

## SPR Therapeutics Masters Peripheral Nerve Stimulation Therapies for Pain

by Jennifer French, senior editor

In the midst of the opioid crisis, SPR Therapeutics, in Cleveland, OH, offers an innovative neuromodulation device for the treatment of pain. The minimally invasive neurostimulation device pioneered by John Chae of Case Western Reserve University evolved as a targeted therapeutic. It is now being promoted as a non-narcotic, reversible, safe, and effective alternative for acute and chronic pain management.

The company's SPRINT device is a percutaneous peripheral nerve stimulation platform technology. Among neuromodulation devices for pain, this treatment category is less invasive than SCS and more targeted than surface stimulation. "PNS is coming into its own," said CEO, Maria Bennett. The clinical evidence is gaining credibility and there are new competitors entering the PNS market such as Bioness and Stimwave.

The SPR device was initially designed for the treatment of shoulder subluxation for stroke survivors. Through initial human trials, the research team discovered that PNS was mainly addressing the pain associated with shoulder subluxation. The device is still available for this indication. But today, the focus of the latest design is for the treatment of chronic intractable pain as well as post-traumatic and post-surgical acute pain.

Clinical distribution is mainly through pain specialists, who are familiar with performing inter-office injections. The administering physician uses a needle type tool to implant the percutaneous lead, which has a thin wire protruding from the skin. The lead is a coiled design to help reduce migration and infection. The user wears a waterproof bandage over the lead wire and an external pulse generator on the surface of the skin. The EPG connects to the percutaneous lead with a cable. The patient may choose a short cable to mount the EPG near the site or a long cable to mount the EPG in another area such as the hip or abdomen.

The initial device featured a single lead (endura). The recently released second generation device has a dual lead (extensa) opening the possibilities for treating other types of pain such as lower back pain and

post-amputation phantom pain. The new version features a rechargeable battery, Bluetooth controller, and customizable parameter capabilities. If the clinician so chooses, adjustments may be made for frequency, amplitude, and pulse generation. Otherwise the algorithm does the work.

The SPRINT device was originally introduced on the market as a 60-day treatment and there is a growing body of clinical evidence to back up the company's claims. In a multi-center, double-blinded, randomized, placebo-controlled clinical trial for the treatment of chronic post-amputation pain, participants were administered an ultrasound-guided dual lead system on the sciatic and/or femoral nerves. Following the eight-week treatment, two-thirds of the participants reported a 50 percent reduction in pain and pain interference. Opioid use decreased by 71 percent among the treatment group and amongst the treatment responders, 80 percent reported pain relief at 12 months following treatment.

"What we are finding from our clinical evidence is that there is a residual pain relief effect post-treatment," said Bennett. "These results position SPRINT as an early neuromodulation therapy implanted for up to 60 days that can provide long-term pain relief, obviating the need for a permanent implant in many patients."

SPR is not sure of the exact mechanisms of action but Ramana Naidu presented insight at the 2019 NANS meeting. Naidu explained how chronic pain receptors can persist in the brain even when the original pain source is absent. Stimulation seems to calm the activity of these receptors through cortical plasticity resulting in a reduction of pain.

SPR has several other on-going clinical trials including the SNAP trial for neuropathic pain and amputation supported by a \$6 million DOD contract and an ultrasound-guided PNS trial for post-surgical pain related to rotator cuff and ankle surgeries. They also landed a DOD-supported multi-center trial contract for pain related to total knee arthroplasty and back pain.

The SPRINT device gained FDA clear-

ance as a Class II device in 2016 with the original single-lead device. In 2018, SPR gained clearance for the second-generation device along with indication for chronic and acute pain relief of up to 60 days in back and extremities. Their recent studies help to support reimbursement for the device and treatments. They are currently using existing codes identified as peripheral nerve stimulation and introduced SPRcare service to assist with reimbursement authorizations and appeals.

Bennett has led the company since its inception and was involved with the early development while working toward her Master's degree in biomedical engineering at Case Western Reserve University. Prior to this venture, Bennett was vice president of clinical affairs at NDI Medical, a medical device development company in Cleveland. She also gained experience at Boston Scientific and NeuroControl

With 25 years of medical device development experience, Mark Stultz serves as vice president of market development. His experience in the medical device space includes positions at Advanced Bionics, Medtronic, Nevro, EnteroMedics (now ReShape) and Gyrus Medical. Joseph Boggs serves as vice president of research and development and David Youngberg serves as senior vice president of sales. Leading the board of directors is Geoffrey Thrope, founder of NDI Medical. Warren Grill of Duke University serves as chief scientific advisor. Most recently, Peter Staats joined as the chief medical advisor, replacing device pioneer Chae in that role.

SPR has been able to secure financing to support the device and company growth. As of 2018, SPR has received approximately \$30 million in DOD and NIH grants and contracts. This includes

**SPR Therapeutics**  
22901 Millcreek Blvd, Suite 110  
Cleveland, OH 44122  
844 378 9108  
www.sprtherapeutics.com

Market: Pain Neuromodulation  
Founded: 2010  
Privately held  
Maria Bennett, CEO

## Neurotech Researchers and Clinicians Tackle Paralysis at SCI2020 Meeting at NIH

by Jennifer French, senior editor

SCI2020, Launching a Decade of disruption in Spinal Cord Injury Research was held earlier this month on the NIH campus in Bethesda, MD. The event was sponsored by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research.

Lyn Jakeman, director of the division of neuroscience at NINDS, kicked off the charge for the audience to “break down silos” and encouraged participants to work collaboratively across disciplines. Jakeman also advised attendees that the spinal cord is now included in the Brain Initiative program. NINDS director Walter Koroshetz also addressed the audience, highlighting the various NIH programs to move innovation from the lab to the bedside. Registrants for the event consisted mainly of scientific researchers, and academics, along with some clinicians and consumer advocates. The intent of the meeting was to set the course for SCI research from 2020 through 2030.

There were two keynote presentations. Michael Boninger of the University of Pittsburgh provided a look into the future of what the treatments for spinal cord injury might look like in 2040. He told the fictional but predictive story of him getting an injury and the innovative treatments to follow which included emergency care, cellular treatments,

neuromodulation implants, and rehabilitation. He also shared the current viewpoint of people living with injuries today provided by Jim Krause from the Medical University of South Carolina and this editor, both living with tetraplegia. The second keynote was provided by Rob Wudlick from Get Up Stand Up to Cure Paralysis. He told his personal story of becoming a quadriplegic after an accident in the Grand Canyon.

The two-day meeting was organized into six sessions. Each session had a moderator, panelists, and facilitators. The session moderator along with the panelist provided short presentations on the state of science and their view of the trends in the given topic while the facilitators sparked audience participation with provocative questions and discussion. With the exception of one, the sessions highlighted various progressions of spinal cord injury or key areas of interest.

The first session focused on the acute phase within a few hours of the injury. Among other presentations, William Whetstone from the University of California San Francisco highlighted the emergency room triage protocols developed for stroke patients. This was developed to quickly diagnose and route the patient to the applicable treatment as quickly as possible. They also highlighted the need to develop an infrastructure for SCI centers of excellence and the need to build awareness among the communities on standard care for SCI.

The second session focused on the sub-acute phase and strategies for repair, plasticity, and regeneration following injury. The discussion centered around progress on cellular therapies, biomarkers, and the need for data sharing. Another session focused on long-term wellness and secondary health effects of SCI. Richard Shields from the University of Iowa led this session. SCI is typically viewed as a stable condition following 12 months post-injury. As the demonstrated research shows, SCI is a systematic disease with the deterioration of muscle and bone impacting the overall health of the body including autonomic functions.

Two sessions had a main focus on technology; one highlighting neuromodulation strategies and the other focusing on prosthetics and robotics. The former was moderated by Edelle Field-Fote of the Shepherd Center and Emory University. The session's discussion circled around the use of neurostimulation for rehabilitation recovery post injury. Stimulation methods coupled with rehabilitation also dominated the discussion to induce plasticity and other health outcomes. However, it was still unclear how to differentiate the effects of rehabilitation from the effects of technology. Some argue that it does not matter as long as there is a functional outcome. The other technology session highlighted developments in exoskeletons, brain-computer interfaces, and epidural stimulation. For all of the various strategies it was clear there is a need for modularity and personalized custom features for individual users. Neurotechnologies were a center of discussion in these sessions.

One of the largest impacts during this meeting was the session titled “With Us, Not for Us,” led by the members of the North American Spinal Cord Injury Consortium. “We want to be disruptive but productive,” said Kim Anderson-Erisman, president of the consortium. The panelists each presented data from a community survey which gathered opinions of 1800 respondents from the SCI community within 37 days. The data showed frustration with the lack of translation and how the quality of treatment for SCI has declined, while costs and mortality rates have both increased over the past decade.

The survey respondents relayed their discontent with media hype of curing SCI and their desire to be part of the integrated knowledge transfer as participants in the research process. Their overall message for the future is that people living with SCI want to be engaged in the research process. Funded research portfolios should reflect the needs of the people living with the condition and these investments should yield tangible impacts. With this future in mind, we shall see what unfolds in the next decade.

\$6 million to support a randomized control trial comparing SPRINT to conventional medical management for chronic back pain, \$3 million for post-surgical pain management related to orthopedic trauma, and \$1 million for product design improvements. SPR has secured three rounds of investment funding including a Series A for \$5 million in 2012 and a convertible debt financing option which rolled into a Series B round for \$5 million in 2015. Last year, they completed a \$25 million Series C of investment targeted for development and commercial launch of the SPRINT endura and extensa systems, as well as sales force development.