

General

Pulsed Electromagnetic Fields for Cervical Spine Fusion in Patients with Risk Factors for Pseudarthrosis

Todd Lansford, MD¹, Peter Campbell, MD², Hamid Hassanzadeh, MD³, Marc Weinstein, MD⁴, Joshua Wind, MD⁵, Andrew Beaumont⁶, Amir Vokshoor, MD⁷, Kristen Radcliff⁸, Ilyas Aleem, MD⁹, Domagoj Coric, MD¹⁰

¹ South Carolina Sports Medicine, Charleston, SC, USA, ² Spine Institute of Louisiana, Shreveport, Louisiana, USA, ³ University of Virginia, Charlottesville, Virginia, USA, ⁴ Florida Orthopedic Institute, Tampa Bay, Florida, USA, ⁵ Inova Neurosurgery, Leesburg, VA, USA, ⁶ Aspirus Spine and Neurosciences Institute, Wausau, Wisconsin, USA, ⁷ Institute of Neuro Innovation, Santa Monica, California, USA, ⁸ Rothman Institute, Philadelphia, Pennsylvania, USA, ⁹ University of Michigan, Ann Arbor, Michigan, USA, ¹⁰ Carolina Neurosurgery and Spine Associates, Charlotte, North Carolina, USA

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Background

Certain demographics and/or risk factors contribute to complications following cervical spinal surgery including pseudarthrosis, prolonged pain, and reduced quality of life (QoL). Pulsed electromagnetic field (PEMF) stimulation is a non-invasive therapy that may enhance fusion success in at-risk patients.

Objective

To evaluate the safety and efficacy of post-operative adjunctive PEMF therapy following cervical spinal surgery in subjects at risk for pseudarthrosis.

Methods

This prospective, multicenter study investigated PEMF as an adjunctive therapy to cervical spinal fusion procedures in subjects at risk for pseudarthrosis based on having at least one of the following: prior failed fusion, multi-level fusion, nicotine use, osteoporosis, or diabetes. Radiographic fusion status and patient-reported outcomes (SF-36, EQ5D, NDI, and VAS-arm pain and VAS-neck pain) were assessed.

Results

A total of 160 subjects were assessed for fusion 12-months postoperative, and 144 subjects were successfully fused (90.0%). Fusion success for subjects with 1, 2+, or 3+ risk factors was 91.7%, 89.0%, and 90.9%, respectively. Significant improvements in NDI, VAS-arm and VAS-neck were observed compared to baseline scores ($p < 0.001$) along with improvements in SF-36 and EQ5D ($p < 0.001$).

Conclusions

Adjunctive treatment with PEMF provides a high rate of successful fusion and significant improvements in pain, function, and quality of life despite having risk factors for pseudarthrosis.

INTRODUCTION

Pulsed electromagnetic field (PEMF) stimulation is a type of targeted non-invasive therapy that utilizes electromagnetic fields to produce beneficial effects in certain clinical indications. PEMF has been established in multiple indications with significant efficacy and favorable safety profiles. Clinical benefit has been reported in musculoskeletal injury and disease including bone fracture healing, cervical disc herniation, nerve regeneration, osteoarthritis, fibromyalgia, and osteoporosis.¹⁻⁵ These effects are due to a variety of key ac-

tions on inflammatory, regenerative and protective cellular processes.⁶⁻⁸

PEMF acts at cell membrane receptors to engage signaling systems through adenosine receptors and impacts synthesis of structural and signaling extracellular matrix (ECM) components.⁹ Through these actions, PEMF can increase the structural integrity of bone and cartilage ECM, enhances repair mechanisms, and increases anti-inflammatory effects.¹⁰⁻¹³ PEMF modulates inflammatory processes through the regulation of pro- and anti-inflammatory cytokine secretion during various stages of the inflammatory response.^{7,14,15} PEMF exerts a pro-anabolic effect on bone

and cartilage matrix and a chondroprotective effect counteracting the catabolic effects of inflammation in the joints.⁶ Beneficial effects of PEMF are also observed through interactions on growth hormone and insulin-like growth factor-1 pathways to stimulate bone growth and remodeling.¹⁶ Collectively, the mechanistic underpinnings and clinical evidence supporting PEMF in musculoskeletal indications underlies further investigations in at-risk patient populations undergoing spinal surgeries.

Identification and quantification of risk factors contributing to complications following spinal surgery are important for clinical treatment plans and successful patient outcomes. Certain risk factors are known to contribute to lower fusion rates (e.g., smoking, diabetes, osteoporosis, advanced age). Unsuccessful fusion may result in worse patient-reported outcomes, development of new pain or recurrent symptoms, continued degeneration at a level next to a previous surgery, revision spinal surgeries, and a higher financial burden.¹⁷ Adjunct therapies that can be used post-operatively to aid in successful fusion are of interest with a potential for high impact in this patient population. PEMF induces a low-level electrical field at the fusion site to stimulate bone healing and in turn improve cervical spine fusion rates. PEMF is indicated as an adjunct to cervical fusion surgery in patients at high risk for pseudarthrosis; there are no known contraindications. Prior studies have shown that PEMF stimulates bone healing and can be a valuable tool to help overcome biological deficiencies in patients at risk for bone healing.¹⁸ The current study further evaluates the adjunct effect of PEMF in subjects undergoing cervical spinal surgery presenting with risk factors for pseudarthrosis.

MATERIALS AND METHODS

STUDY PARTICIPANTS

Subjects were eligible for the study (NCT03177473) if they were at least 18 years of age, had at least 1 risk factor for pseudarthrosis, with a body mass index (BMI) ≤ 45 kg/m² at the time of consent. Subjects were excluded from the study with any active malignancy or prior history of malignancy within the last 5 years prior to fusion surgery (except basal cell carcinoma of the skin), current alcoholism, currently taking pain medications, any known current addiction and any psychiatric illness that prevented subject from completing the study assessments.

STUDY DESIGN

A post-market, open-label, prospective study was conducted to examine the effectiveness of PEMF as an adjunct treatment following cervical spinal fusion surgery using the CervicalStim™ device (Orthofix US LLC, Lewisville, TX, USA). Subjects undergoing cervical spinal fusion surgery with one or more risk factors for pseudarthrosis were identified for enrollment from 11 investigator sites. Risk factors for pseudarthrosis included multilevel (2 or more levels) fusion, prior failed cervical spine fusion, diabetes, osteo-

porosis, or smoking. Exploratory factors included BMI and age. The primary outcome measure was fusion status at the 12-month follow-up period. Fusion status was determined at the 12-month visit using anterior/posterior, lateral, and flexion/extension radiographs and computed tomography (without contrast). patient-reported outcomes including Neck Disability Index (NDI), EQ5D, SF-36, and visual analog scale for pain (VAS pain for neck and arm) were collected as secondary outcome measures.

PULSED ELECTROMAGNETIC FIELD INTERVENTION

Subjects received PEMF therapy via the CervicalStim™ device designed specifically for cervical spinal use in the home setting. CervicalStim™ is the only bone growth stimulation therapy device approved by the FDA as a non-invasive adjunctive treatment option for cervical fusion in patients at high-risk for pseudarthrosis. The CervicalStim™ device generates repeating burst groups of multiple pulses of electromagnetic energy by delivering time varying electrical signals to a treatment coil, where the groups of multiple pulses repeat at a constant interval while a treatment session is active. CervicalStim™ provides 360 degrees of PEMF treatment around the fusion site that evenly penetrates across tissue, bone and fixation.¹⁹ No clinician oversight is necessary for use of the device. Subjects initiated PEMF treatment within 14 days of surgery. Subjects were required to wear the CervicalStim™ device for 4 hours/day for 6 months.

STATISTICAL ANALYSES

Data were analyzed with SAS Version 9.4 (SAS Institute, Cary, NC). Efficacy data including pseudarthrosis rates and patient-reported outcomes used data from the 160 subjects that completed the 12-month post-operative assessment. Safety data was collected from all 211 subjects enrolled. Counts and percentages are reported for categorical baseline variables, the mean standard deviation (SD) and range are reported for continuous variables. Pre-operative and post-operative patient-reported outcomes were compared with a Wilcoxon signed rank test. Correlation of outcomes to risk factors was calculated by chi-square test or by Fishers exact test if a count was less than 5. Alpha was set at 0.05 and a p-value ≤ 0.05 was considered significant. Figures are presented with error bars showing the standard error of the mean ($\pm$ SEM) unless otherwise noted.

RESULTS

PARTICIPANTS

A total of 291 subjects were screened, 211 subjects met the criteria for eligibility and were enrolled. There were 160 subjects with a fusion assessment at 12-months. Fifty-one subjects did not complete the 12-month follow-up visit; 16 subjects withdrew consent, 2 subjects were non-compliant, 6 subjects were withdrawn by the investigator, 1 subject was enrolled but did not meet the inclusion/exclusion criteria,

Table 1. Patient Demographics and Characteristics.

Variable	Total n=160 n (%)
Age (yr)	
Mean (SD)	61.0 (11.4)
Min-Max	27.2 – 89.8
Sex	
Female	88/160 (55.0)
Male	72/160 (45.0)
BMI (kg/m ²)	
Mean (SD)	30.0 (5.2)
Min-Max	18.3–44.8
BMI ≥ 30	82/160 (51.3)
BMI < 30	78/160 (48.8)
Ethnicity	
Hispanic or Latino	5/160 (3.1)
Not Hispanic or Latino	154/160 (96.3)
Unknown	1/160 (0.6)
Race	
Caucasian or White	139/160 (86.9)
Black or African American	14/160 (8.7)
Other	7/160 (4.4)
Average No. of Levels Fused	
Mean (SD)	2.8 (1.2)
Min-Max	1–7
Average No. of Risk Factors	
Mean (SD)	1.8 (0.7)
Min-Max	1–4
≥ 2 Risk Factors	89/160 (55.6)
Work Status	
Full Time	45/160 (28.1)
Part Time	10/160 (6.3)
Not Working	105/160 (65.6)
Insurance	
Private Insurance	60/160 (37.7)
Other Insurance	99/160 (62.3)

and was subsequently removed from the study, and 26 subjects were lost to follow up (12.3%) ([Table 1](#)).

The mean age was 61.0 ± 11.4 (range 27.2–89.8) years, with a mean BMI of 30.0 ± 5.2 kg/m² (range 18.3–44.8), and included 88 (55.0%) females. A total of 51.3% (n = 82/160) of subjects had a BMI ≥ 30 kg/m². Over half of the subjects (55.6%) had 2 or more risk factors for pseudarthrosis ([Table 2](#)).

RISK FACTORS

Risk factors included nicotine use, diabetes, osteoporosis, prior failed fusion, multi-level disease, BMI ≥ 30 kg/m², and age > 65. The presence of osteoporosis was the only risk factor that showed a significant difference in the proportion

of subjects that fused (osteoporosis fusion rate was 82.4% vs. 95.4% without osteoporosis, p = 0.03) ([Table 2](#)).

FUSION SUCCESS

Out of 160 subjects, 90.0% (n=144/160) were graded as fused (all levels) at the 12-month visit with 10.0% graded as non-fused (n=16/160) ([Figure 1A](#)). Fusion success was 91.7% (n=55/60) for subjects with a single risk factor, 89.0% (n=89/100) for subjects with 2 or more risk factors and 90.9% (n=20/22) for subjects with 3 or more risk factors ([Figure 1B](#)).

Out of 160 subjects, 3.7% (n= 6/160) underwent a 1-level procedure, 48.8% (n=78/160) underwent a 2-level procedure, 26.9% (n=43/160) underwent a 3-level procedure, 13.1% (n=21/160) underwent a 4-level procedure, 1.9% (n=3/160) underwent a 5-level procedure, 4.4% (n=7/160) underwent a 6-level procedure, and 1.3% (n=2/160) underwent a 7-level procedure. A total of 47.5% (n=76/160) of subjects had 3 or more levels fused and had an 89.5% fusion rate.

CLINICAL OUTCOMES

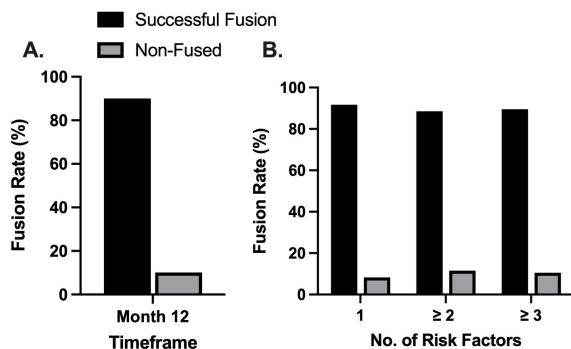
A significant improvement in SF-36 mental component score (MCS) and physical component score (PCS) was observed at 12-months post-operation. The overall pre-operative mean MCS score was 46.2 ± 11.0 and improved to 50.2 ± 11.6 (p = 0.0009) at 12 months. The overall pre-operative mean PCS score was 33.5 ± 7.9 and improved to 41.2 ± 10.4 (p < 0.001) at 12 months ([Figure 2A](#)). A significant improvement in EQ5D was observed at 12-months post-operation. The overall pre-operative mean EQ5D score was 0.66 ± 0.16 and improved to 0.77 ± 0.15 (p < 0.0001) at 12 months ([Figure 2B](#)). A significant improvement in VAS-neck pain score was observed at 12-months post-operation. The overall preoperative mean VAS-neck pain score was 52.7 ± 28.9 and improved to 22.0 ± 25.8 (p < 0.0001) at 12 months. A significant improvement in VAS-arm pain score was observed at 12-months post-operation (p < 0.0001). The overall preoperative mean VAS-arm pain score was 69.7 ± 51.4 and improved to 35.3 ± 45.7 (p < 0.0001) at 12 months ([Figure 2C](#)). A significant improvement in NDI was observed at 12-months post-operation. The overall pre-operative mean NDI score was 43.9 ± 18.9 and improved to 26.2 ± 19.9 (p < 0.0001) at 12 months ([Figure 2D](#)).

SAFETY OUTCOMES

Over the 12-month study, a total of 715 adverse events (AE) and 69 (9.7%) serious AEs (SAE) were reported. In regard to relatedness, the majority of AEs (94.7%, n = 677) were considered unrelated to the PEMF treatment. Whereas two AEs (0.3%) were considered definitely related, 25 (3.5%) possibly related, and 11 (1.5%) probably related ([Table 3](#)). The most commonly reported AEs considered related to PEMF treatment included headaches, pain, stiffness, and muscle spasms. Six subjects reported AEs that led to discontinued treatment.

Table 2. Patient Risk Factors.

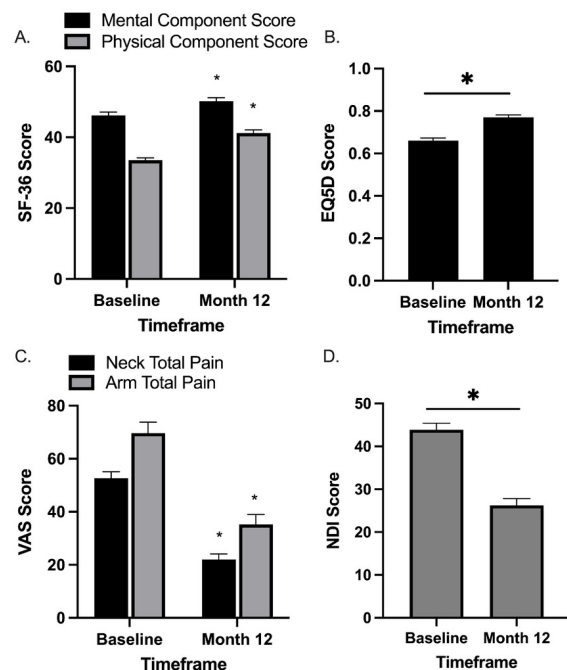
Variable	Fusion Success n (%)	p - value
BMI Risk Factor		
BMI ≥ 30	74/82 (90.2)	1.0
BMI < 30	70/78 (89.7)	
Nicotine Risk Factor		
Smoker	30/36 (83.3)	0.1
Non-Smoker	114/124 (91.9)	
Age Risk Factor		
Age 65 +	59/66 (89.4)	0.7
Age < 65	83/91 (91.3)	
Diabetes Risk Factor		
Diabetes	42/46 (91.3)	1.0
No Diabetes	102/114 (89.5)	
Osteoporosis Risk Factor		
Osteoporosis	28/34 (82.4)	0.03
No Osteoporosis	83/87 (95.4)	
Prior Failed Fusion		
Prior Failed Fusion	24/27 (88.9)	0.7
No Prior Failed Fusion	120/133 (90.2)	
Multiple Levels		
Multiple Levels	140/154 (90.9)	0.1
Single Level	4/6 (66.7)	

**Figure 1. Fusion Success at 12 Months Following Pulsed Electromagnetic Field Stimulation.**

A. Subjects showed an overall successful fusion rate of 90.0% (n=144/160) following pulsed electromagnetic field stimulation. B. High rate of fusion success were observed regardless of the number of risk factors.

DISCUSSION

The current study evaluated PEMF as an adjunct therapy for cervical spinal surgery in subjects with risk factors for pseudarthrosis. A high rate of spinal fusion (90.0%) and improvements in all patient-reported outcomes was observed at 12-month post-operation. The results of our study suggest that adjunctive use of PEMF is effective in cervical spine surgery patients with risk factors associated with pseudarthrosis. Favorable fusion rates were obtained with

**Figure 2. Clinical Assessments Following Pulsed Electromagnetic Field Stimulation at 12-Months.**

A. Significant improvements in SF-36 mental ($p = 0.0003$) and physical ($p < 0.001$) component scores, B. EQ5D scores ($p < 0.0001$), C. VAS-Neck and VAS-Arm total pain scores ($p < 0.0001$), and D. NDI scores ($p < 0.0001$), were observed.

Table 3. Adverse Events.

Adverse Event Reports	# of Events n, %
# of AEs	715
# of SAEs	69
# of Subjects with ≥ 1 AE	167
Expectancy of AE	
Expected	147, 20.6
Unexpected	568, 79.4
Relatedness of AE	
Definitely	2, 0.3
Possibly	25, 3.5
Probably	11, 1.5
Unrelated	677, 94.7
Severity of AE	
Mild	451, 63.1
Moderate	194, 27.1
Severe	70, 9.8

this challenging population, despite having elevated comorbidity and/or complex surgeries.

Fusion rates between subjects having specific risk factors for pseudarthrosis compared to those that did not were similar with the exception of those with osteoporosis. Results suggest that PEMF has potential to overcome risk factor-associated deficiencies with bone healing. Of the risk factors analyzed, only the presence of osteoporosis showed a significant difference in the proportion of subjects that fused vs. those that did not fuse (osteoporosis fusion rate was 82.4% vs. 95.4% without osteoporosis). Osteoporosis predisposes patients to potential complications such as progressive spinal deformities, the need for revision surgery, neurologic compromise, and is therefore a major concern for spinal surgery.²⁰ Patients with osteoporosis show fusion rates ranging from 78.8-95.8% with increased incidences of instrumentation failure, need for revision surgery, and a significantly higher risk of complications such as intraoperative blood volume loss and postoperative thromboembolic events.²¹⁻²⁷ Our findings showed a lower fusion rate of patients with osteoporosis compared to subjects with no osteoporosis. However, the observed fusion rate of 82.4% is within the range observed for fusion success within this patient population. A recent systematic review and meta-analysis found improvement in osteoporosis symptoms such as pain, stiffness, and physical function in patients treated with PEMF compared to other conservative treatments.²⁸ PEMF may pose a useful adjunct treatment modality post-surgery to improve both fusion success and patient symptoms with osteoporosis.

Previous studies have shown a difference in fusion rates based on selected risk factors including smoking, age, diabetes, and multilevel fusion.²⁹⁻³¹ Using the current standard of care, smokers show a poorer early fusion effect and 1-year fusion rate compared to non-smokers. Both gender and smoking status are considered key factors for 1-year

fusion rate. Multivariable analyses show male gender, current smoking status, age, and cervical instability are significantly associated with lower fusion rates and poor surgical outcomes.^{32,33} Diabetic patients show increased complications with multilevel fusion and significantly greater pseudarthrosis rates (success of 74.0-78.0%) compared with controls (95.0%) following lumbar fusion.³⁴ Subjects undergoing multilevel surgery have a high rate of complications with estimates up to 50%.³⁵ Individuals undergoing multilevel surgery show an increased risk for revision surgeries and non-union. Laratta et al. evaluated 46 subjects for outcomes following multilevel surgery and found 35% returned to surgery within two years and 24% returned for non-union.³⁶ The current study showed a 90.9% fusion success rate among subjects that underwent multilevel fusion. Our results suggest that PEMF can offset pseudarthrosis risk for patients that are smokers, have diabetes, have a prior failed fusion, and/or a multilevel fusion with improved outcomes compared to the current standard of care. These findings are in keeping with a previous study using PEMF with the CervicalStim™ device completed by Foley et al. which found statistically significant higher rates of fusion success following anterior cervical discectomy in patients who were smokers and/or were undergoing multilevel fusions. At 6 months postoperatively, a success rate of 83.6% following PEMF (vs. 68.6% for control) was observed and at 12 months, a success rate of 92.8% following PEMF (vs. 86.7% for control) was observed.

Despite having elevated comorbidities, the subjects in this study achieved significant improvements in patient-reported outcomes that measure disability, pain, quality of life and overall well-being. These findings are in keeping with other reports that have investigated similar patient populations with PEMF adjunct therapy. Subjects with cervical osteoarthritis treated with PEMF therapy show improvements in pain, muscle spasm, and joint movements

compared to the control.³⁷ Similarly, a significant improvement in neck pain and joint range of motion was observed in patients with chronic neck pain receiving PEMF therapy compared to control.³⁸ A randomized, controlled trial in subjects with cervical disc herniation showed significant improvement in neck pain, disability, depression, anxiety, and quality of life scores after PEMF treatment.¹ These findings also translate to significant improvements in pain and disability scores following PEMF in other indications with improvements observed following acute treatment.²

The study presents with several limitations. A lack of a comparative arm does not allow for direct comparisons of fusion success and patient-reported outcomes in subjects that were not treated with PEMF. While no comparative arm was included, we pose that the reported rates are in keeping and of interest in this at-risk population when compared with other clinical evidence. Further studies are planned to evaluate direct comparisons with a control group to elucidate the magnitude of benefit using PEMF.

CONCLUSIONS

Treatment with PEMF provides post-operative benefits aiding in fusion outcomes in patients at risk for pseudoarthrosis and complications. Successful fusion was observed in parallel to improved patient-reported outcomes following PEMF treatment with CervicalStim™. Future research is planned to include a control group in a real world setting to better assess the impact of PEMF in at risk populations.

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CORRESPONDING AUTHOR

Name: Todd Lansford, MD
Address: 9100 Medcom St, North Charleston, SC 29406
Phone Number: (843) 572-2663
Email: tlansford@gmail.com

CONFLICTS OF INTEREST

All authors have received financial support from Orthofix US LLC for their involvement in the study. Orthofix US

LLC was involved in the design of the study, analyses, and interpretation of data and in writing of the manuscript. In addition, Ilyas Aleem reports receiving consulting fees from Globus. Peter Campbell reports receiving payment/honoraria from Stryker (speakers' bureau) and serves as a consultant for Nexus Spine. Dom Coric reports royalties/licenses and consulting fees from Medtronic, Globus/Nuvasive, and SpineWave and stock/ stock options from SpineWave and Premia. Kristen Radcliff reports consulting fees from Orthofix, 4 web, and Stryker and stock/stock options from 4web and Orthoson. Amir Vokshoor reports research contracts from Spine Art, Orthofix, and Synergy and royalties/licenses from Globus Medical. Joshua Wind reports payment/honoraria from Orthofix (speaker's fee). Hamid Hassanzadeh reports consulting fees from Nuvasive, Medtronic, DePuy, and Orthofix; payment/honoraria from Pfizer and Nuvasive; support for attending meetings from Nuvasive; and a leadership role at the Scoliosis Research Society.

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AUTHOR CONTRIBUTIONS

All authors have contributed to at least (1) study concept/design, (2) Data acquisition, (3) Statistical analysis and/or Data interpretation. All authors have read and agreed to the published version of the manuscript.

INSTITUTIONAL REVIEW BOARD STATEMENT

The study was conducted in accordance with the Declaration of Helsinki and approved by the Central Western Institutional Review Board (IRB) (20170949) and local IRBs where applicable (Aspirus Research Institute (17.07.487), University of Virginia (20189), and Rothman Institute (2018-0149)).

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study.

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