Use of Pulsed Electromagnetic Fields in Treatment of Loosened Cemented Hip Prostheses

A Double-Blind Trial

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A double-blind trial of pulsed electromagnetic fields (PEMFs) for loosened cemented hip prostheses was conducted at two centers. Of the 40 patients who enrolled, 37 met entry criteria and were available for analysis. All patients completed six months of treatment (either active or control units). Success was determined clinically by a Harris hip score greater than or equal to 80 points (or an increase of ten points if initially greater than or equal to 70 points). Ten of the 19 active units were successes (53%), whereas two of the 18 controls (11%) exhibited a placebo effect, a statistically significant and clinically relevant result. A 60% relapse rate among the active successes was seen at 14 months poststimulation, 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.

More than 100,000 total hip arthroplasties (THAs) are performed in the United States per annum,[1] and there are as many as 300,000 throughout the world in each year.[20] Unfortunately, THA is not free from complications. The most frequent long-term complication in cemented THA is loosening of the prosthetic component. Ten-year follow-up studies show symptomatic loosening requiring revision surgery in 1.3–12% of patients for acetabular loosening, and from 3% to 20% for the femoral side.[3] Roentgenographic loosening is seen in 10–29% of patients for the acetabular component, and in 30–41% for the femoral components.[3] Unfortunately, the clinical results of revision THA are even less satisfactory than those of primary THA.[25]

Although cementless hip prostheses have been introduced to eliminate the inevitable long-term problems of cement fracture, symptomatic loosening has also been observed in hips with these biologically fixed implants.[17,27]

Histologic similarities between the fibrous tissue and fibrocartilage appearing at the interface of the failing cemented implants and acquired nonunions have prompted the consideration of using pulsed electromagnetic fields (PEMFs) in treating the kind of pseudarthrosis associated with THA.[14,19,22,36]

Pulsed electromagnetic fields have been used since 1974 to stimulate the growth and repair of a variety of tissues, including bone.[5,7,9,12,18,21,31,32,35] Clinical studies with

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PEMFs have been reported to demonstrate a beneficial effect in providing bony union in cases involving pseudarthrosis and nonunions.[4,6,33,34]

In 1985, Ascherl *et al.*[2] performed a multicentered trial of PEMFs in more than 1000 patients with loosened hip prostheses using sinusoidal pulsing fields. They reported specifically on 348 arthroplasties in 334 patients, with successful treatment in 69.5% of the patients; 29% of patients were completely free from pain, and 40.5% considered their situation markedly improved. Roentgenographic evidence of refixation of some implants was claimed. More recently, Rispoli *et al.*[30] reported successful treatment in 76% of patients with loose uncemented hip prostheses. However, both studies lacked controls and follow-up data, and from these references it is not possible to determine the dose and type of PEMFs used in the studies.

The advantages and cost benefits of a noninvasive modality for avoiding or delaying revision THA, along with the reported experience in the literature, encouraged a pilot study. In 1988, Kennedy and Roberts[26] reported that 12 of 21 loosened cemented hips (57%) were significantly improved with PEMFs, specifically an increase in Harris hip score from 65 points (range, 50–74 points) to 87 points (range, 80–96).

Given the significance of these preliminary findings, a double-blind trial was initiated to test the application of PEMFs on symptomatic patients with loosened cemented hip prostheses.

MATERIALS AND METHODS

Patients were admitted to the double-blind trial if they met all of the following criteria: (1) clinical symptoms severe enough to warrant revision hip surgery; (2) a hip prosthesis of a cemented type that had been implanted for at least one year; (3) a Harris hip score of less than 80 points; (4) definite roentgenographic findings of loosening of one or both components; (5) negative cultures of joint aspiration; and (6) patient older than 18 years of age, giving informed consent. Roentgenographic evidence of femoral component loosening consisted of an obvious change in position, measurable subsidence, cement fracture with subsidence, or a complete radiolucent line at the cement–bone interface greater than 1 mm in any zone. Roentgenographic evidence of acetabular component loosening consisted of socket migration or a complete radiolucent line at the cement–bone interface greater than 1 mm in any zone.

Patients were excluded for the following reasons: (1) positive culture of hip joint aspiration; (2) steroid drug dependency; (3) uremia requiring dialysis; or (4) patients did not understand the protocol.

The double-blind study was performed at two medical centers. Patients were randomly assigned to receive an active stimulator or a control (dummy) stimulator. The stimulators (Stimetics 3000, BGS Medical, Englewood, Colorado) were supplied to the hospital with sequential serial numbers. The units were randomized before delivery into active and control units, such that every four units included two active and two control units, and the hospital applied the units in serial number order.

All patients were given a stimulator (active or control) with instructions to use the unit for at least eight hours per day for six months. The recommended use was during the sleeping hours, and eight hours was an arbitrary number, except that that had been the time of treatment recommended for nonunions.

The PEMF signal in the active stimulating units was the "pulse burst" type commonly used for nonunions: 5-millisecond pulse train (25 pulses) repeated at 15 Hz. The field strengths were also similar to that used for the standard nonunion application. The control units had all lights and alarms working but had no output to the coils. The devices were visually indistinguishable from one another. The orthopedic surgeon, the clinical staff, and the patients were unaware of the device type supplied for the six-month period.

The clinical protocol consisted of clinical assessments with the Harris hip score[16] at Day 0 and monthly for six months. The hip scores were determined by clinical assessment of gait and range of motion (ROM), and by patient questionnaire regarding hip function and pain. During the six months of treatment, patients were instructed to eliminate all activities causing pain, but the use of ambulatory aids was optional. All medications for nonorthopedic conditions were allowed, with the exception of steroids. The total treatment time was automatically recorded in all units and used to analyze treatment compliance in both groups.

The clinical study was complemented with roentgenographic evaluations done at the start

and end (six months) of the treatment. Standard anteroposterior (AP) and lateral roentgenograms were taken of the hips to assess the status of the interface and component position relative to the films taken on day zero. All patients were examined by the authors before treatment and after the six months of electrical stimulation, and all patients continued to have clinical evaluations at 12, 18, 24, and 36 months.

Success was determined clinically by a Harris hip score greater than or equal to 80 points (or an increase of at least ten points, if the initial hip score was greater than or equal to 70).

At the end of the six-month treatment period, the double-blind code was broken only for patients with a Harris hip score lower than 80 (*i.e.*, "clinical failure"). If the stimulator was inactive, the patient was given the choice to be treated with an active device for six months. After 24 months all codes were broken and the cases were then analyzed by their respective treatment modality. All patients classified as successes were evaluated for an additional 12 months.

Statistical analysis was performed with Fisher's exact test and Student's *t*-test. The *p* values less than or equal to 0.05 were considered statistically significant.

RESULTS

Forty patients were initially enrolled in the double-blind study. Three patients were excluded from analysis: two patients voluntarily withdrew shortly after joining the study, and one patient met the exclusion criteria (patient developed renal failure and required dialysis). This left 37 patients for analysis (nine from one hospital and 28 from another hospital).

Of the 37 patients, 19 received active stimulators and 18 received control units. The average Harris hip score at the start of treatment for the active group was 56 points (SD, 14; range, 21–77), and 53 for the control group (SD, 12; range, 24–72). Sixty-eight percent of the patients in the active group were men, compared with 44% in the control group. The average age in the active group was 65 years (SD, 14; range, 21–78), and for the control group 71 years (SD, 7; range, 55–83). The average weight in the active group was 83 kg (SD, 18; range, 50–117), and 76 kg for the control group (SD, 19; range, 47–124). There was no statistical difference between the active group and the control group regarding pretreatment Harris hip scores ($p = 0.5$), male to female ratio ($p = 0.09$), average age ($p = 0.1$), and average weight ($p = 0.3$). All patients completed six months of treatment. Patient compliance was measured by an hour meter on the stimulator, the active group averaging 1381 hours over the six-month period (7.5 hours per day), compared with 1399 hours for the control group (7.6 hours per day), with no statistical difference between the two groups.

The preoperative diagnoses of the active group before their index THA procedures were primary osteoarthritis (13 hips), avascular necrosis (three hips), rheumatoid arthritis (one hip), osteoarthritis secondary to congenital dysplasia (one hip), and femoral neck fracture (one hip). Diagnoses in the control group were primary osteoarthritis (11 hips), avascular necrosis (one hip), rheumatoid arthritis (three hips), and femoral neck fractures (three hips). The average number of revision procedures was 1.5 for the active group and 1.2 for the control group. Nonsteroidal antiinflammatory medications (NSAIDS) were used by eight of the 19 patients in the active group (42%) and nine of the 18 patients in the control group (50%). There was no statistical difference in the distribution of loosened components (cup, stem, or both) between the control and active groups ($p = 0.29$).

Table 1 summarizes the results, showing ten of the 19 actively stimulated patients (53%) met the success criteria at six months, whereas only two of the 18 controls (11%) met the success criteria at six months ($p < 0.01$). Ten of the 12 successes were with active stimulators.

Table 2 summarizes the pre- and posttreatment average Harris hip scores for the control group, the active group, and the successful patients in the active group. The average posttreatment Harris hip score increased

TABLE 1. Results of Double-Blind Trials at the End of the Six-Month Treatment Period

Group	*Success*	*Failure*	*Total*
Active	10	9	19
Control	2	16	18
Total	12	25	37

There is a statistically significant difference ($p < 0.01$) between the proportion of successes in the active and control groups.

only three points in the control group compared with 17 points in the active group, with the successful patients in the active group showing an average increase of 27 points. This 27-point increase was seen primarily in the pain category (15-point increase) and function category (ten-point increase). The difference in the pre- and posttreatment hip scores between the active group and the control group was statistically significant ($p < 0.05$). The difference in pre- and posttreatment hip scores in the success group (27 ± 8) was not statistically significantly better than the increase seen in the active group as a whole (17 ± 13) because many actively stimulated patients showed increased Harris hip scores, albeit not enough to meet the success criteria. There was no correlation between success and type of loosened component (cup, stem, or both) ($p = 0.35$). The successes were distributed between the two centers (four from one hospital and eight from another hospital). Both placebos were from the same hospital.

TABLE 2. Average Harris Hip Scores of the Control Group, Active Group, and Successful Patients in the Active Group

Group	*Before Treatment*	*After Treatment*	*Hip Score Increase (± standard deviation)*
Control	53	56	3 ± 14
Active	56	73	17 ± 13
Success	64	91	27 ± 8

The hip score difference between the control and active groups was statistically significant ($p < 0.05$). The hip score difference between the active and success groups was not statistically significant.

The success rate observed in the active group (53%) is similar to that observed in the initial pilot study (57%), and that only two of the 18 control patients (11%) responded suggests the placebo effect is small. Figure 1 shows the distribution of the Harris hip scores in the active group. Sixteen of the 19 actively treated patients demonstrated an increased hip score. Ten patients achieved a hip score greater than 80 points and were classified as successes. Only two patients experienced a decreased Harris hip score at six months. Figure 2 shows the distribution of the hip scores in the control group. Six of the 18 patients demonstrated a decreased hip score. Only two patients had posttreatment hip scores that were classified as successes (Harris hip scores greater than 80 points). There was no significant effect from use of NSAIDS between the active and control

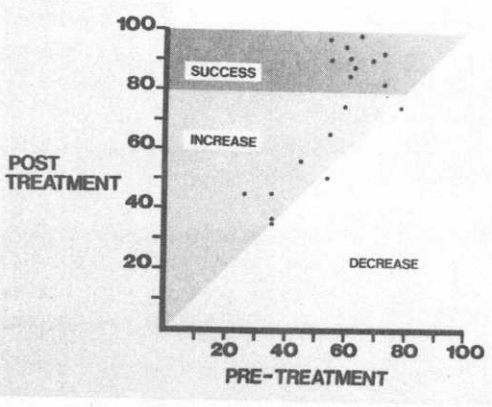

FIG. 1. The distribution of hip scores in the active group. Sixteen of the 19 actively treated patients demonstrated increased hip scores. Ten patients achieved hip scores of more than 80 points, and were classified as successes. Only two patients experienced decreased Harris hip scores at six months.

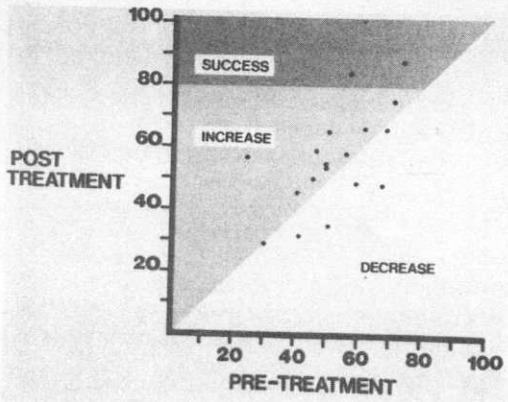

FIG. 2. The distribution of hip scores in the control group. Six of the 18 patients demonstrated decreased hip scores. Only two patients had posttreatment hip scores that were classified as successes (Harris hip scores greater than 80 points).

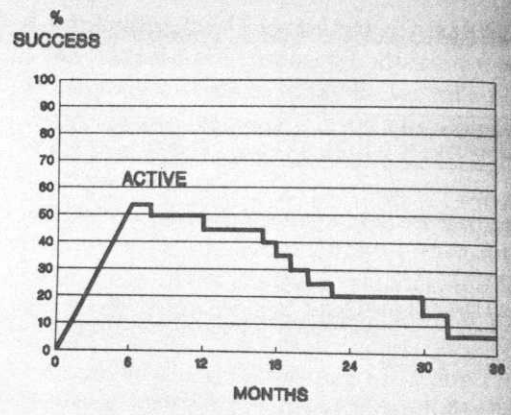

FIG. 3. The success rate percentage with time in the active group. Of the ten successes at six-months posttreatment, six relapsed at eight, 12, 17, 18, 19, and 20 months respectively. The four remaining successes were placed on maintenance therapy of one hour per day. The only patient who has not relapsed at 36 months posttreatment remains on maintenance therapy.

groups ($p = 0.2$), or between the success and failure groups ($p = 0.26$). The average age and standard deviation of the success and failure groups within the 19 active patients was 61 ± 16 years and 70 ± 10 years, respectively ($p = 0.25$). The proportion of men in the success and failure groups within the 19 active patients was 0.60 and 0.78, respectively ($p = 0.28$).

Pretreatment Hip Scores

In those patients with active stimulators, there was a statistically significant difference between the average pretreatment hip score of the active success group (64; SD, 7.4) compared with the active failure group (50; SD, 13) ($p = 0.02$). None of the five patients in the active group entering this study with Harris hip scores lower than 50 reached the success level.

Clinical Relapse

Figure 3 graphs the success rate percentage with time for the active group, showing that the ten of 19 successes in the active group at six months decreased to four successes at 20 months, and one success at 36 months.

Figure 4 graphs the success rate percentage with time in the control group. Of the two patients exhibiting a placebo response, one relapsed at 13 months and was placed on an

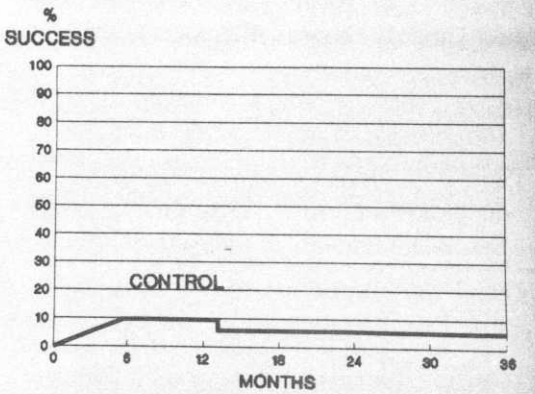

FIG. 4. The success rate percentage with time in the control group. Of the two patients exhibiting a placebo response, one relapsed at 13 months and was placed on an active stimulator. The patient returned to a success level and at ten months had not relapsed. The other patient exhibiting a placebo response remains a success at 36-months posttreatment.

active stimulator. The patient returned to the success level and at the ten-month follow-up examination had not relapsed. The other patient exhibiting a placebo response remains a success at 36 months posttreatment.

Maintenance Therapy

Because of the 60% relapse rate at 14 months poststimulation, it was hypothesized that some type of maintenance dose may be necessary. Consequently, one hour per day maintenance therapy was recommended to those who had not already relapsed. The only patient who has not relapsed at 36 months poststimulation remains on maintenance therapy. The average time to relapse was ten months poststimulation for the six patients not receiving maintenance therapy and 24 months for the three patients on maintenance therapy.

Roentgenographic Analysis

The two groups were equivalent with regard to roentgenographic analysis before treatment. After the six-month treatment period, there was no roentgenographic evidence of bone regeneration detected at the implant surface. None of the patients had roentgenographic evidence of osteogenic refixation of their implants, nor did any of the active group develop osteolysis during the six months of treatment. However, one of the success patients who did not receive maintenance therapy relapsed at 11 months, and subsequently demonstrated localized femoral bone resorption on the 24-month follow-up roentgenogram.

DISCUSSION

The precise mechanism of implant restabilization induced by electrical stimulation is unknown. When specimens of the bone–cement interface have been examined, a pseudomembrane invariably has been present.[14,22] This pseudomembrane participates either directly or indirectly in the bone resorption process. Thus the nature of the membrane itself is of critical importance as it is capable of producing bone resorption leading to loosening of the implant. Although it is possible that use of PEMFs could establish a positive bone balance by reducing the rate of bone resorption, more work is required to understand the basic mechanisms by which electricity influences the behavior of cells responsible for bone remodeling.[10,11,13–15,19,23,24,28,29]

The pulse burst pattern used in this study may or may not be the most efficacious signal for bone regeneration in this condition as it is unclear how electrical fields interact with the interface tissue surrounding a loosened cemented prosthesis. For example, the work of Brighton *et al.*[8,9] on capacitively coupled signals has shown a biologic sensitivity to different frequencies, intensities, and duration in terms of establishing a positive bone balance.

This study has demonstrated that electrical stimulation did produce a temporary improvement in the actively treated patients when compared with the control patients. Factors associated with clinical success were satisfactory bone stock, satisfactory prosthesis position, and Harris hip scores of 50 or greater. However, by three years there was no statistical difference in the two groups. In the active group only 5% (one of 19) remained successful, compared with 6% (one of 18) in the control group. In addition, the incidence of surgical revision was similar in both groups: 37% in the active group and 39% in the control group. Thus, the effect of using PEMFs in the two groups was statistically significant after six months, but despite maintenance therapy, the effects were no different after three years. These results suggest that for loosened cemented hip prostheses, the use of PEMFs is a treatment option only to delay revision hip surgery.

Only further study of this noninvasive alternative to revision hip surgery will determine if additional daily hours of mainte-

nance therapy will favorably influence the long-term results, and if these bioelectrically induced changes in the pseudomembrane will prevent progressive osteolysis about a loose cemented implant.

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