A Case Series Suggests That New Anchoring and Multiple Lead Placement Techniques Reduce the Complications of Spinal Cord Stimulator Implant

April 11, 2013, Fort Lauderdale, Fla. -- Two innovative techniques in the placement of an implanted spinal cord stimulator (SCS) are expected to reduce common complications at the implant site, according to new research revealed today. Results from a case series highlighted an advanced lead anchoring technique and the emerging technology of using large single-port introducers, which enable placement of multiple neurostimulation leads through a single needle-entry point.

Neurostimulation leads are used in SCS therapy for the management of chronic pain. The researchers presented their findings at the 29th Annual Meeting of the American Academy of Pain Medicine.

"The single-port introducers have revolutionized the field by allowing multiple lead arrays and paddle leads to be placed through a single percutaneous port," said Daniel A. Fung, MD, lead study author. “The anchoring technique secures and deeply buries the anchors.”

Dr. Fung explained that the new approach addresses the two most common complications of SCS systems -- lead migration and anchor site pain. In contrast, conventional anchoring technique attempts to secure leads subcutaneously (i.e., under the skin) to connective tissue or the supraspinal ligament using bulky anchors.

“Often the anchor will be palpable under the skin and can cause discomfort. Also, if not anchored securely to strong tissue, it is easy for the sutures to come loose, which could result in lead migration,” Dr. Fung said. “Some patients have stimulators removed due to pain at the

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anchor site despite good coverage of their usual pain. Thus the decrease in anchor site pain should help decrease the need for spinal cord stimulator revisions or removals.”

The research was conducted at the Center for Spine and Joint Restoration in Santa Monica, Calif. In a case series of 3 patients, SCS implantation took place by means of a large single port introducer (the Epiducer™ Lead Delivery System), which was used to place various arrays of lead combinations, including slim paddle electrodes and wire electrodes to the target areas.

Dissection along the spinous process was performed, and a perforating towel clamp was used to create an anchoring point in the spinous process for the electrodes. Anchors were placed along the spinous process deep in the paraspinal musculature.

All 3 patients were successfully implanted with no immediate complications. After the initial post-operative visits, all patients were evaluated every few months for at least 1 year. All achieved good stimulation of the pain location that led to reduced pain complaints. These improvements were sustained on follow-up with no complications noted and no evidence of lead migration or implant discomfort.

SCS uses a low voltage of electricity to stimulate the spinal nerves, blocking the feeling of pain. Long-term electrical stimulation of the dorsal columns was first proposed as a means of pain control in 1967. Since then, many thousands of patients have undergone implantation, and examples from the scientific literature include those with failed back surgery syndrome, reflex sympathetic dystrophy, chronic back and extremity pain, refractory angina and a variety of other painful conditions.

SCS is helpful in controlling chronic pain for many patients (Cameron, J Neurosurg 2004;100(3 Suppl Spine):254-67). Controlled randomized trials have been few, however, and reports of non life-threatening complications are common (Turner et al, Pain 2004;108(1-2):137-47).

The current study investigators stressed the importance of good patient selection and screening that can lead to SCS being an effective, relatively safe and reversible treatment for management of certain pain conditions. Patients who receive spinal stimulation have usually had pain long term and tried many other methods to control it, including surgeries. A psychological evaluation is recommended ahead of the implant trial to be certain depression or other conditions are not contributing to the pain.

The literature indicates that the field of neuromodulation for pain treatment is evolving rapidly with new technologies and improvements. If lead migration and site pain could be reduced, this would serve to further the safety and effectiveness of SCS therapy, Dr. Fung said. He further called for large, randomized studies to validate the current findings and to explore future advancements.

Poster 185 - Advanced Spinal Cord Stimulator Lead Anchoring and Multiple Lead Placement Technique Through an Individual Port: A Case Series

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