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PAIN

Program Overview

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

Accomplishments

- 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.

A TOOL FOR PAIN RELIEF

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

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

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

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

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

Moving from High-Frequency to Direct Current Blocks

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

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

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

Customizing Pain Solutions for Specific Applications

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

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

The researchers are pursuing a wide array of solutions because pain varies depending, for

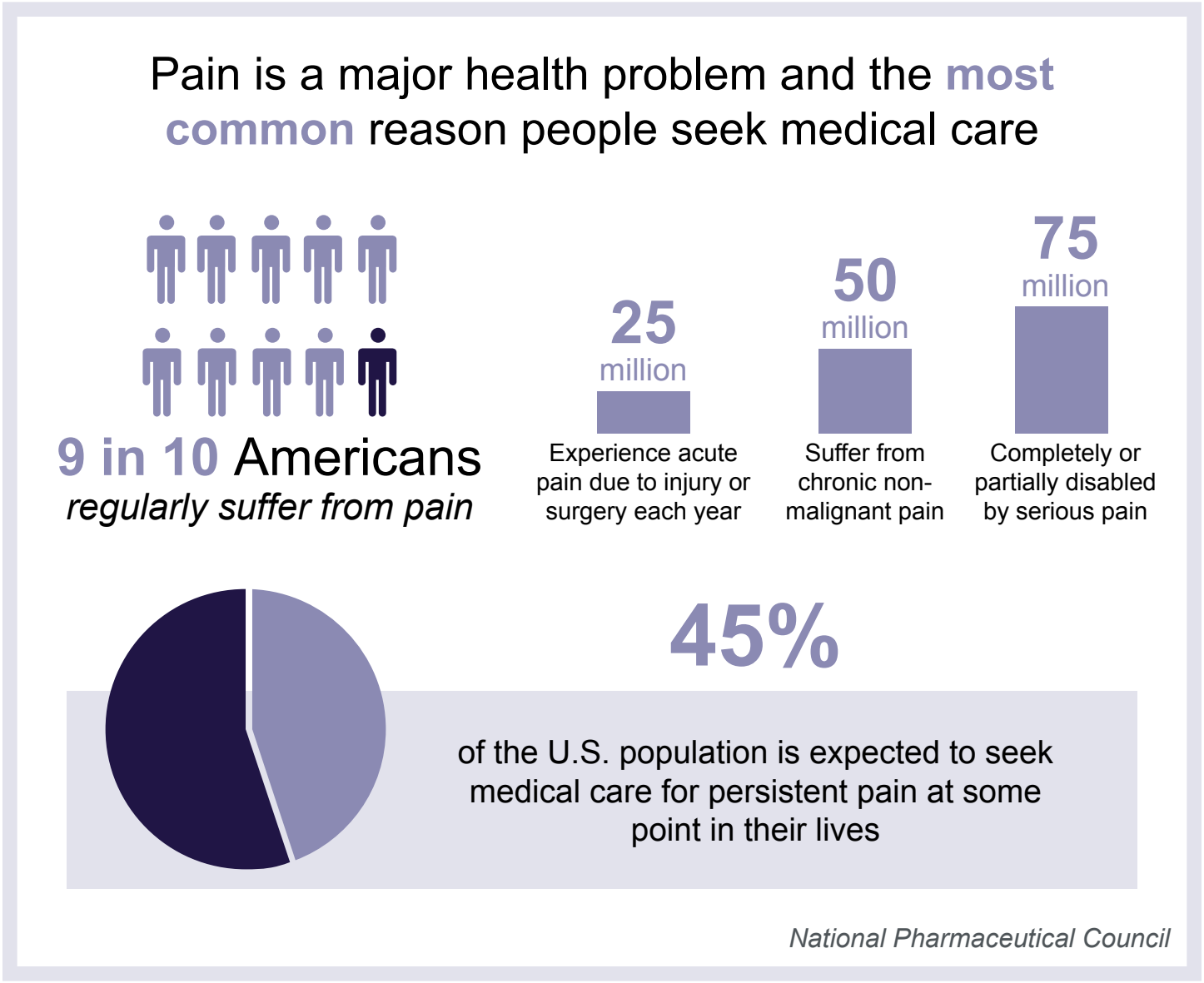
example, on where it's located in the body and whether it's acute or chronic. "One of the big pushes in medical care right now is for customization and patient-specific interventions," says Vrabec. "We have a wide toolbox at our disposal – a bunch of different types of electrodes, from implantable to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

Tapping into the Benefits of Direct Current Blocks

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

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

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



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

Transferring Solutions from the Lab to the Market

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

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

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

For more information about FES research and programs
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About the Cleveland FES Center

The Cleveland FES Center is a consortium of the Louis Stokes Cleveland VA Medical Center, MetroHealth Medical Center, Case Western Reserve University, University Hospitals, and the Cleveland Clinic Neurological Institute. With their support, researchers, engineers and clinicians collaborate together to develop innovative 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.

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