

SPR Therapeutics' neuromodulation system treats phantom-limb pain

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Medical device company SPR Therapeutics makes a neuromodulation system in Minnesota that can treat pain in a person's limbs—even limbs that were amputated long ago.

Treating <u>phantom-limb</u> pain is just one of the applications for the Sprint peripheral nerve stimulation (PNS) system, a <u>medical device</u> that has been shown to create long-lasting <u>pain relief</u> after the 60-day implant is removed in an outpatient procedure.

Military physicians are interested in the technology—the Department of Defense has been a key early funder of the SPR Therapeutics—but so are civilian doctors who are looking for pain treatment options that falls between passively prescribing opioid drugs and permanent medical procedures like burning away nerves or implanting battery-powered nerve stimulators.

SPR Therapeutics is a privately held company founded in 2010 in Ohio, but today the company has an office in Maple Grove that handles marketing and communications, professional education, reimbursement operations and supply chain management. The company works with an array of contractors in Minnesota, including Nextern and Heraeus Medical, and the Sprint PNS system itself is assembled in the state.

The Sprint PNS is a newer system, with about 1,000 of its temporary leads implanted, including in trials and regular clinical settings. Patients who want the treatment may have to battle their insurer to get it. But the



technology has been the subject of several sham-controlled randomized controlled trials and more than 30 peer-reviewed papers and presentations showing long-term relief.

SPR Therapeutics says 74% of patients treated with the Sprint PNS reported a greater than 50% reduction in pain. The recently completed trial of post-amputation pain, considered one of the most challenging forms of nerve pain to treat, found that after four weeks, 58% of Sprint patients and 14% of placebo patients experienced significant pain relief. After 12 months, 80% of unblinded patients—patients who knew that they got the real therapy—reported an average pain reduction of 76%.

Ron Schlicht, 58, of Maple Grove, said he hasn't needed pain medications for his severe leg-pain condition, known as meralgia paresthetica, since getting treatment with the Sprint PNS system nine months ago at the Mayo Clinic in Rochester.

Before that, the side effects from his medications for pain were so significant that he was ready to undergo surgery on the nerve that was sending the pain signals.

"Since my treatment, I haven't taken a pain medication once, which to me is amazing," Schlicht said. "The area on my leg still isn't 100% like it was before I had this problem. ... I may feel a twinge, or a different sensation. But it's not painful."

Applying mild electric current directly to the nerves is a long-standing way of treating many forms of pain, as well as other conditions like epilepsy. It doesn't work for everyone, and researchers at the companies that make neuromodulation devices still lack a definitive explanation for the biological mechanism of action behind neuromodulation therapy.

Mark Stultz, who once worked in Medtronic's neuromodulation division,



is senior vice president of market development at SPR. He said SPR's peripheral nerve stimulation seems to work by interrupting pain signals from the affected nerve and changing how the brain processes the information. Whether the diseased nerve has been sending too much information to the brain, or just not enough healthy information, the result is that the pain has become "centralized"—and the SPR therapy disrupts that.

The difference between SPR's treatment and other neuromodulation techniques used to treat pain may lie in the location of the treatment. Instead of stimulating at the <u>spinal cord</u> or in related nerve cells, Sprint therapy is applied near the peripheral nerves, closer to the source of the pain signals. The most common uses of the Sprint system are to treat pain in the shoulder, back or knee, or nerve pain.

"There is something about being in the periphery that is allowing us to treat <u>pain</u> syndromes that haven't otherwise been well-treated by these other more-invasive permanent technologies. And there's something about stimulating the periphery that is allowing us to have a durable effect, when every other therapy requires the implant to be permanent," Stultz said.

The stimulation is also applied about a half-inch from the nerve, as opposed to directly on the nerve, which may also increase the treatment effect.

The past success rate of neuromodulation therapies has been such that patients often try out a temporary system to see if it will work, before undergoing a permanent implant.

Originally, SPR's system was designed to be the same. But Stultz said the company found in clinical trials that its temporary system was creating lasting results, so it decided to design a device intended to be implanted



for up to 60 days.

"There's always an expectation that you need to have something permanently implanted to have an effect," he said. "And what we are seeing is that we're able to introduce this tiny lead adjacent to peripheral nerve, placed under image guidance—sometimes ultrasound, sometimes fluoroscopy—and the majority of our patients are getting sustained effect."

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