ZUSAMMENSTELLUNG VON WISSENSCHAFTLICHEN PUBLIKATIONEN ZUR WIRKUNG VON PULSIERENDER MAGNETFELDTHERAPIE BEI DISCUSPROLAPS

2000

Spine fusion for discogenic low back pain: outcomes in patients treated with or without pulsed electromagnetic field stimulation

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.

2002

Combined magnetic fields accelerate and increase spine fusion: a double-blind, randomized, placebo controlled study

Abstract

STUDY DESIGN: The clinical study conducted was a prospective, randomized, double-blind, placebo-controlled trial.
OBJECTIVES: The purpose of this study was to evaluate the effect of combined magnetic fields on the healing of primary noninstrumented posterolateral lumbar spine fusion.
SUMMARY OF BACKGROUND DATA: Combined magnetic fields, a new type of biophysical stimulus, have been shown to act by stimulating endogenous production of growth factors that regulate the healing process. This is the first placebo-controlled study to assess the effect of an electromagnetic stimulus on primary noninstrumented posterolateral lumbar spine fusion surgery as well as the first evaluation of combined magnetic fields as an adjunctive stimulus to lumbar spine fusion.
METHODS: This multicenter investigational study was conducted at 10 clinical sites under an Investigational Device Exemption from the United States Food and Drug Administration. Eligible patients had one-level or two-level fusions (between L3 and S1) without instrumentation, either with autograft alone or in combination with allograft. The

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combined magnetic field device used a single posterior coil, centered over the fusion site, with one 30-minute treatment per day for 9 months. Randomization was stratified by site and number of levels fused. Evaluation was performed 3, 6, and 9 months after surgery and 3 months after the end of treatment. The primary endpoint was assessment of fusion at 9 months, based on radiographic evaluation by a blinded panel consisting of the treating physician, a musculoskeletal radiologist, and a spine surgeon.
RESULTS: Of 243 enrolled patients, 201 were available for evaluation. Among all patients with active devices, 64% healed at 9 months compared with 43% of patients with placebo devices: a significant difference (P = 0.003 by Fisher's exact test). Stratification by gender showed fusion in 67% of women with active devices, compared with 35% of those with placebo devices (P = 0.001 by Fisher's exact test). By contrast, there was not a statistically significant effect of the active device in this male study population. In the overall population of 201 patients, repeated measures analyses of fusion outcomes (by generalized estimating equations) showed a main effect of treatment, favoring the active treatment (P = 0.030). In a model with main effect and a time by treatment interaction, the latter was significant (P = 0.024), indicating acceleration of healing. Performed in the full sample of 243 patients, results of the intent-to-treat analysis were qualitatively the same as in the evaluable sample of 201 patients.
DISCUSSION: This investigational study demonstrates that combined magnetic field treatment of 30 min/d increases the probability of successful spine fusion, and statistical analysis using the generalized estimating equations model suggests an acceleration of the healing process. This is the first randomized clinical trial of noninstrumented primary posterolateral lumbar spine fusion, with evaluation by a blinded, unbiased panel. This is the first double-blind study performed to date assessing noninstrumented fusion outcome with extremely critical radiographic criteria. The lower overall fusion rates in this study are attributed to the high-risk patient group with an average age of 57 years, the use of noninstrumented technique with posterolateral fusion only, and the reliance on extremely critical radiographic and clinical criteria and blinded panel for fusion assessment without surgical confirmation.
CONCLUSIONS: In conclusion, the adjunctive use of the combined magnetic field device was statistically beneficial in the overall patient population, as has been shown in previous studies of adjunctive bone growth stimulation for spine fusion. For the first time, stratification of fusion success data by gender demonstrated that the female study population responded positively to the adjunctive combined magnetic field treatment, with no statistically significant effect observed in the male study population. Adjunctive use of the combined magnetic field device significantly increased the 9-month success of radiographic spinal fusion and showed an acceleration of the healing process.

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