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**Anterior Cervical Discectomy and Fusion: Correlation of Fusion Status with Clinical Outcome**

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**INTRODUCTION:** Although fusion is a common surgical treatment for cervical disc disease, there is no definitive study that demonstrates that radiographic union is associated with an improved clinical outcome as compared to nonunion. In fact, several studies have suggested that pseudoarthrosis of the cervical spine is typically asymptomatic and that clinical outcome cannot be correlated with fusion status. The purpose of this study was to investigate the relationship of fusion status and clinical outcome in a multicenter, prospective, randomized controlled clinical trial of the safety and efficacy of pulsed electromagnetic field stimulation as an adjunct to cervical spine fusion.

**METHODS:** Patients with symptomatic radiculopathy and correlating radiographic evidence of cervical nerve root compression were candidates for entry into the study. All patients were either smokers (at least one pack/day) or required multi-level surgery and underwent anterior cervical discectomy and Smith-Robinson fusion using allograft bone and anterior cervical plating (single plating system). Patients were randomized to receive pulsed electromagnetic field stimulation (PEMF) or not (non-PEMF). They were assessed preoperatively and at 1, 3, 6, and 12 months postoperatively and annually thereafter until the last patient enrolled had reached 12 months follow-up. Parameters included a focused neurological exam, a visual analogue scale for pain, the Oswestry Neck Disability Index (NDI) for function, and radiographs. Fusion status was determined in a blinded fashion by two independent orthopedic spine surgeons as well as an independent radiologist and rated as "fused" or "not fused" based upon radiolucency, bony bridging, and motion on flexion-extension views. For this study, the fusion status was correlated with the patient-derived outcome measures. Student's t-test was used for statistical analysis and significance was set at  $p \leq 0.05$ .

**RESULTS:** Three-hundred-twenty-three patients were enrolled in the study; 160 in the non-PEMF (control) group and 163 in the PEMF group. Both groups were comparable with regard to gender, age, race and risk factors. Equal numbers were lost to follow-up in both groups. Of the 240 patients available for evaluation at 6 months, the fusion rate was 83.61% (102/122) in the PEMF group and 68.64% (81/118) in the non-PEMF group ( $p=0.0065$ ). There were no significant differences in outcome measures between the PEMF and non-PEMF groups. However, when correlating fusion status with clinical outcome, statistically significant differences in visual analogue pain scores at rest ( $p=.0189$ ) and with activity ( $p=.0125$ ) were seen, with fused patients having significantly less pain at 6 months postoperatively than patients who were not rated as fused (Table 1).

**CONCLUSIONS:** This is the first randomized, prospective, multicenter trial to investigate the relationship between fusion status and clinical outcome for anterior

cervical discectomy and fusion (ACDF). The study results indicate that fusion does correlate with greater pain relief at rest and upon activity than does nonunion 6 months following surgery. Thus, efforts to enhance fusion rates would seem to have a demonstrable clinical rationale. Analysis of the relationship between fusion and clinical outcome at one year following ACDF are ongoing.

Table 1

Correlation between Radiographic Fusion Outcome and Pain, General Health Status, and Neck Disability Index at 6 Months Follow-up

	Fused			Not Fused			
Assessment	N	Mean	SD	N	Mean	SD	p-value [1]
Pain at Rest (VAS)	163	2.1	2.6	52	3.1	2.9	0.0189
Pain upon Activity (VAS)	163	2.9	3.0	52	4.2	3.4	0.0125
SF-12 Physical Health Score	150	42.0	11.2	46	39.0	10.8	0.1110
SF012 Mental Health Score	150	48.4	11.9	46	49.3	11.2	0.6434
Neck Disability Index	162	26.0	20.2	50	30.8	24.2	0.1588