Pseudarthrosis After Lumbar Spine Fusion: Nonoperative Salvage With Pulsed Electromagnetic Fields

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Abstract

We studied 100 patients in whom symptomatic pseudarthrosis had been established at more than 9 months after lumbar spine fusion. All patients were treated with a pulsed electromagnetic field device worn consistently 2 hours a day for at least 90 days. Solid fusion was achieved in 67% of patients. Effectiveness was not statistically significantly different for patients with risk factors such as smoking, use of allograft, absence of fixation, or multilevel fusions. Treatment was equally effective for posterolateral fusions (66%) as with interbody fusions (69%). For patients with symptomatic pseudarthrosis after lumbar spine fusion, pulsed electromagnetic field stimulation is an effective nonoperative salvage approach to achieving fusion.

The number of lumbar spine fusions performed has risen greatly since 1980. Katz[1] reported that from 1978 to 1990 the rate of lumbar fusion procedures increased from 13 to 26 per 100,000 population. The success rate of fusion healing varies widely and has been found to be related to risk factors such as smoking, the use of allograft, instrumentation, surgical techniques, and the number of levels fused.[2-9] When pseudarthrosis occurs and the patient has continued pain and disability, revision surgery has been the most common treatment method.

Pulsed electromagnetic field (PEMF) stimulation has been found effective for enhancing fusion with primary spine fusion.[7] In a multicenter, randomized, double-blind clinical trial, solid fusion was achieved in 92% of PEMF-treated patients compared with 68% of patients in a placebo group. In a retrospective study of using PEMF as an adjunct to lumbar spine fusion, successful fusion was noted in 97.6% of patients in a PEMF group compared with 52.6% of patients in an unstimulated group.[10] Previously, one of us (JWS) reported on 13 patients who had evidence of radiographic nonunion 18 months after fusion surgery and who were treated with PEMF. Significant increase in bone formation was achieved in 11 patients (85%), and fusion was achieved in 10 patients (77%).[11]

The purpose of this multicenter study was to determine the effectiveness of PEMF stimulation as a nonoperative salvage treatment for patients with pseudarthrosis after lumbar spine fusion.

Materials and Methods

Twenty-five investigators representing multiple sites participated in an open trial of the PEMF device (Spinal-Stim®, Orthofix Inc, McKinney, Texas). Inclusion criteria were radiographic documentation of pseudarthrosis and clinical symptoms indicative of pseudarthrosis at 9 months or more after the last surgical attempt at arthrodesis and no evidence of progression of healing for 3 months as evaluated with radiographs. Each physician determined the presence of pseudarthrosis based on vertebral motion and the lack of visable bone healing as seen on computed tomography, magnetic resonance imaging, or plain flexion/extension radiographs. Exclusion criteria were cardiac pacemakers, spinal trauma, spondylitis, Paget's disease, severe osteoporosis, metastatic cancer, uncontrolled diabetes mellitus, or renal dysfunction.

During the 21-month study period, 100 patients consistently used the device at least 2 hours per day for at least 90 days. Patient compliance of device usage was confirmed with an internal computer chip. The device signal was 160 mG with a pulse burst duration of 26 milliseconds and a positive and negative excursion of approximately 5.85 G. The study group included 64 men and 36 women with a mean age of 43.3 ± 10.1 years.

Study Variables

Information obtained on the baseline evaluation for each patient at the time of device placement included diagnosis, surgical technique, graft source, use of internal fixation,

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TABLE I PATIENT CLINICAL CHARACTERISTICS AND FUSION SUCCESS RATE

Variable	Number of Patients	Number Healed	Percent Healed
Age			
<50 years old	78	51	65.4
>50 years old	22	16	72.7
Sex			
Male	64	41	64.1
Female	36	26	72.2
Surgical Technique			
Interbody	36	25	69.4
Posterolateral	64	42	65.6
Fusion Attempts			
Primary	72	45	62.5
Revision	28	22	78.6
Number of Levels Involved			
One	53	36	67.9
Multiple	47	31	66.0
Graft Type			
Autograft	62	38	61.3
Allograft	18	14	77.8
Mixed	20	15	75.0
Smoking Status			
No smoking	67	45	67.2
Smoking	33	22	66.7
Fixation Status			
No fixation	19	13	68.4
Fixation	81	54	66.7
Workman's Compensation Status			
Yes	68	45	66.2
No	32	22	68.8
TOTAL	100	67	67.0

previous treatment, medical history, pain assessment, current occupation, physical activity, and most recent imaging radiographs. The final evaluation form noted determination of fusion healing or failure, pain, function, and overall clinical assessment at treatment conclusion. Clinical assessment ratings of excellent, good, fair, or poor were based on the pain intensity, medications taken, and return to activity and work as described by Vamvanij and colleagues.[12]

Fusion Success Criteria

Radiographic testing was used to determine the percentage of graft assimilation. A successful solid fusion was defined as 50% or more assimilation; the determination was confirmed with blinded review by an independent radiologist. In cases of disagreement between clinician and radiologist, an independent orthopedic surgeon acted as a third, deciding reviewer. An investigator's assessment of failure, however, was never allowed to be overturned by the independent review.

Data Analysis

Descriptive analyses for patients were obtained from clinical demographic data for the study population and baseline clinical characteristics. Treatment outcomes among patients with different demographic and clinical variables were compared using a one-sided Fisher exact test. Logistic regression modeling (forward stepwise) was further employed to explore the combined effects of these variables. The statistical confidence level was set at 0.05. Data analysis was performed using SAS software (PC–6.12, SAS Institute Inc, Cary, NC).

Results

Baseline demographic and clinical characteristics, as well as fusion success rates, are presented in Table I. Most patients underwent posterolateral fusion surgery with internal fixation. Most patients were nonsmokers, and distribution was fairly equal regarding single or multilevel fusions. Graft type was predominantly autograft, and 2/3 of the cases involved workman's compensation claims.

The PEMF device was placed at a mean of 18.7 months (range: 9 months to 12.5 years) after surgery. The mean time of PEMF treatment was 8.3± 0.4 months (range: 3 to 21 months). The overall fusion success rate was 67%. Logistic regression analysis showed no statistically significant difference in fusion success for each variable. The relationship between radiographic outcome and final clinical assessment is shown in Table II. Forty-two of the 67 patients whose radiographs showed fusion had an excellent or good

Table II. Relationship of Fusion Success and Clinical Assessment

Clinical Assessment	Radiographic Evaluation			
	Fusion Success		Fusion Failure	
	N	Percent	N	Percent
Excellent	12	17.9	4	12.1
Good	30	44.8	6	18.2
Fair	15	22.4	14	42.4
Poor	10	14.9	9	27.3

clinical outcome, whereas only 10 of the 33 patients with a failed radiographic fusion assessment had a good or excellent clinical assessment.

Discussion

The results of this study show that PEMF is an effective nonoperative treatment for pseudarthrosis after lumbar spine fusion. The 67% success rate is comparable to results reported with revision surgery for pseudarthrosis.[13-16] Lauerman and colleagues[14] studied 43 patients who underwent surgical repair of pseudarthrosis and found significant improvement in symptoms of 21 patients (49%) who achieved a solid fusion. Thalgott and colleagues[15] reported on 45 patients with failed lumbar surgery, half of whom had pseudarthrosis. The fusions were reconstructed with AO dynamic compression plates. Overall, 27 patients (60%) went on to a solid fusion after reconstruction, and in an additional 9 patients, solid fusion was achieved after a subsequent anterior interbody fusion. The authors did not report the specific fusion success rate of patients being treated for pseudarthrosis. West and coworkers,[16] as part of a larger series, treated 17 patients with pseudarthrosis with pedicle screw-plate fixation. The fusion success rate was 65% (11 of 17 patients). When evaluated as to function and pain, 8 of the 17 patients were considered to be clinical failures. In a study of 86 patients who underwent operative repair of pseudarthrosis, Carpenter and coauthors[13] found that fusion occurred in 71 patients (83%) with a first repair and in an additional 10 patients after a subsequent repair. Studies of anteroposterior fusion for lumbar pseudarthrosis show a 90% to 100% fusion success rate but only 50% to 65% functional outcome success.[17,18]

Fusion success rates have been found to be lower when patients have risk factors such as smoking, the absence of fixation, multiple levels involved, allograft material, and surgical technique.[2-9] Other authors have found higher fusion success with the use of fixation.[19-23] Randomized prospective studies, however, have found no statistically significant differences with or without the use of fixation.[5,24] Internal fixation can cause stress shielding and osteopenia. In an animal study, PEMF was found to increase bone density and flexion stiffness regardless of the presence or absence of fixation.[25] The use of PEMF in our current study overcame fusion failure without additional surgical intervention, even in the presence of negative risk factors.

Most of the patients in this study underwent a posterolateral fusion with autograft bone. Some authors have questioned the effectiveness of PEMF to enhance fusion with the posterolateral technique.[26,27] These canine studies of PEMF for posterior spine fusion involved a fracture-healing signal of short duration, which has not been found to be efficacious in human beings. In contrast, the PEMF signal used in our study has been found to be effective in human clinical trials.[7] In our patient population with pseudarthrosis, PEMF was equally effective for stimulating fusion healing in a posterolateral technique (66%) and in an interbody technique (69%).

Before considering further surgery, it is important to associate the patient's symptoms and pain with the apparent nonunion. Some researchers have found that apparent pseudarthrosis as evaluated by radiographs may not be entirely accurate.[28] In general, however, patients with a successful fusion demonstrate better function and less pain.[10,29-32] In a review article of outcomes after lumbar spine fusion, Turner and colleagues[33] found a positive relationship of bony fusion to satisfactory outcomes. Using PEMF gives physicians a noninvasive method to enhance healing and allows time for the physician to evaluate whether the patient's symptoms are related to the pseudarthrosis.

The risk of an additional surgery, in some patients, can be eliminated with a noninvasive PEMF device. The treatment is an especially good option for patients who are medically poor candidates for revision surgery. Also, using PEMF can be a tremendous cost savings compared with the cost of additional surgery.[34,35] Parfenchuck and coauthors[35] reviewed the cost of single- and double-level spine fusion and found that in 1993 the average hospital cost was $19,712 and the average surgeon fee was $8,338. Katz and colleagues[34] reported that an average hospital cost was $18,495 for arthrodesis without instrumentation and $25,914 for arthrodesis with instrumentation. The PEMF device, when successful for achieving fusion, demonstrates a significant savings of health care dollars.

Conclusion

For patients with established pseudarthrosis, the use of PEMF was 67% effective for achieving fusion healing without additional surgical intervention, even in the presence of negative risk factors.

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