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Effects of pulsed electromagnetic stimulation on patients undergoing hip revision prostheses: a randomized prospective double-blind study.

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Abstract

In this prospective, randomized, double-blind study, the effect of Pulsed Electromagnetic Fields (PEMFs) was investigated in 30 subjects undergoing hip revision using the Wagner SL stem. The subjects were treated for 6 h/day up to 90 days after revision. Study end points were assessed clinically by the functional scale of Merle D'Aubigné and instrumentally by Dual-Energy X-ray Absorptiometry (DXA) at the Gruen zones. Subject improvement according to Merle D'Aubigné scale was higher ($P < 0.05$) in subjects undergoing active stimulation compared to placebo. In analyzing the DXA findings, we subtracted for each area the postoperative bone mineral density (BMD) values from those measured at 90 days and we considered all results above 3.5% as responders. There were no significant differences in the average BMD values at each Gruen zone between the two groups both postoperatively and at 90 days investigation. In Gruen zones 5 and 6, corresponding to the medial cortex, we observed six responders (40%) in both areas in the control group, while in the stimulated group we observed 14 (93%) and 10 (66%) responders, respectively (both $P < 0.05$). This study showed that PEMF treatment aids clinical recovery and bone stock restoration.

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In this respect, PEMF-treatment may be particularly suitable for ODs of the talus since its bone-healing capacity has been proven [8,26,27,66].

This trial will contribute to the knowledge of the effectiveness of PEMF, and may improve health care of patients with an OD. Given the modality's relatively simple technology and ease of use, it has high potential to provide a safe and effective additional treatment option for ODs of the talus.

PEMFs have been studied for the osteointegration of joint replacement prostheses. There are 2 aspects to this: the treatment of loosened prostheses and the use of PEMFs after a revision.

In the first scenario (treatment of loosened prostheses) the intention is to reduce the need for a revision. In one study, 132 patients had PEMF therapy for advanced loosening of their prosthesis. Treatment was done 2-3 times a day for 40 minutes each time, for 20 weeks. Follow up was done over the course of 5 years. A revision procedure was no longer deemed necessary in 70% of patients.

In an extension of this research, PEMF therapy was administered to more than 1,000 patients with loosened artificial hips. The PEMF signal used was 30 gauss with frequencies ranging from 2 to 20 Hz. The treatment lasted for either 6 months, or until patients reported complete relief from pain and discomfort, whichever came first. Treatment was successful in 70% of the patients. Before treatment, 76% used crutches; this was reduced to 48% after the study. In more than 65% of the patients, further surgery could be avoided within a follow-up of 10 years. The treatment took an average of 16 weeks. Before treatment, 54% of the patients suffered from permanent pain; this was reduced down to 6.5% afterwards. Before PEMF treatment, 36% of patients used

analgesics and after treatment only 2% did. Researchers concluded that PEMFs are best considered for patients at an early stage of aseptic loosening.

In another double-blind study using PEMFs for loosened cement hip prostheses, 37 patients completed 6 months of treatment (either active or placebo). Success was determined clinically using a Harris hip score greater than or equal to 80 points. Ten of the 19 active patients (53%) were considered successes, compared to two of the 18 placebo patients. This is a statistically significant and clinically relevant result. A 60% relapse rate among the active successes was seen at 14 months after stimulation, and despite maintenance therapy of one hour per day, the relapse rate increased to 90% at three years. These data suggest that for loosened cemented hip prostheses, use of PEMFs is a treatment option only to delay revision hip surgery.

Loosening in the absence of infection (aseptic) is the most common problem of hip replacements, limiting their long-term success. There was a study of PEMF treatment in 24 patients with this complication. **At the end of treatment, six months and one year later, pain and hip movements improved significantly**. Both bone scans and ultrasonography improved significantly, but not in plain X-ray. The decreased pain and improved function suggest that PEMF is effective in improving symptoms of patients with loose hip replacement, supported by objective improvements in bone scan and ultrasound. No improvement, however, can be expected in patients with severe pain due to gross loosening.

Another group of 30 patients undergoing hip revision with a replacement prosthesis were treated with a 20 gauss PEMF signal for 6 hours per day, starting from the 7th through 90th days after revision in a double-blind study. PEMF-treated individuals were functionally better. Postoperative bone mineral density (BMD) was 66–93% versus 40% in controls, or more than double the improvement, even at 90 days after surgery. In addition, the PEMF group had a reduction in pain of 77% compared to 40% in the control, even as far out as 90 days after the procedure. The treatment was not associated with any negative side effects; nevertheless, it must be noted that the use of the electromagnetic stimulation at the hip required considerable patient commitment. Still, this important study showed that PEMF treatment aids clinical recovery and bone restoration.

In another study, 45 patients were studied using a 75 Hz, 20 gauss PEMF stimulator for 60 days, at a minimum of 6 hours per day. Of those, 76% had good or excellent results. The more treatment that was done, the better the results were, with 80% of those who used it for more than 30 days reporting good results. But, of those who used it for more than 60 days with at least 360 hours of exposure, 92% had good results. There appears to be a dose-related effect which is possibly cumulative. No side effects of stimulation were seen.

In addition to the benefits seen with PEMFs in the treatment of loosened implants, the therapy has also been studied immediately following joint replacement surgery, with the long-term goal being extended life of the implant and prevention of loosening in the first place.

During the healing process, bone cells first proliferate, then mature, and finally deposit minerals. In the active growth phase, osteoblasts have elevated production of extracellular matrix (ECM) genes such as type I collagen (COL I). When cells enter the maturation phase, cell growth slows down and the expression of matrix formation proteins such as COL I and alkaline phosphatase (ALP) increase. The last stage involves adding minerals to the area of the injured soft tissue. Since inflammation can hinder bone repair, it is important to know whether PEMF could stimulate bone repair under conditions of inflammation. Bone implants themselves lead to inflammation, which can hinder the progress of bone repair.

Conditions of bone repair were studied in experiments simulating implant placement. On day 7, the PEMF-exposed bone culture released more nitric oxide (NO) than the control. PEMFs resulted in a significant increase in NO release. PEMF-induced NO production in macrophages takes on an oscillating pattern and peaks at 7 days. The survival of osteoblasts in a control group decreased from days 0 to 7. The PEMF-exposed osteoblasts had significantly higher survival on day 7. Osteoblasts stimulated by PEMF began to synthesize internal NO and probably developed their own protective mechanisms such as intracellular detoxifying agents and heat-shock proteins to prevent NO from damaging themselves. NO subsequently promoted osteoblastic activities such as growth, viability and collagen expression.

As a result of increased collagen synthesis in the ECM, the cells produced elevated alkaline phosphatase (ALP) activity. Higher ALP activity eventually leads to more mineral deposition and superior bone repair. The high osteoblast proliferation stimulated by PEMF is the primary determinant of the rate of bone formation.

The above studies show a strong correlation between PEMF therapy and successful treatment and longevity of joint replacement implants. There appears to be a dosing effect where longer treatment times or treatments at higher intensities have higher long-term success than shorter treatment times or lower intensity treatments.

References for Joint Replacement

: Dallari D, Fini M, Giavaresi G, et al. Effects of pulsed electromagnetic stimulation on patients undergoing hip revision prostheses: a randomized prospective double-blind study. Bioelectromagnetics 2009 30:423-430 Kraus W.

The causality of elastic, electrical and magnetic forces in the healthy and defective bone. European Society of Biomechanics, 2nd Meeting and 1st Symposium of the Groupe d'Etudes de Biomecanique Oste-Articulaire de Strasbourg, 13-15 September, 1979, Strasbourg, France:C-1, 1979. Ascherl R, Blumel G, Lechner F, et al. 1985.

On the treatment of loosening of endoprostheses by means of pulsing electromagnetic fields. Bioelectricity Bioenerg 14:161–167. Kennedy WF, Roberts CG, Zuege RC, Dicus WT. 1993. Use of pulsed electromagnetic fields in treatment of loosened cemented hip prostheses. Clin Orthop 286:198–205. Konrad K, Sevcic K, Folde K, Piroska E, Molnar E. 1996. Therapy with pulsed electromagnetic fields in aseptic loosening of total hip prostheses.

A prospective study. Clin Rheumatol 15:325–328. Rispoli FP, Corolla FM, Mussner R. 1988. The use of low frequency pulsing electromagnetic fields in patients with painful hip prostheses. J Bioelectricity 7:181–187.

Pulsing Electromagnetic Field Treatment in Ununited Fractures and Failed Arthrodeses

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FullText

Abstract

Pulsing electromagnetic fields (PEMFs) induce weak electric currents in bone by external coils on casts or skin.

This surgically noninvasive, outpatient method, approved by the Food and Drug Administration in November 1979, produced confirmed end results in 1,007 ununited fractures and 71 failed arthrodeses,

worldwide. Overall success at Columbia-Presbyterian Medical Center was 81%; internationally, 79%; and in other patients in the United States, 76%. Treatment with PEMFs was effective in 75% of 332 patients (a subset) with an average 4.7-year disability duration, an average of 3.4 previous operative failures to produce union, and a 35% rate of infection. Eighty-four percent of carpal naviculars and 82% of femoral neck-trochanteric nonunions were united. After attempted arthrodeses could not salvage a failed total-knee prosthesis, PEMFs promoted healing in 85% of patients. When coils were unsuccessful alone, combining them with surgical repair was effective.

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