

EFFECT OF PULSED ELECTROMAGNETIC FIELD ON THE CONSOLIDATION OF POSTEROLATERAL ARTHRODESES IN THE LUMBOSACRAL SPINE: A PROSPECTIVE, DOUBLE-BLIND, RANDOMIZED STUDY

EFEITO DO CAMPO ELETROMAGNÉTICO PULSADO NA CONSOLIDAÇÃO DAS ARTRODESES POSTEROLATERAIS LOMBOSSACRAS: ESTUDO PROSPECTIVO, DUPLO-CEGO E RANDOMIZADO

EFFECTO DEL CAMPO ELECTROMAGNÉTICO PULSADO EN LA CONSOLIDACIÓN DE ARTRODESIS POSTEROLATERALES EN LA COLUMNA LUMBOSACRAL: ESTUDIO PROSPECTIVO, DOBLE CIEGO, RANDOMIZADO

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ABSTRACT

Objective: To assess the effect of pulsed electromagnetic field (PEMF) on the consolidation of instrumented lumbar posterolateral arthrodeses in patients who have been surgically treated for degenerative spine disease. **Methods:** Forty cases were recruited from 163 consecutive patients undergoing lumbar arthrodesis at the same center. The patients were randomized into two groups of 20 patients: Active Group, who were exposed to PEMF for 4 hours a day for 90 days after surgery, and Inactive Group, who received an identical device, with the same instructions for use but without the ability to generate PEMF. The patients underwent computed tomography scans at 45, 90, 180 and 360 days after surgery to check for the occurrence of arthrodesis at each operated spinal level. **Results:** In the course of the study, two patients were excluded from each group. There were no significant differences between the groups with respect to age, gender, smoking habit, or the number of vertebral levels included in the arthrodesis. The percentage of consolidation of the vertebral levels increased at 90, 180 and 360 days compared to 45 days ($p < 0.001$) in both groups. The Active Group had a 276% greater chance of consolidation in the vertebral levels (OR = 3.76; 95% CI: 1.39-10.20), regardless of the time of evaluation. Patients in the Active Group presented 16% more consolidation than patients in the inactive group ($p = 0.018$). **Conclusions:** Post-operative exposure to PEMF following instrumented arthrodesis of the lumbar spine for degenerative spine disease increased consolidation in the first year after surgery.

Keywords: Randomized controlled trials as topic; Spinal fusion; Spine; Electromagnetic fields; Arthrodesis.

RESUMO

Objetivo: Avaliar o efeito do campo eletromagnético pulsado (CEMP) na consolidação de artrodeses posterolaterais lombares instrumentadas em pacientes que foram tratados cirurgicamente de doença degenerativa da coluna vertebral. **Métodos:** Quarenta casos foram recrutados de 163 pacientes consecutivos submetidos à artrotese lombar no mesmo centro. Os pacientes foram randomizados em dois grupos de 20 pacientes: Grupo Ativo, que foi exposto a CEMP por 4 horas por dia durante 90 dias após a cirurgia e Grupo Inativo, que recebeu um dispositivo idêntico, com as mesmas instruções de uso, mas sem a capacidade de gerar CEMP. Os pacientes foram submetidos a exames de tomografia computadorizada aos 45, 90, 180 e 360 dias após a cirurgia para verificar a ocorrência de artrotese em cada nível espinhal operado. **Resultados:** No decorrer do estudo, dois pacientes foram excluídos de cada grupo. Não houve diferenças significativas entre os grupos com relação à idade, sexo, tabagismo ou número de níveis vertebrais incluídos na artrotese. A percentagem de consolidação dos níveis vertebrais aumentou aos 90, 180 e 360 dias em comparação com 45 dias ($p < 0,001$) em ambos os grupos. O Grupo Ativo teve uma chance de consolidação 276% maior nos níveis vertebrais (OR = 3,76; IC 95%: 1,39-10,20), independentemente do momento da avaliação. Os pacientes do Grupo Ativo apresentaram 16% mais consolidação do que os pacientes no grupo inativo ($p = 0,018$). **Conclusões:** A exposição pós-operatória ao CEMP após artrotese instrumentada da coluna lombar na doença degenerativa da coluna vertebral aumentou a consolidação no primeiro ano após a cirurgia.

Descritores: Ensaios clínicos controlados aleatórios como assunto; Fusão vertebral; Coluna vertebral; Campos eletromagnéticos; Artrotese.

RESUMEN

Objetivo: Evaluar el efecto del campo electromagnético pulsado (CEMP) en la consolidación de la artrodesis posterolateral lumbar instrumentada en pacientes tratados quirúrgicamente por enfermedad degenerativa de la columna vertebral. **Métodos:** Cuarenta casos fueron

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reclutados de 163 pacientes consecutivos sometidos a artrodesis lumbar en el mismo centro. Los pacientes fueron asignados al azar a dos grupos de 20 pacientes: Grupo Activo, que fue expuesto a CEMP durante 4 horas al día durante 90 días después de la cirugía y Grupo Inactivo, que recibió un dispositivo idéntico, con las mismas instrucciones de uso pero sin la capacidad de generar CEMP. Los pacientes fueron sometidos a tomografía computarizada a los 45, 90, 180 y 360 días después de la cirugía para comprobar la presencia de artrodesis en cada nivel operado de la columna. Resultados: En el curso del estudio, dos pacientes fueron excluidos de cada grupo. No hubo diferencias significativas entre los grupos con respecto a la edad, el sexo, el tabaquismo o el número de niveles vertebrales incluidos en la artrodesis. El porcentaje de consolidación de los niveles vertebrales aumentó a los 90, 180 y 360 días en comparación con 45 días ($p < 0,001$) en ambos grupos. El Grupo Activo tenía una probabilidad 276% mayor de consolidación en los niveles vertebrales (OR = 3,76; IC del 95%: 1,39-10,20), independientemente del momento de la evaluación. Los pacientes del Grupo Activo presentaron 16% más de consolidación que los pacientes del Grupo Inactivo ($p = 0,018$). Conclusiones: La exposición postoperatoria a CEMP después de la artrodesis instrumentada de la columna lumbar en la enfermedad degenerativa de la columna vertebral aumentó la consolidación en el primer año después de la cirugía.

Descriptores: Ensayos clínicos controlados aleatorios como asunto; Fusión vertebral; Columna vertebral; Campos electromagnéticos; Artrodesis.

INTRODUCTION

Lumbar arthrodesis has been widely indicated and performed for the treatment of lumbar diseases with several causes, particularly in the conservative treatment of refractory degenerative diseases.¹⁻³ The most common degenerative changes arise from disc injury, which can manifest as interbody arthrosis and disc protrusion and extrusion, and are associated with facet arthrosis, ligament hypertrophy and intervertebral instability. When symptoms arising from these degenerative changes do not respond to conservative treatments, surgical procedures are indicated. In certain cases, where there is clinical instability or instability resulting from the decompression of neural structures during surgery, arthrodesis^{1,4} is indicated.

Arthrodesis suppresses physiological and pathological movements in the treated intervertebral joints because bone growth between these structures will fuse them rigidly and definitively with a bone bridge.^{5,6} Lumbar arthrodeses can be performed between the vertebral bodies (anterior or interbody) or between the elements that form the vertebral arch (posterior or posterolateral), i.e., the laminae, transverse processes and zygapophyseal joints. Posterolateral arthrodesis is the most widespread treatment for degenerative lumbar spine diseases.⁷

The literature is inconsistent in relation to the techniques used in lumbar spinal arthrodesis,^{1,8} especially in regard to the use of instrumentation⁹⁻¹¹ and the need for combined interbody and posterolateral arthrodesis.^{1,5,6} Theoretically, interbody arthrodesis is advantageous due to an increased fusion surface area and the possibility of grafting in an area with better vascular supply and compressive load action.¹² However, this modality causes greater morbidity, is more expensive, and does not improve long-term prognosis.^{1,13}

Regarding the use of instrumentation in lumbar arthrodesis, reports indicate that the application of rigid pedicle fixation increases the fusion rates of posterolateral lumbar arthrodeses and that the success of consolidation in arthrodesis is related to better functional results in the long term.¹⁴

The main advantage of posterior arthrodesis is that it is less invasive because it avoids an anterior access or interbody approach through the vertebral canal, which is characterized by manipulation of nervous tissue. Studies indicate that pedicular instrumentation increases the rigidity of the fusion and optimizes the rate of arthrodesis consolidation.¹⁰ However, studies show that when it is performed in isolation, posterior arthrodesis presents a greater pseudarthrosis rate,¹³ which is the main cause of post-operative lumbar pain and surgical revision.¹⁵

The bone grafting technique also influences the consolidation of arthrodeses and is related to surgical morbidity. The literature attributes the best arthrodesis consolidation success rates to the use of iliac autograft, but this approach has a higher morbidity.^{16,17} The use of autograft obtained from the site of decompression offers consolidation rates equivalent to those of iliac autografts when the arthrodesis involves one or two levels.^{12,17-19}

Several methods are described to optimize posterior intervertebral fusion, such as electrical stimuli application,²⁰⁻²² the use of autologous growth factors and the use of recombinant proteins with osteoinductive potential (rhBMP).²²

Electrical stimulation results in bone consolidation via mechanisms related to the increased activity of osteoblasts and osteocytes. Electrical stimulation can be applied directly or indirectly, with indirect electrical stimulation being generated from a pulsed electromagnetic field (PEMF).²²

The use of a PEMF was found to be effective in studies that evaluated bone consolidation in long bone fractures, cervical interbody arthrodesis, and interbody arthrodesis associated with posterolateral lumbar arthrodesis.^{2,3} This application is based on the fact that the bone tissue responds when exposed to the electrical current. Specifically, electrical stimulation promotes bone vascularization, stimulates the migration of osteoblasts, and induces the synthesis of bone matrix and its mineralization.² The use of electromagnetic stimulus generates an induced electrical current that stimulates osteogenesis. This technique is non-invasive and non-radioactive and shows no evidence of causing cell damage.^{2,23}

There is a lack of studies in the literature evaluating the effect of the pulsed electromagnetic field on lumbar posterolateral arthrodesis, and there are no controlled studies in this specific group of patients. In addition, existing studies evaluating the consolidation of lumbar arthrodeses have used diverse and poorly reproducible methods to access the consolidation status of arthrodeses, without adequate periodicity to interpret the evolution of the consolidation process.

New studies that aim to evaluate, in a standardized and more reproducible way, the consolidation process of lumbar and lumbosacral posterolateral arthrodesis under the effect of the pulsed electromagnetic field, are therefore justified.

The objective of the present study was to assess the effect of a PEMF on the consolidation rate of lumbar posterolateral instrumented arthrodesis with pedicular screws in patients undergoing surgical intervention for degenerative lumbar spine disease.

MATERIALS AND METHODS

The study was approved by the Research Ethics Committee of Campinas State University (Universidade Estadual de Campinas – UNICAMP) under opinion n°. 856/2009, and written informed consent was obtained from each subject. All procedures followed the criteria established by Resolution no. 196/96 of the National Health Council, in force at the time.

A randomized, prospective, double-blind, controlled study was conducted at the Spinal Surgery Unit, Department of Orthopedics and Traumatology, School of Medical Sciences, Campinas State University (Universidade Estadual de Campinas – UNICAMP).

A pre-established sample of 40 patients was randomized into two groups. A total of 163 consecutive patients undergoing spinal surgery between March 2010 and March 2013 at the Spinal Surgery Unit, Department of Orthopedics and Traumatology, School of Medical Sciences, UNICAMP, were considered. Of these, 98 met the inclusion criteria and did not present any exclusion criteria. On the date of the first outpatient consultation, the patients were invited to participate in the study in the post-operative period. Of these patients, 58 refused to participate in the study and 40 agreed to participate after being informed of the risks and potential benefits by researchers. These patients then

signed a free and informed consent form. When the targeted sample size of 40 volunteers was reached (which occurred with the agreement of the 98th consecutive patient invited), recruitment ceased.

These patients were operated under the same technique by two of the three specialized spine surgeons of the Spine Surgery Unit, and the same rehabilitation protocols were followed for all cases.

Inclusion criteria

The inclusion criteria were as follows: (I) older than 20 years; (II) undergoing posterolateral lumbar or lumbosacral arthrodesis performed with pedicular screws and autograft harvested from the decompression site; and (III) an indication for treatment of degenerative spinal disease.

Exclusion criteria

The exclusion criteria were as follows: (I) use of a pacemaker, defibrillator, electrical stimulation implant, or cochlear implant; (II) history of invasive spinal procedure or spinal infection or tumor; (III) use of an autograft harvested from a site other than the lumbar spine; (iv) use of a heterograft or bone replacements; and (v) use of BMP or devices for interbody arthrodesis. Pregnant women or women intending to become pregnant in the 12 months of follow-up were also excluded, although there is no direct evidence that PEMF affects embryonic or fetal development.

Population

The pre-established sample size was 40 individuals, who were randomized into two groups of equal size: the Active Group, which received a PEMF-emitting device, and the Inactive Group, which received an identical device but without the ability to emit PEMF. Among the patients who were eligible to participate in the study, all were invited to participate until 40 individuals were obtained, after which the patients were randomized. Each patient drew a number for participation in the study, and received a PEMF emitting device (or an inactive device) for daily home use, according to the established protocol.

Exposure to a PEMF protocol

A total of 20 PEMF-emitting devices (active) and 20 devices incapable of emitting PEMF (inactive) but otherwise identical, were randomly allocated to the patients. The patients were instructed to use the device (Spinal Stim, Orthofix Inc., McKinney, TX, USA) for four hours daily for 90 consecutive days, totaling 360 hours. Use of the device was started between the third and fourth post-operative week. At the end of the period of use of the device, the device memory was read to confirm the use time and regularity of each individual. The minimum acceptable use was 300 hours over 100 days, or until the time of tomographic consolidation assessment in cases where this occurred before 100 days.

The researchers involved in the study had no knowledge of which patients were in the Active Group and which were in the Inactive Group until the end of the follow-up of the last patient.

Assessment of arthrodesis consolidation

The assessment of arthrodesis consolidation during the study was conducted using computed tomography (CT) scans. Each patient underwent four CT scans in a 64-channel device with multi-slice volume acquisition in the axial plane²⁴ at the following established intervals: 45, 90, 180 and 360 days after the initiation of the use of the PEMF-emitting device.

The tomographic images, which included the entire arthrodesis area, were reconstructed with bone window imaging in the sagittal and oblique coronal planes²⁵ for each vertebral unit to be studied. Arya Pixon© version 1.5.5 software was used for this analysis. We defined the oblique coronal plane as the plane perpendicular to the line that passes through the center of the intervertebral disk in the sagittal plane. The scans were analyzed systematically using high-resolution monitors with reconstructed images, adjusting the thickness to 3 mm for the oblique coronal plane for each operated level. (Figures 1, 2 and 3) After evaluation of this reconstruction



Figure 1. Tomographic image confirming L4-L5 solid unilateral arthrodesis.



Figure 2. Tomographic image confirming L4-L5 solid bilateral arthrodesis.



Figure 3. Tomographic image confirming absence of L4-L5 consolidation.

plane, the analysis was supplemented by reconstructed images in the parasagittal plane, also with a thickness of 3 mm. The images were interpreted by a radiologist and an orthopedic spinal surgeon who did not participate in the surgeries of the study patients.

Each operated level was considered a unit and was classified as consolidated or not consolidated according to the tomographic interpretation criteria proposed in the literature.²⁵⁻³⁰ The identification of continuity of trabecular bone between posterior elements of two adjacent vertebrae, either unilateral or bilateral, was considered consolidation.

Statistical analysis

Demographic characteristics were described using absolute and relative frequencies, and association was verified using the chi-square test or Fisher's exact test.³¹ The comparison of consolidation time of the arthrodesis between groups was done using the log-rank test.³²

The consolidation of each spinal level included in the surgery was described at each evaluation time (45, 90, 180 and 360 days), for each group, using absolute and relative frequencies, represented with line graphs.

The comparison of the percentages of consolidation between the groups and evaluation times was performed by generalized estimation equations (GEE) with Binomial marginal distribution and logit link function with a matrix of symmetrical component correlations between the evaluation times.³³

The Bonferroni multiple comparisons test was performed to compare arthrodesis consolidation times between the groups.³⁴

The tests were performed with a significance level of 5%.

Statistical analysis was performed using SPSS software, version 20.0.

RESULTS

Of the 40 individuals participating in the study, four were excluded, two from each group. In the Inactive Group, two patients were excluded during the study; one because they developed an infection on the 22nd day after surgery, and another who abandoned the study voluntarily after the second visit. In the Active Group, two patients were excluded after the end of the study because it was found, in the final report issued by the PEMF emitting device, that the device was used for less than the minimum time established.

Thus, 36 individuals (18 in each group) were considered in the analysis of the results. None of these patients presented any treatment-related complications in the follow-up of the study.

The patients' ages ranged between 24.2 and 83.4 years, and the mean ages in the Active and Inactive Groups were, respectively, 50.4 and 51 years. (Table 1) There was no significant difference between the groups with respect to gender or smoking. Considering the number of levels included in the arthrodesis, there were no significant differences between the groups when considering the patients who underwent arthrodesis of one or two levels and those who underwent arthrodesis of three or more levels. (Table 1)

Table 1. Description of patient characteristics according to group.

Variable	Group				Total		p
	Inactive (N = 18)		Active (N = 18)		n	%	
	n	%	n	%			
Age (years)							0.915*
Mean (SD)	51 (13.1)		50.4 (18.0)		50.7 (15.5)		
Median (min.; max.)	49.6 (29.1; 79.0)		47.5 (24.2; 83.6)		48.6 (24.2; 83.6)		
Gender							0.505
Female	10	55.6	8	44.4	18	50.0	
Male	8	44.4	10	55.6	18	50.0	
Levels affected							> 0.999
Less than 3	12	66.7	12	66.7	24	66.7	
3 or more	6	33.3	6	33.3	12	33.3	
Smoking							> 0.999**
Yes	16	88.9	16	88.9	32	88.9	
No	2	11.1	2	11.1	4	11.1	

Chi-square test; * Student's t-test; ** Fisher's exact test

Table 2. Consolidation of vertebral levels according to group and assessment time.

Time	Inactive				Active				p
	Consolidated		Non-consolidated		Consolidated		Non-consolidated		
	n	%	n	%	n	%	n	%	
45	6	18.8	26	81.2	21	65.6	11	34.4	<0.001
90	27	69.2	12	30.8	32	86.5	5	13.5	0.071
180	30	78.9	8	21.1	37	92.5	3	7.5	0.086
360	36	94.7	3	5.3	39	97.5	1	2.5	0.610*

Chi-square test; * Fisher's exact test

Figure 4 and Table 2 show the occurrence of consolidation in each group over the evaluation time. The observed data suggest an increase in the percentage of consolidation throughout the follow-up for both groups of patients, with the rate of consolidation being greater in the Active Group. Table 2 shows that the times of assessment influenced the percentage of consolidation ($p < 0.001$), with the percentage of levels considered consolidated increasing over the assessment time; this effect was independent of group.

GEE analysis show that groups had the same behavior over the observed times ($p = 0.567$), groups are different in all assessment times ($p = 0.001$) and in both groups consolidation changed between assessment times ($p < 0.001$). Table 3 shows that the percentage of consolidation of vertebral levels increased over the assessment times, especially from 45 days to the 1 time points ($p < 0.001$). No significant increases were observed between 90 and 180 days ($p > 0.999$) or between 180 and 360 days ($p = 0.110$). Comparing both groups over one year, considering the consolidation of arthrodeses in each level operated, we found, using the Bonferroni method, that patients in the Active Group presented 16% more consolidation than patients in the Inactive Group ($p = 0.018$), independent of assessment time.

Patients in the Active Group presented a statistically higher percentage of consolidation, with a 276% greater chance of consolidation than patients in the Inactive Group (OR = 3.76; 95% CI: 1.39-10.20), regardless of the assessment time.

DISCUSSION

Lumbar arthrodesis is a routine procedure performed for the treatment of various degenerative diseases of the spine. Posterolateral arthrodesis, despite being widely used, can result in the incidence of pseudarthrosis, with rates ranging from 3% to 55%.²⁷ The wide variation in consolidation success rates found in the literature raises questions about which factors favorably or unfavorably influence success. Among these variables, we highlight the use of fixation,^{10,29} the type of graft or bone substitute used,^{12,18} associated interbody arthrodesis,^{1,5,13} patient-related factors (e.g., nutritional status, bone mass, and smoking), and the extent of surgery. Many of these studies consider morbidity and complications related to each technique, in addition to successful consolidation. This variability makes lumbar lumbosacral and arthrodesis a large and complex field.

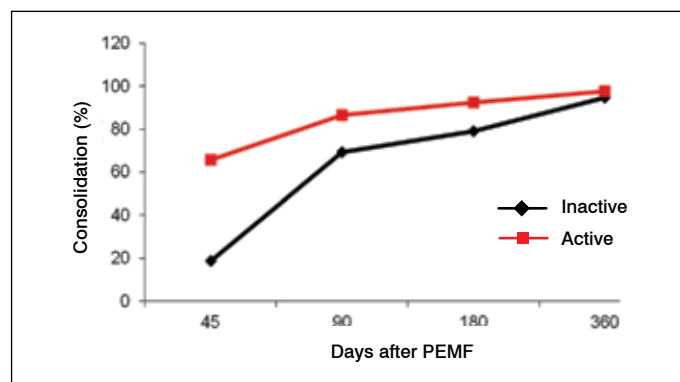


Figure 4. Percentage of consolidation of vertebral levels according to group and assessment time.

Table 3. Result of multiple comparisons between assessment times for the consolidation rates between groups.

Group/Time	Comparison		Mean or percent difference	Standard error	df	p	CI (95%)	
							Lower	Upper
Both groups	45 days -	90 days	-36.0	7.3	1	< 0.001	-55.0	-17.0
	45 days -	180 days	-43.0	7.0	1	< 0.001	-61.0	-25.0
	45 days -	360 days	-51.0	6.8	1	< 0.001	-69.0	-33.0
	90 days -	180 days	-7.0	4.9	1	0.912	-20.0	6.0
	90 days -	360 days	-15.0	4.6	1	0.005	-28.0	-3.0
	180 days -	360 days	-8.0	3.6	1	0.124	-18.0	1.0
All times	Inactive -	Active	-16.0	7.0	1	0.018	-30.0	-3.0

Another point to be discussed is the methods used to assess the occurrence of fusion.³⁵ Studies using simple static radiography,^{2,3,23} dynamic radiography,³⁶ computed tomography,^{23,30} and clinical criteria, in particular the complaint of pain,² were found in the literature. In addition to the variety of methods, the interpretation of the results is occasionally subjective and has low reproducibility.^{26,28}

The tomographic method with fine slices and volume acquisition was defined in recent studies as an option for assessment of the consolidation condition of lumbar arthrodesis.^{2,35,37}

We adopted CT with volume acquisition to define the occurrence of arthrodesis, performing the assessment with high-resolution monitors and the latest software. This method is currently regarded as the best non-invasive technique for diagnosing pseudarthrosis of the spine.^{28,35} Recent studies comparing the accuracy of CT with surgical exploration for the assessment of lumbar arthrodesis consolidation showed sensitivities of 53% to 63% and specificities of 78% to 86%.^{18,35} In our study, we interpreted the presence or absence of fusion using the Glassman method,^{24,30} to which we added the correction of the coronal plane at each level of arthrodesis to be studied.²⁵ The specific orientation of the coronal plane for each level of consolidation assessment makes the interpretation of the Glassman method clearer and more reproducible, especially at levels where there is a greater vertebral slope, as in the lumbosacral transition. The images were interpreted by two physicians who were experienced in the method, one of whom is a radiologist and the other an orthopedic spinal surgeon who was not involved in the surgical procedures.

A criticism to be raised in our methodology consists of exposing the patient to radiation to perform CT in the assessment of arthrodesis consolidation; however, we consider this risk justifiable, as it is the best noninvasive method available for this assessment.^{25,26,28}

Iliac autografts are considered the gold standard in studies evaluating spinal arthrodesis, as they present the best osteogenic, osteoinductive, and osteoconductive characteristics.^{16,38,39} However, their use can contribute to morbidity in the donor area, prolonging surgical time, increasing blood loss and the risk of infection, and causing post-surgical pain.^{16,17,38,40} As iliac graft substitutes, the literature cites the use of autografts obtained from the site of decompression,^{17,19} bone substitutes (e.g., bioceramics),¹⁸ and recombinant morphogenetic protein (rBMP).¹⁶

All of the patients in this study received autologous grafting with grafts harvested from the decompression area. According to the literature, this technique is equivalent to iliac grafts in arthrodeses of up to two levels.^{17,19,39} We had a statistically equivalent number of patients receiving arthrodeses of up to two levels and more than two levels in both groups. The arthrodesis bed was prepared with decortication of the entire available surface without the use of a high-speed burr.

The use of interbody arthrodesis to treat degenerative disease of the lumbar and lumbosacral spine has gradually become popularized since the 1980s.^{27,41} The theoretical advantages of interbody arthrodesis are: a larger area for fusion, better vascular supply, and positioning of the graft in an area of compressive forces.^{12,41} This

method also allows the restoration of both lordosis and disc height, with possible favorable effects on sagittal balance, and size gains in the spinal canal and foramen resulting from indirect decompression of neural structures.^{1,42}

Interbody arthrodesis can be performed via an anterior (ALIF - anterior lumbar interbody fusion), lateral (LLIF - lateral lumbar interbody fusion), transforaminal (TLIF - transforaminal lumbar interbody fusion) or posterior (PLIF - posterior lumbar interbody fusion) approach, with the latter two being the most common alternatives in our setting. These procedures carry a risk of higher morbidity and higher costs⁵, but optimize arthrodesis consolidation rates according to some studies.^{13,27,43} However, recent studies question the value of combining interbody and posterolateral arthrodesis to treat degenerative disease of the lumbar and lumbosacral spine, especially in terms of its cost-benefit ratio. This conclusion was reached because this technique may not add clinical benefit or present greater fusion success in the long term, compared to instrumented posterolateral arthrodesis alone.^{1,13,41,43-45}

Our experience confirms the most recent data from the literature, i.e. that posterolateral arthrodesis alone is still a good choice in the treatment of diseases of the lumbar and lumbosacral spine that have an indication for stabilization.

The ability of electricity to stimulate osteogenesis has been demonstrated in spinal surgeries since 1974.⁴⁶ Among the types of electrical stimulation studied as osteogenic techniques are direct current and current induced by a PEMF. Dwyer and Wickham⁴⁶ and Dwyer⁴⁷ were the first to report the use of electrical stimulation of spine. This group used an implanted device with direct current and showed an increased bone consolidation rate after arthrodesis surgery.

The first clinical study showing efficacy of a PEMF via an external, and therefore non-invasive, device was performed by Simmons⁴⁸ in 1985. This study involved 13 patients with pseudarthrosis after posterior interbody lumbar fusion (PLIF) surgery; 77% consolidation was reported, and no additional procedures were required. Since that time, several studies have been conducted with PEMF with differing results,^{49,50} but all favorable to the effect of PEMF. In animal models, increased mineral bone density,⁵¹ increased bone stiffness,^{22,52} and more rapid incorporation of bone grafts were observed with the use of PEMF, but no significant improvement was found in the final consolidation rate.^{21,23} In a prospective, double-blind, randomized clinical study, Mooney⁵⁰ observed a bone consolidation rate of 92% in interbody lumbar arthrodesis surgeries with the use of PEMF versus 65% in the control group. Bose³ found a consolidation rate of 97.9% after posterolateral lumbar arthrodesis, but the study was performed without a control group. In a more recent study by Simmons et al.,⁴⁹ using PEMF was found to be an effective and non-invasive procedure for consolidation of pseudarthrosis after posterolateral lumbar arthrodesis. Silver² retrospectively evaluated patients undergoing lumbar arthrodesis using PEMF, of whom 28 were subjected to posterolateral arthrodesis; a bone consolidation rate of 100% was reported. In another retrospective study, Marks⁴ evaluated 61 patients undergoing lumbar arthrodesis, with 42 using the device with PEMF and 19 not using the device. The

consolidation rate in the group using PEMF was 97.6% versus 52.6% in the group that received no stimulation ($p < 0.001$). None of the patients who received stimulation underwent posterolateral arthrodesis. A multicenter, prospective, randomized clinical trial was conducted to evaluate the use of PEMF in cervical arthrodesis. An acceleration of consolidation was observed with PEMF, with an increased consolidation rate at 6 months after surgery, but no statistically significant results were observed at 12 months.⁵³

Our study aimed to evaluate the most widespread type of arthrodesis in our setting and the use of local autograft, which is a method with lower morbidity and surgical cost. We found that consolidation in the group using the PEMF generating device occurred earlier than in the control group, although there was a trend over the follow-up period for the consolidation rates to become closer to those of the control group. This information calls into question the hypothesis that PEMF is a determinant in the final evolution of the consolidation process. However, the observed radiological signs of consolidation earlier in the group receiving PEMF suggests that this group would have a reduction of complications related to fatigue of the implant or bone-implant interface because these events are less frequent after the consolidation of arthrodesis. However, evidence is still lacking as to whether the earlier consolidation of arthrodesis translates into real clinical and functional benefits.

The main positive aspects of our study were the fact that it was the only prospective, double-blind clinical study to evaluate the effect of electromagnetic stimulus on the consolidation of instrumented posterolateral arthrodeses. We also highlight the fact that we used computed tomography as a method of measuring consolidation, which

according to the literature, is the best non-invasive method for this purpose. Performing serial computed tomography at specific times allowed us to verify the moments of occurrence of the consolidation. It should be noted that the main weakness of the study is that the small sample, which produced statistically significant data, did not allow us to evaluate the effect of the electromagnetic field in groups at risk for pseudoarthrosis such as diabetics, the elderly and smokers.

CONCLUSION

According to our results, the usage of PEMF in the post-operative period following instrumented arthrodesis of the lumbar spine in a heterogeneous group of patients with degenerative spine disease proved effective, increasing the rate of consolidation in the first post-operative year.

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REFERENCES

- Høy K, Bünger C, Niederman B, Helmig P, Hansen ES, Li H, et al. Transforaminal lumbar interbody fusion (TLIF) versus posterolateral instrumented fusion (PLF) in degenerative lumbar disorders: a randomized clinical trial with 2-year follow-up. *Eur Spine J*. 2013;22(9):2022–29.
- Silver R. Application of pulsed electromagnetic fields (PEMF) after lumbar interbody or posterolateral spinal fusion surgery in a heterogenous patient population. *J Neurol Orthop Med Surg*. 2001;21:51–62.
- Bose B. Outcomes after posterolateral lumbar fusion with instrumentation in patients treated with adjunctive pulsed electromagnetic field stimulation. *Adv Ther*. 2001;18(1):12–20.
- Marks RA. Spine fusion for discogenic low back pain: outcomes in patients treated with or without pulsed electromagnetic field stimulation. *Adv Ther*. 2000;17(2):57–67.
- Neumann P, Jalalpour K, Johansson C, Hedlund R. A RCT between transforaminal lumbar interbody fusion (TLIF) and posterolateral fusion in DDD and postdiscectomy syndrome. *Eur Spine J*. 2009;18(4 Suppl):S408.
- Faundez AA, Schwender JD, Safriel Y, Gilbert TJ, Mehdod AA, Denis F, et al. Clinical and radiological outcome of anterior–posterior fusion versus transforaminal lumbar interbody fusion for symptomatic disc degeneration: a retrospective comparative study of 133 patients. *Eur Spine J*. 2009;18(2):203–11.
- Barrera A, Chacón JG, Váscónez P, García Y. Evaluación clínico-radiológica de pacientes tratados con artrodesis posterolateral vs artrodesis circunferencial (360°) en columna lumbosacra: 10 años de experiencia. *Coluna/Columna*. 2012;11(2):162–5.
- Gibson JNA, Waddell G. Surgery for degenerative lumbar spondylosis: updated cochrane review. *Spine (Phila Pa 1976)*. 2005;30(20):2312–20.
- Fischgrund JS, Mackay M, Herkowitz HN, Brower R, Montgomery DM, Kurz LT. 1997 Volvo Award winner in clinical studies. Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective, randomized study comparing decompressive laminectomy and arthrodesis with and without spinal instrumentation. *Spine (Phila Pa 1976)*. 1997;22(24):2807–12.
- Angevine PD, Dickman CA, McCormick PC. Lumbar fusion with and without pedicle screw fixation. *Spine (Phila Pa 1976)*. 2007;32(13):1466–71.
- Andersen T, Videbæk TS, Hansen ES, Bünger C, Christensen FB. The positive effect of posterolateral lumbar spinal fusion is preserved at long-term follow-up: a RCT with 11–13 year follow-up. *Eur Spine J*. 2008;17(2):272–80.
- Christofer R, Timoty R. Transforaminal lumbar interbody fusion/posterior lumbar interbody fusion. In: Bridwell KH, Dewald RL. The textbook of spinal surgery. 3rd ed. Philadelphia: Lippincott Williams and Wilkins; 2011. p. 436–444.
- Han X, Zhu Y, Cui C, Wu Y. A meta-analysis of circumferential fusion versus instrumented posterolateral fusion in the lumbar spine. *Spine (Phila Pa 1976)*. 2009;34(17):E618–25.
- Kornblum MB, Fischgrund JS, Herkowitz HN, Abraham DA, Berkower DL, Ditkoff JS. Degenerative lumbar spondylolisthesis with spinal stenosis. *Spine (Phila Pa 1976)*. 2004;29(7):726–34.
- Frymoyer JW, Matteri RE, Hanley EN, Kuhlmann D, Howe J. Failed lumbar disc surgery requiring second operation. A long-term follow-up study. *Spine (Phila Pa 1976)*. 1978;3(1):7–11.
- Marchesi DG. Spinal fusions: bone and bone substitutes. *Eur Spine J*. 2000;9(5):372–8.
- Sengupta DK, Truemes E, Patel CK, Kazmierczak C, Hughes B, Elders G, et al. Outcome of local bone versus autogenous iliac crest bone graft in the instrumented posterolateral fusion of the lumbar spine. *Spine (Phila Pa 1976)*. 2006;31(9):985–91.
- Chen WJ, Tsai TT, Chen LH, Niu CC, Lai PL, Fu TS, McCarthy K. The fusion rate of calcium sulfate with local autograft bone compared with autologous iliac bone graft for instrumented short-segment spinal fusion. *Spine (Phila Pa 1976)*. 2005;30(20):2293–7.
- Inage K, Ohtori S, Koshi T, Suzuki M, Takaso M, Yamashita M, et al. One-, two-, and three-level instrumented posterolateral fusion of the lumbar spine with a local bone graft. *Spine (Phila Pa 1976)*. 2011;36(17):1392–6.
- Goodwin CB, Brighton CT, Guyer RD, Johnson JR, Light KI, Yuan HA. A double-blind study of capacitively coupled electrical stimulation as an adjunct to lumbar spinal fusions. *Spine (Phila Pa 1976)*. 1999;24(13):1349–56.
- Gan JC, Glazer PA. Electrical stimulation therapies for spinal fusions: current concepts. *Eur Spine J*. 2006;15(9):1301–11.
- Lind M, Bünger C. Factors stimulating bone formation. *Eur Spine J*. 2001;10(Suppl 2):S102–9.
- Linovitz RJ, Pathria M, Bernhardt M, Green D, Law MD, McGuire RA, et al. Combined magnetic fields accelerate and increase spine fusion. *Spine (Phila Pa 1976)*. 2002;27(13):1383–8.
- Laoutliv B, Havsteen I, Bech BH, Narvestad E, Christensen H, Christensen A. Interobserver agreement in fusion status assessment after instrumental desis of the lower

- lumbar spine using 64-slice multidetector computed tomography: impact of observer experience. *Eur Spine J*. 2012;21(10):2085–90.
25. Risso-Neto MI, Zuiani GR, Rossanez R, Mistro Neto S, Amato Filho ACS, Cavali PTM, et al. Reproducibility of tomographic evaluation of posterolateral lumbar arthrodesis consolidation. *Coluna/Columna*. 2015;14(2):108–12.
 26. Williams AL, Gornet MF, Burkus JK. CT evaluation of lumbar interbody fusion: current concepts. *Am J Neuroradiol*. 2005;26(8):2057–66.
 27. Gertzbein SD, Hulloper MR, Hall S. Pseudarthrosis of the lumbar spine. Outcome after circumferential fusion. *Spine (Phila Pa 1976)*. 1998;23(21):2352–6.
 28. Choudhri TF, Mummaneni PV, Dhall SS, Eck JC, Groff MW, Ghogawala Z, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 4: radiographic assessment of fusion status. *J Neurosurg Spine*. 2014;21(1):23–30.
 29. France JC, Yaszemski MJ, Lauerman WC, Cain JE, Glover JM, Lawson KJ, et al. A randomized prospective study of posterolateral lumbar fusion. *Spine (Phila Pa 1976)*. 1999;24(6):553–60.
 30. Carreon LY, Djurasovic M, Glassman SD, Sailer P. Diagnostic accuracy and reliability of fine-cut CT scans with reconstructions to determine the status of an instrumented posterolateral fusion with surgical exploration as reference standard. *Spine (Phila Pa 1976)*. 2007;32(8):892–95.
 31. Kirkwood BR, Sterne JA. *Essential medical statistics*. 2nd ed. Blackwell Science: Massachusetts, USA; 2006.
 32. Kleinbaum DG. *Survival analysis: a self-learning text*. New York: Springer; 1996.
 33. McCullagh P, Nelder JA. *Generalized linear models*. 2nd ed. New York: Chapman and Hall; 1989.
 34. Neter J, Kutner MH, Nachtsheim CJ, Wasserman W. *Applied Linear Statistical Models*. 4th ed. Homewood, IL: Richard D. Irwing; 1996.
 35. Chun DS, Baker KC, Hsu WK. Lumbar pseudarthrosis: a review of current diagnosis and treatment. *Neurosurg Focus*. 2015;39(4):E10–15.
 36. Rompe JD, Eysel P, Hopf C. Clinical efficacy of pedicle instrumentation and posterolateral fusion in the symptomatic degenerative lumbar spine. *Eur Spine J*. 1995;4(4):231–7.
 37. Gruskay JA, Webb ML, Grauer JN. Methods of evaluating lumbar and cervical fusion. *Spine J*. 2014;14(3):531–9.
 38. Muchler G, Tkigami H, Nakamoto C. Principles of bone fusion. In: Herkowitz H, Garfin SR, Eismont FJ, Bell GR, Baldestron RA. *Rothman-Simeone the spine*; 2006. p. 385–406.
 39. Miura Y, Imagama S, Yoda M, Mitsuguchi H, Kachi H. Is local bone viable as a source of bone graft in posterior lumbar interbody fusion? *Spine (Phila Pa 1976)*. 2003;28(20):2386–9.
 40. France J, Schuster J, Moran K, Dettori J. Iliac crest bone graft in lumbar fusion: the effectiveness and safety compared with local bone graft, and graft site morbidity comparing a single-incision midline approach with a two-incision traditional approach. *Global Spine J*. 2015;5(3):195–206.
 41. Glassman SD, Carreon LY, Ghogawala Z, Foley KT, McGirt MJ, Asher AL. Benefit of transforaminal lumbar interbody fusion vs posterolateral spinal fusion in lumbar spine disorders. *Neurosurgery*. 2015;79(3):397–405.
 42. Tohmeh AG, Khorsand D, Watson B, Zielinski X. Radiographical and clinical evaluation of extreme lateral interbody fusion. *Spine (Phila Pa 1976)*. 2014;39(26):E1582–91.
 43. Xiaoyang L, Wang Y, Qiu G, Weng X, Yu B. A systematic review with meta-analysis of posterior interbody fusion versus posterolateral fusion in lumbar spondylolisthesis. *Eur Spine J*. 2014;23(1):43–56.
 44. Liu XY, Qiu GX, Weng XS, Yu B, Wang YP. What is the optimum fusion technique for adult spondylolisthesis—PLIF or PLF or PLIF plus PLF? A meta-analysis from 17 comparative studies. *Spine (Phila Pa 1976)*. 2014;39(22):1887–98.
 45. Gottschalk MB, Premkumar A, Sweeney K, Boden SD, Heller J, Yoon ST, et al. Posterolateral lumbar arthrodesis with and without interbody arthrodesis for L4–L5 degenerative spondylolisthesis. *Spine (Phila Pa 1976)*. 2015;40(12):917–25.
 46. Dwyer A, Wickham G. Direct current stimulation in spinal fusion. *Med J Aust*. 1974;1(3):73–5.
 47. Dwyer A. The use of electrical current stimulation in spinal fusion. *Orthop Clin North Am*. 1975;6(1):265–73.
 48. Simmons JW. Treatment of failed posterior lumbar interbody fusion (PLIF) of the spine with pulsing electromagnetic fields. *Clin Orthop Relat Res*. 1985;(193):127–32.
 49. Simmons JW Jr, Mooney V, Thacker I. Pseudarthrosis after lumbar spine fusion: non-operative salvage with pulsed electromagnetic fields. *Am J Orthop (Belle Mead NJ)*. 2004;33(1):27–30.
 50. Mooney V. A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions. *Spine (Phila Pa 1976)*. 1990;15(7):708–12.
 51. Androjna C, Fort B, Zborowski M, Midura RJ. Pulsed electromagnetic field treatment enhances healing callus biomechanical properties in an animal model of osteoporotic fracture. *Bioelectromagnetics*. 2014;35(6):396–405.
 52. Glazer P, Heilmann M, Lotz J, Bradford D. Use of electromagnetic fields in Spinal Fusion. A Rabbit Model. *Spine (Phila Pa 1976)*. 1997;22(20):2351–6.
 53. Foley KT, Mroz TE, Arnold PM, Chandler HC Jr, Dixon RA, Girasole GJ, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J*. 2008;8(3):436–42.