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REPRINT

CERVICAL-STIM® BONE-GROWTH STIMULATOR PROMOTES CERVICAL SPINE FUSION

The **Cervical-Stim® 505L** bone-growth stimulator has recently been approved by the FDA to promote healing of cervical fusions. The Cervical-Stim is the first and only product clinically proven and approved for use with cervical spine fusion patients.

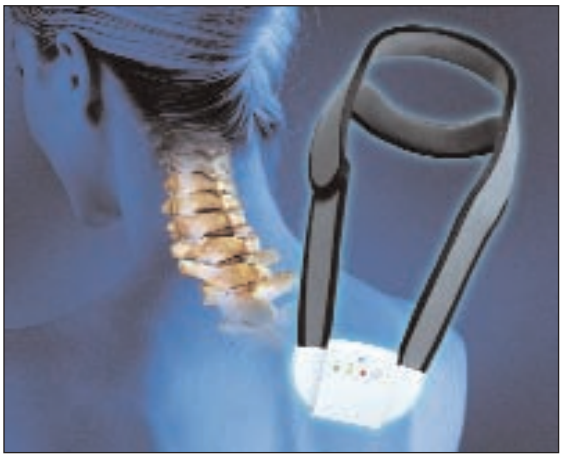
Cervical spine fusion is currently the most common surgical treatment for cervical degenerative bone disease, with an estimated 200,000 cervical fusions performed annually. Some patients, however, are at risk of non-fusion because of medical and/ or other conditions. Non-fusion can lead to continued pain and disability, as well as the need for repeated surgical intervention. In general, patients at high risk for a non-fusion include those who smoke, undergo multilevel fusion, are obese, have diabetes mellitus, have osteoporosis or metabolic bone disease, and those who have received steroids for a long period. Approximately 30% of cervical fusions are performed in high-risk patients.

Orthofix® Inc. (McKinney, TX), received FDA approval in December 2004 for its new product, Cervical-Stim, the world's first and only bone-growth stimulator clinically proven and FDA-approved for use as an adjunct to cervical spine fusion in patients at high risk for non-fusion. Cervical-Stim was approved by the FDA based on the results of a prospective, randomized, multicenter clinical trial led by Kevin Foley, MD, of the Semmes-Murphey Clinic and the University of Tennessee's Department of Neurosurgery. The trial evaluated the safety and effectiveness of the Cervical-Stim device in subjects considered at high risk for non-fusion who had undergone cervical fusion for degenerative conditions.

Orthofix is the only company that offers surgeons and their patients a full range of FDA-approved, clinically proven, noninvasive bone growth stimulation devices that enhance the healing of the cervical spine, lumbar spine, and long-bone nonunion fractures. Cervical-Stim is a valuable addition to the Orthofix line of bone-growth stimulators, which includes the **Physio-Stim** and **Spinal-Stim** devices.

Pulsed Electromagnetic Field Stimulates Bone Growth

Cervical-Stim works by delivering a low-level pulsed electromagnetic field (PEMF) signal that helps activate and augment the body's natural biological healing process after fusion surgery. The Cervical-Stim device contains a microprocessor (computer chip) that generates the treatment signal. The PEMF technology used in the Cervical-Stim is the same as that of Orthofix's other FDA-approved bone-growth simulators. Since 1990, the clinical effectiveness of PEMF bone growth stimulation has been clinically demonstrated in more than 200,000 spine patients.



The Cervical-Stim is worn 4 hours per day and can be worn in addition to a brace.

The Cervical-Stim is an external device that the patient wears around the neck. It is a battery-powered, single-piece device with an integrated control unit and treatment transducer. The Cervical-Stim is worn for 4 hours daily.

Clinical Studies Show Efficacy

The multicenter clinical trial randomized 323 patients with symptomatic radiculopathy and correlating radiographic evidence of cervical nerve root compression who underwent cervical fusion surgery. All patients were either smokers or required multi-level surgery (or both), and underwent anterior cervical discectomy and fusion using the Smith-Robinson technique with allograft bone and anterior cervical plating (Danek Atlantis System). There were 70 one-level fusions, 192 two-level fusions, 53 three-level fusions, and eight four-level fusions. Subjects were randomized to receive PEMF stimulation (treatment group, n=163) or no PEMF stimulation (control group, n=160). Fusion status was evaluated in a blinded fashion by two independent orthopedic spine surgeons and a radiologist.

There were 240 patients available for evaluation at 6 months (PEMF, n=122, non-PEMF, n=118). At 6 months, the fusion rate in the PEMF group was 83.6% versus 68.6% in the non-PEMF group (p=0.0065). These data show that patients undergoing cervical fusion surgery who were treated with the Cervical-Stim had an increase in the frequency of fusion over the non-treated control group. There were no significant differences in quality-of-life measures between the PEMF and non-PEMF groups.

Researchers reanalyzed the data to evaluate the relation between fusion status and clinical outcome. The results showed statistically significant differences when comparing clinical outcomes between those fused and those not fused, as measured by visual analog pain scores. The results indicate that the fused group had significantly less pain at 6 months postoperatively than non-fused patients ($p = 0.0189$ at rest, $p = 0.0125$ with activity).

PEMF Shown To Be Safe and Effective

PEMF treatment with the Cervical-Stim is proven safe and effective. Dr. Foley, the study's principal investigator, states that, "the study showed that 84% of patients who got the stimulator fused by six months postoperatively, versus 69% of the patients who did not, and we consider those results to be very promising. This is good news for patients who undergo cervical fusion and this is good news for their doctors." Further, the clinical trial showed few adverse events, primarily neck pain, shoulder/arm pain, adjacent level pathology, and lumbar pathology. There were no differences in adverse events between the Cervical-Stim treatment group and the non-treatment control group.

Orthofix began marketing the Cervical-Stim immediately following FDA-approval. Orthofix is currently sponsoring mechanism-of-action studies, which show that PEMF activates specific bone cell membrane receptors and initiates internal signaling within the bone cell, causing proliferation. Results of these studies are expected to be published in 2005.

Proven Over Time

In 1990, Orthofix introduced the first and still the most effective external bone-growth stimulator for lumbar fusion. Since then, over 200,000 spine fusion patients have healed with bone-growth stimulation from Orthofix. Orthofix now offers Cervical-Stim, the first and only FDA approved device clinically proven safe and effective in promoting healing of cervical fusion.

For more information concerning Orthofix Inc., call 1-800-535-4492, or visit the company's Web site at www.orthofix.com.