Advances In Therapy® | *Volume 17 No. 2 March/April 2000*

Spine Fusion for Discogenic Low Back Pain: Outcomes in Patients Treated With or Without Pulsed Electromagnetic Field Stimulation

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ABSTRACT

Sixty-one randomly selected patients who underwent lumbar fusion surgeries for discogenic low back pain between 1987 and 1994 were retrospectively studied. All patients had failed to respond to preoperative conservative treatments. Forty-two patients received adjunctive therapy with pulsed electromagnetic field (PEMF) stimulation, and 19 patients received no electrical stimulation of any kind. Average follow-up time was 15.6 months postoperatively. Fusion succeeded in 97.6% of the PEMF group and in 52.6% of the unstimulated group ($P<.001$). The observed agreement between clinical and radiographic outcome was 75%. The use of PEMF stimulation enhances bony bridging in lumbar spinal fusions. Successful fusion underlies a good clinical outcome in patients with discogenic low back pain.

Keywords: spine fusion; pulsed electromagnetic field stimulation; clinical outcome

INTRODUCTION

Patients who suffer from discogenic low back pain or continued pain after a failed spine fusion represent both a challenge and a frustration. Nonoperative treatment is recommended before initial or repeat surgery is considered and can include a short period of bed rest, exercise, bracing, transcutaneous electrical nerve stimulation, drug therapy (oral or locally

0588

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injectable), traction, manipulation, and massage. The success of these methods varies widely.[1-13]

When conservative treatment fails to relieve pain, spine fusion is a surgical option. Although its use is controversial in discogenic low back pain,[14-17] most of these patients are willing and even eager to regain by almost any means a normal lifestyle that allows the comfortable performance of work and daily activities.

The rationale for spine fusion surgery rests on the belief that if a healed fusion can produce joint stability, the patient will be relieved of pain. Studies that analyzed the association between fusion healing and a successful clinical outcome have reported contradictory results: the correlation was[18-20] and was not[21-24] established.

Factors that affect fusion healing include graft source, history of smoking, preexisting medical conditions, number of levels of fusion, and previous lumbar fusion.[25-27] Several adjunctive devices and therapies have been used to enhance healing of lumbar spine fusion. Among the most common is electrical stimulation with direct current or inductive current with pulsed electromagnetic field (PEMF) stimulation.[28-33] An analysis of the value of electrical stimulation in enhancing spine fusion healing and its correlation to clinical outcome might help physicians who need to decide on surgery, especially for high-risk patients.

This study had two purposes: (1) to determine the radiographic healing and clinical outcomes of spine fusion in patients with discogenic low back pain treated with or without PEMF stimulation; and (2) to analyze demographic and clinical factors that might affect outcomes.

PATIENTS AND METHODS

Between 1987 and 1994, 287 patients underwent lumbar spine fusion surgery for a diagnosis of persistent discogenic low back pain. The records of 245 patients were available for review by an independent researcher. Owing to the clinic's limited resources, patients were randomly selected for the study. The PEMF stimulation device was not available during the early years. When it became available, its use depended on available money or coverage from each patient's insurance company. To minimize bias that could be introduced by changes in medical technology over the years, a year-stratified computer schedule selected 61 patients for study. All had a diagnosis of either discogenic low back pain or failed back-surgery syndrome. Patients with failed back-surgery syndrome had an initial diagnosis of discogenic low back pain and had undergone a spinal fusion that failed to unite.

All patients had undergone at least 6 months of conservative treatment with nonsteroidal anti-inflammatory drugs (unless contraindicated) and comprehensive physical therapy. This regimen included heat or ice therapy or both, ultrasound, possible transcutaneous electrical nerve stimulation, and progressive stretching and strengthening exercises directed at the back, abdomen, upper hip, and all related musculature. If this conservative protocol did not produce symptomatic relief and if the pathologic findings were appropriate, the patient was offered an epidural steroid injection, facet injection, or a sacroiliac injection. A lumbosacral corset was prescribed for wear during maximal physical stress. Only after this multifactorial approach had failed was surgery offered as an option.

Conservative treatment, medical history, and risk factors were recorded preoperatively, and the baseline form also included details of the operation (date, levels of fusion, surgical approach, graft source, use of internal fixation and electrical stimulation). Table 1 lists the patients' demographic and baseline characteristics.

Table 1. Demographic and Clinical Characteristics at Baseline

Variable	PEMF Group (n=42) No.	%	Unstimulated Group (n=19) No.	%	*P* Value
Age, y					
<30	6	14.3	1	5.3	.100
30–39	17	40.5	3	15.8	
40–49	14	33.3	12	63.2	
50	5	11.9	3	15.8	
Sex					
Male	22	52.4	9	47.4	.717
Female	20	47.6	10	52.6	
Related medical history*					
Smoking	19	45.2	3	15.8	NA
Obesity	6	14.3	2	10.5	
Diabetes	2	4.8	1	5.3	
Osteoporosis	1	2.4	0	0.0	
Steroid therapy	10	23.8	1	5.3	
Previous lumbar fusion	4	9.5	5	26.3	
Number of levels fused					
1	18	42.9	12	63.2	.223
2	21	50.0	5	26.3	
3	3	7.1	2	10.5	
Type of bone graft					
Autograft	20	47.6	11	57.9	.158
Allograft	11	26.2	7	36.8	
Mixed	11	26.2	1	5.3	
Internal fixation					
No	32	76.2	18	94.7	.081
Yes	10	23.8	1	5.3	
Risk status					
High†	37	88.1	13	68.4	.064
Low	5	11.9	6	31.6	

*A patient may present in more than one category; statistical comparison is not applicable.
†A patient was considered to be high risk if one of following conditions existed: previous lumbar fusion, smoking, allograft, or multilevel fusion.

Postoperatively, all patients were fitted with a thoracolumbosacral orthosis (TLSO) that was to be worn 16 hours a day for 4 to 6 months. PEMF stimulation was delivered by means of a Spinal-Stim® (Orthofix Inc., Richardson, Tex), which patients wore for at least 4 hours a day beginning 2 days postoperatively.

Neither the TLSO nor the electrical stimulator was worn during sleep unless the patient had (1) an inordinate amount of back and/or leg pain before solidification of the fusion that caused motion and hypersensitivity at the operated segments; (2) possible early graft displacement suggested by reports of shifting or clicking in the back on motion; or (3) significant apprehension about unprotected movement while asleep (eg, sleepwalking, dreaming).

Once fusion had begun, as demonstrated by radiographs and physical examination (approximately 4 to 6 months postoperatively), the patient was slowly weaned from use of the TLSO brace; the time of daily wearing was reduced by 1 hour each week. During the weaning process, vigorous range of motion and strengthening exercises were prescribed for the back and abdominal muscles to minimize secondary pain caused by weak musculature.

Final evaluation with assessment of fusion and clinical success was performed between 6 months and 2 years postoperatively. Fusion was determined radiographically relative to each level by means of standard anteroposterior, right and left bending, and lateral flexion and extension films. Before the radiographs were obtained, the importance of maximal bending effort was emphasized. Poor bending effort led to postponement of obtaining the radiograph, and the patient received additional physical therapy to increase range of motion so that bending radiography could be accurately read for fusion solidity. Successful fusion was defined as incorporation of the graft, with no radiolucency between the graft and the vertebral bone and no motion at each level of fusion. Clinical success was graded as excellent, good, fair, or poor according to the criteria described in Table 2.

The Pearson ^{2} test was used to compare baseline characteristics and overall success rates between groups. Treatment outcomes were also compared by means of the Mantel-Haenszel ^{2} test, controlling for baseline demographic and clinical characteristics. The confidence level was 95%.

RESULTS

Of the 61 patients selected for review, 42 received PEMF stimulation and 19 patients were unstimulated. Baseline and demographic variables were comparable between groups. At surgery, the patients' average age was 40.6 ± 8.3 years (PEMF group, 39.6 ± 8.9 years; unstimulated group, 43.2 ± 6.4 years). The unstimulated group had the highest proportion of single-level fusions. Autograft bone was used for the posterolateral fusion, and allograft bone was used for the anterior interbody fusions. The PEMF group showed a greater proportion of high-risk patients, but the difference was not statistically significant.

The final follow-up evaluation occurred at an average of 15.6 months after surgery. Table 3 tabulates fusion outcomes according to risk factors and baseline characteristics. Overall, 97.6% of PEMF-stimulated patients (41/42) and 52.6% of unstimulated patients (10/19) had a successful fusion. Statistically significant ($P<.001$) between-group differences were found.

Despite the high-risk factors of smoking, multilevel fusion, use of allograft, and previous lumbar fusion, operative success was achieved in 97% of patients in the PEMF group (36/37) and 61.5% of the unstimulated group (8/13). The number of patients who achieved a healed fusion for each clinical assessment is shown in Table 4. Patients who were rated as "excellent" and "good" generally were able to return to activity levels approximating those enjoyed preoperatively. Patients with "fair" and "poor" grades could do minimal self-care only and may have experienced considerable pain 1 year after surgery. Moderate agreement (75.4%) was evident between radiographic and clinical outcomes (Table 5).

Table 2. Grading Criteria for Clinical Assessment

Grade	Criterion
Excellent	Back and/or leg pain completely relieved No further surgical intervention required at the involved level Able to return to previous employment No restriction on physical activities No medications
Good	Significant relief of back and/or leg pain Return to previous employment Few restrictions on physical activity Occasional use of nonsteroidal anti-inflammatory drugs or mild analgesic medication (no narcotics)
Fair	Some back and/or leg pain relief Return to lighter duty or work Mild restrictions on physical activities Regular use of nonsteroidal anti-inflammatory drugs or mild analgesic medications (no narcotics) Patient feels that pain relief is adequate for lifestyle, although not as good as desired; wishes no further surgical treatment
Poor	Little or no relief of back and/or leg pain Unable to return to work Severe restrictions on physical activities Occasional or regular use of narcotic pain medication

Table 3. Treatment Outcomes by Baseline and Clinical Characteristics

Variable	PEMF Group*			Unstimulated Group		
	Total	Healed	Success, %	Total	Healed	Success, %
Age, y						
<30	6	6	100	1	0	0
30–39	17	16	94	3	1	33
40–49	14	14	100	12	9	75
50	5	5	100	3	0	0
Sex						
Male	22	21	95	9	4	44
Female	20	20	100	10	6	60
Smoking status						
Smoker	19	18	95	3	0	0
Nonsmoker	23	23	100	16	10	62
Number of levels fused						
1	18	18	100	12	6	50
2	21	20	95	5	2	40
3	3	3	100	2	2	100
Type of bone graft						
Autograft	20	19	95	11	5	45
Allograft	11	11	100	7	4	57
Mixed	11	11	100	1	1	100
Internal fixation						
No	32	32	100	18	9	50
Yes	10	9	90	1	1	100
Surgical attempts						
Initial	38	38	100	14	6	43
Repeated	4	3	75	5	4	80
Surgical approach						
ALIF	20	19	95	14	6	43
PL	0	0	0	3	2	67
360°	22	22	100	2	2	100
Risk status						
High†	37	36	97	13	8	62
Low	5	5	100	6	2	33
Total	42	41	98	19	10	53

ALIF = anterolateral, internal fixation; PL = posterolateral
*P<.001 vs unstimulated group for all variables.
†As defined in Table 1.

Table 4. Number of Fusions Healed, by Radiographic Assessment

Clinical Assessment	PEMF Group	Unstimulated Group	Total
Excellent	7/7	0/0	7/7
Good	24/24	8/11	32/35
Fair	9/9	1/5	10/14
Poor	1/2	1/3	2/5
Total	41/42	10/19	51/61

Table 5. Agreement Between Radiographic and Clinical Assessment

	Radiographic Assessment		
Clinical Assessment	Healed	Failed	Total
Excellent/good	39	3	42
Fair/poor	12	7	19
Total*	51	10	61

*Observed agreement between clinical and radiographic assessment was 75.4%; the kappa coefficient was 0.341.

DISCUSSION

This analytic review of spine fusion surgery for discogenic disease demonstrated that the rate of fusion was statistically significantly higher with than without PEMF stimulation. In addition, the rate of fusion healing was higher in the PEMF group, even though more of these patients were designated as high risk. Risk factors that can compromise spinal fusion have been described in the literature. In 1985, Brown and colleagues[34] reported pseudarthrosis rates of 8% for nonsmokers and 40% for smokers—a difference of 32%. Other authors have since confirmed the association of pseudarthrosis and smoking.[18,20,27,35] In the present study, all three smokers in the unstimulated group failed to achieve fusion, whereas fusion succeeded in 18 of 19 smokers who received PEMF stimulation.

The use of allografts has been recognized as another explanation for unsatisfactory fusion rates.[25,36] In a study by Mooney,[31] 73% of allograft recipients exhibited successful fusion without electrical stimulation. In the current study, only 4 of 7 allograft patients in the unstimulated group achieved fusion, compared with all 11 patients in the PEMF group.

Lower rates of fusion also occurred with operative revision for failed back-surgery syndrome than with primary fusion surgery.[37-39] Kim and Michelsen[38] reported 55% success for the repair of pseudarthrosis or failed fusion. In the present review, the low number of patients undergoing repeat fusion precluded specific conclusions or recommendations; however, 75% of the PEMF group (3/4) and 80% of the unstimulated group (4/5) achieved a solid fusion, which compares favorably with other reports.

Kozak and O'Brien[40] reported a combined anterior and posterior success rate of 90% with one- and two-level fusion but a drop to 78% with three-level fusions. Chow and coworkers[41] found similar results with multilevel fusions. Electrical stimulation has been found to enhance healing in patients undergoing multilevel fusions.[32,33] In this study, the success rate for patients in the PEMF group was never lower than 95% (two-level) and was 100% in those with single- and three-level fusions. These results were statistically significantly better than those in the unstimulated group ($P<.001$).

The clinical success in this study is contrary to findings in canine studies that showed inadequate healing with PEMF stimulation,[42] although the experimental results may stem from use of an unproven and ineffective signal, duration (30 to 60 minutes) below the minimum threshold dose, insufficient interval between the procedure and fusion evaluation (6 and 12 weeks), and the animal model itself. Boden[25] and Glazer et al[43] have suggested that rabbits, rather than dogs, might represent an animal model more similar to humans. Using rabbit models, Glazer and associates[43] recently studied the use of PEMF stimulation for 4 hours a day over 6 weeks. A decrease from 40% to 20% in pseudarthrosis was found. Biomechanical evaluation showed increases of 35% in fusion stiffness in the PEMF group versus a control group, 37% in resistance to stress, and 42% in load to failure of the mass fusion.

Some studies have assessed clinical outcome after fusion surgery, but only a few were specific to patients with discogenic disease. Parker and colleagues[44] studied 23 patients who underwent posterolateral fusion for discogenic low back pain. Eighteen patients achieved a solid fusion, but 7 of them (39%) had poor clinical results. Of the 5 patients who had pseudarthrosis, 4 (81%) had an unfavorable clinical outcome. Blummenthal et al[18] found that 81% of patients with solid fusion healing were clinical successes, whereas only 56% of patients considered clinical failures had fusion healing. Similar findings of healing and clinical success in patients with discogenic low back pain have been reported.[19,45]

The current study demonstrated that, in general, a radiographically confirmed spinal fusion correlated with a good or excellent clinical outcome. Conversely, lack of fusion was linked to fair or poor clinical results. Among the 42 patients evaluated, 39 whose clinical assessment grade was excellent or good achieved a solid fusion; the 3 who did not were in the unstimulated group. Of the 19 patients rated fair or poor, 7 failed to exhibit a solid fusion; 6 of them were in the unstimulated group.

The results of this review support the efficacy of adjunctive PEMF stimulation in achieving spine fusion. In these patients with discogenic low back pain, a successful clinical outcome was related to fusion success. Given the expense of managing discogenic low back pain, it seems prudent to use this noninvasive method to enhance fusion healing.

CONCLUSION

The use of PEMF stimulation significantly enhanced fusion healing, both statistically and clinically, in patients with discogenic low back pain. An excellent or good clinical outcome was related to fusion success.

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