The Cleveland Functional Electrical Stimulation (FES) Center has seen significant progress over the past year and has developed a strong plan for the future in our recent VA Office of Rehabilitation Research and Development (RR&D) Center proposal. We are excited that over the past 25 years we have received core support for the FES Center to drive FES research, technologies, and translational opportunities.

The FES Center is a global leader in Neurostimulation and Neuromodulation research that addresses the unmet rehabilitation needs of individuals with spinal cord injuries and neurological disorders. The FES Center consists of individuals who perform and support cutting edge research projects focused on the development and clinical translation of a wide spectrum of rehabilitation interventions based on functional electrical stimulation (FES).

The FES Center broadly facilitates the research of its investigators by nurturing a trans-disciplinary research community and providing unique, shared resources and infrastructure. The FES Center attracts and maintains top research talent, strategically guides research directions and facilitates institutional synergies and individual collaborations.

**FES Center Advocates**

Our advocates come in all shapes and sizes – individuals including research participants and families, sponsors, and institutions that have led to our successes along the way. Due to the support and passion of so many we are closer to realizing our goal!

We encourage you to share our research and stories and to connect with us to continue to strengthen and support the drive of the Cleveland FES Center.

Sincerely,

Ronald Riechers, MD  
Medical Director

Robert Kirsch, PhD  
Executive Director

Robert Kirsch, PhD  
Executive Director

Ronald Riechers, MD  
Medical Director
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.

Who We Are

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.

Redefining FES
The scope of the Cleveland FES Center and applications of “functional electrical stimulation” have grown significantly over the past several years. The FES Center has been a significant engine of this expansion. The scope of research of the FES Center has correspondingly evolved and expanded.

The FES Center has five research thrusts:

**MOVEMENT RESTORATION**
Restoring limb and other body movements

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

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

**PAIN**
Pain mitigation through stimulation of peripheral nerves and the spinal cord

**TOOLS & TECHNOLOGY**
Development of implantable systems and electrodes, modeling & simulation tools and other rehabilitation approaches complementary to FES
Upper Extremity

The FES hand grasp system stimulates muscles and nerves to produce movement of the paralyzed hand. Programmed to activate the muscles in a coordinated manner, the stimulation can provide a variety of functional grasp patterns.

Program Overview

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

The FES Center enables the Movement Restoration research by promoting collaborations between complementary investigators from disparate disciplines and institutions, in particular between engineers and physicians. The FES Center provides key infrastructure, such as shared engineering and surgical expertise, access to electrical stimulation devices, clinical trial and outcome assessment experience, and regulatory oversight and support. FES Center investigators have led clinical trials of several FES-based functional movement applications, as well as the commercialization of technology including Neurocontrol Corp. for hand grasp, Synapse Biomedical for diaphragm pacing, and Institute for Functional Restoration for upper extremity applications.

Accomplishments

- The first implant of a new, Networked Neuroprosthetic (NNP) System for upper extremity movement restoration and seated posture control was performed in a Veteran with SCI in February 2016.
- The first system that combines FES-based arm and hand functional restoration with a user interface based on an intracortical brain-computer interface was implemented in 2015 and is undergoing testing.
- Clinical assessment of a gait-assist FES system for stroke is underway.
- A clinical feasibility trial for FES-evoked cough is underway for individuals with SCI.

Left: Jen participates in the Stand & Transfer Program for Spinal Cord Injury and is able to walk short distances using a walker.

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Using Video Games to Foster Pediatric Hand Function

Motivating kids with physical disabilities to do occupational therapy exercises at home can be challenging. It got a little easier this summer for one of Cleveland Clinic Children’s occupational therapists, Anna Curby, MS, OTR/L. For six weeks, Curby helped two children with hemiplegia caused by cerebral palsy gain motor skills using a home-based treatment of hand therapy video games in combination with Contralaterally-Controlled Functional Electrical Stimulation (CCFES).

We can give kids all the exercises and checklists in the world, but they have school and friends and other things that distract them,” says Curby. “But when we say, ‘Your home exercise program is to play video games twice a day,’ that’s appealing!”

Curby utilized an intervention developed by Michael Fu, PhD, an investigator with the Cleveland FES Center, a research assistant professor at Case Western Reserve University and a member of the bioscientific staff at MetroHealth Medical Center. “There aren’t a lot of intervention options for kids with cerebral palsy who have hand hemiparesis to facilitate motor practice based on learning principles such as goal-oriented movement, intense repetition and task variation.”

Curby first heard about the intervention during an in-service educational session led by Knutson at Cleveland Clinic Children’s rehabilitation hospital. “I sat in the presentation thinking, ‘Oh, my goodness! I could use this for my kids,’” recalls Curby. “I was excited about the possibilities.” She contacted Fu that day and proposed they work together.

Throughout the summer, Curby met with two cerebral palsy patients with hemiplegia twice a week for two hours during the first three weeks, then once a week for a two-hour session the remaining three weeks. CCFES enabled the children to open their paretic hand by stimulating finger and thumb extensors with surface electrodes. The stimulation was proportional to the degree of cerebral palsy patient opening as detected by an instrumented glove worn on that hand. Volitional opening of the non-paretic hand produces stimulated opening of the paretic hand. The games the children played included paddle ball, skee ball, sound tracker (following a moving track generated by different songs) and marble maze (guiding marbles out of a maze and into a bucket).

“It was really fun to sit in a treatment session with the kids,” says Curby. “Six weeks is a fairly short treatment period, but we saw improvements in both kids.” One of the patients had a moderate to severe level disability. Prior to the CCFES-mediated video game intervention, he didn’t use his paretic hand. By the end of the summer, he was using that hand to pick up things. “Because he was able to play video games that were exciting to him, he figured out really quickly how to use his unaffected hand to help move his affected hand,” says Curby. “It was amazing to watch him gain awareness of that whole limb!”

Though he still didn’t independently open his hand without stimulation, he has begun using his arm, shoulder and elbow in ways he never has before, says Curby. He recently picked up a ball using two arms during an occupational therapy session, something he never did before the intervention. “I can only imagine the benefits if we’re able to use this treatment over a longer period of time with kids with a moderate disability” says Curby. “For any kid, there’s big potential.”

Fu agrees that the results are encouraging. He is currently applying for grants to conduct a larger, controlled study to ascertain why they are getting results and how they can design and optimize the treatment for a more general population of cerebral palsy patients. “We have some ideas on why the stimulation is helping, but we really need to do more experiments,” says Fu. “If we can figure it out, maybe we can provide targeted therapies for kids with impaired hand function.”

For more information on Hand Therapy Video Games research contact: info@FEScenter.org | (216) 231-3257

Hand Therapy Video Games

Right-impaired feasibility trial participant plays the marble maze using CCFES

instrumented glove worn on that hand. Volitional opening of the non-paretic hand produces stimulated opening of the paretic hand. The games the children played included paddle ball, skee ball, sound tracker (following a moving track generated by different songs) and marble maze (guiding marbles out of a maze and into a bucket).
Pain

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

Ongoing research in post-stroke shoulder pain began with the application of electrical stimulation to reverse shoulder subluxation. However, researchers discovered that the applied electrical stimulation likely alleviated pain directly via nerve activation rather than indirectly by improving shoulder biomechanics. Ongoing research into methods for electrical nerve conduction block was originally developed for the control of muscle spasticity in spinal cord injury and stroke. Since then, the potential to use these developing techniques to treat pain became clear and has led to a significant interest from the field of neuromodulation. Both of these approaches have resulted commercial translation – via SPR Therapeutics and Neuros Medical, respectively – and are already finding multiple clinical applications. Furthermore, these successes have attracted a number of additional clinicians and researchers with a direct focus on acute and chronic pain.

The work being performed by investigators in the FES Center in the area of pain includes fundamental experimental studies, development of new technologies, computational modeling of existing and proposed concepts, clinical feasibility studies, and clinical trials.

### Program Overview

- Demonstrated the effective use of peripheral FES in the treatment of shoulder pain following stroke and for (non-stroke) musculoskeletal pain, such as lower back pain.
- Developed several new approaches for using electrical stimulation for blocking neural responses, and began applying these techniques for amputee pain and several other acute and chronic pain applications.
- Developed a new research program on neural modeling of spinal cord stimulation to improve the effectiveness of this established technique and reduce or eliminate its side effects.
- Initiated new FES collaborations for facial pain, migraines, and several other applications.

### Accomplishments

<table>
<thead>
<tr>
<th>Spinal Cord Stimulation</th>
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<tbody>
<tr>
<td>Spinal cord stimulation (SCS) applies electrical pulses to a patient’s spinal cord to help mask the patient’s pain. Computer models can be used to calculate the electric fields generated during SCS and to study how neurons respond to the stimulation.</td>
</tr>
</tbody>
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Right: Computer model of the voltage distribution generated during SCS (image by Scott Lempka, PhD)
Brain Health

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

Program Overview

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Non-Invasive, Innovative FES Treatments for Stroke

Stroke commonly results in loss of hand function. Contralaterally-Controlled Functional Electrical Stimulation (CCFES) is a rehabilitation technique developed by FES Center investigators to improve recovery of hand function after stroke. With CCFES, stroke patients control stimulation to their paretic finger and thumb extensors with an instrumented glove worn on the unaffected, contralateral hand and practice using it in therapy sessions to incorporate principles that are important for driving neuroplasticity and motor relearning. To address proximal arm paresis in severely impaired stroke patients, FES Center investigators are combining FES with robotics to reduce effort-related hypertonia and thus provide full upper limb function. For lower limb function after stroke, FES Center investigators are implementing multi-channel implantable stimulators targeting hip, knee, and ankle impairments to augment retained gait capabilities. Virtual reality environments and interactive video games are being used more and more in neurorehabilitation. FES Center investigators have developed a unique set of hand therapy video games specifically for integration with CCFES to create the first integrated FES videogame therapy in which the two approaches are working synergistically and simultaneously on the patient. FES Center investigators also create and use virtual reality environments to train SCI participants to modulate cortical activity in BCI control of FES systems. Non-invasive brain stimulation with repetitive transcranial magnetic stimulation (rTMS) has been increasingly used for investigating the neuroanatomy and effects of therapeutic interventions as well as a therapeutic modality itself. Transcranial direct current stimulation (tDCS) is another non-invasive method to activate cortical networks and facilitate beneficial neuroplastic changes. FES Center investigators use these methods along with fMRI, diffusion tensor imaging (DTI), cortical thickness analyses, EEG-based assessments, and functional near-infrared spectroscopy to enhance gait training in stroke patients and to individualize and optimize brain stimulation treatment for stroke patients. tTMS is also being used by investigators to enhance recovery of sensory function, an important issue in stroke rehabilitation.

FES Center investigators are active participants in the national StrokeNet program sponsored by the NIH National Institute of Neurological Disorders and Stroke (NINDS). Case Western Reserve University became a StrokeNet site in 2013. Currently, we are conducting a StrokeNet study investigating the efficacy of telerehabilitation. FES Center participation in StrokeNet provides greater opportunities for nation-wide collaboration, as well as for development of multi-site studies to disseminate FES Center expertise.

Accomplishments

• Completed a RCT of 80 chronic (>6 mo) stroke patients and showed that Contralaterally Controlled FES improved hand dexterity and function more than conventional cyclic electrical stimulation.
• Demonstrated that stroke patients can self-administer video game therapy integrated with FES at home.
• Showed that contralesional regions play an important role in supporting sensory-motor recovery post-stroke, and that stimulating higher motor regions enhances outcomes, especially for severe impairment.
• Began a Phase II clinical trial to test the efficacy and safety of low frequency stimulation for epilepsy.
• Demonstrated that people with SCI can control the movements of cursors and robots via a brain computer interface (BCI).
• Commercialized a clinical DBS software system (GUIDE DBS).

Bolu Ajiboye, PhD running a program developed by his students to learn how to interpret brain waves from an able-bodied subject for BrainGate research.
Deep Brain Stimulation (DBS) is improving the quality of life for patients with Parkinson’s disease and shows great promise for epilepsy. Still, many questions remain about its efficacy, delivery, and side effects. Successfully engineering DBS technologies requires a multi-disciplinary approach.

“Our group is integrating imaging, neurophysiology, neuroanatomy, and computational modeling to increase our understanding of precisely how DBS works,” says McIntyre, associate director of industrial relations at the FES Center, a biomedical engineering professor at Case Western Reserve University and a biomedical engineer with the Louis Stokes Cleveland VA Medical Center. “Deep brain stimulation is a complex technology, and we’re working to better engineer the next generation of these devices to help patients receive even better outcomes.”

Creating the Next Generation of DBS Technology

McIntyre’s team is developing therapies based off the research that basic science has previously done and tailoring it to neurological diseases and patients. “The map helps us see pathways in the brain that are affected by these diseases, and we use that ‘connectomic-based’ philosophy to tailor it to one patient and their anatomy,” says McIntyre.

His research group is creating clinical software technologies that can be used by neurosurgeons in the DBS surgical planning process as well as by neurologists who manage patients after surgery. The technology allows clinicians to see a model of the patient’s brain and helps them target where to place DBS electrodes and how and where to stimulate the brain to receive the best estimated outcome.

The impetus for the research team’s work comes from observing clinicians implement current neuromodulation technologies. Some parts of current commercial systems aren’t user-friendly to the patient or clinician. “When we as scientists observe clinicians using the technology, then we can find ways to make it better,” says McIntyre. “Our motivation comes from finding the little nuggets that we can tweak that would totally change the way the clinician interfaces with a very expensive piece of technology.”

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

The fundamental techniques long used by FES Center investigators to devise peripheral motor applications (e.g., electrical activation for spinal cord injury movement restoration) can be directly applied to applications in the autonomic nervous system. The FES Center is leading the development of stimulation techniques to down-regulate or block nerve conduction. The FES Center has expertise in characterizing neuroanatomy and developing the needed neural interfacing approaches, and there is a significant need to achieve corresponding understanding of the neuroanatomy of the autonomic nervous system, with sufficient detail and resolution to accurately model the fascicular structure of the vagus nerve and sympathetic chain/ganglia, the myelination characteristics along these nerves, and the branching patterns of these nerves as they near their target organs. Simulations using these neuroanatomical data can then be used to optimize electrode geometries and simulation parameters that provide maximum and natural effectiveness.

Over the last 5 years, the FES Center has greatly expanded our projects and expertise in autonomic physiology and clinical disorders and related research areas. We have expanded into areas of hypertension, nerve block, bowel function and afferent nerve stimulation, sleep disorders, gastric function, and ventilation and pulmonary care.

Accomplishments

• Demonstrated the efficacy of afferent stimulation to improve bladder function, both continence and emptying, in SCI and other disorders.
• Established a FES-based research activity to improve bowel motility following SCI and other disorders.
• Developed new FES approaches for addressing challenges in sleep disorders, pulmonary care, cardiac arrhythmias, hypertension, and post-stroke swallowing to prevent aspiration.
• Have begun to develop FES interventions for gastric function and autonomic dysreflexia.

Robert Kirsch, PhD

A hallmark of our research activities has been collaboration. We’ve always had teams of whatever the mix of expertise was needed in order to address the clinical problem at hand.
The work is funded by a Merit Review and a CDA-1 award from the U.S. Department of Veterans Affairs. The researchers are completing a short-term chronic test of genital nerve stimulation (GNS) to improve bladder control in human subjects. “We are beginning to look ahead at testing this approach for longer periods of time in more subjects and move toward an implantable system,” says Bourbeau. The team also is collaborating with Margot Damaser, PhD, a biomedical engineer with Cleveland Clinic, to couple its approach with her implantable bladder sensor technology for closed-loop control. During the bladder control research, many study participants reported that they also experience bowel dysfunction, so Bourbeau and his peers began to study bowel function restoration as well. People with neurogenic bowel dysfunction use digital rectal stimulation – a gloved finger inserted into the rectum – to evoke a colon reflex that promotes emptying of the bowel. The team of researchers are conducting preclinical experiments to develop and validate an electrical stimulation approach to improve colonic motility, which is severely slowed in people with spinal cord injury. Their work is funded by a CDA-2 award from the VA.

The ultimate goal of both the bladder and bowel research is to improve quality of life for people with SCI or other neurological disorders. “If our approaches are successful, we hope to improve confidence, independence and dignity for these individuals as well as significantly reduce costs and burdens related to care,” says Bourbeau.
Helping Prevent Lung Infections

Pulmonary Research

Tucked away on the 5th floor of Cleveland’s MetroHealth Medical Center is the Respiratory Physiology Lab. While the lab’s wooden medicine cabinets, piles of books and mountains of research papers may seem old-fashioned, the research and clinical trials conducted here are at the forefront of helping patients worldwide.

Anthony DiMarco, MD, principal investigator, and Krzysztof Kowalski, PhD, lead co-investigator, are developing pulmonary procedures devoted to increasing the quality of life of patients with respiratory muscle paralysis. Their work has led to a significant decrease in pneumonia – the greatest cause of mortality among patients with spinal cord injury.

In addition to serving as an investigator at the Cleveland FE$ Center, DiMarco is a CT physician at MetroHealth and a professor at Case Western Reserve University’s School of Medicine. Kowalski is a neuropathologist at MetroHealth, an associate professor at Case’s School of Medicine and a research health scientist at the Louis Stokes Cleveland VA Medical Center. The participation of Nickle and other patients in research projects at the lab helps lead to new advancements. This year marks a milestone for the Respiratory Physiology Lab. The team introduced a pioneering clinical trial procedure still aimed at the goal of reducing susceptibility to upper respiratory tract infection in qualified patients. The new outpatient procedure, eliminating long hospital stays or extra home care, has resulted in several distinct and successful procedures, including a clinical trial involving the actor Christopher Reeve, who was ventilator-dependent.

During a procedure that lasted seven hours, Nickle was implanted with a disk the size of a dime and provided a hand-held remote control to stimulate the nerves on the spinal cord. The stimulator produces abdominal compression. Today, thanks to the lab, patients (such as Reeve) who are ventilator-dependent now have access to outpatient procedures where electrodes can be placed via laparoscopic surgery. Patients like Nickle with paralyzed respiratory muscles can undergo life-enhancing outpatient procedures, eliminating long hospital stays or extra home care.

Patients used to be dependent upon suctioning, insufflation-exsufflation or abdominal compression. Today, thanks to the Respiratory Physiology Lab, these practices have been supplanted by more adaptable technologies aimed at improving the quality of life of patients. "When I first started looking at the lungs, paralyzed individuals barely survived on mechanical ventilation requiring 24-hour assistance," says DiMarco. "Not enough was being done."

A picture of Reeve hangs on a wall in the lab, a reminder of more than two decades of demonstrated successes aimed at improving the quality of life of patients. "Not enough was being done."

"It’s the ‘lives being saved’ that count."

Thanks to the lab, patients (such as Reeve) who are ventilator-dependent now have access to outpatient procedures where electrodes can be placed via laparoscopic surgery. Patients like Nickle with paralyzed respiratory muscles can undergo life-enhancing outpatient procedures, eliminating long hospital stays or extra home care. Patients used to be dependent upon suctioning, insufflation-exsufflation or abdominal compression. Today, thanks to the Respiratory Physiology Lab, these practices have been supplanted by more adaptable technologies aimed at greater ease of use among patients. In fact, patients participating in the Respiratory Physiology Lab’s newest research study already demonstrate reduced susceptibility to life-threatening respiratory tract infection. Improving patients’ quality of life is paramount to DiMarco and Kowalski. "Not enough was being done."

"Not enough was being done."

For more information on Pulmonary Research Programs contact:
info@FEScenter.org  |  (216) 231-3257

"It’s the ‘lives being saved’ that count."
The Cleveland FES Center has the ability to conceive, fabricate, test, and produce advanced technologies addressing clinical applications. Our technological capabilities are divided into two segments: innovation and technical.

The innovation group is charged with identifying the cutting edge techniques, materials and concepts from across the industry for possible inclusion into neural applications. The technical production group is charged with fabricating small quantities of implantable and external devices to a quality level fit for clinical use.

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

Kevin Kilgore, PhD

Established 1991, the FES Center’s Technical Development Laboratory (TDL) facilitates the design, development, and fabrication of prototypes for implantable research devices. These medical devices are intended for use in clinical feasibility studies conducted under Investigational Device Exemptions (IDEs).

To discuss potential collaborations regarding FES technologies contact:

Technical Development Laboratory (TDL)  
info@FEScenter.org | (216) 368-3153

Implantable electrode designs. More information on page 27.
Implantable Electrode Design

Epimysial & Intramuscular Electrodes
Both electrodes have a tandem conductor close coiled lead wire from the connector, covered with a silicone tube (“closed helix”). The epimysial electrode terminates in a Pt-Ir disc mounted in a silicone backing reinforced with dacron. The intramuscular electrode has a stainless steel stimulating area wound around the lead’s distal end.

Cuff Electrode
This automatic spiraling electrode is designed to form to the natural shape of the nerve. The cuff electrode has four contracts that can be grouped together to create a stimulation that will activate groups of muscles.

Myoelectric Signal (MES) Electrode
The MES electrodes are bipolar epimysial electrodes surgically implanted on the fascia of the target muscle. They are made of two 4mm diameter Pt-Ir discs mounted on a medical grade Dacron reinforced silicone backing. The discs are positioned 10mm apart. The distal lead wires for the bipolar MES electrodes begin with a Y-junction and run together to the distal recording electrode pair, with an impedance of 2 Ohms/cm.

To place an order or for more information on electrodes contact:
Ardiem Medical
(866) 349-0855 | info@ardiemmedical.com | ardiemmedical.com

Networked Neuroprosthetic (NNP) System
The Networked Neuroprosthetic (NNP) System is based on a network of small implanted modules – “neuroprosthetic building blocks.” Modules are distributed throughout the body and each one is dedicated to a specific function. They are linked to a centralized power source via a network cable, through which they all communicate. There are many advantages to the NNP System: Neuroprosthesis capacity can be tailored to the individual’s needs, hardware is scalable from simple to complex applications, multiple needs can be addressed in a single individual, the system is upgradeable – in hardware and/or software – to accommodate new technologies (upgrades), and it is adaptable to the changing needs of the user (functional enhancements.) Lastly, it frees the user of external components, which means that neuroprosthesis function is available spontaneously in any environment.

Neuroprosthetic Devices
Neuroprosthetic devices are powerful tools providing life sustaining and functional enhancement for individuals with central nervous system disorders. In general, a neuroprosthetic system should provide:
• The robust functions that users deserve
• Understandable and intuitive tools that clinicians need to implement those functions
• The technical transparency for surgeons to implant the system
• The power, flexibility, and upgradeability to meet the demanding and changing needs of researchers for continued development of new and improved functionality and control

Implantable Stimulator Telemeter (IST)
This device is used as a 10, 12, or 16 channel implantable pulse generator (IPG). It is inductively powered and controlled via an external coil which is placed on the skin over the coil. Communication is bidirectional and can accommodate up to 2 bipolar EMG signals.
The overall goal of the research taking place at the Cleveland FES Center is to improve the function and quality of life in individuals with disabilities by developing new technologies and methods, performing clinical evaluation and feasibility testing, and promoting the widespread deployment of the new technologies into clinical practice. This requires that the research programs address significant needs in a manner that ensures safety and efficacy. The safety and protection of our participants is the foundation of our clinical research protocols and regulatory processes. It is understood that there is no greater statement of trust and clinical need than when a person enrolls in research. The FES Center adheres to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP). These principles are universally recognized as a critical requirement to the conduct of research involving human subjects. Within each of our active clinical protocols, real human needs are being addressed to bring research and technology advances into the clinic. Regulatory and clinical oversight is addressed through dedicated team members working with the individual investigators. Leading the charge with the research community, the FES Center continues to expand and work closely with the Associate Medical Directors and the University Hospitals Case Medical Center - Clinical & Translational Science Collaborative for quality, consistency, safety and significance.
The goal of everyone in the FES Center is to positively impact the lives of patients with neurological disorders using advanced neuromodulation technologies. While academic research can initiate new concepts for clinical care, we need to work together with the neuromodulation industry to turn those concepts into clinical reality.

Cameron McIntyre, PhD

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

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

Industrial Relations & Partnerships
Much of the mission of the Center is to bring technologies to those who need it, and this work is accomplished through partnerships with existing industry partners or through formation of new companies. By partnering early with prospective partners, the Center can de-risk the technology transfer process by designing solutions to regulatory, documentation, and reimbursement hurdles. Tackling these problems early in the development cycle greatly facilitates the adoption of university technology by new or established industry partners.

In addition, the FES Center can leverage years of device expertise and neural technology research to de-risk early stage research for companies. Differing from a traditional sponsored project, these types of explorations combine industrial development, academic research, and federal funding opportunities to answer specific questions relevant to both the academic investigator and the industrial partner. These types of collaborations have been enormously successful and represent a new model for rapid advances and transfer of academic research.

For more information and to discuss strategic collaborations or industrial partnerships contact:
Andrew Cornwell, PhD
Director of Strategic and Industrial Collaborations
info@FEScenter.org | (216) 231-3257 | Twitter: @andy_cornwell
Concussion, A National Challenge was designed to bring experts from engineering and medicine together to identify and discuss emerging methods of detection, prevention and treatment of concussion. Discussion topics included understanding the problem, tissue injury, biomechanics of the concussive impact, and detection and prevention.

Spreading the Word

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

Concussion2015.org

Speakers

Jay L Alberts, PhD
Christopher M Bailey, PhD
Jeffrey J Bazarian, MD, MPH
David T Branch
Thomas F Budinger, MD, PhD
Robert C Cantu, MD
Jeffrey A Claridge, MD
Charles L Eneman, MD, FAEM
Cal Dallas C Haas, MD, MPH
Brian W Hainline, MD
S-Allan Hoffer, MD
Susan M Joy, MD
Geoffrey SF Ling, MD, PhD
Susan S Margulies, PhD
Ann C McKee, MD
Jeffrey Michael, EdD
Daniel P Perl, MD
Robert L Ruff, MD, PhD
Douglas H Smith, MD
Thomas M Talavage, PhD
Mary M Vargo, MD

What is ClevelandNEW?

ClevelandNEW is a facilitated, participant-driven workshop. Instead of passive listening, all attendees and organizers are participants, with discussion leaders providing moderation and structure for attendees. This non-traditional format is centered on integrated working groups identifying opportunities; preparation and participation are essential.

Workshop Objective

Bring the neural engineering leaders from industry, academia, and government together as a resource and forum committed to providing the neural technology solutions for individuals with neurological disorders or injury. The workshop is an effort to identify the opportunities and roadblocks for improving clinical care, bolster the neural engineering community, and develop a cohesive vision and plan for the field to best advance neural technology for the next century.

Visit ClevelandNEW.org for more information about ClevelandNEW 2017

John Chae, MD on the moderating panel at Concussion 2015
The Neural Prosthesis Seminar Series debuted in 1988. Since its debut, this series has sponsored numerous distinguished clinicians and scientists, working in areas that include functional neuromuscular & electrical stimulation, cortical prosthesis, neuromodulation, brain computer & machine interfaces, simulation & modeling, 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 Greater Cleveland Research Community to encourage the exchange of scientific information on global emerging neuromodulation and neurostimulation topics.

The Neural Prosthesis Seminar Series is sponsored by the Cleveland FES Center in partnership with our seminar co-hosts. Visit FEScenter.org/seminar to check out the 2016-17 series.

Seminar Co-Hosts

Visit FEScenter.org/seminar for more information and webstreams of each event.
This comprehensive program brought together leaders in the field of joint preservation, joint replacement, traumatology, neuro-restorative care, and neuro-spine surgery to provide practical scientific information, advances in medicine, research, and cutting-edge innovative technology in the fields of:

- Reconstructive Neurosurgery
- Cutting-edge Joint Replacement
- Joint Preservation
- Reanimation
- Caring for Injuries of our Wounded Warriors

About the Conference

Speakers

Jay Alberts, PhD
Gary Calabrese, PT
Ryan Carr, MD
John Chae, MD, MS
Robin C Crandall, MD
Dominique Durand, PhD
Ryan Farris, PhD
Mark Froimson, MD, MBA
Levi Hargrove, PhD
Salim Hayek, MD
John D Hsu, MD
Kevin Kilgore, PhD
Glenn Klute, PhD
Jayme Knutson, PhD
Rudi Kobetic, MS
Lisa L Lattanza, MD
Kevin Malone, MD
Cameron McIntyre, PhD
Jonathan Miller, MD
Joseph Ruzbarsky, MD
Dustin Tyler, PhD
Ronald Triolo, PhD
Seth Vilensky, MBA
Richard Wilson, MD

The Cleveland FES Center continues to actively support the regional VA Wheelchair Games, through the planning committee, administrative tasks, and volunteering in teams for events. Nearly 60 athletes enjoyed competitions in air rifle, billiards, boccia ball, bowling, slalom, table tennis, track and field events, swimming, and weightlifting.
Health Success HPAC Tours the VA Labs
Northeast Ohio Medical University Health Professions Affinity Community (NEOMED HPAC) toured the FES Center labs at the Louis Stokes Cleveland VA Medical Center to learn about careers in biomedical engineering.

Great Lakes Science Center | Engineering Careers Day
The FES Center adapted a robotic toy Hexapod to demonstrate how FES technology works. EMG signals are detected by surface electrodes and used to control the hexapod, similar to the activation of an FES system in a clinical application.

Cleveland State University Visits the Buckeye Wellness Center
Anne Bryden, OTR/L led an FES demonstration for Cleveland State occupational therapy students at the Buckeye Wellness Center (BWC), a facility specific to spinal cord injury recovery and wellness. Chris, BWC Founder and Owner and FES Center research participant, along with Maria, demonstrated their respective FES Hand Grasp Systems.
The Louis Stokes Cleveland VA Medical Center (LSCVAMC) provides clinical care to veterans with complications due to spinal cord injuries, head injuries, or strokes, among other illnesses. Along with significant support of individual research projects, the Louis Stokes Cleveland VAMC provides the core infrastructure to further this veteran-relevant mission.

**Research Laboratories**
Louis Stokes Cleveland VAMC
B-E210
10701 East Boulevard
Cleveland, Ohio 44106
(216) 231-3257

Barbara F. Snyder
President

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

**Technical Development Laboratory**
Bingham Building, Room 306
2104 Adelbert Road
Cleveland, Ohio 44106
(216) 368-3153

**Research Laboratories**
Wickenden Building
2211 Martin Luther King Jr. Drive
Cleveland, Ohio 44106
(216) 231-3257

**School of Medicine**
Health Sciences Campus
2109 Adelbert Road
Cleveland, Ohio 44106
(216) 368-3450

**MetroHealth Medical Center**
Akram Boutros, MD, FACHE
President, CEO

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

**MetroHealth Main Campus**
2500 MetroHealth Drive
Cleveland Ohio 44109-1998
(216) 957-3368

**Old Brooklyn Health Center**
4229 Pearl Road
Cleveland, Ohio 44106
(216) 957-3368

**University Hospitals of Cleveland**
Akram Boutros, MD, FACHE
President, CEO

UHC is a medical affiliate of Case Western Reserve University, 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 LSCVAMC and MHMC.

**University Hospitals of Cleveland**
11100 Euclid Avenue
Cleveland, OH 44106
(216) 844-1000

Institutional Partners & Facilities
By the Numbers

2015 Innovation Statistics

- 69 Research Investigators
- 59 Technical / Clinical
- 24 MS / PhD Students

Profile

- 17 Invention Disclosures
- 35 Patent Applications
- 8 Issued Patents

Economic Impact

Job Creation

>10 Biotech Start-Ups

2015 Research Funding

- $17.15 million
- Full funding portfolio on page 56

Innovation Statistics

- Research Funding 2015
- Federal, State, & Foundation
- Full funding portfolio on page 56

Biotech Start-Ups

994 Research Participants

1986-2016

- Job Creation
- >10

994 Research Participants

- Full funding portfolio on page 56

- Invention Disclosures
- 17
- Patent Applications
- 35
- Issued Patents
- 8

- Research Investigators
- 69
- Technical / Clinical
- 59
- MS / PhD Students
- 24

- 2015
- Innovation Statistics

- 10+

- 5-9

- 1-4

- Alabama 4
- Arizona 3
- Arkansas 1
- California 13
- Colorado 3
- Connecticut 3
- Delaware 1
- Florida 14
- Georgia 3
- Illinois 1
- Iowa 1
- Kansas 1
- Kentucky 1
- Louisiana 2
- Maryland 4
- Massachusetts 2
- Michigan 11
- Minnesota 6
- Mississippi 2
- Missouri 4
- Nevada 1
- New Jersey 2
- New Mexico 1
- New York 15
- North Carolina 6
- North Dakota 1
- Ohio 19
- Oklahoma 4
- Oregon 1
- Pennsylvania 13
- Rhode Island 2
- South Carolina 6
- Tennessee 2
- Texas 19
- Vermont 1
- Virginia 7
- Washington 4
- Wisconsin 2
- 4342

- Brazil 1
- Canada 6
- Columbia 1
- Delaware 1
- Florida 14
- Georgia 3
- Illinois 1
- Iowa 1
- Kansas 1
- Kentucky 1
- Louisiana 2
- Maryland 4
- Massachusetts 2
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- Full funding portfolio on page 56

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- South Carolina 6
- Tennessee 2
- Texas 19
- Vermont 1
- Virginia 7
- Washington 4
- Wisconsin 2

- Full funding portfolio on page 56
Differential frequency modulation of neural activity in the lateral cerebellar nucleus in failed and successful grasps.


