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Three- and 4-Level Lumbar Arthrodesis Using Adjunctive Pulsed Electromagnetic Field Stimulation: A Multicenter Retrospective Evaluation of Fusion Rates and a Review of the Literature

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ABSTRACT

Background: The incidence of 3- and 4-level lumbar arthrodesis is rising due to an aging population, and fusion rates affect clinical success in this population. Pulsed electromagnetic field (PEMF) stimulation is used as an adjunct to increase fusion rates following multilevel arthrodesis. The purpose of the study was to evaluate the fusion rates for subjects who underwent 3- and 4-level lumbar interbody arthrodesis following PEMF treatment.

Methods: In this retrospective, multicenter study, patient charts that listed 3- or 4-level lumbar arthrodesis with adjunctive use of a PEMF device were evaluated. Inclusion criteria included patients who were diagnosed with lumbar degenerative disease, spinal stenosis, and/or spondylolisthesis (grade 1 or 2). A radiographic evaluation of fusion status was performed at 12 months by the treating physicians. Fusion rates were stratified by graft material, surgical interbody approach, and certain clinical risk factors for pseudoarthrosis.

Results: A total of 55 patients were identified who had a 12-month follow-up. The radiographic fusion rate was 92.7% (51 patients) at 12 months. There were no significant differences in fusion rates for patients treated with allograft or autograft, for patients with different interbody approaches, or for those with or without certain clinical risk factors.

Conclusions: With modern fusion techniques and PEMF, the overall fusion rate was high following 3- and 4-level lumbar arthrodesis.

Level of Evidence: 4.

Clinical Relevance: PEMF may be a useful adjunct for treatment of patients with surgical risk factors, such as multilevel arthrodesis, and clinical risk factors.

Lumbar Spine

Keywords: pulsed electromagnetic field stimulation, lumbar arthrodesis, adjunctive therapy, spinal fusion, bone stimulation, lumbar fusion, pseudarthrosis, failed fusion

INTRODUCTION

Due to increases in life expectancy and health longevity, the incidence of degenerative lumbar disease is rising, and the frequency of multilevel arthrodesis is correspondingly higher.[1] Arthrodesis of at least 3 levels is a risk factor for significantly lower fusion rates.[2] Higher pseudoarthrosis rates are associated with worse clinical outcomes.[3] In addition, if fusion fails, patient disability increases, return-to-work rates fall, and pain-medication usage increases.[4] Furthermore, certain risk factors including diabetes, obesity, tobacco use, advanced age, and osteoporosis have been linked to higher rates of nonunion or delayed union, inhibition of bone repair, and/or higher complication rates.[5–14] Given these challenges, adjunctive measures are often recommended to mitigate the risk of pseudoarthrosis.[11]

One such adjunctive measure that has been demonstrated to improve bone healing in procedures including fracture repair and spinal arthrodesis is pulsed electromagnetic field (PEMF) stimulation.[15–21] Specifically, in a randomized, controlled clinical trial of PEMF for anterior cervical discectomy and fusion (ACDF), PEMF significantly improved the fusion rate in smokers and in participant who received multilevel arthrod-

esis as compared with controls who did not receive PEMF treatment.[20] Similarly, in a double-blind, randomized, placebo controlled study, adjunctive PEMF treatment resulted in significantly increased fusion rates compared with placebo treatment after primary posterolateral lumbar spinal fusion at 1 or 2 levels.[17]

Although these level 1 studies convincingly demonstrate increased fusion rates resulting from adjunctive PEMF treatment, they do not describe fusion rates after lumbar interbody arthrodesis of 3 and 4 levels. Furthermore, the participants enrolled in those Food and Drug Administration (FDA) studies may not represent everyday patients seen in clinical practice, such as those with clinical risk factors including diabetes, advanced age, tobacco use, obesity, and osteoporosis.

The primary aim of this study was to retrospectively evaluate the fusion rate of adjunctive PEMF stimulation following lumbar 3- and 4-level arthrodesis. The secondary aim was to assess fusion rates between patients with and those without risk factors for pseudoarthrosis. A retrospective study was performed on a population of patients requiring a variety of lumbar interbody arthrodeses to evaluate fusion rate outcomes.

METHODS

Aims and Study Design

The primary aim of this study was to retrospectively evaluate fusion rates of 3- and 4-level lumbar arthrodeses that were performed with the adjunctive use of PEMF stimulation; a secondary aim was to assess fusion rates between patients with and without certain demographic risk factors for pseudoarthrosis.

A retrospective, multicenter, open-label study using the Spinal-Stim device (Orthofix, Inc, Lewisville, TX) was performed with patients undergoing lumbar arthrodesis. Institutional review boards at each institution approved the study and waived the requirement for informed consent (WIRB No. 20152038; COMIRB No. 15-1496; ARMC No. 15-042).

Patients were enrolled at 5 institutions and were included in the study if they had undergone 3- or 4-level lumbar interbody arthrodesis with adjunctive use of the Spinal-Stim device (Orthofix), which was designed specifically for the lumbar spine. In addition, participants were required to be at least 18 years of age and have been diagnosed with lumbar degenerative disease, spinal stenosis, and/or spondylolisthesis (grade 1 or 2). Participants were also required to have a fusion assessment at 12 months either radiographically or by computed tomography (CT) scan. Potential participants were excluded from the study if they solely had posterolateral fusion (without interbody cages); had significant lumbar instability, defined as sagittal or coronal plane listhesis greater than grade 2 spondylolisthesis; had scoliosis greater than 30°; had surgery due to traumatic injury; had a body mass index (BMI) of >40; or had an overt or active bacterial infection, either local or systemic, during the 12-month postoperative period. There were no restrictions placed on the surgical approach, fixation, graft material, or postoperative care regimen. Surgeries were performed between January 2010 and March 2015.

PEMF Device

Spinal-Stim (Orthofix) is a Class III commercial electromagnetic field device approved by the FDA for osteogenesis stimulation. Specifically, it has been approved as an adjunct for lumbar spine fusion surgery in patients at high risk for nonfusion. The device consists of a single coil placed posteriorly to the spine covering all lumbar levels.[22]

End Points

The primary end point was the treating surgeon's assessment of fusion status at 12 months as determined by the presence of continuous bridging bone by plain films or CT. Twelve months was the latest follow-up time that was common at all sites. Information on revisions that occurred postoperatively and after PEMF treatment were also collected.

Statistical Analysis

Descriptive statistics were provided for both clinical and surgical risk factors and demographic parameters. In the comparison of 12-month fusion status by risk and surgical factors, the Fisher exact test was used for binary variables. Exact χ^2 test was used if there were more than 2 categories. The significance level for all statistical tests was set at a 2-sided P value of less than .05. No adjustment for multiple comparisons was made. Due to the high fusion rate, logistic regression was not performed.

Table 1. Demographic frequency.

Demographic	n	%
Age, y		
<65	32	58
65+	23	42
Gender		
Female	35	64
Male	20	36
Weight status (BMI)		
Underweight (<18.5)	1	2
Normal weight (18.5–24.99)	10	18
Overweight (25–29.99)	24	44
Obese (30–39.99)	20	36
Race		
Unknown/undisclosed	10	18
Black or African American	1	2
White	43	78
Asian	1	2
Nicotine use at time of surgery		
Yes	9	24
No	29	76
Diabetes diagnosis		
Yes	9	16
No	46	84
Osteoporosis diagnosis		
Yes	6	11
No	49	89
Prior failed lumbar fusion		
Yes	4	11
No	34	89
Indications for Surgery		
DDD	36	—[a]
Stenosis	45	—[a]
Spondylolisthesis	11	—[a]
Scoliosis (including kyphoscoliosis)	6	—[a]

Abbreviations: BMI, body mass index; DDD, degenerative disc disease.
[a]Multiple indications per patient.

RESULTS

There were 55 patients and 186 surgical levels enrolled in the study, and all patients underwent a 3- or 4- level arthrodesis.

Demographics and Surgical Factors

Of the 55 participants, the mean age was 62.2 years and the range was 29–80 years. The demographics and risk factors varied across the participant population (Table 1). In addition to the multilevel surgical risk factor for pseudoarthrosis, the next largest single risk factor was for patients who were overweight (BMI, 25–29.9) or obese (30–39.9; both categories totaled 80% of participants). The majority of patients were treated for stenosis and/or degenerative disc disease (Table 1). Three-level arthrodesis, levels L3-L4 and L4-L5 (100% of participants) and anterior lumbar interbody fusion (ALIF) and posterior lateral interbody fusion (PLIF; each representing 44% of patients) were most common (Tables 2 and 3).

Table 2. Surgical factor frequency.

Surgical Factor	n	%
Number of levels		
3	34	62
4	21	38
Levels[a]		
L2-L3	40	73
L3-L4	55	100
L4-L5	55	100
L5-S1	36	65

[a]A total of 186 levels were treated.

Fusion Outcomes

The overall fusion rate was 92.7% (51/55 patients), which was determined by x-ray (69.1%), CT (20.0%), or MRI (1.8%). In 9.1% of patients, the imaging modality was not specified. There were 2 revision surgeries, 1 which was attributed to breakage of instrumentation and the other for pedicle subtraction osteotomy and hardware removal. The fusion rate for patients with risk factors for pseudoarthrosis that included high-weight status, nicotine use, a diagnosis of osteoporosis or diabetes, a prior pseudoarthrosis, a multilevel

Table 3. Fusion rate for subpopulations.

	N Fused/Total	% Fused	*P* Value
All subjects	51/55	92.7	NA
Age, y			1.0
<65	30/32	93.8	
65+	21/23	91.3	
Weight status (BMI)			.17
Underweight or normal weight	9/11	81.8	
Overweight or obese	42/44	95.5	
Nicotine use at time of surgery			1.00
Yes	8/9	88.9	
No	27/29	93.1	
Diabetes diagnosis			1.00
Yes	9/9	100.0	
No	42/46	91.3	
Osteoporosis diagnosis			1.00
Yes	6/6	100.0	
No	45/49	91.8	
Prior failed lumbar fusion			1.00
Yes	4/4	100.0	
No	33/34	97.1	
Arthrodesis levels			.64
3	32/34	94.1	
4	19/21	90.5	
Surgical approach			.60
Lateral	4/4	100.0	
ALIF	21/24	87.5	
PLIF	23/24	95.8	
Other	3/3	100.0	
Surgical approach			1.00
Minimally invasive	42/46	91.3	
Open	9/9	100.0	
Graft material			.86
Allograft	26/28	92.9	
Autograft	21/23	91.3	
Other (graft type not identified)	3/3	100.0	

Abbreviations: ALIF, anterior lumbar interbody fusion; BMI, body mass index; NA, not applicable; PLIF, posterior lateral interbody fusion.

Table 4. Multilevel interbody lumbar arthrodesis literature.

Reference	No. of Patients	No. of Levels; (% of total patients)	IB Type	Graft Material	Fusion Rate, %	Follow-up Time, mo
Current study	55	3- & 4-level (100)	XLIF, ALIF or PLIF	Autograft or allograft	92.7	12
Min 2013[1]	18	18 at least 3-level (100)	TLIF	Autograft or autograft + HA	88.9	18–52
Studies that report combined 1- through 7-level fusion rates						
Ahmadian 2015[23]	59	9 3-level (15.3); 2 4-level (3.4)	Stand alone MIS-LIF	allograft	100 100	12–24
Berjano 2015[24]	53	53 1–4 levels fused (100)	XLIF; stand alone or w/ posterior fixation	CaP- Attrax CaP- Nanostim ABG TCP	83 100 75 89	12–62
Dorward 2013[25]	42 42	7 3-level (16.7) 7 3-level (16.7)	TLIF ALIF	INFUSE	95.2 88.1	24 24
Farrokhi 2018[26]	44	2–7 levels (including thoracic)	PLIF	Autograft + synthetic bone substitute	77.3 88.6	12 24
Lauweryns 2015[27]	40	1 3-level (3.6); 1 4-level (3.6)	PLIF	I-FACTOR autograft	97.8 82.2	12 12
Lechner 2017[28]	50	4 (8.0) 3-level	ALIF	b-TCP + BMA	78–85	12
Ni 2015[29]	40	11 3-level (27.5): combined with long PLF	ALIF	allograft	96.4	13–49
Parker 2016[30]	110 25	5 3-level (5) 2 3-level (8)	IB; stand alone or instrumented	INFUSE b-TCP	96 80	24
Thaler 2013[31]	34	3 3-level (8.8)	PLIF	b-TCP + BMA	26.7	12
Watkins 2014[32]	23	3 3-level (13.0); 1 4-level (4.3)	LLIF stand alone	Infuse + Nanoss	73	NS
Zhu 2018[33]	17 19	2 3-level (11.8) 3 3-level (15.8)	OLIF (stand alone) PLIF	Allograft or autograft	100 100	12

Abbreviations: ABG, autologous bone graft; ALIF, anterior lumbar interbody fusion; BMA, bone marrow aspirate; CaP, calcium phosphate; HA, hydroxyapatite; IB, interbody; LIF, lumbar interbody fusion ; LLIF, lateral lumbar interbody fusion; MIS, minimally invasive surgery; NS, not stated; OLIF, oblique lateral interbody fusion; PLF, posterolateral fusion; PLIF, posterior lateral interbody fusion; TCP, tricalcium phosphate; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lumbar interbody fusion.

arthrodesis, or at least 2 of the aforementioned risk factors resulted in fusion rates ranging from 90.5%–100% (Table 3). A comparison between patients with risk factors as compared with those without risk factors showed no statistical differences (Table 3). In addition, the fusion rate for different surgical approaches such as extreme lumbar interbody fusion, transforaminal lumbar interbody fusion, and ALIF ranged from 87.5%–100%, and for 3- and 4-level arthrodesis the rates were 94.1% and 90.5%, respectively, neither of which was statistically significant. Last, there was no significant difference in fusion rates between patients treated with allograft or autograft. Of note, there were no documented adverse events attributed to PEMF use.

DISCUSSION

In a multicenter cohort of patients undergoing 3- and 4-level lumbar arthrodesis with adjunctive PEMF treatment, the incidence of fusion at 12 months was 92.7%, and there were no significant differences between participants with and those without clinical risk factors.

As a comparator for fusion rates in the absence of PEMF, a literature search was performed for publications that described 3- and 4-level lumbar interbody fusion rates. Twelve publications were identified (Table 4) that described a fusion rate ranging from 26.7%–100%. One publication reported fusion rates separately for 3- and 4-level arthrodesis,[1] whereas all others reported a combined fusion rate for single-level and multilevel interbody arthrodesis, which may have resulted in higher fusion rates than if multilevel fusion rates had been reported separately.[1] To our knowledge, the number of patients in the current study comprises the largest population of 3 and 4 level lumbar fusions. Although the fusion rates of the current study falls within the range that is reported in the literature, a direct comparison is difficult due to the differences in number of arthrodesis levels, graft type used, and follow-up duration. The fusion assessment for the current study was performed at 12 months. Although this may be considered early by some to assess fusion, the literature review demonstrated that about 40% of reports evaluated fusion at 12 months.

The secondary aim of this study was to assess fusion rates between participants without and those with risk factors. Clinical factors, such as advanced age, nicotine use, and diabetes, have been demon-

strated to increase the complication rate following lumbar arthrodesis.[5,8,12] One potential complication is psuedoarthrosis, and recent publications confirm a positive correlation between clinical risk factors and pseudoarthrosis given that pseudoarthrosis rates were significantly higher in smokers, those of advanced age, and obese patients undergoing lumbar arthrodesis than in nonsmokers.[13,14,34] In the presence of PEMF stimulation, the current study demonstrated no significant differences in fusion rates between participants without and those with risk factors. Although this finding may indicate that PEMF increases the fusion rates for patients with these risk factors, the sample size is small and caution is warranted for interpretation. Appropriately powered randomized controlled studies are required.

The results of the current study concur with the findings of previous PEMF studies that demonstrate high fusion rates in the presence of surgical and clinical risk factors following spinal arthrodesis. The fusion rate following adjunctive PEMF stimulation for at least 3-level ACDF procedures for patients who had at least 1 additional risk factor for pseudoarthrosis was 97.3%–100% at 12 months,[35] and PEMF significantly improved the fusion rate in smokers and in patients who received multilevel arthrodesis as compared with controls who did not receive PEMF treatment.[20]

Limitations of the current study include the lack of a concurrent control. This was a retrospective study that evaluated the standard clinical practice of 4 surgeons using PEMF for multilevel arthrodesis and no non-PEMF comparator was available. Another limitation is that the treating surgeon determined the fusion status, and surgeon bias is known with respect to consideration of other clinical outcome parameters. Also, retrospective studies have the potential for selection bias, and no assessment of patient accountability is possible with the data collected. However, data from all patients who met the inclusion and exclusion criteria were reported in this study. Certain risk factors for pseudoarthrosis such as at least grade 2 spondylolisthesis, scoliosis, trauma, being morbidly obese, and an active bacterial infection were excluded from the study, and thus the effect of PEMF on a population with these risk factors is unknown. Although PEMF was prescribed for 3–6 months, PEMF compliance was not measured.

CONCLUSIONS

The results of the current clinical evaluation suggest that PEMF treatment following 3- and 4-level lumbar arthrodesis results in a high fusion rate despite risk factors.

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