Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Description

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the chances of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion.

Background

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site with the production of direct current (DC) electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

- Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using either pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours per day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed into a back brace or directly onto the skin and are worn for 6–8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Patient compliance may be an issue with externally worn devices.
• Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply obviating the need for a surgical procedure to remove the generator when treatment is finished.

Regulatory Status

Several implantable devices have received U.S. Food and Drug Administration (FDA) premarket approval (PMA):

• The OsteoStim® (Electro-Biology, Inc.), which may also be marketed under the trade name SPF (Biomet), has received FDA PMA.

Noninvasive bone growth stimulators that have received FDA PMA include:

• The SpinalPak® bone growth stimulator system, a capacitive coupling system Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a capacitive coupling system, received PMA in 1999 for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.

• The EBI Bone Healing System® from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a pulsed electromagnetic field system which was first approved in 1979 with FDA PMA and indicated for nonunions, failed fusions, and congenital pseudarthroses. The device is secured with a belt around the waist.

• SpinaLogic Bone Growth Stimulator® (Regentek, a division of dj Orthopedics, LLC (formerly OrthoLogic, Tempe, AZ) received PMA in 1994 as a combined magnetic field portable device. This device is secured with a belt around the waist.

• Spinal-Stim Lite ® (Orthofix, Inc., Richardson, TX) received PMA in 1996 as a spinal adjunct to the Physio-Stim®. This device was approved to increase the probability of fusion success and as a non-operative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.

• The Cervical-Stim® from Orthofix is a pulsed electromagnetic field system that was approved in 2004 as an adjunct to cervical fusion surgery in patients at high risk for non-fusion. An illustration of how this particular device is worn is available at http://www.orthofix.com/products/spine_cervstim.asp.

No semi-invasive electrical bone growth stimulator devices were identified with FDA approval or clearance.

Related Policies

1.01.05 Ultrasound Accelerated Fracture Healing Device
7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton
7.01.100 Bone Morphogenetic Protein
Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to lumbar spinal fusion surgery in patients at high risk for fusion failure, defined as any one of the following criteria:

- one or more previous failed spinal fusion(s);
- grade III or worse spondylolisthesis;
- fusion to be performed at more than one level;
- current tobacco use;
- diabetes;
- renal disease;
- alcoholism;
- steroid use.

Noninvasive electrical bone stimulation may be considered medically necessary as a treatment of patients with failed lumbar spinal fusion. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months.

Semi-invasive electrical stimulation is considered investigational as an adjunct to lumbar fusion surgery and for failed lumbar fusion.

Invasive, semi-invasive, and noninvasive electrical stimulation are considered not medically necessary as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

Rationale

The policy regarding electrical bone stimulation as an adjunct to spinal fusion surgery or as a treatment of failed spinal fusion surgery (i.e., salvage therapy) is based in part on 2 TEC Assessments (1, 2). The initial TEC Assessments (1, 2) offered the following conclusions:

- Data from a randomized, controlled clinical trial of patients meeting the criteria for high risk for development of failed fusion suggest that invasive or noninvasive electrical bone stimulation as an adjunct to spinal fusion surgery is associated with a significantly higher spinal fusion success rate in the treated group compared with the control group. (3, 4)

- Data from uncontrolled studies of patients with failed spinal fusion suggest that noninvasive electrical stimulation results in a significantly higher fusion rate. The lack of controlled clinical trials is balanced by the fact that these patients served as their own control.
Analysis of the data from clinical trials is limited by the following factors:

- Trials frequently include heterogeneous groups undergoing a variety of surgeries, which may have different risk levels for fusion failure.
- Trials frequently include patients undergoing spinal fusion both with and without additional surgical adjuncts, i.e., pedicle screws or back “cages,” both designed to increase the fusion rate. Therefore, those patients undergoing instrumented spinal fusion procedures may have a decreased risk of fusion failure compared to those without instrumented procedures.
- While most trials have focused on “high-risk” patients, others have also included average-risk patients. The outcomes associated with average-risk patients are often not reported separately.
- Trials have used different outcomes for spinal fusion, based on varying clinical and radiologic outcomes.
- The presence or absence of spinal fusion may be considered an intermediate outcome, with the final health outcome typically focusing on relief of pain. Final health outcomes are typically not reported.

With the above limitations in mind, results of controlled trials are summarized below.

**Implantable Electrical Stimulation**

*Instrumented Spinal Fusion*

Kucharzyk reported on a controlled prospective nonrandomized trial of implantable electrical stimulation in patients undergoing instrumented posterior spinal fusion with pedicle screws. (5) A series of 65 patients who did not use electrical stimulation were compared with a later series of similar patients who did receive implantable electrical stimulation. Fusion success was 95.6% in the stimulated group compared to 87% in the nonstimulated group, a statistically significant difference. It appears that all patients had at least 1 or more high-risk factors for failed fusion, i.e., smoking history, prior surgery, multiple fusion levels, diabetes, etc. While this trial supports the use of electrical stimulation as an adjunct to instrumented posterior lumber fusion, it did not specifically identify the outcomes in patients considered to be at low risk for failed fusion. Rogozinski and Rogoinski reported on the outcomes of 2 consecutive series of patients undergoing posterolateral fusions with autologous bone graft and pedicle screw fixation. (6) The first series of 41 patients were treated without electrical stimulation, while the second group of 53 patients received invasive electrical stimulation. Those receiving electrical stimulation reported a 96% fusion rate, compared to an 85% fusion rate in the unstimulated group. The fusion rate for patients receiving stimulation versus no stimulation was also significantly higher among those considered at high risk due to previous back surgery or multiple fusion levels. No significant increase in the fusion rate was noted among non-smokers (i.e., without a risk factor), but the comparative fusion rates for all patients without high-risk factors is not presented.

*Non-instrumented Spinal Fusion*

In 2009, Andersen et al. published 2-year radiographic and functional outcomes from a European multicenter randomized controlled trial (RCT) of direct current (DC) stimulation with the SpF-XL IIb for
posterolateral lumbar spinal fusion (PLF) in 98 patients older than 60 years of age. (7, 8) This age group has decreased fusion potential. In addition, instrumentation was not used due to risks related to longer operating times and screw loosening due to osteoporosis. All patients received fresh frozen allograft bone mixed with autograft obtained from the decompression procedure and were braced for 3 months after surgery. Dummy electrodes were placed in the control group to allow blinded radiographic evaluation, but patients and surgeons were not blinded to treatment group. Stimulator-specific complications included 3 cases of hematoma after removal of the battery and 2 patients who had pain at the site of the subcutaneous pocket. Three patients dropped out before the 1-year radiologic evaluation, 1 patient died, and an additional 25 patients did not complete the functional outcome questionnaires, resulting in 70% follow-up at 2-years. The percentage of dropouts was similar for the 2 treatments; patients who missed their 2-year evaluation had poorer outcomes on the Dallas Pain Questionnaire at the 1-year follow-up. Blinded evaluation of fusion by computed tomography (CT) scan indicated the same low percentage of cases with fusion in the 2 groups (33%). Fusion rates by plain radiographs were 57% in the control group (24/42) and 64% in the standard DC-stimulation group (27/42). Patients who achieved a solid fusion had better functional outcome and pain scores at their latest follow-up. At 2-year follow-up, electrical stimulation was associated with improved functional outcomes on 3 of 4 Dallas Pain Questionnaire subscales (daily activity, work/leisure, and social interest) but not for the Low Back Pain Rating Scale or the validated short form (SF)-36. These functional results have a high potential for bias due to the dropout of patients who had poorer outcomes and unequal patient expectation in this unblinded study.

In a 2010 publication, Anderson et al. evaluated bone quality of the fusion mass in 80 of the patients described above (82% of 98) who underwent dual energy x-ray absorptiometry (DEXA) scanning to evaluate bone mineral density (BMD) at the 1-year follow-up. (9) This report describes 40 (n=46) and 100 (n=8) microAmp DC stimulation compared with a non-stimulated control condition (n=36). Fusion rates determined by CT scanning at the 2-year follow-up were 34% in the control group and 33% and 43% in the 40 and 100 microAmp groups, respectively (not significantly different). Patients classified as fused after 2 years had significantly higher fusion mass BMD at 1 year (0.592 vs. 0.466 g/cm2), but DC electrical stimulation did not improve fusion mass bone quality (0.483 g/cm2 for 40 microAmp; 0.458 g/cm2 for 100 microAmp; 0.512 g/cm2 for controls). Using linear regression, fusion mass bone quality was significantly influenced by gender, age of the patient, bone density of the remaining part of the lumbar spine, amount of bone graft applied, and smoking.

No studies of semi-invasive (semi-implantable) stimulators were identified during the most recent literature search. In addition, none of these devices has U.S. Food and Drug Administration (FDA) clearance or approval. Thus, use of these devices is considered investigational.

**Noninvasive Electrical Stimulation**

**Lumbar Spine**

Goodwin and colleagues reported on the results of a study that randomly assigned 179 patients undergoing lumbar spinal fusions to receive or not receive capacitively coupled electrical stimulation. (10) A variety of surgical procedures both with and without instrumentation were used, and subjects
were not limited to high-risk patients. The overall successful fusion rate was 84.7% for those in the active group compared to 64.9% in the placebo group, a statistically significant difference. While the actively treated group reported increased fusion success for all stratification groups (i.e., according to fusion procedure, single or multilevel fusion, smoking or nonsmoking group), in many instances, the differences did not reach statistical significance because of small numbers. For example, the subgroups in which there was not a significant difference in fusion between the active and placebo groups included patients who had undergone previous surgery, smokers, and those with multilevel fusion. In addition, there were numerous dropouts in the study and a 10% noncompliance rate with wearing the external device for up to 9 months.

Mooney reported on the results of a double-blind study that randomly assigned 195 patients undergoing initial attempts at interbody lumber fusions with or without fixation to receive or not receive pulsed electromagnetic field electrical stimulation. (4) Patients were not limited to high-risk groups. In the active treatment group, the success rate was 92%, compared to 65% in the placebo group. On subgroup analysis, the treated group consistently reported an increased success rate. Subgroups included graft type, presence or absence of internal fixation, or presence or absence of smoking.

Linovitz and colleagues conducted a double-blind clinical trial that randomly assigned 201 patients undergoing 1- or 2-level posterolateral fusion without instrumentation to undergo active or placebo electrical stimulation using a combined magnetic field device. (11) Unlike capacitively coupled or pulsed electromagnetic field devices, the combined magnetic field device requires a single 30-minute treatment per day with the device centered over the fusion site. Patients were treated for 9 months. Among all patients, 64% of those in the active group showed fusion at 9 months compared to 43% of those with placebo devices, a statistically significant difference. On subgroup analysis, there was a significant difference among women, but not men.

Mooney and Linovitz et al. excluded from their studies patients with severe osteoporosis and Goodwin et al. excluded patients with osteoporosis of unspecified severity. (4, 10, 11) None of the studies mentioned steroid use; however, authors of two papers summarizing the available evidence on inhibition of bone healing (12) and the effects of drugs on bone healing (13) agree that long-term (longer than 1 week) steroid use has an inhibitory effect on bone healing. Thus, steroid use is added as an additional condition that results in high risk of non-fusion.

Cervical Spine

In 2008, Foley et al published results of the industry-sponsored investigational device exemption (IDE) study of pulsed electromagnetic field (PEMF) stimulation as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants. (14, 15) This study described results using the Cervical-Stim device from Orthofix that received premarket approval (PMA) from the FDA in 2004. A total of 323 patients were randomized, 163 to PEMF and 160 to no stimulation. All patients were active smokers (more than 1 pack of cigarettes per day, 164 patients) or were undergoing multilevel ACDF (192 patients). Patients with pertinent history of trauma, previous posterior cervical approach or revision surgery, and certain systemic conditions or steroid use, and regional
conditions such as Paget’s disease or spondylitis were excluded. Beginning 1 week after surgery, patients in the treatment group wore the Cervical-Stim device for 4 hours per day for 3 months.

Efficacy was measured by radiographic analysis at 1, 2, 3, 6, and 12 months. At 6 months, 122 patients in the treatment group and 118 in the control group were evaluable; 15 in the PEMF group and 13 in the control group voluntarily withdrew, 7 in the PEMF group and 1 control violated study protocol, and 19 in the PEMF group and 28 controls had radiographs that were not evaluable or radiographs that were not done within 2 weeks of the 6-month postoperative window. Fusion rates for the 240 (74%) evaluable patients at 6 months were 83.6% for the PEMF group and 68.6% for the control group (p=0.0065). By intent-to-treat (ITT) analysis, assuming that nonevaluable patients did not have fusion, PEMF and control groups fusion rates were 65.6% and 56.3%, respectively; these rates were not significantly different (p=0.0835). (FDA analysis, however, indicated that the results at 6 months were still statistically different in sensitivity analysis performed with the last observation carried forward or with all missing data imputed as non-fusion.) Of 245 patients available for follow-up at 12 months, fusion was achieved in 116 of 125 (92.8%) PEMF patients and 104 of 120 (86.7%) control patients; these rates were not significantly different (p=0.1129). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not included in the paper.

Clinical outcomes were not reported in the 2008 publication, but were reported to the FDA. With clinical success defined as no worsening in neurological function, an improvement in VAS pain assessment, and no worsening in Neck Disability Index, the study found no significant difference between groups in the percent of subjects considered a clinical success at 6 months (p=0.85) or 12 months (p=0.11). The marginal difference in fusion rates by ITT analysis at 6 months, non-significant difference in fusion rates at 12 months, and lack of difference in functional outcomes at either 6 or 12 months do not support the efficacy of this device.

The single other report of electrical stimulation as an adjunct to cervical fusion identified in a case report from 2004 that describes treatment with pulsed electromagnetic field stimulation for delayed union of anterior cervical fusion . (16)

Due to methodologic limitations in the only controlled trial published to date, the efficacy of electrical stimulation has not yet been established. Therefore, this technology is considered not medically necessary for the cervical spine.

**Practice Guidelines and Position Statements**

The 2005 American Association of Neurological Surgeons and the Congress of Neurological Surgeons guideline states that there is Class II and III evidence (non-randomized comparative trials and case series) “to support the use of direct current stimulation or capacitative coupled stimulation for enhancing fusion rates in high-risk patients undergoing lumbar PLF [posterolateral lumbar fusion]. A beneficial effect on fusion rates in patients not at "high risk" has not been convincingly demonstrated, nor has an effect been shown for these modalities in patients treated with interbody fusion. There is limited evidence both for and against the use of pulsed electromagnetic field stimulation (PEMFS) for
enhancing fusion rates following PLF. Class II and III medical evidence supports the use of PEMFS for promoting arthrodesis following interbody fusion. Although some studies have purported to demonstrate functional improvement in some patient subgroups, other studies have not detected differences. All of the reviewed studies are significantly flawed by the use of a 4-point patient satisfaction scale as the primary outcome measure. This outcome measure is not validated. Because of the use of this flawed outcome measure and because of the conflicting results reported in the better-designed studies that assess functional outcome, there is no consistent medical evidence to support or refute use of these devices for improving patient outcomes.” (17)

Summary

Evidence from RCTs suggests that electrical stimulation leads to higher fusion rates for patients undergoing lumbar surgery. Interpretation of clinical trial data is limited by the heterogeneous populations studied and the variety of surgical procedures within the populations. Most patients in these studies were at high-risk for non-fusion, suggesting that the patients most likely to benefit are those at highest risk. The policy therefore indicates that electrical stimulation of the lumbar spine, whether invasive or noninvasive, should be limited to those patients with high-risk features. For patients at average risk for non-fusion, the scientific data are inadequate to determine the magnitude of benefit associated with electrical stimulation. Accordingly, either invasive, or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to lumbar spinal fusion surgery in patients at high risk for fusion failure.

At present, the evidence does not demonstrate that electrical stimulation as an adjunct to fusion of the cervical vertebrae improves health outcomes. In addition, clinical input regarding the efficacy of the technology was mixed. Therefore, electrical stimulation as an adjunct to fusion of cervical spine is considered not medically necessary.

In addition, since there are no FDA-approved semi-invasive devices, these are considered investigational.

Medicare National Coverage

Medicare covers noninvasive electrical stimulators for the following (18):

- Failed fusion, where a minimum of 9 months has elapsed since the last surgery AND
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Medicare covers invasive electrical stimulators

- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).
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Policy History

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<tr>
<td>June 2012</td>
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<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; added policy statement that semi-invasive stimulators are investigational.</td>
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Keywords

Bone Growth Stimulation, Spine
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Spinal Fusion, Electrical Stimulation
Cervical-Stim
EBI Bone Healing System
Osteo Stim
SpinalPak
SpinaLogic Bone Growth Stimulator
Spinal-Stim Lite

This policy was approved by the FEP Pharmacy and Medical Policy Committee on December 6, 2013 and is effective January 15, 2014.

Signature on File
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