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HOW SPINAL CORD STIMULATION CAN HELP ALLEVIATE CHRONIC PAIN

BY NICOLA DAVIES, PH.D.

ain struck 50-year-old Dawn Tavener as she strolled down a mountainside in France a few years ago. At the bottom of the slope, she could barely walk. Back home in California, she was diagnosed with a herniated disc that would require surgery. Sadly, what was supposed to be a three-hour procedure caused further nerve damage and turned into a two-week nightmare with one complication after another. Worst of all, the pain persisted after she left the hospital, making it impossible to work, drive, or sit comfortably.

Anthony Torres, a 36-year-old crane operator at a cargo port, was critically injured in an on-the-job accident. He had severe spinal, brain, and foot injuries, partial paralysis, balance issues, and unbearable back, leg, and foot pain.

Torres had numerous procedures to alleviate the pain, including the insertion of 10 screws and two rods, a titanium cage, L5-S1 vertebrae fusion, and 23 epidural injections. Nothing was successful in remedying the agonizing pain throughout his body.

In the past, most patients like Tavener and Torres could not foresee an end to their pain, but over the last 50 years, advances in spinal cord stimulation therapy have enabled people with chronic pain to return to everyday activities.

Neel Mehta, M.D., director of the Weill Cornell Pain Medicine Center in New York City, is an advocate for spinal cord stimulation (SCS). "It is important to formulate a treatment plan that doesn't simply rely on opioids," he says. "We're trying to give people a second chance at life."

SCS has proven effective for many chronic pain conditions. Previously recommended only after traditional first-line treatments (medication, chiropractic or physical therapy, and corrective surgery) had been ineffective, SCS is more often considered a primary option.

Timothy Deer, M.D., president and CEO of the Center for Pain Relief in Charleston, West Virginia, identifies three situations in which surgeons may recommend SCS: when surgery has a 50/50 chance of success, when insurance companies deny spinal fusion for discogenic pain because they see better outcomes with SCS, or when SCS is believed to provide a better alternative to opioids.

Laura Tyler Perryman, chair and CEO of the medical device company Stimwave, says SCS systems have the potential to significantly reduce the lifetime cost of care for chronic pain patients, making the devices feasible and effective alternatives to pain medications.

WHAT IS SPINAL CORD STIMULATION?

According to the International Neuromodulation Society, SCS, or neuromodulation, is "therapeutic interaction with the central, peripheral, or autonomic nervous system for therapeutic effect by means of targeted electrical stimulation or pharmacological delivery from implanted devices." Most SCS devices are small paddle-like pulse generators that are implanted through a minimally invasive surgical procedure into the opening between the spine and the spinal cord, in the area where the pain occurs. In some SCS models, electrical contacts connect the paddle to a battery implanted under the skin. However, more recent devices are wireless. A clinician initially programs the device, and patients then use a wireless remote to control the level of stimulation being delivered by the pulse generator.

Michael Kaplitt, M.D., Ph.D., associate professor of neurological surgery and associate attending neurosurgeon at New York's Memorial Sloan-Kettering Cancer Center and New York-Presbyterian/Weill Cornell, says the idea behind SCS is to trick the brain into feeling an alternate sensation to pain and ultimately to block the electrical signal of the pain neuron to the spine and brain. Here's how it works.

The nervous system is made up of the central nervous system, which is comprised of the brain and the spinal cord,

and the peripheral nervous system, which includes all the nerves that branch out from the spinal cord.

The thalamus, in the lower part of the brain, relays sensory impulses from receptors in different parts of the body to the higher part of the brain (the central cortex within the central nervous system). It is in the central cortex where sensations are interpreted as touch, pain, or temperature. The thalamus serves as a "gateway" of sorts, filtering which information is relayed for processing. Therefore, by stimulating the thalamus, the brain can be tricked into feeling an alternative sensation to pain.

Older SCS devices would send low levels of electrical energy to nerve fibers, replacing pain with a tingling or warm sensation, therefore preventing pain signals from reaching the brain. The most recent SCS devices operate at high frequencies that are not felt by patients at all, and yet they provide the same relief as when patients are distracted by alternative sensations.

Within the peripheral nervous system, special nerve cell clusters called dorsal root ganglion (DRG) help transmit the sensory messages of pain and touch. The DRG, lying at the base of individual branching spinal nerves, very close to the spinal cord itself, transmit sensory information from the skin to the spinal cord. In 2016, the U.S. Food and Drug Administration approved the first SCS system, Axium from St. Jude Medical, to treat pain from the DRG. (See sidebar below.)

WHEN TO OPT FOR SCS

People who have back surgery but don't experience quick relief should give themselves time to heal, says Mehta, but they shouldn't wait too long to consider SCS if they continue to have chronic pain.

One study found that family physicians treat patients for an average of 3.13 years before referring them for SCS. The time lag allows pain to become ingrained in the body and causes many physiological changes.

"If the body is used to being in pain, it gets used to sending pain signals and in fact becomes more efficient at doing so," says Mehta. "It's just like if your house keeps getting robbed: You install an alarm system and you become more alert. Things like muscles and joints that would usually not hurt begin to hurt."

This unrelieved pain can also lead to psychological damage such as depression, anger, and frustration, since the

SPINAL CORD STIMULATORS

SYSTEM

densely populated

Here are five spinal cord stimulation systems approved by the U.S. Food and Drug **Administration** in the last two years.

► AXIUM NEUROSTIMULATOR



with sensory nerves that transmit information to the brain via the spinal cord. The goal is to relieve moderate to severe chronic intractable pain of the lower limbs in adult patients with complex regional pain syndrome, a disorder known as CRPS that often affects the extremities. The system's leads are placed directly over the DRGs, directing the stimulation solely to the neurons thought to be creating and perpetuating a person's pain. In a clinical trial, after one year of treatment, about 75 percent of patients reported a reduction in pain relief of more than 50 percent, and onethird said their pain was down 80 percent or more.

BURSTOR STIMULATION St. Jude Medical FDA approval: October 2016

This physician-designed SCS technology utilizes intermittent "burst" pulses designed to mimic the body's natural nerve impulse patterns. BurstDR is the only approved form of burst stimulation to have been evaluated in a large-scale clinical trial. The technology is now featured in St. Jude Medical's Proclaim Elite and Prodigy MRI SCS systems. In addition, patients previously implanted with upgradeable Protégé and Proclaim SCS systems will be able to upgrade their systems to deliver BurstDR stimulation without additional surgery. The Bluetooth wireless technology, allowing



clinicians to program and adjust their patient's SCS therapy with an iPad Mini, and patients can adjust their stimulation amplitude via the **Patient Control**-

ler app for the iPod

patient can see no end to the pain. Mehta explains that the longer the pain is left to wreak havoc on the body, the harder it is to resolve. In fact, research shows that SCS is far more effective when it's started between six months to a year after conventional treatments failed.

Fortunately, people who endure long battles with chronic pain can benefit from SCS. For instance, Deer recalls a 54-year-old man who had a laminectomy (an operation to remove the back of one or more vertebrae to relieve pressure on the spinal cord or nerves) in 2003.

His back and leg pain persisted, and he agreed to spinal fusion surgery in 2014 and again in 2015. Frustrated with unrelieved pain and the side effects of opioids, he met with Deer and was offered a trial SCS implant. Less than a week after receiving the device, his pain was reduced 70 percent. After 12 weeks with a permanent implant, he achieved an 80 percent reduction in pain. The man was soon able to gradually reduce his pain medications and has resumed his active lifestyle.

After Dawn Tavener, who injured her back in France, had an SCS device implanted, the relief from her pain was almost immediate. When Mehta came to check on her the morning following the procedure, he found her dressed and sitting in a chair — something she had been unable to do for almost two years. Later, she and her husband returned to the mountains in France, leaving a painful ordeal behind her.

safe

to full

access

SENZA SPINAL CORD STIMULATION SYSTEM Nevro Corp. FDA approval: May 2015

This is a rechargeable SCS for treatment of chronic pain of the trunk or limbs. The leads and signal generator are implanted through a small incision in the patient's back. The generator receives radio signals from the doctor or patient controller, telling it when and how to deliver appropriate electrical stimulation to the spinal cord. Unique to the device is its delivery of a high-frequency 10 kHz output that does not cause a tingling sensation (paresthesia). The rechargeable batteries have a lifespan of up to 10 years before surgery is required to replace them. Recharging, via a charging pad worn over the device, 0 takes 30 minutes.



► PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEM **Boston Scientific Corp.** FDA approval: May 2016



This system offers customized relief to patients with chronic pain while also enabling

body magnetic resonance imaging (MRI) under certain conditions. The system's MultiWave Technology enables delivery of multiple waveforms, including burst and higher rates, intended to help respond to changes in pain over time. In an analysis of registry information from 800 patients, it was determined that 72 percent used multiple wave-

forms to customize their therapy and optimize pain relief. The new system also allows doctors to use a three-dimensional, anatomy-driven computer model designed for simple point-and-click pain targeting.

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In November 2015, Anthony Torres had a successful SCS device trial for the relief of his injury-induced chronic pain. "The best thing is that it gave me relief from the pain and allowed me to get off the pain medications," he says.

Spinal cord stimulation may be the answer for people whose lives have been seriously inhibited by pain. Although not a cure or panacea, it offers many advantages: costeffective treatment at lower lifetime health-care cost; better long-term outcomes; a minimally invasive procedure that is fully reversible; and the ability to reduce the need for strong, addictive pain medication.

In addition, according to Mehta, the scope of SCS is continuing to grow. Recent trials are exploring its use in control of the bladder or anal sphincter and in producing movement in people with spinal cord injuries. With such clear benefits, SCS holds much promise and hope for people struggling with life-limiting pain.

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► STIMQ PNS SYSTEM Stimwave March 2016

This system provides relief to people who experience severe intractable chronic pain of peripheral origin, including shoulder, upper extremity neuropathies, mid- and lower-back pain, chest and abdominal-wall pain, hernia pain, pelvic pain, as well as lower extremity neuropathies in the knee, tibia, ankle, and foot. The StimQ PNS System is a tiny wireless microchip that delivers small pulses of energy to electrodes near surrounding nerves. Since the device is less than 5 percent of the size of standard implanted options, a minimally invasive insertion through a standard-size needle or small incision minimizes the need for surgery. A small wearable fabric patch unit powers the implant.