

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion

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Recommendations

Treatment Standards. There is insufficient evidence to recommend a treatment standard.

Treatment Guidelines. Either DCS or CCS is recommended as an adjunct to spinal fusion to increase fusion rates in patients who are at high risk for arthrodesis failure following lumbar PLF. Pulsed electromagnetic field stimulation is recommended as an adjunct to increase fusion rates in similar patients treated with lumbar interbody fusion procedures.

Rationale

One of the goals of a lumbar fusion is to produce a solid arthrodesis across the unstable motion segment(s). Laboratory studies and human studies performed over the last 30 years have demonstrated that bone healing is associated with electrical potentials developing at the fusion site.^{2–5,9} Attempts have been made to harness this electrical–biological link through the use of applied electrical fields to pro-

mote bone healing. Several bone growth stimulators are now available as adjuncts to promote osseous fusion. These devices are expensive, require different ES techniques, and are not universally accepted as efficacious. The purpose of this paper is to review the evidence for the efficacy of these devices as adjuncts for bone fusion following lumbar surgery.

Literature Search

A computerized search of the database of the National Library of Medicine from 1966 through May 2003 was performed using the key terms “bone stimulator and spine and human and English language,” or “electrical stimulation and spinal fusion and human,” or “electrical stimulation and pseudarthrosis and spinal fusion.” A total of 127 papers were identified. After discarding duplicates and reviewing the abstracts of each paper, eight clinical studies were identified that compared fusion rates between groups of patients treated with or without stimulation. A number of review papers, technical notes, and animal studies served as supporting data. The bibliography of each paper was reviewed and other relevant studies were identified. All peer-reviewed clinical studies regarding the use of ES to promote healing after lumbar spinal fusion are summarized in Table 1. Several reviews, metaanalyses, and chapters are referenced as background material.

Abbreviations used in this paper: CCS = capacitive coupled stimulation; CT = computerized tomography; DCS = direct current stimulation; ES = electrical stimulation; PEMFS = pulsed electromagnetic field stimulation; PLF = posterolateral fusion; RCT = randomized controlled trial.

Scientific Foundation

Electrical stimulation devices for the promotion of lumbar fusion consist of three types. Direct current stimulation involves electrodes implanted within or very close to the location of the desired fusion.^{4,7,11,13,16–18} Modern devices consist of a sealed electrical source that is implanted at the time of surgery. These devices may or may not be removed following the achievement of a solid arthrodesis. Capacitative coupling stimulation involves two electrodes placed on the skin over the fusion site and connected to an external battery-powered device. The batteries are changed daily, and the patient is encouraged to use the stimulator as much as possible, up to 24 hours per day.⁶ Pulsed electromagnetic field stimulation requires coils (usually embedded in a brace) that produce a time-varying magnetic field around the area of the desired fusion. Patients are generally instructed to wear the device for 3 to 8 hours per day.^{9,12} For an overview of the basic principles governing the application of electrical fields and a discussion of the theoretical benefits of each type of stimulation technique, the reader is referred to several recently published reviews.^{1,8,16}

Direct current devices were the first devices used for bone growth stimulation following lumbar fusion.⁴ Several randomized prospective clinical studies have been performed to evaluate the efficacy of this technique for the promotion of arthrodesis. Jenis and colleagues⁷ reported the results of an RCT comparing the use of DCS, PEMFS, and no stimulation. They randomized 61 patients to undergo implantation of a DCS (17), a PEMFS (22), or no stimulation device (22) following an instrumentation-augmented PLF in which autogenous iliac crest bone graft was placed. Although blinding was not possible due to the obvious presence of the device in the DCS group, independent plain and flexion–extension radiography was performed at 3 months and 1 year. Clinical outcomes were measured at 1 year and were rated as excellent, good, fair, or poor based on return to work, analgesic requirements, and subjective pain status. The authors failed to identify a significant effect of stimulation on either fusion rates or clinical outcomes in patients undergoing instrumentation and autograft-augmented PLF. This paper is considered to provide Class III medical evidence in terms of radiographic outcomes despite its design, primarily because of the small sample size. In addition, concerns exist regarding the criteria used to assess radiographic fusion. A much larger percentage of DCS-treated patients were found to have “questionable” fusions than the other groups, perhaps indicating that the presence of the device on the radiographic images made it difficult to judge fusion status. The clinical outcomes were assessed at 1 year and were based on a nonvalidated subjective satisfaction scale. For these reasons, the medical evidence provided by this study documenting the lack of clinical effect is considered Class III.

Kane¹⁰ performed a randomized prospective study assessing DCS in a series of 59 “difficult patients” who were treated with noninstrumented lumbar PLF. All patients had one or more of the following risk factors: 1) previous failed fusions; 2) Grade II or greater spondylolisthesis; 3) extensive bone grafting necessary for multilevel fusion; or 4) other high risk factor for failure of fusion, including obesity. Fusion was assessed using plain and “stress bend-

ing” radiography.¹⁰ Originally, 99 patients were entered into the study but only 59 were followed because patients treated by surgeons who managed fewer than four randomized cases were excluded. Kane found that patients treated with DCS had a higher fusion rate than those not treated with ES. Overall, 25 (80%) of 31 of ES-treated patients were considered to have successful fusion compared with 15 (53%) of 25 control patients. No functional outcome results were reported. This study was considered to provide Class II medical evidence despite its randomized design because of high patient dropout following randomization and because of the selected patient population (affecting the external validity of the study). Kane also reported an observational cohort of patients treated with the same stimulator in whom a 91.5% fusion rate was achieved compared with a historical cohort with an 80.5% fusion rate, providing corroborative Class III medical evidence.

Rogozinski and Rogozinski¹⁷ reported favorable results of DCS in a small randomized sample of patients undergoing instrumented lumbar PLF as well as a larger historical cohort. These investigators found that patients treated with DCS had a higher fusion rate than those not receiving ES (96 vs 85%) following attempted lumbar fusion. The majority of patients described in this report were considered at high risk for nonunion because of previous surgery, smoking, or other factors. Fusion was assessed using plain radiographs and dynamic images by the operating surgeons. These authors did not assess functional outcome. Kucharzyk¹¹ found that implantation of a DCS device improved fusion rates in a large historical cohort study of patients considered to be at high risk for nonunion. The author performed plain radiography as well as tomography, and in many cases CT scanning, to assess fusion. Using a four-point satisfaction survey, he found that patients with implanted stimulators had a higher clinical success rate following instrumented PLF (95% compared with 79%; $p = 0.02$). Both of these studies provide Class II medical evidence supporting the efficacy of DCS as a means to improve fusion rates. The Kucharzyk study also provides Class III medical evidence supporting a beneficial effect on functional outcome. Meril¹³ reported the beneficial effect of implanted DCS devices in a historical comparison of patients receiving stimulators and patients treated prior to the use of ES, undergoing noninstrumented interbody fusion procedures. Fusion status was assessed with multiplanar CT imaging.¹³ Smokers, patients treated without instrumentation, and those with L4–5 fusion derived the greatest benefit from the addition of ES. Meril did not assess functional outcomes. Tejano and colleagues¹⁸ as well as others¹⁵ have also contributed corroborating evidence in observational studies. These studies all provide Class III medical evidence supporting the role of DCS for promotion of bone healing following PLF. Therefore, there is Class II and III medical evidence indicating that implanted DCS devices increase fusion rates, particularly in high-risk patients undergoing lumbar PLF. There is conflicting Class III medical evidence regarding any effect on functional outcome.

The effect of CCS was studied by Goodwin, et al.,⁶ who performed a double-blinded RCT of CCS in a large group of patients ($n = 337$) who underwent various fusion procedures for a variety of indications. They used rigorous radiographic criteria to define fusion. Clinical success was