptive bicycling exercise therapy that changes from one day to the next, depending on the participant’s performance.

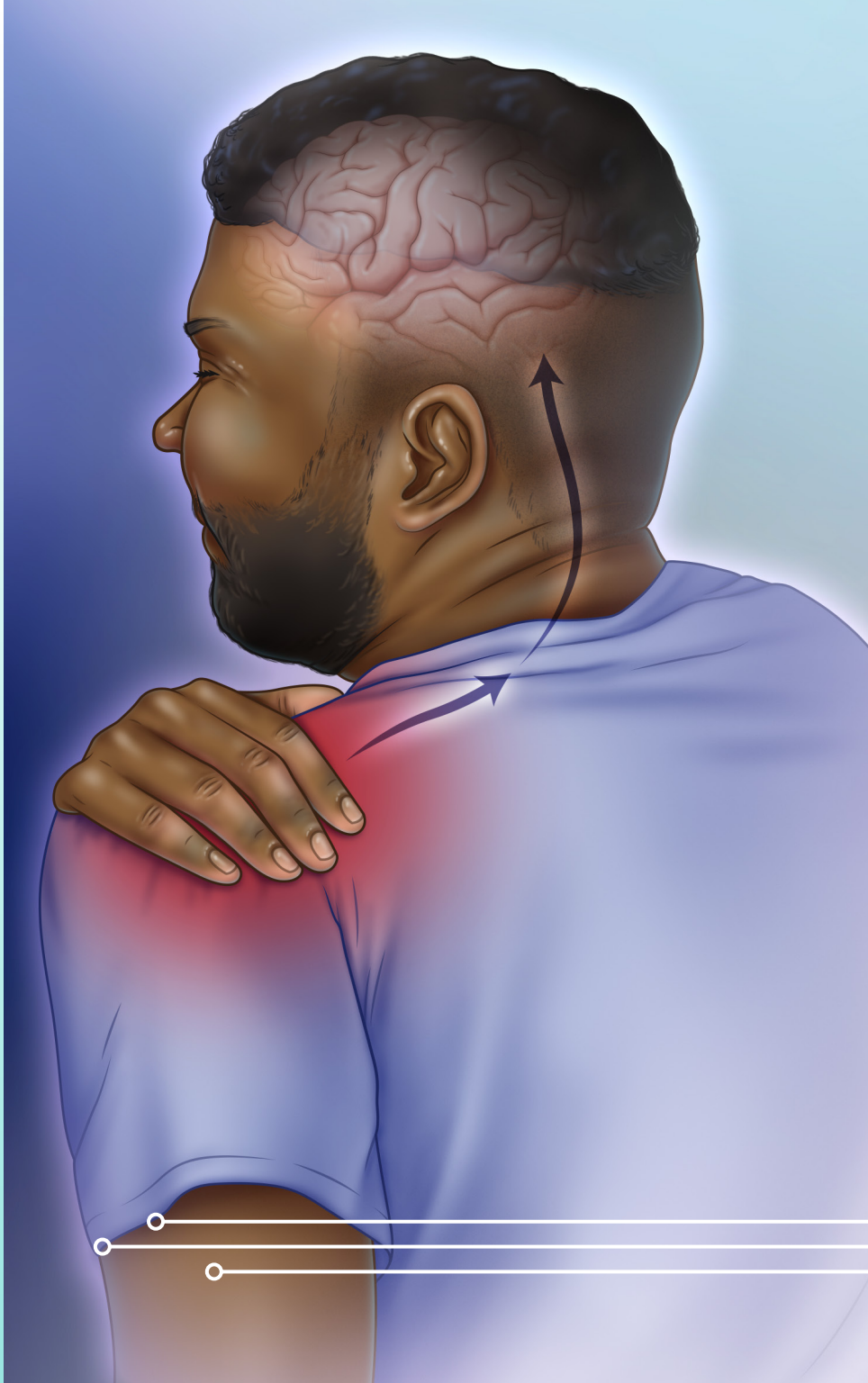
“If the person does well one day, it will give them a more challenging paradigm the next day,” Shaikh says. “If they don’t do so well, the training becomes less challenging.”

The research is in early stages, with the team currently collecting data to create algorithms leading to adaptive training plans.

“We found that there are certain parts of the brain that respond to exercise. And when you stimulate those parts of the brain during exercise, it’s possible that you can improve symptoms like movement, tremor and stiffness to an even greater extent.”

Pain Mitigation

Effective pain management is a critical component of healthcare, leading to improved patient outcomes in recovery time, hospital stays, and overall quality of life. While pharmaceuticals are a pillar of pain treatment, researchers at the Cleveland FES Center are studying neuromodulation and neurostimulation as potentially powerful replacements for pain-relieving medications. By focusing on the effects of electrical current on neural structures – alongside collaborations with top clinical partners – the center's world-class investigators are at the forefront of optimizing patient care and well-being.



FES Researchers Study the Brain in the Battle Against Chronic Pain

Treatments for chronic pain are as diverse as the causes – from over-the-counter and prescription drugs to acupuncture and various mind/body techniques. As no single method is guaranteed to produce complete or even prolonged relief, researchers at the Cleveland FES Center are seeking to alter the pain signals themselves as they travel through the body.

Known as neurostimulation or neuromodulation, the therapy works by delivering electrical stimulation to parts of the nervous system, whether a peripheral nerve, the brain, or nerves and/or cells in the spinal cord. Using either a noninvasive or implantable device, the treatment aims to reduce the user's perception of certain types of pain inside the body.

In recent years, FES Center investigator Rich Wilson has harnessed electrical stimulation to alleviate long-lasting shoulder pain for stroke patients – a notoriously difficult-to-treat problem that impacts upwards of 84% of stroke survivors, according to the American Stroke Association.

"One of the things most associated with the development of chronic shoulder pain after stroke is the severity of the stroke," says Wilson. "If someone has a high level of paralysis around the muscles of their shoulder, they lose the ability to protect the shoulder joint, making it more likely they develop chronic pain."

A stroke survivor-study participant under Wilson's care will have an FDA-approved electrode implanted. The wire is plugged into a stimulator the size of a small remote control. The stimulator provides current to the shoulder muscles six hours per day for three weeks. After the period of stimulation, the electrode is removed.

Theoretically, creating a muscle contraction every 30 seconds for hours at a time tells the brain that the shoulder is moving, even if it is not, Wilson says.

"So, this information going into the nervous system induces it to change from that chronic pain state to saying, 'Let's shut down this chronic pain phenomenon,'" says Wilson, who chairs both the Physical Medicine and Rehabilitation Department at MetroHealth System and at the School of Medicine at Case Western Reserve University (Case). "We don't know yet if this is an active process or if it's inhibiting another process, but somehow it's creating long-term pain reduction for patients."

More recently, Wilson, working with collaborators Gustaf Van Acker, MD, and Chong Kim, MD, has been seeking innovative solutions around the treatment of knee pain. Through the partnership with FES Center, the team completed two pilot trials where participants had electrodes implanted into muscles around the knee – subjects with arthritis or a recent knee arthroplasty had reduced pain after using electrical stimulation for seven weeks, allowing them to complete daily activities.

With this promising data, Wilson has submitted a National Institutes of Health (NIH) grant to study effects of exercise-based therapy both with and without electrical nerve stimulation.

Overall, about 20,000 stimulation devices designed specifically to manage pain have been implanted into individuals over the last eight years – Wilson is thrilled to be at the forefront of this potentially transformative technology, he says.

"With this sort of research, we can figure out how to help a large group of people," says Wilson, also co-director of the MetroHealth Rehabilitation Institute, part of the MetroHealth System, and a professor of physical medicine and rehabilitation at the Case school of medicine. "I think about all the patients I'll never meet who this innovation could make a big difference for, and that's pretty exciting."

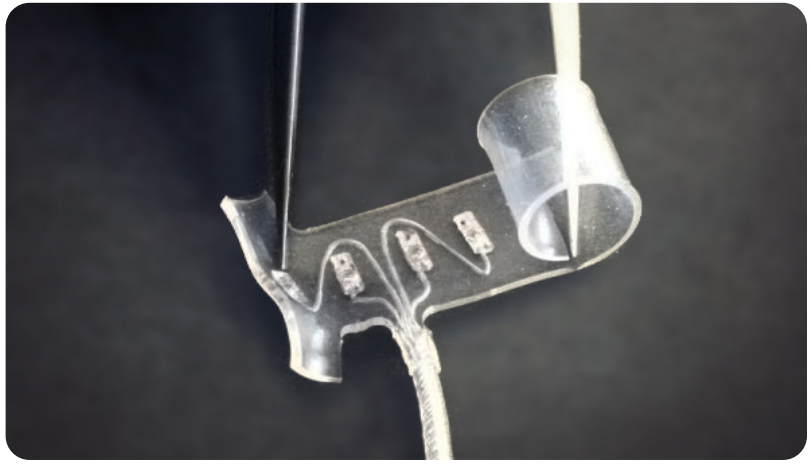
"If we don't pause to build new tools and devices to probe these new questions, we're not going to be able to solve the chronic pain problem." ***-Carl Saab, PhD***

Harnessing Electrical Power

Chronic pain is discomfort that persists longer than 12 weeks, according to the NIH. Although the original source of pain may be known – such as a sprain or injury – the body sometimes sends pain messages to the brain even when the original source is gone or diminished.

Wilson's work is just one vital facet of the ongoing research taking place through the FES Center, a consortium of six nationally recognized institutions: VA Northeast Ohio Healthcare System, Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center, Case Western Reserve University (Case),

MetroHealth System, University Hospitals, and Cleveland Clinic Neurological Institute.



Tina Vrabec, PhD, also a research investigator with the Center, is focused on nerve block treatments utilizing a tiny electrode of her design. Vrabec is also a biomedical engineer with Case and an assistant research faculty member at MetroHealth System.

The level of block is controlled by the patient via an external device. In light of the nation's ongoing opioid crisis, people who suffer from chronic pain tend to be more willing to try a non- or minimally invasive solution over a potentially addictive pain pill, Vrabec says.

"There's a lot of suspicion of opioids and what they've done for people," she explains. "People are wary of things that could have side effects or affect them in unknown ways. The nice thing about a nerve block is that it's something that could be turned on and off. When you take any kind of pharmaceutical, it can't just be turned off."

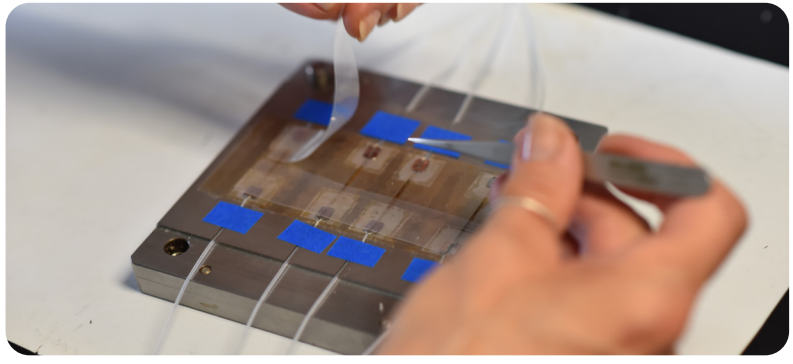
Vrabec joined the FES Center in 1997, developing electrodes that range from fully implantable to operating externally on the skin. Pre-clinical testing continues on a patient-controlled external device that would allow users to actively manage their level of nerve block. Researchers are working with a local biotech company H-Cubed on the project.

"The nerve block is mostly a numbness sensation," says Vrabec, a biomedical engineer at Case. "There is spinal cord stimulation that masks pain signals, but with the nerve block, it's like you're putting lidocaine on the nerve."

Meanwhile, a current pilot project at the FES Center combining nerve block technology and electrical stimulation could provide patients both pain relief and enhanced functionality. Currently, this "bimodal" control is being tested in response to cardiac biomarkers essential in assessing heart health and diagnosing various cardiovascular conditions, Vrabec says.

"The combination of block and stimulation can both upregulate and downregulate cardiac function, providing patients with an adaptable solution to cardiac dysfunction," says Vrabec. "This system would work in much the same way as a heater and air conditioner work together to regulate temperature. A system with both of these elements can adapt to the patients' disease progression over time as well as immediate cardiac demand."

Vrabec continues, "To apply this concept to pain, we could develop a sensor to detect inflammation, for example. Then you have a way of turning on the block preemptively to prevent the onset of pain. What we really want to work toward



is something that's convenient for the patient, and can be adapted over time. The more solutions you have, the easier it is to push forward to the commercialization path."

Going to the Source

The interdisciplinary research group at FES Center encompasses neurologists, pain physicians, engineers and physical therapists. Stroke neurologist Svetlana Pundik, MD, MS, is attempting to "image" the brain state of pain relief achieved by spinal cord stimulation for chronic pain. Her imaging tool is a technique called resting state Near Infrared Spectroscopy and Electroencephalography (rs-fNIRS/EEG).

Investigators including Pundik are enrolling military Veterans for the noninvasive neuroimaging technique. Her participants are either longstanding users of spinal cord stimulation (SCS) for chronic back and leg pain or are currently being evaluated for its use.

Although SCS is effective for many people, some individuals do not benefit from the treatment, notes Pundik. To that end, researchers will evaluate patterns in brain signals in response to spinal electrical stimulation. Finding the signature for

pain relief would improve understanding of the therapeutic effect of SCS, and may even help identify the individuals most responsive to the pain-mitigating technique.

"We are a year into the pilot – the hope for it is to become a foundation for a bigger study to understand where pain lives in the brain, what brain states are related to pain, and when pain is reduced with spinal cord stimulation," Pundik says. "If we know where pain lives, we can potentially intervene with other means, like brain stimulation rather than spine stimulation. Most importantly, this study will hopefully help us figure out how to best select patients who will benefit from SCS."

The study, funded by the U.S. Department of Veterans Affairs Research and Development Service, will enroll participants for each test group – cohorts that include current SCS patients and those not yet under care.

Participants are fitted with a sensor-laden cap, while an infrared light is

flashed into the brain. The cap also picks up electrical brain signal with EEG. Light reflection off the tissue and electrical signal are then used to evaluate brain function, with experts in near infrared spectroscopy and EEG assisting researchers on the data processing side, says Pundik.

"This technology allows us to assess the connectivity of different brain regions," says Pundik. "The cap is collecting data from the whole brain – data that we think is important to understand pain processing. We will try to understand how connectivity of different brain region is related to pain and pain relief."

The near infrared/EEG project has funding for another year, a span in which investigators are aiming to build a strong foundation for future research for improving current methods of pain relief and develop new ones.

"Spinal cord treatment requires putting a wire electrode in the spinal column, along with implantation of a stimulator under the skin," Pundik says. "People are living with this hardware, so it's expensive, and there's risk associated with the procedure, too. The question is, how can we predict who will continue benefiting from SCS for a long time."

While it may be years before near infrared/EEG is commonly used, Pundik cannot help but be enthusiastic by the possibilities.

"As a neurologist, I am excited to contribute to further understanding of brain function," she says. "There is improper use of narcotics because we don't have perfect tools to treat pain. By studying the brain, we are evaluating the headquarters of chronic pain. That's my reason for doing this study."

"What we really want to work toward is something that's convenient for the patient, and can be adapted over time. The more solutions you have, the easier it is to push forward to the commercialization path." ***-Tina Vrabec, PhD***

Identifying Brain Biomarkers of Pain

In his 16 years as a professor at Brown University, the research conducted by Carl Saab, PhD, in neurosurgery and neuroscience led him to a question: How can we translate neuroscientific discoveries to help pain patients and their clinicians?

The FES Center and the Cleveland Clinic provided a possibility. In 2020, Saab moved to Cleveland to serve as director of the Pain STAR (Science Technology And Research) Lab, and as scientific director of the Cleveland Clinic Consortium for Pain. The consortium fosters research and collaboration in diagnosing and

finding novel methods to treat pain. Along with these appointments, Saab also became an investigator with the Cleveland FES Center.

Now, Saab observes, there is a transformation taking place in how researchers understand pain from a biological perspective. He believes researchers have a special opportunity because research indicates that pain – and particularly chronic pain – might be detectable via physiological characteristics of the brain.

Saab explains that in order for pain treatments to be effective, researchers and clinicians need to account for the way brain networks and circuits behave.

"We have to start asking questions about where these neural circuits are in the brain, how they form networks and how they behave," Saab explains.

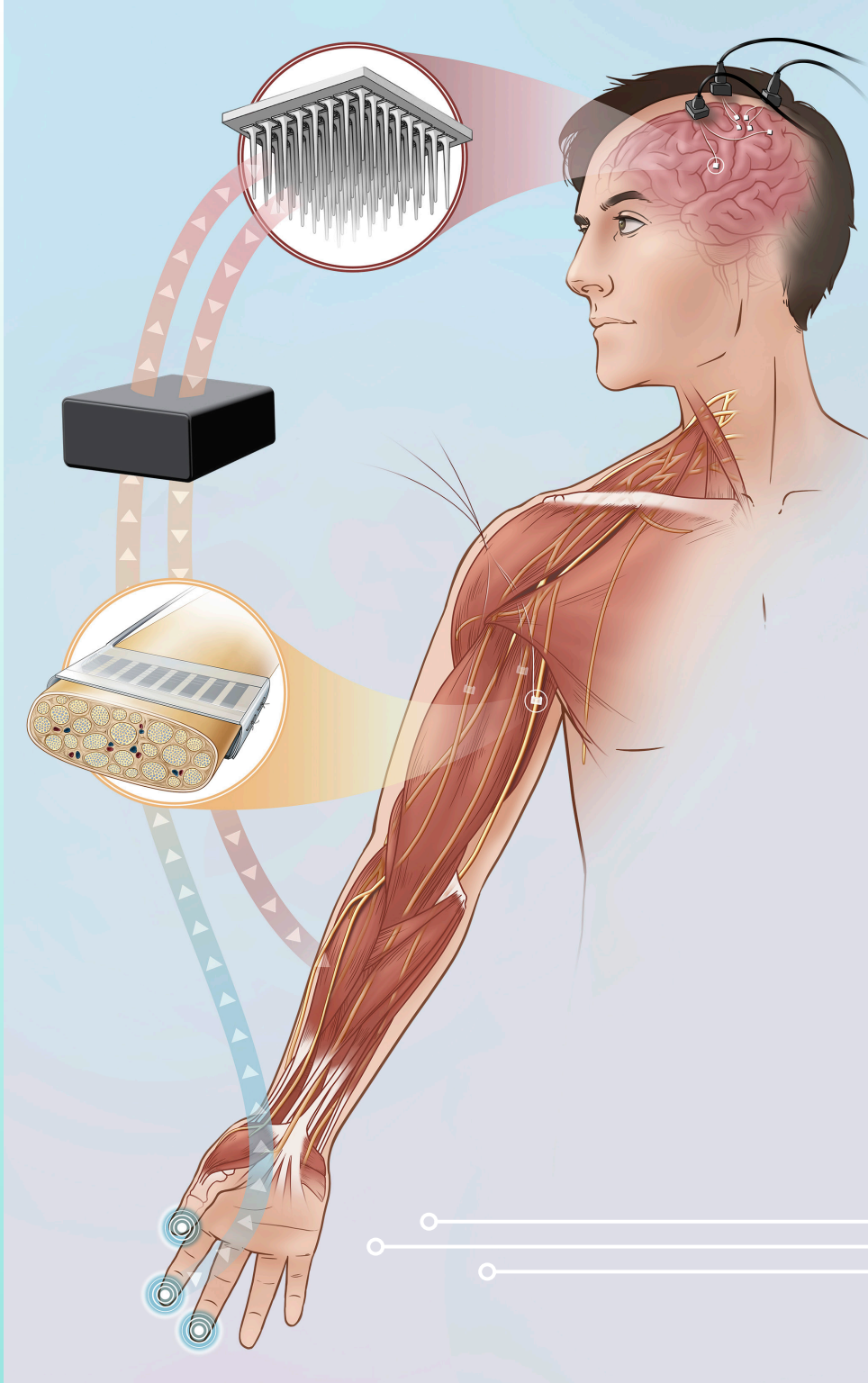
To that end, a major element of Saab's work has been translating chronic pain to a diagram resembling a circuit board comprising interconnected neural cells in the brain. It's a scientific approach that Saab describes as quite novel.

"If we don't pause to build new tools and devices to probe these new questions, we're not going to be able to solve the chronic pain problem," he says.

Saab's lab also incorporates optogenetics – the use of light to control neurons with unprecedented cellular and temporal precision – in pre-clinical trials to map neural pathways. The study has allowed Saab to focus on a particular sensory circuit that misbehaves during pain, and at a level that is not observable with traditional imaging systems. Saab's hope is that the work will lead to more objective, comprehensive diagnostics for pain, ultimately resulting in more effective measures of pain relief.

Movement Restoration

The Cleveland FES Center was founded in 1990 to improve the lives of stroke and spinal cord injury patients with severe limb and respiratory disabilities. FES stands for Functional Electrical Stimulation, and the goal is to use FES – or electrical stimulation – to return movement to patients with varying levels of paralysis. The field has undergone rapid development in the past three decades, leading to a wealth of scientific knowledge and clinical treatments. In building upon this work, the FES Center has established comprehensive research programs around the developing area of movement restoration. As a leading innovator, the center continues to bridge the gap between laboratory discovery and real-world patient benefit.



Using Electrical Stimulation to Restore Movement and Sensation After Spinal Cord Injury

Northwest Ohio native Austin Beggin learned about the Cleveland FES Center in the midst of his recovery. After a devastating 2015 spinal cord injury that paralyzed him from the shoulders down, Beggin began to explore potential research opportunities early on in his recovery journey.

In the first several months after his injury, Beggin received treatment at the Rehabilitation Institute of Chicago, now known as the Shirley Ryan AbilityLab, before transitioning to outpatient rehabilitation at Ohio State University's Center for Brain and Spinal Cord Research.

Treadmill and stationary bike sessions with an occupational therapist led to incremental increases in Beggin's movement capabilities, and the use of surface stimulation was also introduced. However, Beggin was not satisfied with his functional recovery.

"I felt like I was in great shape, but unfortunately, I never saw much recovery in the sense of anything coming back," says Beggin, whose spinal cord was injured in a diving accident on Florida's Gulf Coast. "I started to get much stronger in my lungs and other parts of my body, but the treadmill and surface stim didn't bring much movement back."

Beggin's occupational therapist pointed his patient to groundbreaking research taking place at the FES Center – namely, the use of brain implants and surgically implanted electrodes to revive movement and feeling for people with neurological impairments.

It's the work of the ReHAB project, which stands for Reconnecting the Hand and Arm to the Brain (ReHAB). The team comprises FES investigators A. Bolu Ajiboye, PhD; Emily Graczyk, PhD.; Robert F. Kirsch, PhD; Dawn Taylor, PhD; and Jennifer Sweet, MD. Since 2019, the ReHAB team has been developing an innovative implantable system that enables patients to directly control and move paralyzed limbs using their brain.

Beggin joined this work in late 2020, when he had cuff electrodes surgically implanted. Microelectrode arrays were also placed in Beggin's brain to record brain signals associated with movement and to stimulate the sensory areas of the brain for touch restoration.

Beggin acknowledged the significance of opting for brain surgery when making the decision to pursue the opportunities presented by the study.

"My body was almost this perfect vessel to be used for some type of research that could benefit me and others," Beggin says. "It's about giving people with spinal cord injuries some type of independence and a better quality of life."

Beggin dedicates two weeks monthly to the Center's ReHAB study, with research sessions averaging four hours each.

The months and years since Beggin had his brain mapped onto a computer have been marked by a series of small but significant milestones, he says.

"The first year, we didn't get much movement in the hand, but starting in year two, I got to the exciting part of finally getting to open and close my hand under brain control," says Beggin. "I'd get to do it for a couple minutes at a time. It wasn't drastic movements, but it was definitely a squeeze and the fingers and thumb opening up."

Sophisticated algorithms convert brain signals into commands that control arm movement. The ongoing clinical trial allows participants with spinal cord injury to govern limb movement directly with their thoughts, a breakthrough that garnered national interest during a segment on "60 Minutes" in spring 2023.

Attention from the popular news program also helped the project secure a $4.5 million gift from an anonymous donor. Funding will expand the ReHAB team's research capabilities, ideally bringing the high-tech system to more people with spinal cord injury and/or paralysis.

An injury like Beggin's – specifically at the C3 or C4 level of the cervical spine – generally causes paralysis of all four limbs. Providing patient improvement is a daily motivator for Ajiboye, a professor in the Case Western Reserve University Department of Biomedical Engineering and a research investigator at the VA Northeast Ohio Healthcare System.

"There is a scientific interest and there is a personal interest, because you have an opportunity to fundamentally change the lives of people living with these injuries." ***-A. Bolu Ajiboye, PhD***

A Fundamental Life Change

The ReHAB Project harnesses a Brain Machine Interface (BMI) to measure the brain's electrical activity that occurs when Beggin attempts to make movements with his hand or arm. Electrodes are placed in the part of the brain responsible for sending movement information to the body's muscles, as well as other brain areas associated with movement planning. FES electrodes are implanted in a paralyzed upper limb as well, stimulating nerves which in turn send the signals to the paralyzed muscles, so the person can voluntarily move their own arm and fingers.

"There is a scientific interest and there is a personal interest, because you have an opportunity to fundamentally change the lives of people living with these injuries," says Ajiboye. "It can give a new level of independence for the most severe cases – this population has very little or few options for volitional movements otherwise."

Ajiboye is joined in this effort by Graczyk, an assistant professor of biomedical engineering at Case and an investigator at the VA Northeast Ohio Healthcare System.

Together, the team is unraveling the complex network of neural pathways

between a patient's brain and arm using multiple methodologies. The system's electrodes stimulate neural pathways, enabling individuals with disabilities, including SCI and amputation, to experience varying levels of sensation required for grasping, touching, or even holding their child's hand.

"We are able to restore function to people who, due to their injury, can't do simple things like feed themselves or drink a glass of water," Graczyk says. "That's something they rely on others to do, and that can be very challenging for them to deal with."

Showcasing the Center's Research

The FES Center, housed in the VA Northeast Ohio Healthcare System, researches innovative solutions to improve quality of life for people with neurological or other musculoskeletal limitations. The Center is a collaboration among the Stokes facility, the Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center, MetroHealth System, Case Western Reserve University, University Hospitals of Cleveland, and the Cleveland Clinic Neurological Institute.

The organization studies the use of electrical stimulation to help patients manage pain, regain hand and arm function, restore autonomic bodily functions, and treat nervous system disorders like Parkinson's Disease.

The ReHAB project focuses on tetraplegia, or paralysis of both upper and lower limbs, typically caused by spinal cord injury at the neck level. Individuals with tetraplegia experience varying degrees of movement and sensory loss and may require assistance with everyday activities.

About 300,000 people in the U.S. have tetraplegia, with approximately 12,000 new cases treated each year. VA support is a cornerstone of the Center's work, and for this project in particular, because Military Veterans account for a disproportionately higher share of tetraplegia patients. Besides motor function impairments, those with partial injuries may suffer sensory deficits, including an inability to perceive touch.

Through electrical stimulation applied to his nerves and brain, Beggin is experiencing real-time sensory response akin to having his fingertip gently squeezed, Graczyk explains.

"We've used nerve stimulation to restore sensation to other participant groups in prior studies," Graczyk says. "But we've demonstrated (with Beggin) that we can get very repeatable, reliable sensation from stimulation of the brain that the participant perceives as existing on their finger."

The Most Freedom Possible

After three-plus years of at-times grueling work, Beggin can reach a hand to his face with the help of the FES provided by the ReHAB system. Enhanced sensation also lets him know how much force to apply when handling a hard or soft object.

"Right now, we're at the point where we can incorporate everything together, which I'm excited about," Beggin says. "We did a lot of sensory tests with the brain, but never incorporated it with moving. For example, grabbing objects

while being stimulated at the exact same time to give you that enhanced sense of touch. So, we talked about different objects where you have to apply a certain amount of force without breaking it, like an egg."

Graczyk explains that the integration of sensory feedback and movement is the team's next immediate goal. "We have not yet integrated the full system together but are working towards it and should be ready to go with a fully integrated system demonstration in a few months," she says. "The full system would be BMI decoding plus FES for reanimation, plus stimulation for sensory feedback."

Similarly, Ajiboye notes that restoration of movement and sensory feedback remain the core objectives of the ReHAB project – not only the simple closing and opening of a hand, but more involved movements like reaching out to grab an object as well as performing basic personal hygiene activities.

"Our focus has been to restore the ability to move the shoulder and elbow, and, more recently, improve dexterous hand function," Ajiboye says. "Those complex hand patterns allow people to be more precise with activities of daily living."

Among the program's long-term goals is developing a take-home version of the brain recording and electrical stimulation system, a project funded via a U.S. Department of Veterans Affairs merit review. Work on a home-based platform is in the lab phase, and researchers will be tasked with creating a portable system that people can use 24/7.

While many FES technologies are often employed for at-home therapeutic exercises as well as functional activities, existing systems fall short of the ReHAB project's larger mission, Ajiboye says.

"The brain-controlled FES system has not been developed for robust home use, so our goal with the grant is to integrate the systems and show feasibility in design criteria," Ajiboye says. "We haven't talked about commercialization yet – our immediate goal is to develop these systems further, show their efficacy, then talk about what it would take to make them more widespread and available for people."

Realizing these ambitious goals depends on a skilled team along with brave patients willing to pioneer new research, Graczyk says.

"That's why we do the work that we do – to see the impacts that it's having on people with spinal cord injuries," says Graczyk. "Austin has the best attitude and is a joy to be around. He's always excited to be doing sessions and to advance this technology. It's great to see him getting excited to do this science, and the students (at FES Center) being excited to work with him."

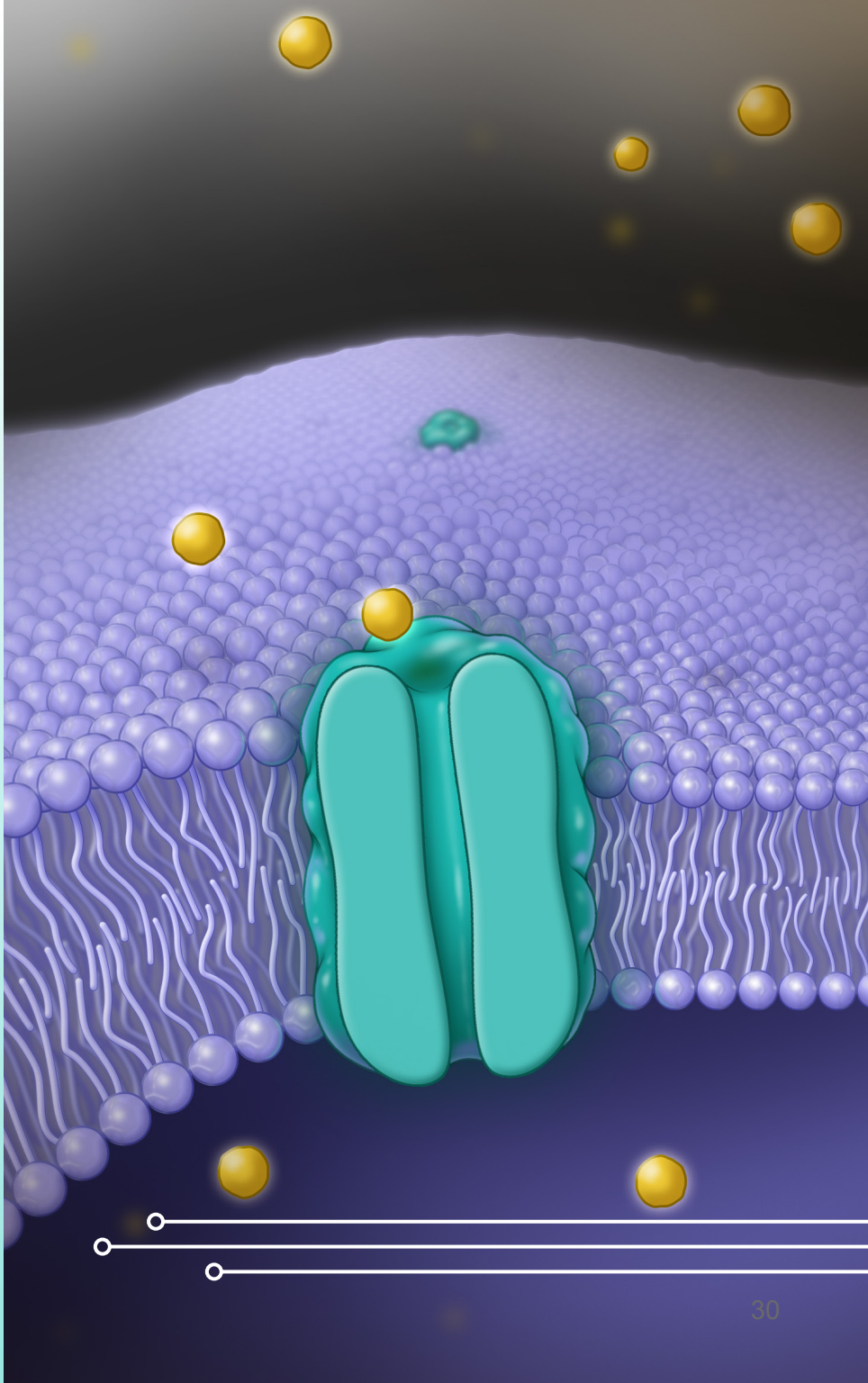
For Beggin's part, he says he feels blessed to contribute to an innovation with potential to transform lives.

"I've been honored to come across this technology," Beggin says. "I'm hoping the system can really take off from me to participant No. 2, to participant No. 3, to hopefully allow us the most independence and freedom possible."


BUCKEYE

Autonomic Restoration

The autonomic nervous system is involved in the control or regulation of almost all internal bodily functions, including glucose and electrolyte concentrations, blood pressure, inflammatory responses, respiration, appetite, bladder and bowel function, autonomic dysreflexia, and pulmonary function, and many others. The use of electrical stimulation, particularly of the spinal cord, 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 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.



Restoring Bladder and Bowel Control After Spinal Cord Injuries

A Veteran with a spinal cord injury (SCI) took part in a Cleveland FES Center research study to help prevent bladder accidents.

The man had a difficult time attending sporting events for his grandson because of bladder incontinence. Instead of sitting in the stands, he would sit in his car and watch from the parking lot. An electrical stimulation device developed by investigators at the Cleveland FES Center allowed him to watch his grandson's games from the stands with his family.

The device, part of an ongoing study, was activated when the participant hit a button when he felt the need to urinate. The stimulation gave him 30 to 45 minutes to get to the bathroom, vital time for those with SCI and in a wheelchair.

Another participant found benefits at work. The device helped the man get down the hall to the bathroom, and his work performance improved so much, he earned a promotion and eventually his own private bathroom.

These anecdotes illustrate the potential impact of the efforts facilitated by the FES Center to study electrical stimulation to treat and restore function of the autonomic nervous system.

Many don't realize that restoring bladder and bowel function is one of the top priorities for people with SCI. To that end, FES Center researchers have been looking for ways to help prevent incontinence as well as empty the bladder or bowel efficiently.

The challenges are real, and the research to champion them is driven by empathetic men and women motivated to bring real-life solutions to as many people as they can.

Collaboration and Shared Knowledge

The FES Center propels the work of scientists, engineers and clinicians in the use of Functional Electric Stimulation (FES) to improve the lives of those with neurological or other musculoskeletal impairments. Some of the medical challenges researchers aim to solve include pelvic function, post-stroke limitations, chronic pain, sensation or movement after paralysis.

At the core of the Center's work is a consortium of six nationally recognized institutions: the VA Northeast Ohio Healthcare System (VANEOHS), the Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center, Case Western Reserve University (Case), MetroHealth System, University Hospitals and the Cleveland Clinic Neurological Institute.

In the area of autonomic function, researchers Dennis Bourbeau, PhD; Steven Brose, DO; Kenneth Gustafson, PhD; and Kimberly Anderson, PhD; all are working on various aspects of pelvic function.

The team thrives on the FES Center's atmosphere of collaboration in search of solutions. Collectively, these investigators and their teams have been advancing multiple projects including:

- Studies to develop stimulation regimens and devices to improve bladder and

bowel continence

- A study to empty the bowel more efficiently using a minimally invasive stimulation device
- A project to develop an implanted stimulation device that would facilitate bladder and bowel emptying without a catheter and without having to cut nerves

Bourbeau, a biomedical engineer at the VA Northeast Ohio Healthcare System, a staff scientist at the MetroHealth System and an assistant professor of Physical Medicine and Rehabilitation at Case, says the research could lead to unprecedented solutions for those with SCI.

"With these collaborations, we're trying to restore bladder and bowel function after neurogenic disease or trauma," Bourbeau said, noting that the approaches under study might also prove helpful for people who don't have spinal cord injuries.

Bourbeau also points out that while bladder incontinence aids are widely available for the general population, that isn't the case for those with SCI. It makes the technologies under study so much more critical.

Having new approaches might also reduce the health threats associated with bladder dysfunction and catheterization, the researchers point out. Using catheters increases the risk of infection. And bladder dysfunction can cause dangerously high blood pressure swings.

Brose, chief of the Spinal Cord Injury and Disorders Service at Syracuse VA Medical Center, has been a member of the Cleveland FES Center for close to 15 years, starting with his role as a SCI physiatrist at the VA Northeast Ohio Healthcare System. Even though he transferred to Syracuse in 2021, he maintained his work with the Center.

"The Syracuse population didn't have access to this technology and in fact very few of the patients were aware that electrical stimulation was an option or that research was being done on it," Brose said.

He also acknowledges the vital importance of Veterans' willingness to take part in these studies, and how the work has benefited their health and quality of life.

"The patients tell tremendous stories of their participation in the research," Brose said. "We have patients saying that they can sleep better at night and have much less bladder leakage. And Veterans love to take part in the advancement of science and helping their fellow Veterans."

Solving the Challenges of Bladder Incontinence

To treat bladder continence, the investigators are studying the use of a minimally invasive device attached to nerves in the pelvic area and controlled by a small remote control used by the study participant.

The team has adapted a commercially available product to determine if bladder activity can be inhibited and what benefits that might provide. When the urge to urinate is felt, the research participant can hit a button, triggering stimulation, which reduces the urge to go. The clinical trial is underway via a collaboration with the Syracuse VA and has already shown positive results.

"This approach involves stimulation of the genital nerves," says Brose. "It affects a neural circuit that relaxes the bladder, which allows the bladder to

hold more urine, improves continence, and allows study participants more time to get to bathroom."

Bourbeau says the stimulation appears to be effective at reducing unwanted bladder activity, promoting urinary continence and giving participants some bladder control. The device not only delays the urge to urinate, but when left on it might be able to help with spasticity that causes incontinence as well. Currently, the team is using a commercially available device for testing, but they are developing a new, purpose-designed prototype and plan to collaborate with industry partners in the future.

to empty the bowel can be challenging both for themselves and for caregivers. They also can take a long time, such as an hour or more. The most common process is a manual routine using digital stimulation to trigger the reflex that empties the bowel.

"I know a gentleman who took every Friday off from work because his bowel routine took six hours." said Ken Gustafson, PhD, director of research and education at the FES Center as well as associate professor of biomedical engineering and urology and the associate director of the Neural Engineering Center at Case.

"Translation is baked into everything we do." ***-Dennis Bourbeau, PhD***

Innovating Bladder and Bowel Routines for People with Spinal Cord Injury

The researchers are using what they've learned about bladder continence to study the use of electrical stimulation, via an implant, that might efficiently empty the bladder and bowel without having to cut nerves or use a catheter. The team recently secured U.S. Department of Defense funding to study potential solutions using electrical stimulation.

"There is early research into what nerve you stimulate and in what way to get bladder and bowel emptying efficiently," Bourbeau said. "That would translate to something that would be an implantable, available device. We're still testing out different electrode configurations and stimulation patterns to identify what we think is going to be a good way forward."

In another project, researchers are studying the use of electrical stimulation to empty the bowel specifically. For many individuals living with SCI, current methods

Early feasibility studies have indicated that using electrical stimulation to empty the bowel might be faster and easier. Gustafson, Brose, and Bourbeau are early in this research, studying the use and development of a device that study participants and their caregivers can use at home. The small probe can be inserted and will provide stimulation to trigger the reflex that empties the bowel.

While it may not sound pleasant to use a probe to help with bowel emptying, Bourbeau says many people with SCI have expressed preference for such an alternative to existing methods.

"We talked to nurses who do the procedure, and we talked to people with a spinal cord injury, who are recipients of the procedure," Bourbeau said. "They all agree it would be wonderful to not have manual stimulation by hand."

Additional goals of the research, Bourbeau said, are helping to put more predictability into a person's bowel routine as well as getting the process done in less time.

"That's a huge difference for the person, especially if they are confident they're empty," Bourbeau points out.

As the work proceeds, the investigators have received positive results and are optimistic about the study's success.

"It's made a difference in the quality of life of the patients, and helped improve job satisfaction for the staff," Brose said.

Stimulation to Prevent Bowel Accidents

After learning that genital nerve stimulation reduced spasms in the bladder, investigators have also begun studying whether the same technology might be applied to the bowel. The idea is that improving bladder control via stimulation might also improve bowel control.

Bourbeau has joined investigators Kim Anderson, PhD, and Robert Hoey, PhD, faculty members at Case School of Medicine and at MetroHealth System, to lead a new research study in this area.

The research involving adults with SCI is assessing whether stimulation of the skin in the pelvic area can reduce the reflexes that cause bowel accidents.

Currently Anderson is leading step one of the two-part study, which began in 2024. The team will recruit participants during phase one, asking them to come to the lab for a one-time assessment via interview, examination and study.

"The goal is to get a wide variety of injury levels and severities, along with different human characteristics," Anderson says. "We want to get a wide range of data, because that does not exist yet."

For a second phase of the study, which is also funded by the Department of Defense, the team plans to assess all of the variable information plus individual physiology and clinical information to determine which individuals may be most responsive to stimulation. The team then will identify a subset of participants who will use and test a take-home device. The hypothesis is that activating stimulation might help prevent bowel accidents.

"Those are some of the questions we're looking to answer," Anderson says.

Translating Results into Solutions

A common thread within these projects is the goal to develop and make available safe and innovative devices that people can use daily to prevent accidents and assist with bladder and bowel emptying. These are the thoughts echoed time and again by the investigators.

"We want to meet a need for a population we care about," says Gustafson. "And I'm motivated to meet a need for people I personally care about."

Similarly, Bourbeau says his dedication is motivated by friends and family with SCI.

"Translation is baked into everything we do," Bourbeau observes. He says the team has completed two FDA pre-submissions and is working on a third with respect to the stimulation device for suppressing unwanted bladder activity. "Through these efforts, we're working to ultimately get these devices out of the lab and into the community."

Meanwhile, Anderson, a professor in the Department of Physical Medicine and Rehabilitation at Case School of Medicine and the MetroHealth System, says she remains motivated to helping those with SCI partly because of the spinal cord injury she sustained at the age of 17. During her career, Anderson has worked to elevate the science, voices and issues paramount to people with SCI. Joining the FES Center in 2018 was part of that dedication.

"The FES Center was the leader on this in the very beginning when stimulation wasn't even thought of for spinal cord injury," Anderson says. "The teams and wealth of knowledge brought together through the FES Center is a powerhouse for looking at neurostimulation, especially for spinal cord injury but for many other disabilities as well."


Vital Signs
CareFusion
Stop
Synguard Nitrile Exam Gloves

Translation & Clinical Dissemination

Along with clinical and laboratory research, the Cleveland FES Center seeks opportunities to move its partners' research discoveries from the lab into the clinical setting to benefit both Veteran and civilian patients. It's a complex and dynamic venture that spans research and commercial entities. To that end, the translational & clinical dissemination efforts at the Cleveland FES Center focus on pursuing and developing industry connections and collaborations, particularly those with a shared interest in FES Center achievements. At the same time, the Center looks for opportunities to help researchers visualize how their technologies, processes and devices could translate to the clinical setting. Investigators have a growing number of translation options open to them, and the Center specializes in coaching its teams and navigating the pathways.

From Discovery to Solutions: FES Center Brings Science to Life

Recently, a technology developed by FES Principal Investigator Jayme Knutson, PhD, was licensed for commercialization. Knutson, also Director of Research at the MetroHealth Rehabilitation Institute, focuses on developing new therapies for stroke.

"Having our technology commercialized will be exciting, for a lot of reasons," Knutson shared, "but above all, it means that our years of hard work and research to address a specific health concern are getting that much closer to being applied in clinical practice, where people can experience relief and recovery."

The path exemplifies a common option available to FES researchers, though it is not the only one. In fact many FES Center investigators are currently working to get their innovations or novel methodologies translated into the clinical setting, where they can benefit both Veterans and civilians.

For example, Dominique Durand, PhD, is researching a novel neurotechnology to prevent epileptic seizures. Tina Vrabec, PhD, and Kevin Kilgore, PhD are collaborating on an electrical nerve block technology that could have multiple clinical applications. And Dennis Bourbeau, PhD, and Kenneth Gustafson, PhD, have been collaborating on a device to treat bladder incontinence after spinal cord injury.

All of these developments and others are moving along paths that could allow them to reach the clinical setting, where they might improve quality of life for potentially millions of Veterans and civilians.

However, translation is a process that takes time. The possible options and

pathways are also numerous and increasing, and researchers may have to navigate a circuitous route along the way.

It's why translational research is such a vital part of the work done by and through the FES Center, which facilitates and propels neuromodulation research via a consortium of six nationally recognized institutions: the VA Northeast Ohio Healthcare System, the Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center, Case Western Reserve University, the MetroHealth System, University Hospitals, and Cleveland Clinic Neurological Institute.

Researchers, engineers and clinicians collaborate within the FES Center to develop innovative solutions that improve the quality of life of individuals with

neurological or other musculoskeletal impairments. By using neurostimulation and neuromodulation research and applications (functional electrical stimulation), investigators vigorously seek solutions in a culture of collaboration and support.

Translational research is the step that takes the research to the clinical environment. It takes proven ideas discovered through years of study to companies, businesses and/or collaborators that can help with production and making technologies available to patients in need. It turns discovery into ways to improve lives.

Moving Innovations from the Lab to the Clinic

FES Center Director of Industrial Relations Christopher Pulliam, PhD, is responsible for coordinating the translational research efforts within the FES Center. Pulliam is also the primary contact in pursuing and managing relationships with industrial partners interested in and willing to manufacture devices, and with other academic centers interested in working with FES investigators.

"I see my role as helping to connect investigators who are leading research here in the FES Center with companies that are working in adjacent spaces, where the combination of what we're doing and what that partner is doing can provide a unique value," Pulliam says.

Pulliam, also an investigator at the FES Center and assistant professor of biomedical engineering at Case Western Reserve University, says he hopes to encourage investigators to consider collaborations that combine FES with other types of innovations.

"My philosophy is to look for opportunities where one plus one equals three. In other words, seeing where we can add to what's already happening. I'd like to take the innovations we're leading here and add them to innovations that others are working on. This can lead to the creation of something new and valuable, and is a focus that may be a little different than how translation has been visualized in the past," he says.

Pulliam adds that this type of collaboration may be easiest to spark when working with partners with a similar mission as that of the FES Center. "My goal is to help put the pieces together in a way that fits with the direction that the potential partner is headed and also facilitates our technology getting out and ultimately helping patients."

To that end, Pulliam introduced a new livestreamed, hybrid seminar series in the summer of 2024 designed to bring together professionals from both industry and academia to facilitate and strengthen collaboration between the groups. The presentations, held on the Case Western Reserve University campus, included a community discussion and networking component and highlighted emerging neurotech investigations from both sectors related to a shared topic.

For example, the first seminar covered sensing approaches to improving outcomes in restoration of bladder function, while the second event presented novel stimulation waveforms for modulating neural activity. After the presentations, attendees were invited to talk with the experts about their own career paths.

"Our goal with this series has been to enhance an already vibrant community by featuring speakers from both sectors who are addressing similar challenges in neurotechnology," Pulliam said. "Besides sharing invaluable insights, the event also provides a unique platform for all participants, from seasoned investigators to trainees and students, to explore diverse career pathways in neuroscience." Another goal, he said, is to help early-career professionals gain a closer look into the similarities and differences of professional landscapes in both sectors.

Multiple Technology Transfer Options

FES Investigator Ken Gustafson, PhD, points out that translation has become a national strength of the FES Center, and is the ultimate goal for just about every project its investigators pursue. As executive committee member of the Center, one of his focus areas has been helping investigators to explore how the VA's

"I'd like to take the innovations we're leading here and add them to innovations that others are working on. This can lead to the creation of something new and valuable, and is a focus that may be a little different than how translation has been visualized in the past" ***-Christopher Pulliam, PhD***

Office of Research and Development might assist with tech transfer, particularly for technologies that arise within the VA system.

"I can't think of a single investigator that isn't trying to translate their work," he says. "And there are a lot of different ways that FES Center investigators can get their ideas translated," Gustafson says. "That's a big part of what the Center does, helping investigators and their teams to figure out which of those many ways is best for their situation."

The options are complex and growing. Investigators might choose to find a business partner, they might find a research partner, they might find a clinical partner, or they might choose to build the technology themselves. Or, they could adopt some combination of these efforts.

While translation can take years, Gustafson says researchers affiliated with the

VA have additional resources for translating their work within the Department of Veteran Affairs. What's more, the agency is working to implement improvements in the tech transfer process that may help to streamline the process for innovations developed with VA support.

Besides this assistance, FES Center members also have the benefit of being able to leverage existing FES Center approaches and technologies, saving significant amounts of time and financial resources.

Gustafson explains that FES investigators can and often do learn from each other's work, using, sharing or adopting technologies, methodologies and devices previously studied and created by other FES teams that can be leveraged in new ways. And it's an activity that happens every day.

"Some investigators might borrow a stimulator, for example, created by another member and test it with their device. Or they might choose to refine a device so it can be helpful to others, if not today, then perhaps years down the road," Gustafson said. "In this way it saves everyone time and money, which is ultimately the value of the Center."

VA-TEAM

Translation Training Especially for VA Researchers

FES Center investigators who are affiliated with the Department of Veterans Affairs have access to the Veterans Affairs Translational Education and Mentoring (VA-TEAM) Center.

The VA-TEAM is an entirely separate Center within the VA's Office of Research and Development, but its creation is linked to the FES Center.

Now in its fourth year, the VA-TEAM Center was initially launched in 2021 by a team of investigators including FES Center Executive Director Robert Kirsch PhD, as a nationally funded initiative through the Biomedical Laboratory Research and Development arm of the VA's Office of Research and Development.

The group hosts an educational program and offers resources to help VA researchers all over the country move their research into the clinical setting.

As such, the VA-TEAM's primary objective is to serve as an entrepreneurial mentorship course guiding VA investigators through the process of translating early-stage biomedical technologies from the lab to clinical use.

Investigators within the program learn how to evaluate unmet needs, assess viable business opportunities, and build a compelling pitch for potential investors and collaborators.

FES Investigator and executive committee member Ken Gustafson, PhD, now serves as the director of the national VA-TEAM Center. He shares that the VA-TEAM Center is all about helping VA investigators learn what it takes to move their idea or innovation out of the lab and into the commercial or clinical sphere where it can be used by Veterans and civilians.

The VA-TEAM Center offers different forms of assistance all linked to this goal. One avenue is by sponsoring a 24-week training program for teams working on specific projects, ideas or innovations. Up to 16 teams are accepted into the course per cycle.

Teams have the opportunity to participate in two phases of training. The first phase is all about identifying end markets and end-user research, while the second phase covers in-depth commercialization planning and pitching.

At the culmination of the program, research teams present their pitch to a team of business and technical advisors for feedback and an outline with suggested next steps. The effort is focused on moving VA-funded research toward commercial activity while helping researchers consider the challenges of translation as they continue research.

However, VA research teams don't have to participate in the training program to benefit from VA-TEAM resources, Gustafson points out. A separate focus area is helping to match VA researchers with other VA research groups or government programs elsewhere that might help with or benefit from their idea or innovation.

"In some respects, we're putting people in touch with others from around the country who might have a shared interest in the work or have the ability to fill a need for them," Gustafson explained.

Gustafson says the VA-TEAM Center also exists to help VA investigators make sense of the sometimes complex and dynamic world of federal ethics in relation to transferring their innovations.

"We know conflicts of interest related to the VA's tech transfer process can be concerning, and we're taking steps to help, especially as process improvements are on the way. I encourage investigators to reach out to us and see how we can help them navigate the challenges, consider different options, and ease their concerns about the process," Gustafson says.

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.

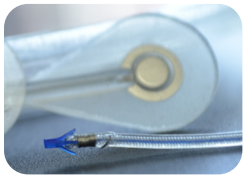
The innovation group is charged with identifying the cutting edge techniques, materials and concepts from across the industry for possible inclusion into neural applications.

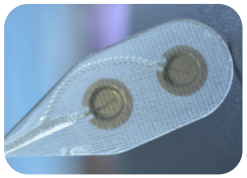
The technical production group is charged with fabricating small quantities of implantable and external devices to a quality level fit for clinical use.

"It's been a long road, and it's a lot of work to get from the point of needs, concepts, and ideas 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 44)

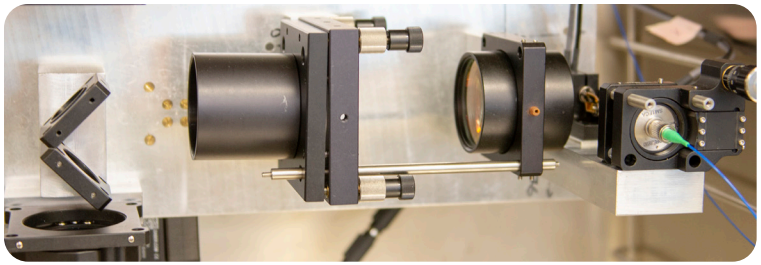




From left: Epimysial & Intramuscular Electrodes stimulate movement in the muscle. Myoelectric Signal (MES) Electrodes record muscle activity as a control. Nerve Cuff Electrodes stimulate or inhibit neural signals.

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

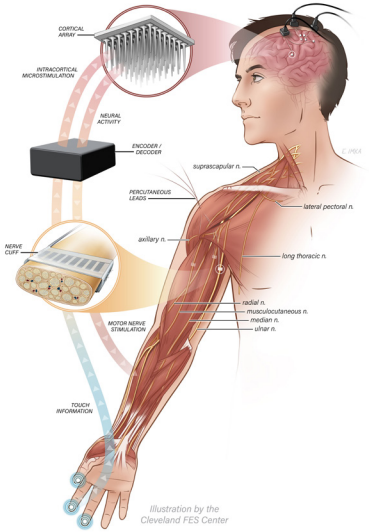
Infrared Light Neuromodulation



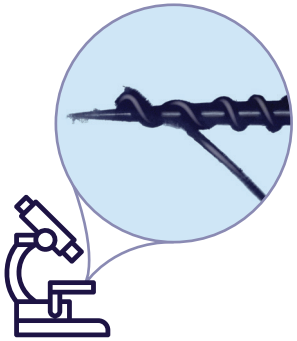
Researchers are harnessing infrared light to modulate, block and excite electrical signals that control organ function.

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 24)



Carbon Nanotube (CNT) Yarn Electrode

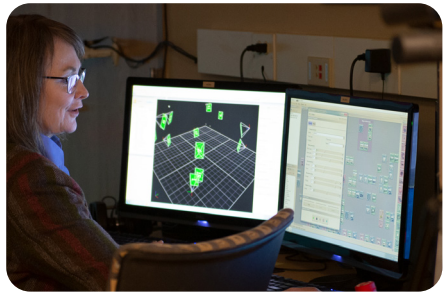


CNT yarn is a new chronic nerve interface that uses highly flexible materials with axon-like dimensions to record neural activity. The results demonstrate the possibility of regulating internal organ function, leading to new bioelectronic therapies and patient health monitoring.

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.



COSMIIC Project

COSMIIC Open-Source Device Brings a New Approach to Implantable Technology

Active implantable devices, such as deep brain stimulators and pacemakers, use electrical stimulation to activate and block nerves in order to treat a range of diseases and disabilities. As understanding of the nervous system continues to deepen, development of additional implantable devices will underpin new medical interventions.

However, the pathway to translate new neuromodulation therapies and devices from the research lab or startup to use in humans is long, requires significant resources, and spans several expert domains, Further, the inaccessibility and fixed specifications of technology from major medical device companies and intimidating FDA requirements can stifle the development of studies attempting to translate discoveries to humans.

A group of FES Center researchers sought to make it easier to test new neuromodulation therapies using an open source concept – design materials are made freely available – to release their human-ready implantable system.

In 2022, funding was obtained from the NIH SPARC program to create the Cleveland Open Source Modular Implant Innovators Community (COSMIIC), a world's first initiative to establish an open source implantable neuromodulation platform.

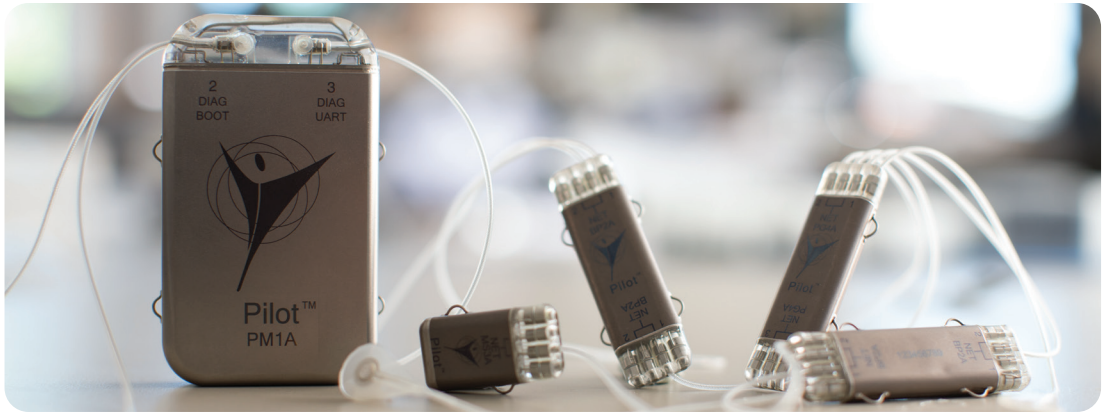
The heart of COSMIIC is its tech, the modular implant system based on the Networked Neuroprosthesis (NNP) from the FES Center. The NNP was designed specifically to target muscular restoration in people with high-level spinal cord injury and has already been used in human studies under an Early Feasibility Investigational Device Exemption from the FDA.

The flexibility of the modular NNP makes it a worthy candidate to be applied to new neuromodulation therapies. The untapped power of open source in medical devices is that the design history, sterilization and biocompatibility validation, clinical history, and regulatory pathways of the existing NNP can be leveraged by future users. This concept of giving away the design and knowledge base for reuse or adaptation is a total re-envisioning of how neuromodulation research can be performed in the collaborative modern world. COSMIIC hopes to lead a major mindset shift towards open source concepts for the development of clinical research tools and commercial medical devices.

COSMIIC is in the process of releasing all source materials on the SPARC portal and COSMIIC GitHub, yet the open source outlook is not to just deliver designs but to engage users in capitalizing on the designs and contributing back to the knowledge base. Additionally, open source does not disincentivize competition nor nullify business cases – the open source licensing for COSMIIC is as permissive as possible and allows for future commercialization of tech adaptations and applications.

Beyond an open source design, COSMIIC is building a tech platform and collaborative user ecosystem across neuromodulation indications to support users with the educational and regulatory resources. Users will be able to integrate new modules into the COSMIIC System network or use only the components they need to take their science from the benchtop to animal studies to human use. At the root of it all, the COSMIIC System will advance new and improved therapies leading to better patient outcomes.

Learn more about COSMIIC at **development.cosmiic.org**.



Bioethics

Research Built on Ethical Practices

Ethical questions surrounding medical research aren't always easy to answer. Consider:

- How do we design fair and equitable research consent processes for those with vulnerabilities?
- How long should researchers continue to support technologies under investigation after a study is complete?

These are just some of the considerations researchers and participants must make before entering into research. It's precisely why the Cleveland FES Center has established a bioethics core service for its members.

FES Center Bioethicist Paul Ford, PhD, explains that Center's existing bioethics initiative was formalized in recent years with more staff and resources.

"Our goal is to help people think through the ethical questions in detail, so we can pursue the most robust research protocols possible while minimizing health risks," says Ford. "In doing this, we're able to justify the work, assuring sponsors that the ethics considerations have been thought through."

Ford said while the ethical questions aren't always easy to answer, arriving at a consensus isn't necessarily the objective.

"Both investigators and participants want to avoid sacrificing things that are important to each of them," Ford explained. "We help provide balance between the research goals and what a reasonable person would be willing to risk in order to gain a benefit from the interventions under study."

The FES Center does this through a team of professionals specializing in neuroethics principles. Together, they help researchers consider the ethical aspects of their research, posing critical questions and juxtaposing real-world scenarios about the work and its impacts.

Investigators Paul Ford, PhD; Mark Aulisio, PhD; Lauren Sankary, JD, MA; and Xavier Williams, MS; comprise the Center's bioethics team, with each person offering their own affiliations and specialties.

Sankary, a lawyer, and Ford, a philosopher, direct the Neuroethics Program at Cleveland Clinic and have medical school faculty appointments in the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University (Case). Aulisio, also a philosopher, chairs the Department of Bioethics at Case School of Medicine, directs the MetroHealth System's Center for Biomedical Ethics, and is co-director of University Hospitals Center for Clinical Ethics. Xavier Williams, a Master's trained biomedical engineer, is pursuing a PhD in bioethics at Case.

The team offers case-by-case bioethics support as researchers plan studies, write proposals and seek funding, whether from the National Institutes of Health, the U.S. Department of Defense, or other funding entities.

Separately, the team creates educational seminars and resources to help raise FES Center investigators' awareness of trending bioethics considerations and best practices.

For example, in 2023, the team invited Shelly Benjaminy, PhD, a senior bioethicist with the Shirley Ryan Ability Lab in Chicago to speak to a group of FES Center members, sharing information on bioethics in the context of regenerative medicine. The team also recently launched a monthly "Tips" email for researchers, supporting grant writing.

With services like these, the team hopes to keep bioethics justifications top of mind for investigators.

"We're here to help researchers as they include neuroethics components in their research initiatives, which is increasingly an explicit requirement," said Ford. "We can help guide people with that, either behind the scenes or as co-investigators."

The ethics core can be reached at **ethics@fescenter.org.**

Industrial Relations

New Ventures and Partnerships

The Cleveland FES Center works to translate research technologies to clinical practice through partnerships with industrial collaborators 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.

FES Center Investigator Christopher Pulliam, PhD, is Director of Industrial Relations for the Center, and is the primary contact in pursuing and managing relationships with both industrial and academic partners.

Additionally, the FES Center leverages years of device expertise and neural technology research to benefit 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.

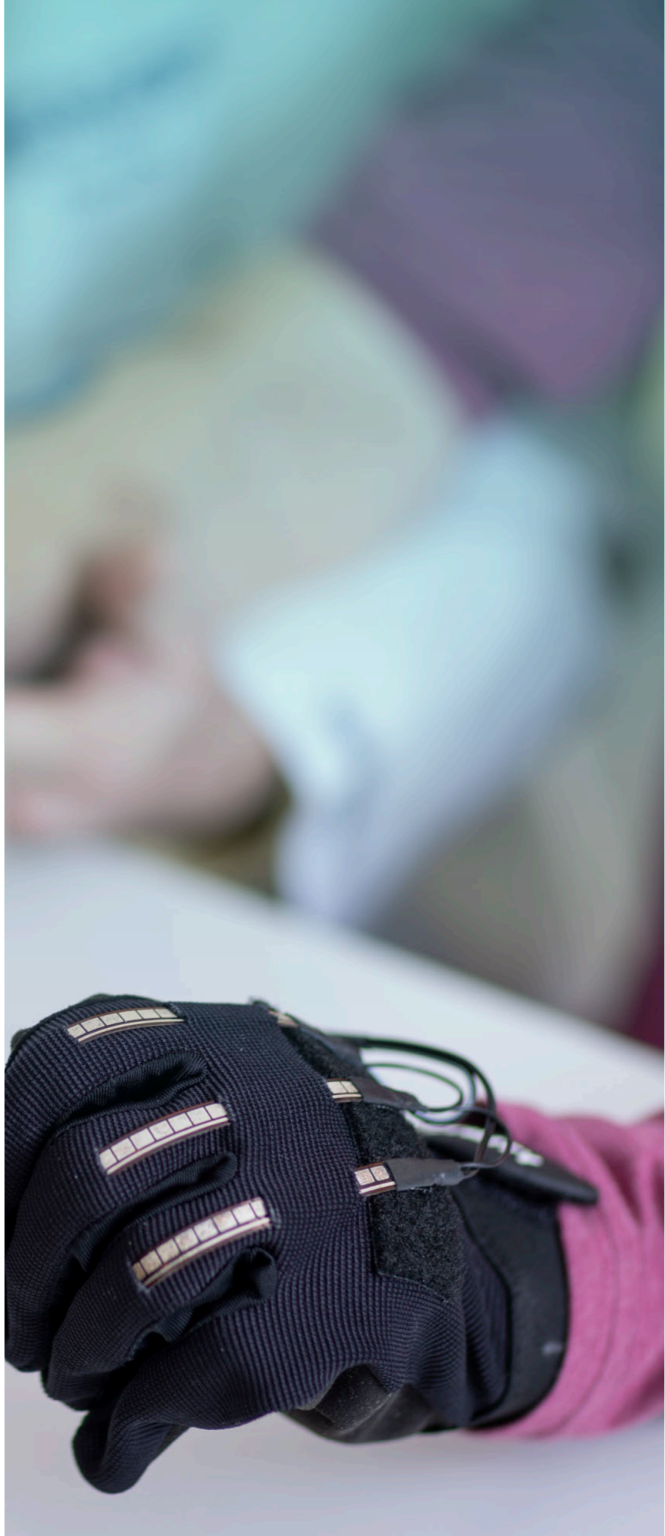
FES Center investigators affiliated with the Department of Veterans Affairs also have access to the Veterans Affairs Translational Education and Mentoring (VA-TEAM) Center. VA-TEAM hosts an educational program and offers resources to help VA researchers move research toward commercial activity. Learn more about VA-TEAM on page 41.

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

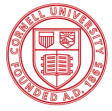
A Focus on Strategic Collaborations

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 the National Institutes of Health (NIH) and the Defense Advanced Research Projects Agency (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.



Collaborative Partners



Education

Cleveland NeuroDesign Entrepreneurs Workshop

Now in its fifth year, the Cleveland NeuroDesign Entreprenuers Workshop is an interactive, accelerated training program for advanced-degree students and early-career professionals.

The program, which takes place at Case Western Reserve University, teaches the entrepreneurship process in the context of neuroscience. As such it focuses on the needs of neurotechnology professionals, researchers and clinicians, making the program highly unique among others.

The weekend workshop uses a project-based approach to explore the healthtech entrepreneurship process through the lens of neurotechnology.

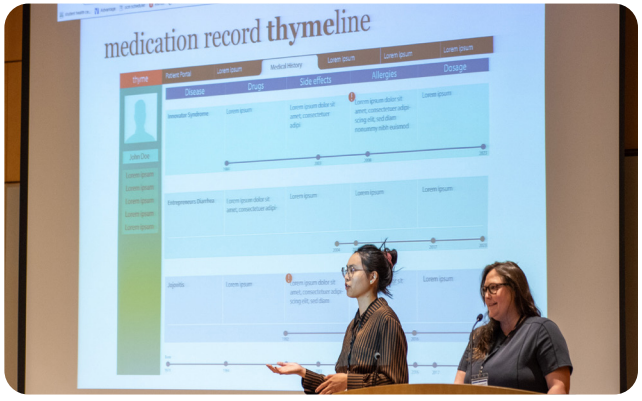
Executive faculty member Andy Cornwell, PhD, shares, “It’s a way to teach the biodesign process in a short amount of time and with a focus on neurotechnology.” Cornwell is also an investigator with the Cleveland FES Center.

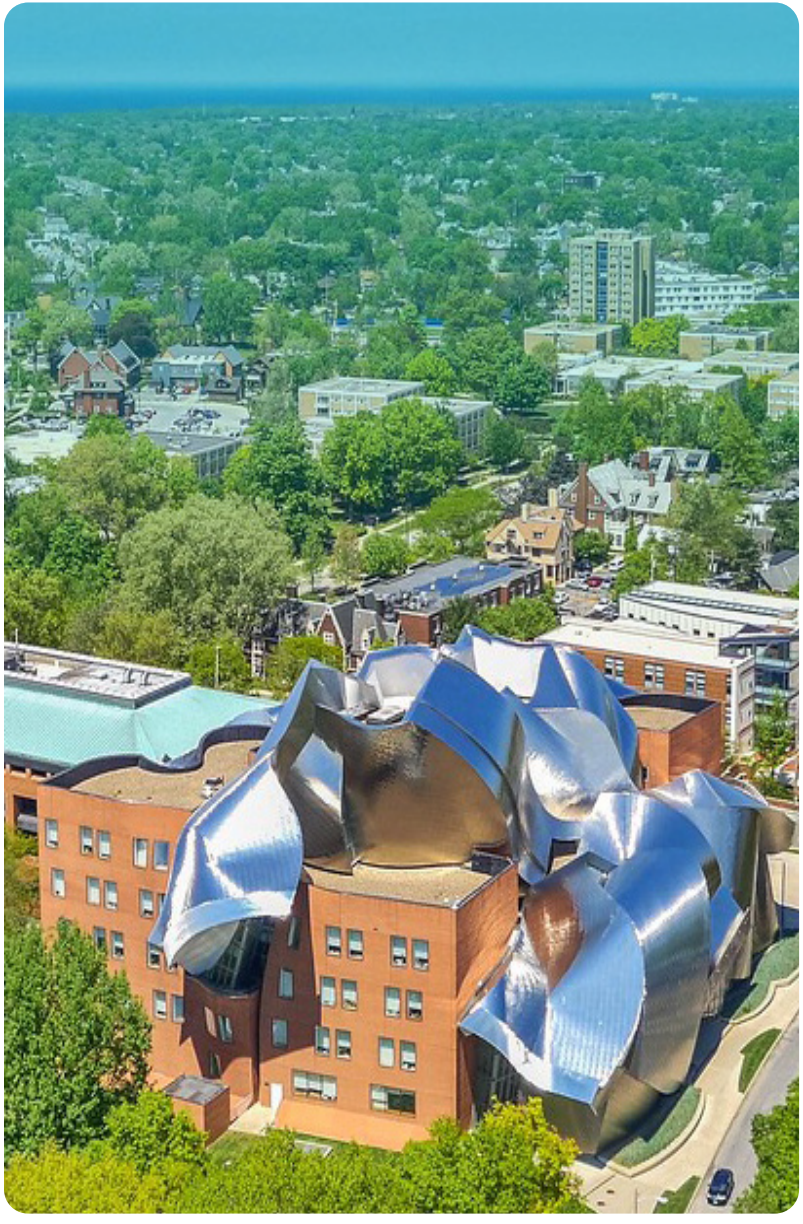
Featuring an amazing faculty representing organizations from around the industry, and an outstanding cohort of students, the course is designed to prepare participants for a career in neurotech startups while also introducing them to a network of colleagues in the neurotech field from across the country and beyond.

For the program, up to 32 accepted participants are formed into teams and assigned a clinical need. Over the four days of the program the teams work with faculty, advisors, and mentors to concept and design a neuroscience solution and build a business plan around their solution.

Along the way, teams receive didactic instruction, mentoring, and one-on-one advising. To end the program, teams pitch their solutions to a group of judges.

Title sponsors include the Cleveland FES Center and Case Western Reserve University, along with support from a series of organizations working in the neurotech sector.





Weatherhead Executive Education Program

The Cleveland FES Center contracts with the Case Western Reserve University Weatherhead School of Management to enroll up to 15 Center members in the business school's Executive Education Program. The accelerated training programs are designed to deliver immediate, practical, and actionable results.

Specifically, participants gain the opportunity to develop their leadership skills through courses and training leading to a Case Weatherhead Executive Education Leadership Course Certificate.

The program curriculum includes two recommended courses: The Managers' Tool Kit for Delegation, Accountability, and Results; and Introduction to Emotional Intelligence. Additionally, each student can participate in two elective courses, such as Operational Excellence, Project Leadership, or Financial Decision Making.

CASE WESTERN RESERVE UNIVERSITY
Weatherhead School of Management

Neural Prosthesis Seminar Series

The Neural Prosthesis (NP) 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.

In 2019, the Cleveland FES Center launched the NP Live Webinar Series to allow the live stream audience to participate in the seminars. Submitted questions are addressed during the Q&A following the presentation.

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

2023-24 Speakers

Robert Sainburg, PhD

Reza Shadmehr, PhD, MS

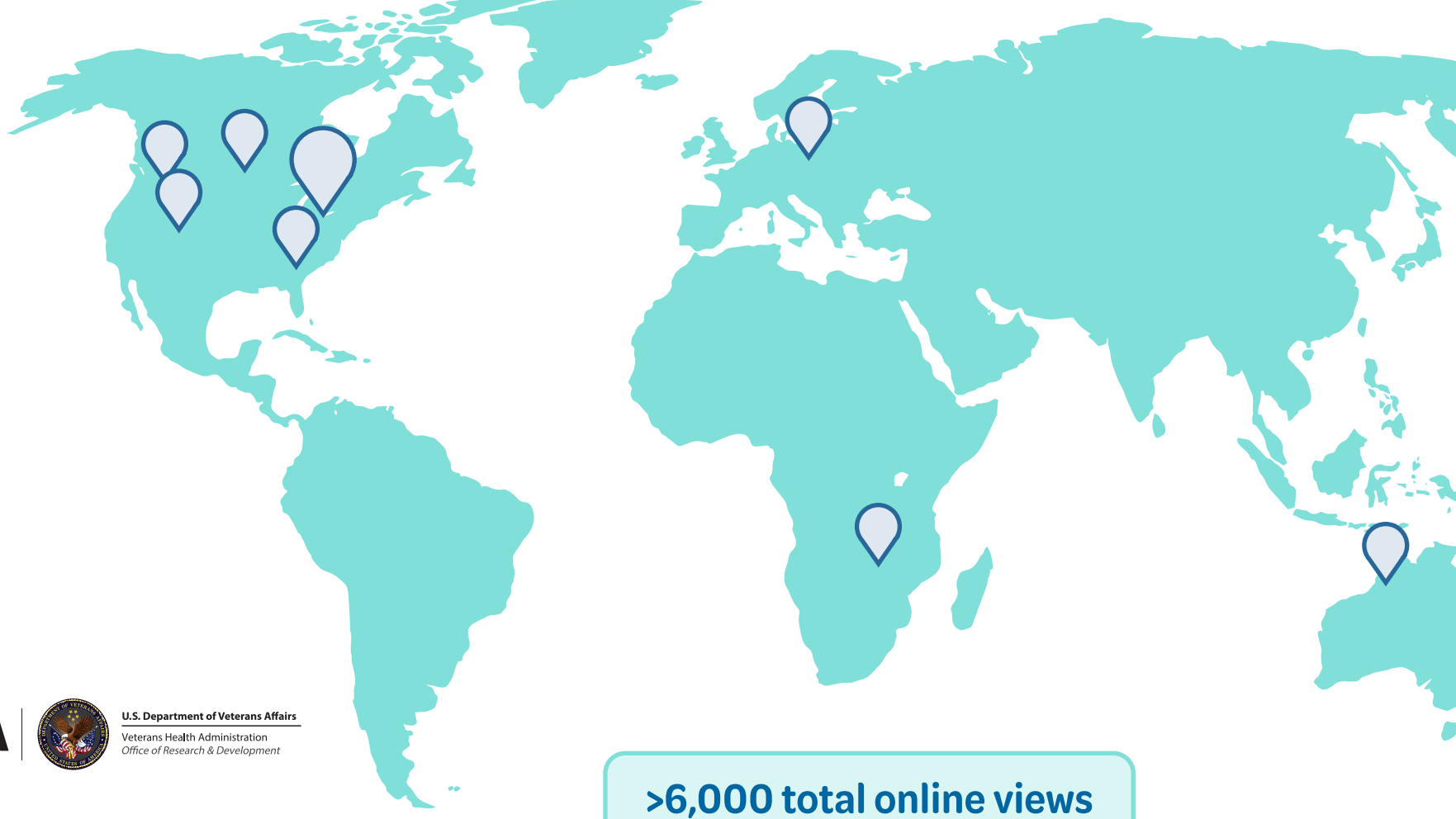
Lee Miller, PhD

Andre Machado, MD, PhD

Doug Weber, PhD

Emery N Brown, MD, PhD

Vivian K Mushahwar, PhD



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

CASE WESTERN RESERVE UNIVERSITY

MetroHealth

University Hospitals

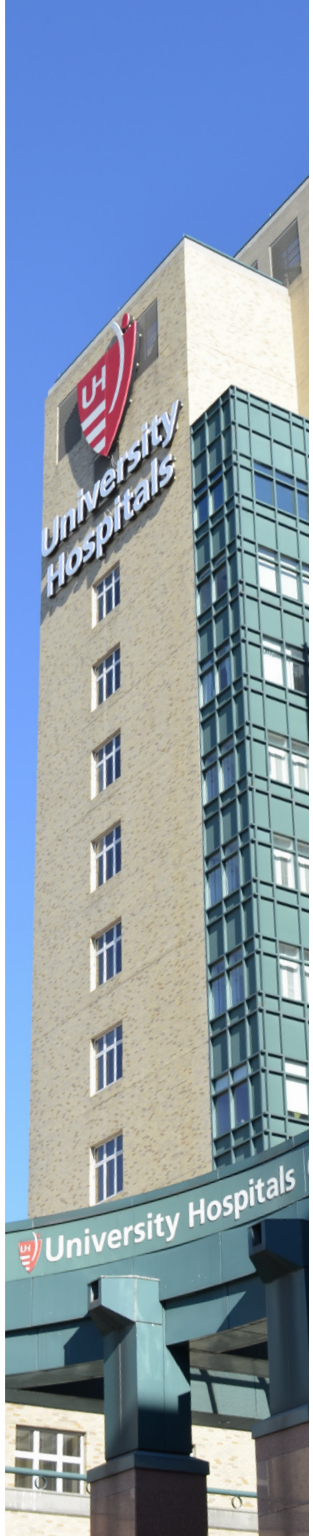
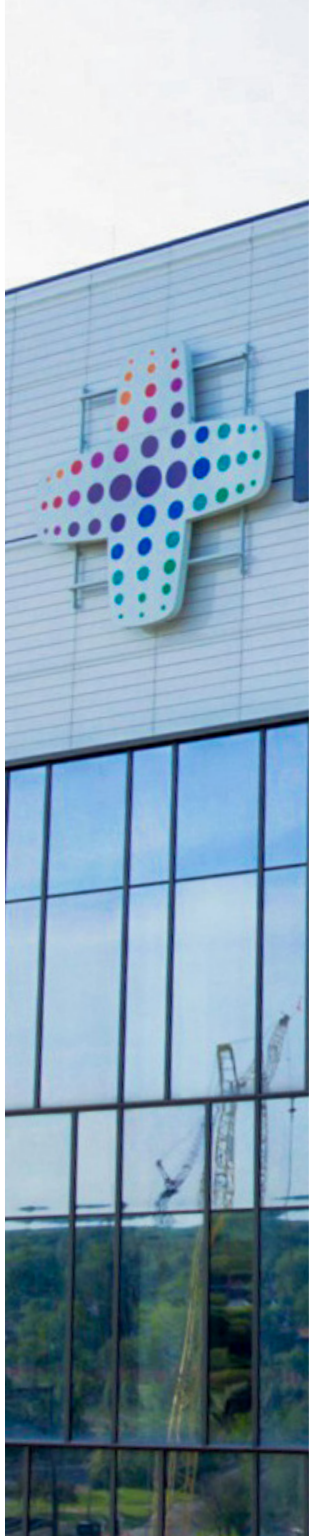
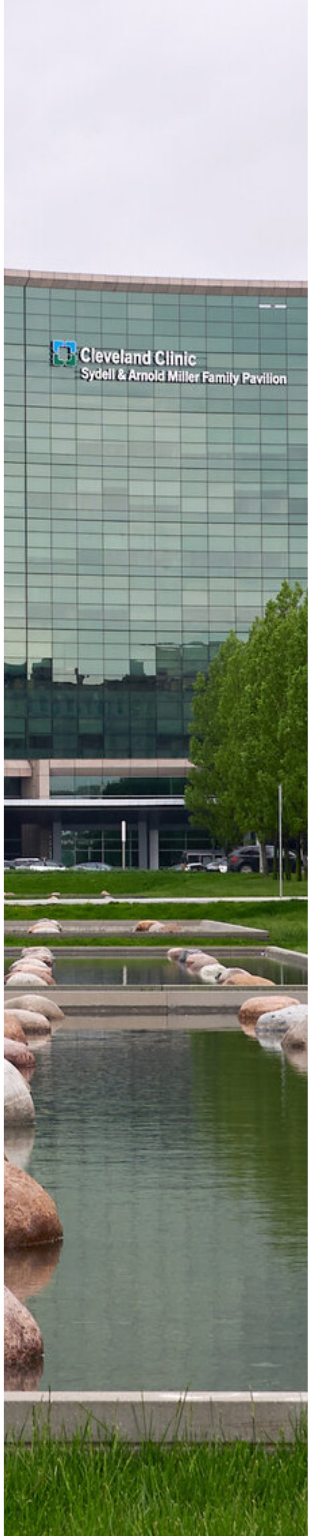
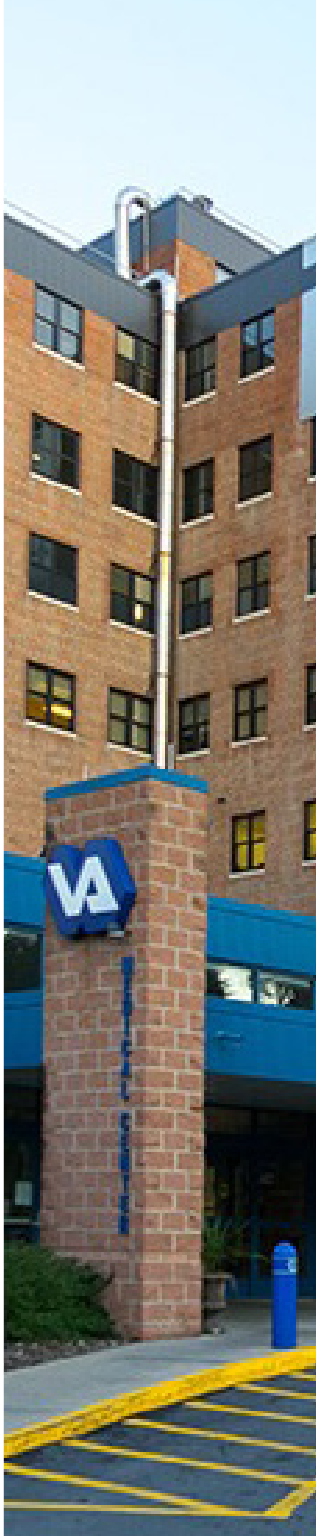
Cleveland Clinic

>6,000 total online views

NP Seminar livestream link and speaker details available at:

https://fescenter.org/events/np-seminar-series/


VA Medical Center


University Hospitals
University Hospitals


Cleveland Clinic
Sydell & Arnold Miller Family Pavilion

VA

Consortium Partners

ClevelandFES

The **Cleveland FES Center** is a consortium of six nationally recognized institutions: VA Northeast Ohio Healthcare System, Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center, Case Western Reserve University, MetroHealth System, 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 **VA Northeast Ohio Healthcare System** 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

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.

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 Case, 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 System.

MetroHealth

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

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.

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

Researchers at the **Syracuse VA Medical Center - Spinal Cord Injury/Disorders (SCI/D) Center** officially joined the Cleveland FES Center in 2024, particularly in connection with research focusing on spinal cord injury and returning functional independence. Research and development programs underway at the Syracuse VA Medical Center - SCI/D Center comprise traditional scientific research, numerous clinical studies and trials. Projects and activities center on a range of health and wellness conditions of importance to Veterans.

By the Numbers

PEOPLE

- 77 Principal Investigators
- 6 Post-Docs
- 47 Technical/Clinical Support Staff
- 19 PhD/MS Trainees
- 5 Operations

35M Funding

Full portfolio on page 60

SOCIAL MEDIA

Reaching over 7,000 people each week

1,500+ Followers

111 Scientific Publications

1 Book Cover

6 Book Chapters

87 Presentations

TECH TRANSFER

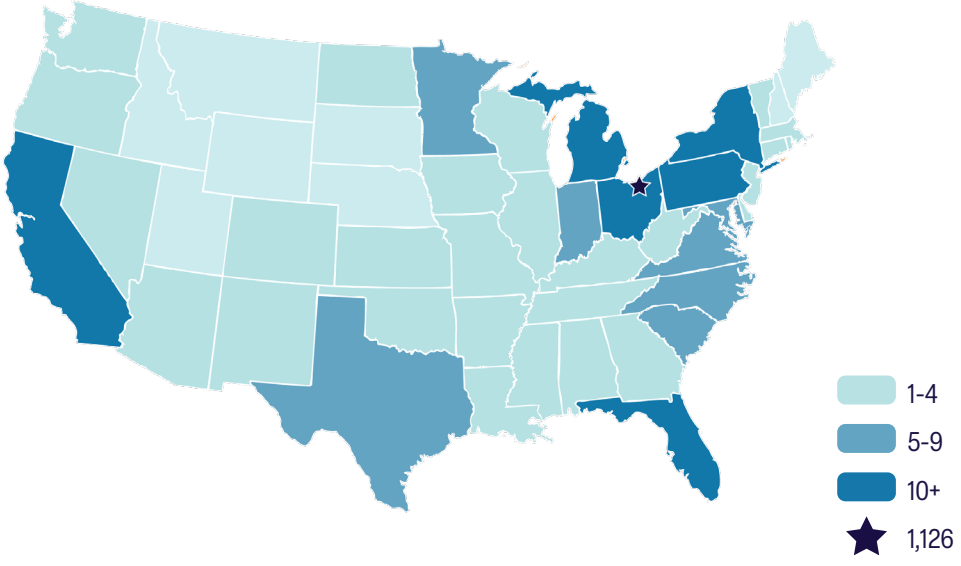
15 Patents Issued

40 Invention Disclosures

ClevelandFES

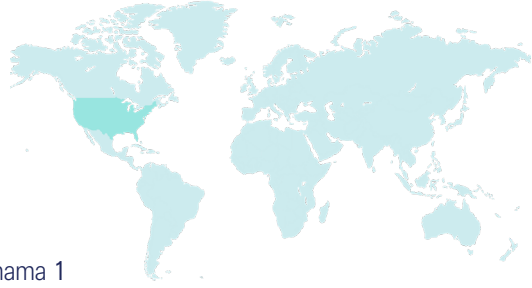
>1,500 RESEARCH PARTICIPANTS

1986-2024



GLOBALLY

Australia 1
Brazil 1
Canada 6
Columbia 1
India 2
Ireland 1
Israel 1
Jordan 1
Iran 1
Republic of Panama 1
United Kingdom 1



UNITED STATES

Alabama 4
Arizona 3
Arkansas 1
California 13
Colorado 3
Connecticut 3
Delaware 1
Florida 14
Georgia 3
Illinois 2
Indiana 8
Iowa 1
Kansas 1
Kentucky 1
Louisiana 2
Maryland 5
Massachusetts 2
Michigan 13
Minnesota 6
Mississippi 2
Missouri 4
Nevada 1
New Jersey 2
New Mexico 1
New York 16
N. Carolina 6
N. Dakota 1
Ohio >1,000
Oklahoma 4
Oregon 1
Pennsylvania 23
Rhode Island 2
S. Carolina 6
Tennessee 2
Texas 6
Vermont 1
Virginia 11
Washington 4
W. Virginia 1
Wisconsin 2

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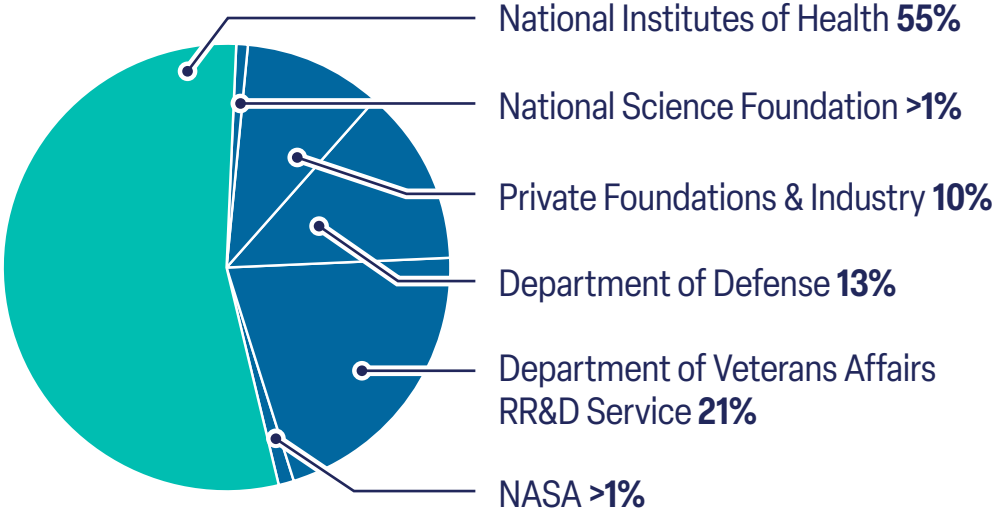
FY 2023-2024 Funding Portfolio

$35
Million



Department of Veterans Affairs RR&D Service

Bourbeau, Dennis, PhD
Electrical Rectal Stimulation to Promote Bowel Emptying after Spinal Cord Injury

Bourbeau, Dennis, PhD
High Frequency sacral root stimulation to improve bladder and bowel emptying follwing SCI

Brose, Steven, DO
Leg Stretching Using a Controllable Wearable Exoskeleton on Demand for People with Spasticity

Graczyk, Emily PhD
Proprioceptive Sensorimotor intergration for hand prosthesis

Henderson, Geoffrey, MD
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VA RR&D Center in Functional Electrical Stimulation, plus equipment funding

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Pundik, Svetlana, MD
Transcranial Direct Current Stimulation for Post-Stoke Gait Rehab

Shaikh, Aasef, MD, PhD
Deep brain stimulation for visuomotor function in Parkinson's disease

Shaikh, Aasef, MD, PhD
Mechanistic Understanding of Dynamic Cycling Induced Change in Motor Function in Parkinson's Disease

Shaikh, Aasef, MD, PhD
Remote dynamic cycling for the customized off-site rehab in Parkinson's

Shoffstall, Andrew, PhD
Optimizing Delivery of a Known Therapeutic Agent, Dexamethasone, to Improve Microelectrode Recording Performance

Tyler, Dustin, PhD
Peripheral Interfaces in Amputees for Sensorimotor Intergration

Tyler, Dustin, PhD
Research Career Scientist

National Institutes of Health

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Improving Intracortical Reaching after Paralysis

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Northeastern Ohio Regional Spinal Cord Injury System (NORSCIS)

Baker, Kenneth, PhD
Deep Brain Stimulation of the Cerebellar Dentate Nucleus to Enhance Chronic; Post- Traumatic Brain injury Rehabilitation

Bourbeau, Dennis, PhD
Noninvasive genital nerve stimulation to promote urinary continence for women with SCI

Cunningham, David, PhD
tDCS During Contralaterally Controlled FES for Upper Extremity Hemiplegia

DiMarco, Anthony, MD
Spinal Cord Stimulation: A Novel Method to Restore Breathing in Spinal Cord Injury

DiMarco, Anthony, MD
Multi-Center Clinical Trial of Spinal Cord Stimulation to Restore Cough

Durand, Dominique, PhD
Low-Frequency Stimulation of Fiber Tracts to Control Seizures

Durand, Dominique, PhD
Seizure control by electric field control

Gopalakrishnan, Raghavan PhD, MBA
Pain Avoidance Behavior and It's Relation to Risk for Opiod Use in Chronic Pain Patients

Jacono, Frank, MD
Neuroinflammation Maladapts Cardio Respiratory Circuits and Patterns

Jacono, Frank, MD
Neuroinflammation disrupts cardio-respiratory circuits and patterns

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Understanding neural control of the ocular surface

Jenkins, Michael, PhD
Optical Tools to Assess the Role of Cardiac Function in the Development of Congenital Heart Defects

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Augmenting Implanted Neuroprosthestics with Targeted Health Monitoring for SCI- the LIFELINE

Kilgore, Kevin, PhD
Cleveland Open Source Modular Implant Innovators Community (COSMIIC)

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Restoration of Grasp and Reach in Cervical Spinal Cord Injury

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Contralaterally Controlled FES vs Cyclic NMES for hand function after stroke

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Contralaterally controlled FES Combined with Brain Stimulation for Severe Upper Limb Hemiplegia

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Cleveland NeuroDesign Entrepreneurs Workshop

Saab, Carl, PhD
Spatiotemporal Coding in the Pain Circuit Along the Spine-Brain Continuum

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RECONSTRUCTING VAGAL ANATOMY

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Improving intracortical control of reaching after paralysis

Taylor, Dawn, PhD
Targeting and Stimulating Cortical Area 3a to Restore Proprioception

Vrabec, Tina, PhD
Investigation of Partial Electrical Nerve Block for Autonomic Regulation

Vrabec, Tina, PhD
Minimally Invasive On Demand Electrical Nerve Block (OD-ENB) Device for Peripheral Pain

Vrabec, Tina, PhD
Nest#4-Nerve Excitation Control Through AC Regulation (NECTAR)

Wilson, Richard, MD
Peripheral Nerve Stimulation for Subacromial Impingement Syndrome

Food and Drug Administration

Kilgore, Kevin, PhD
Phase 2 Study of the NNP for Grasp and Trunk in SCI: IDEG140225

Department of Defense

Ajiboye, Bolu, PhD
Restoring Multi-Dimensional Coordinated Reaching and Dexterous Grasping to Persons with Chronic Tetraplegia

Anderson, Kim, PhD
Genital Nerve Stimulation to Modulate Anorectal Reflex Activity in Neurogenic Bowel Dysfunction in Individuals Living with Spinal Cord Injury

Plow, Ela, PhD, PT
Improving Spinal Cord Injury Rehabilitation Interventions by Retraining the Brain

National Science Foundation

Fu, Michael, PhD
CAREER: Maintaining volitional effort during electrical stimulation-assisted stroke rehabilitation

Schearer, Eric, PhD
NRT: Human-Machine Systems for Physical Rehabilitation

Schearer, Eric, PhD
Collaborative Research: Assistive Robotics and Functional Electrical Stimulation - A Synergistic Combination to Reanimate Paralyzed Arms

Schearer, Eric, PhD
REU Site: RE@CSU Rehabilitation Engineering at Cleveland State University

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Baker, Kenneth, PhD
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Plow, Ela, PhD, PT
Contralaterally controlled FES Combined with Brain Stimulation for Severe Upper Limb Hemiplegia

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Functional network changes across cerebral, cerebellar, and muscular nodal points in patients undergoing deep brain stimulation for essential tremor revealed using magnetoencephalography

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Pain Avoidance Behavior and It's Relation to Risk for Opiod Use in Chronic Pain Patients

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CWRU Coulter Translational Program

Moynahan, Megan, MS
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Saab, Carl, PhD
Spatiotemporal Coding in the Pain Circuit Along the Spine-Brain Continuum

American Academy of Neurology

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Ohio Department of Higher Education/NSF

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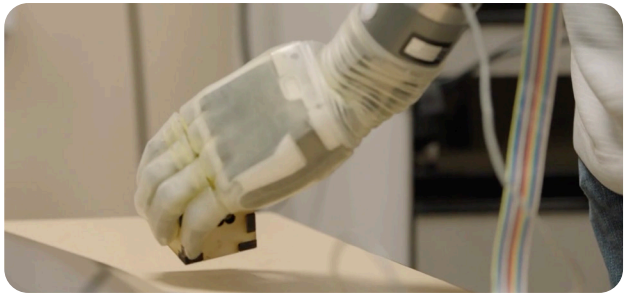
How sensors, rewiring nerves could help prosthetics feel and function like real limbs



PBS' Miles O'Brien shares a personal look at how researchers at the Cleveland FES Center are working to connect prosthetics to the nerves that communicate both with the muscles and the brain, to help restore the sensation of touch.

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