

## Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: Bone growth stimulators as an adjunct for lumbar fusion

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The relationship between the formation of a solid arthrodesis and electrical and electromagnetic energy is well established; most of the information on the topic, however, pertains to the healing of long bone fractures. The use of both invasive and noninvasive means to supply this energy and supplement spinal fusions has been investigated. Three forms of electrical stimulation are routinely used: direct current stimulation (DCS), pulsed electromagnetic field stimulation (PEMFS), and capacitive coupled electrical stimulation (CCES). Only DCS requires the placement of electrodes within the fusion substrate and is inserted at the time of surgery. Since publication of the original guidelines, few studies have investigated the use of bone growth stimulators. Based on the current review, no conflict with the previous recommendations was generated. The use of DCS is recommended as an option for patients younger than 60 years of age, since a positive effect on fusion has been observed. The same, however, cannot be stated for patients over 60, because DCS did not appear to have an impact on fusion rates in this population. No study was reviewed that investigated the use of CCES or the routine use of PEMFS. A single low-level study demonstrated a positive impact of PEMFS on patients undergoing revision surgery for pseudarthrosis, but this single study is insufficient to recommend for or against the use of PEMFS in this patient population. (<http://thejns.org/doi/abs/10.3171/2014.4.SPINE14326>)

**KEY WORDS** • lumbar spine • lumbar fusion • bone growth stimulator • practice guidelines

### Recommendations

There is no evidence that conflicts with the previous recommendations regarding bone growth stimulation published in the original version of the “Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.”<sup>18</sup>

*Abbreviations used in this paper:* BMP = bone morphogenetic protein; CCES = capacitive coupled electrical stimulation; DCS = direct current stimulation; DEXA = dual energy x-ray absorptiometry; DPQ = Dallas Pain Questionnaire; LBPRS = Low Back Pain Rating Scale; PEMFS = pulsed electromagnetic field stimulation; SF-36 = 36-Item Short Form Health Survey; VAS = visual analog scale.

### Grade C

The routine use of DCS in patients over the age of 60 years is not recommended, as the evidence demonstrates no impact on fusion rates (single Level II study).

For patients younger than 60 years of age, undergoing a lumbar fusion, the use of DCS is an option as studies have demonstrated a positive impact on fusion rate; however, there is insufficient evidence regarding its impact on clinical outcome (single Level III study/multiple Level IV studies).

### Grade I

There is insufficient evidence to recommend for or against the use of PEMFS as a treatment alternative to re-

vision surgery in patients presenting with pseudarthrosis following posterior lumbar fusion (single Level IV study).

### Rationale

Since the publication of the original “Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine,”<sup>16</sup> the evidence supporting the role of lumbar fusion as an effective treatment alternative for a variety of degenerative spinal conditions continues to expand.<sup>6,9,12,22</sup> As the role of lumbar fusion becomes more established, increasing emphasis has been placed on maneuvers to enhance the potential for a solid arthrodesis. The positive impact of spinal instrumentation on fusion rates is well recognized.<sup>5,11,17</sup> There is also a growing body of evidence demonstrating a beneficial effect on fusion rates with osteoinductive agents.<sup>1,7,8</sup> The data supporting the role of bone growth stimulators remain inconclusive and more controversial.<sup>15,18</sup>

The interaction between electrical energy and the formation of an osseous union is a well-recognized concept, with the majority of clinical data focusing on long bone healing.<sup>15</sup> Dwyer published one of the first manuscripts describing the utilization of direct current stimulation (DCS) for spinal fusion.<sup>10</sup> Since this report, 3 forms of electrical stimulation have gained acceptance for use in spinal fusion: DCS, pulsed electromagnetic field stimulation (PEMFS), and capacitive coupled electrical stimulation (CCES). DCS requires the insertion of cathodes, attached to an implanted battery, directly into the fusion substrate. PEMFS is a noninvasive means of delivering electromagnetic energy to the fusion by wearing an external coil driven by an electrical current. CCES relies on the generation of an electrical field through capacitive plates placed on the patient’s skin.<sup>15</sup> The purpose of this update was to review the current literature and examine the evidence supporting the clinical utility of various bone growth stimulators for lumbar fusion surgery, although no studies investigating the efficacy of CCES were identified.

### Search Criteria

A computerized search of the National Library of Medicine MEDLINE database, utilizing the online search engine PubMed, was conducted for the period from 2003 through December 2011 utilizing the following search terms (((“Lumbosacral Region”[MeSH] OR “Lumbar Vertebrae”[MeSH]) AND “Spinal Fusion”[MeSH]) OR “lumbar fusion”[All Fields] OR (“lumbar”[title] AND “fusion”[title])) AND ((bone growth stimulator[title] OR bone growth stimulators[title]) OR (“Electric Stimulation”[MeSH] OR “Electric Stimulation Therapy”[MeSH] OR (“bone and bones”[MeSH] OR (“bone”[All Fields] AND “bones”[All Fields]) OR “bone and bones”[All Fields] OR “bone”[All Fields]) AND stimulator[All Fields]) OR (“bone and bones”[MeSH] OR (“bone”[All Fields] AND “bones”[All Fields]) OR “bone and bones”[All Fields] OR “bone”[All Fields]) AND stimulators[All Fields])). The search was limited to the English language and human subjects and yielded a total of 44 articles. The titles and abstracts of these publications

were reviewed and those specifically investigating the clinical efficacy of bone growth stimulation were selected. A secondary review of the bibliographies of these articles was conducted to identify any additional relevant manuscripts. A total of 5 manuscripts were selected and serve as the scientific foundation for the updated review.

### Scientific Foundation

Andersen et al. performed a randomized, controlled, multicenter trial to determine the impact of DCS on functional outcome of noninstrumented lumbar fusion for patients over 60 years of age.<sup>3</sup> One hundred seven patients presenting with a variety of spinal degenerative disorders and undergoing single or multilevel posterolateral lumbar fusion (PLF) with local autograft and allograft were randomized into cohorts with a 40-mA (n = 44) or 100-mA (n = 11) DCS implanted stimulator or without (n = 43) DCS. For a variety of reasons, 9 randomized patients were excluded either prior to surgery or due to intraoperative complications. Patients completed a series of validated, objective outcome instruments (the 36-Item Short Form Health Survey [SF-36], the Dallas Pain Questionnaire [DPQ], and the Low Back Pain Rating Scale [LBPRS]), and statistical analysis was performed to compare treatment effect. Patients were followed up for 2 years; however, 27% of patients did not complete the functional outcome questionnaires at this end point. At the 2-year point, the patients in the combined treatment group demonstrated significantly greater improvement in 3 of the 4 domains of the DPQ, although no significant difference in LBPRS or SF-36 scores was observed. Based on these results the authors concluded that surgery led to an improvement in functional outcome and that DCS may have a beneficial effect on lumbar fusion in older patients. This is a relatively well-designed randomized trial, but the study does suffer from several limitations. The validity of separating the results of the individual domains within the DPQ is unclear because the overall percentages are graphed to create a profile summary of the patient.<sup>14</sup> Variability existed with respect to the presenting diagnosis and surgical intervention. It is not clear who performed the functional assessment and whether that individual was blinded to the treatment received. At the 2-year follow-up, only 73% of the participants completed the functional assessment questionnaires. Finally, the statistical analysis was limited by the authors’ failure to determine the confidence intervals for the observed results. Due to these limitations the study was downgraded to Level II evidence supporting the role of DCS for this patient population undergoing noninstrumented lumbar fusion (Table 1).

Anderson and colleagues published 2 additional studies based on the same patient population with the intention of determining the effect of DCS on fusion rate, correlating the radiographic outcome to clinical outcome, and clarifying whether DCS had an impact on the quality of fusion.<sup>2,4</sup> Of the original 107 patients randomized, 95 were available for fusion assessment at 1 year and 84 were available at 2 years. Thin-slice CT images and plain radiographs were used to assess fusion status. In both the control and treatment cohorts the observed fusion rate was

TABLE 1: Bone growth stimulators as an adjunct for lumbar fusion: summary of evidence\*

Authors & Year	Level of Evidence	Description	Comments
Andersen et al., 2009 <sup>3</sup>	II	This is a randomized, controlled, multicenter trial to investigate the impact of DCS on functional outcome in pts over the age of 60 yrs undergoing noninstrumented lumbar fusion. 107 pts presenting w/ various spinal degenerative disorders & undergoing PLF w/ local autograft & allograft were randomized into cohorts w/o (n = 43) or w/ the insertion of a 40-mA (n = 44) or 10-mA (n = 11) DC electrical stimulator. Validated, objective outcome instruments (SF-36, DPQ, LBPRS) were utilized to evaluate the functional outcome, & statistical analysis was performed to compare treatment effect. Patients were followed for 2 yrs, but 27% did not complete the functional outcome questionnaires at this time point. At 2 yrs' follow-up the pts in the combined treatment group demonstrated significantly greater improvement in 3 of the 4 domains of the DPQ; however, no significant difference in LBPRS or SF-36 was observed. The authors concluded that surgery led to an improvement in functional outcome & that DCS may have a positive effect on fusions in this pt population.	This is a relatively well-designed randomized trial. There was some variability regarding surgical intervention. Participant flow & care providers are incompletely described. It is not clear who tabulated the functional outcome measures & whether the assessor was blinded to the intervention. Only 73% of pts were available for 2-yr follow-up. The authors failed to provide confidence intervals w/ the statistical analysis.
Andersen et al., 2009 <sup>2</sup>	II	This companion study to the authors' original investigation was intended to determine the effect of DCS on fusion status & correlate radiographic outcome w/ clinical outcome. From the original 107 pts randomized, 95 were available for fusion assessment at 1 yr, & 84 were available at 2 yrs. Fusion status was evaluated through thin-slice CT & plain radiographs. Fusion rates were low in the control & treatment cohorts (33% & 32%, respectively). The insertion of a DC stimulator had no impact on fusion rate. Functional outcome correlated w/ presence of a solid arthrodesis. There was a poor correlation of fusion assessment btwn CT & plain radiographs. The authors concluded that DCS had no significant impact on fusion rate; however, a solid fusion defined by CT resulted in better functional outcome & less pain.	The study's limitations are highlighted above. This arm of the study benefited from the blinded radiographic evaluation of the imaging studies. The authors claim that 89% of pts were available at 2-yr follow-up, but this percentage was calculated based on the 95 pts who underwent imaging at 1 yr rather than on the original 107 pts randomized into study cohorts. No information is available regarding the participants not available for 1-yr follow-up.
Rogozinski et al., 2009	III	This single-center, prospective, nonrandomized trial compared radiographic outcome of a heterogeneous group of 31 pts undergoing instrumented PLF supplemented w/ either BMP or an implanted spinal fusion stimulator. Fusion status was assessed using plain radiographs &/or CT, & pain status was determined through a 10-point VAS. The BMP cohort demonstrated a 100% fusion rate while the stimulator group demonstrated a 93.4% fusion rate. BMP cohort was considered to achieve more robust fusion & at a faster rate than the stimulator cohort. Pain improved in both cohorts. The authors concluded that use of BMP led to more rapid graft maturation & more robust fusion compared to fusions supplemented w/ an internal stimulator.	This is a poorly designed & conducted cohort study consisting of an exceedingly small heterogeneous population of pts. Inclusion & exclusion criteria were not defined. A variety of surgical procedures were implemented. The no. of pts available for follow-up is not provided; however, only 9 pts were available for CT analysis at the 2-yr study end point. This would indicate a loss to follow-up of 79%. Radiographic evaluation was not blinded but performed by the operating surgeons, & the criteria for fusion were not defined. Statistical analysis was not adequately described & no confidence intervals were provided.
Simmons et al., 2004	IV	This case series involved pts who presented w/ pseudarthrosis after attempted lumbar fusion & were treated w/ PEMFS. 25 investigators from multiple institutions enrolled 100 pts who received PEMFS for at least 90 days. Radiographic evaluation of fusion was performed by the investigators as well as a blinded radiologist and, if disagreement occurred, a blinded orthopedist. Fusion success rate was 67%, w/ 63% of these pts demonstrating an excellent or good outcome. Only 30% of pts w/ persistent pseudarthrosis demonstrated an excellent or good outcome. The authors concluded that PEMFS was an effective alternative to revision surgery for pts presenting w/ pseudarthrosis.	This case series provides information that demonstrates feasibility of PEMFS for the treatment of pseudarthrosis; however, the true treatment effect cannot be determined given the lack of an appropriate control group. Any comparison to alternative therapies is not substantiated by the current data. The study is further compromised by a lack of criteria defining the diagnosis of pseudarthrosis & by heterogeneity of the pt population.

(continued)

TABLE 1: Bone growth stimulators as an adjunct for lumbar fusion: summary of evidence\* (continued)

Authors & Year	Level of Evidence	Description	Comments
Kucharzyk, 1999	IV	This retrospective review was intended to determine the efficacy of DCS in high-risk pts undergoing fusion. 65 pts treated w/ DCS were compared w/ an equal no. of pts not treated w/ DCS. Variation existed w/ respect to presenting diagnosis & no. of levels fused. Fusion status was determined through radiographs & CT (evaluated by an independent radiologist). Clinical status was determined w/ a modified Smiley-Webster scale. Follow-up was conducted at regular intervals, w/ an average follow-up of 3.8 yrs. The overall fusion rate was 95.6% in the DCS group & 87% in the control group. The rate of clinical success was greater in pts receiving DCS (91% vs 79%). These differences were statistically significant. In a subgroup analysis of Workers' Compensation pts, fusion success was observed in 93% receiving DCS & in 81% of controls. Clinical success in this group was 57% in pts receiving DCS & 46% in the no-DCS group. The authors concluded that DCS significantly improved fusion & clinical success.	Limited baseline demographic data are provided. Although baseline demographics were similar in the DCS and no-DCS groups, the authors failed to adequately analyze these data to determine if significant heterogeneity existed btwn groups. The average follow-up was excellent, w/ no pts lost to follow-up in either group. The study benefits from an independent review of imaging, w/ fusion criteria being well defined. A nonvalidated clinical outcomes instrument was used. The study was downgraded to Level IV evidence due to the limitations described.
Rogozinski & Rogozinski, 1996	IV	The objective of this retrospective review was to determine the efficacy of DCS in pts undergoing instrumented fusion. 94 pts (53 receiving DCS) w/ varying diagnoses & surgical procedures were included. 26 pts were randomly assigned to treatment & control groups. Treating surgeons evaluated static & dynamic radiographs to determine fusion status. Follow-up was performed at 3, 6, & 12 mos after surgery. Fusion was demonstrated in 96% of pts receiving DCS while only 85% of control pts achieved solid fusion. The authors concluded that DCS can improve fusion rates in pts undergoing fusion, including high-risk pts (smokers, pts undergoing multilevel fusions).	Potential for selection bias exists due to the heterogeneous population of pts, w/ respect to both diagnosis & no. of levels fused. The follow-up period was limited to 12 mos. The authors failed to perform a blinded assessment of fusion, w/ questionable means of fusion assessment in presence of instrumentation. No clinical data were provided. Description of the statistical analysis was not provided. Due to these limitations, the study was downgraded to Level IV evidence in support of DCS.

\* BMP = bone morphogenetic protein; DC = direct current; DCS = DC stimulation; DPQ = Dallas Pain Questionnaire; LBPRS = Low Back Pain Rating Scale; PEMFS = pulsed electromagnetic field stimulation; pt = patient; SF-36 = 36-Item Short Form Health Survey.

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low—33% and 32%, respectively. The authors concluded that the utilization of DCS had no impact on fusion rate. There was a poor correlation between the observations made from CT images and plain radiographs, although a solid fusion, as defined by CT, resulted in better functional outcome and less pain<sup>2</sup> (Table 1). The final study from this series demonstrated, through the use of dual energy x-ray absorptiometry (DEXA), that the application of DCS had no impact on the bone mineral density of the fusion mass.<sup>4</sup> These investigations suffer from the same limitations as the first study in this series. The blinded radiographic assessment of the CT imaging strengthens the observations and conclusions regarding the impact of DCS on fusion rate. Although the authors claim that there was an 89% follow-up rate at 2 years, this was calculated from the 95 patients undergoing imaging at 1 year and not from the original 107 patients randomized at the onset of the study. Like the original study, this investigation was downgraded and provides Level II evidence against the utility of DCS to enhance the fusion rate for noninstrumented lumbar fusion. In a follow-up study, Andersen et al. investigated the impact of DCS on the quality of fusion formation by examining 80 of the original 107 patients with DEXA at 1 year after surgery. No significant difference in bone mineral density was observed between the 3 treatment groups.

Rogozinski et al. conducted a prospective, nonrandomized trial comparing radiographic outcome in 31 patients with the diagnosis of degenerative disc disease, who underwent 1- to 3-level instrumented PLF supplemented with either bone morphogenetic protein (BMP) or an implanted DC stimulator.<sup>20</sup> Fusion status was assessed using plain radiographs and/or CT, and pain status was determined through a 10-point visual analog scale (VAS). The BMP cohort demonstrated a 100% fusion rate, while the stimulator group demonstrated a 93.4% fusion rate. The BMP cohort was considered to achieve more robust fusion at a faster rate than the stimulator cohort. Pain improved in both cohorts. The authors concluded that the use of BMP led to more rapid graft maturation and a more robust fusion compared with fusions supplemented with an internal stimulator. The actual treatment effect of DCS compared with traditional fusion techniques cannot be determined from this study because all patients received some form of fusion supplement, but the fusion rate observed in the DCS cohort is comparable to previously reported rates of fusion for similar patients without DCS. This investigation also suffers from major limitations with respect to study design, including a small, heterogeneous patient cohort, lack of inclusion and exclusion criteria, and heterogeneous surgical treatments. Only 9 patients were available for CT imaging at 2 years after surgery (79% lost to follow-up), the assessment of the images was performed by the treating surgeon, and the criteria for fusion were not defined. This study was therefore downgraded to Level III evidence, although one may consider it simply a case series with respect to the DCS data (Table 1).

Two additional studies have also demonstrated a positive impact of DCS on fusion formation. Kucharzyk performed a retrospective review of 130 cases involving patients undergoing lumbar fusion with (n = 65) and with-

out (n = 65) placement of DCS.<sup>13</sup> Fusion status was determined through both CT images and plain radiographs. The average follow-up was 3.8 years. The fusion rate in the DCS cohort was 95.6%, while the rate in the control group was 87%. Clinical success, utilizing a nonvalidated outcome measure, was superior in the DCS group. Rogozinski and Rogozinski also performed a retrospective review of 94 cases, with 53 of the patients receiving a DCS, and observed a fusion rate of 96% in the DCS cohort and 85% in the control arm.<sup>19</sup> Both of these studies suffer from a heterogeneous population of patients, limited baseline demographic data, and either failure to report clinical outcome or use of a nonvalidated instrument. Due to these limitations these studies are downgraded to Level IV evidence in support of the use of DCS with lumbar fusions.

Simmons et al. published a case series involving 100 patients with a mean age of 43.3 years who presented with pseudarthrosis after an attempt at single- or multi-level lumbar fusions and were treated with pulsed electromagnetic field stimulation (PEMFS).<sup>21</sup> Pseudarthrosis was confirmed by the presence of motion on dynamic imaging and the lack of visible bone healing on CT, MRI, or radiographic images. Twenty-five investigators from multiple institutions enrolled the 100 patients, who received PEMFS for at least 90 days. The investigators as well as a blinded radiologist performed radiographic evaluation of fusion. If there was disagreement among reviewers, an independent evaluation was performed by a blinded orthopedist. A solid fusion was defined as 50% or more assimilation of the graft based on radiographic imaging; the specific imaging technique was not defined. Clinical outcome was rated as excellent, good, fair, or poor, based on patients' reported pain intensity, medication usage, and return to work. The fusion success rate was 67%, and 63% of the patients with successful fusion demonstrated an excellent or good outcome. Only 30% of patients with persistent pseudarthrosis had an excellent or good outcome. The authors concluded that PEMFS was an effective alternative to revision surgery for patients presenting with pseudarthrosis. Although this study provides evidence that the utilization of PEMFS is a feasible intervention for the management of pseudarthrosis, the true treatment effect cannot be determined due to the study design and lack of an adequate control group. The authors also fail to define the criteria used to diagnose pseudarthrosis and included a heterogeneous population of patients. The study therefore provides at best Level IV evidence in support of PEMFS for treatment of pseudarthrosis (Table 1).

### Summary

Based on the recommendations from the original guidelines, both DCS and CCES may be considered in patients at high risk for pseudarthrosis who are undergoing PLF, while PEMFS may be considered in a similar patient population undergoing an interbody fusion. Since the publication of the previous guidelines, there have been few clinical trials that provide further insight into the clinical utility of bone growth stimulation. The current data do not contribute to the previous recommendations.

The few studies that have investigated the use of bone growth stimulators have methodological flaws that compromise the conclusions and prohibit the formulation of strong recommendations. Based on a single Level II study, there is a suggestion that the use of DCS in patients over 60 years of age may provide a clinical benefit; however, this benefit was only observed in a subset of measures from a single outcome instrument and therefore is considered a weak correlation. This potential beneficial effect is further weakened by the fact that DCS did not have a positive impact on the fusion rate or quality in the same patient population. The weak correlation to clinical outcome may therefore be an artifact of the flawed study design or simply due to chance. Since the intended purpose of DCS was not supported by the authors' observations, the routine use of DCS in patients over 60 years of age undergoing a noninstrumented fusion was not recommended.

The second recommendation supports the use of PEMFS in patients suffering from a pseudarthrosis, but no comment can be made regarding the routine use of PEMFS. Due to the noninvasive nature of PEMFS, its application appears to be relatively benign with few drawbacks; however, in today's medical climate one cannot ignore the costs associated with an intervention that has not been proven to provide definitive benefit. Unfortunately, the quality of the current literature does not help to address these concerns.

### Key Issues for Future Investigation

The impact of bone growth stimulators on fusion rates is likely to be minimal, and this makes it difficult to conduct a clinical trial to determine the actual treatment effect and/or compare the efficacy of different types of stimulators. Given the noninvasive nature of PEMFS, a well-designed randomized controlled trial is feasible. Such a study would, however, require an exceedingly large number of patients to demonstrate the difference in treatment effect. Nevertheless, such information would prove valuable, not only from a clinical perspective, but also for effective cost analysis, which ultimately may be the more relevant issue in today's medical climate. Utilization of a prospective patient registry may also provide relevant information by identifying specific patient populations that would benefit from any advantage provided by fusion enhancers, such as bone growth stimulators.

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