Long-term Follow-up of Fracture Nonunions Treated with PEMFs

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ABSTRACT

One hundred thirty-nine established fracture nonunions were treated using a pulsed electromagnetic field (PEMF) device that also recorded patient usage. Patients who used the device less than an average of three hours a day had a success rate of 35.7% (5/14), while those who used the device in excess of three hours daily had an 80% success rate (108/135). The difference in the success rate was statistically significant at $p<.05$.

Treatment success was unaffected by long versus short bone, open versus closed fractures, nonunion of nine to 12 months duration compared to one to ten years, age of patient (whether less than or greater than age 60), gender, recalcitrant versus first time treatment, infected versus noninfected nonunions, fracture gaps up to 1cm, or weightbearing versus nonweightbearing.

Ninety-seven fractures in 90 patients (90% follow-up) who averaged more than three hours of PEMF treatment daily and were originally classified as healed were reevaluated clinically and radiographically at four years following treatment (range: 3.6-5.4 years; mean: 4.1 years). Eighty-nine (92%) maintained a solid union. The success rate of PEMF treatment for nonunion repair demonstrated no statistically significant change over long-term follow-up.

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INTRODUCTION

Much has been published on clinical applications and results of PEMFs.[1] PEMF treatment effects on osseous tissue repair have been validated by double-blind studies in tibial delayed union fractures (Sharrard, 1990)[2] and fresh lumbar fusion (Mooney, 1990).[3] Few studies have addressed effective treatment dosage (hours/day) or long-term safety and effectiveness. Based on animal research and clinical extrapolation, treatment times of ten to 12 hours per day previously have been recommended.[4] Pethica and Brownell[5] compared ten hours/day PEMF treatment of fracture nonunion to one hour/day and noted a 60% reduction in healing time at the higher dosage.

The purpose of the current study was to prospectively evaluate the long-term safety and effectiveness of PEMF therapy for fracture nonunions and failed arthrodeses and to determine the effective treatment dosage ranges (hours/day) to achieve

Fig. 1 Use of a pulsed electromagnetic stimulation device for treatment of a scaphoid nonunion. Device also may be used in non-casted applications. A variety of transducer configurations are available to accommodate use in different fracture sites.

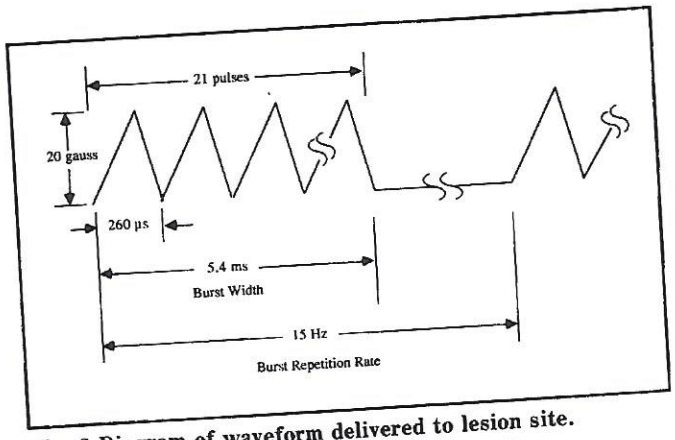

Fig. 2 Diagram of waveform delivered to lesion site.

union, documented both clinically and radiographically.

MATERIALS AND METHODS

A nonunion was defined as a fracture or an arthrodesis that failed to demonstrate both clinical and radiographic union at least nine months after the original insult.[6,7] Established nonunions that underwent a bone grafting procedure or internal fixation became candidates for PEMF treatment if evidence of healing was not apparent radiographically by three months after the procedure or if no radiographic progression of healing occurred during the three-month period.

Patients were asked to use a pulsed electromagnetic stimulation device for a minimum of eight hours per day for six months or until union. The device used is portable and consists of a rechargeable nickel-cadmium battery pack that drives a cuff-shaped treatment transducer (Fig. 1). The PEMF waveform (Fig. 2) is determined by microprocessor-based control circuits, which also record patient usage. Immobilization, bracing, or weight-bearing judgments were left up to the discretion of the treating physician; however, full weight-bearing was restricted if the patient presented with gross motion at the nonunion site.

From September 1983 through July 1984, 181 subjects (193 fractures) were enrolled by 131 investigators at 74 institutions. A cohort of 139 patients (149 fractures) completed treatment. The remaining 42 subjects did not complete the 12-week minimum PEMF trial for the following reasons: six were lost to follow-up, seven chose alternative surgical treatment, nine were reported to be noncompliant, 17 elected to withdraw, two had a systemic disease that was likely to impair healing, and one died from causes unrelated to the injury being treated.

Data evaluated included: gender, age, location of fracture or failed fusion, open versus closed injuries, number and type of prior surgical procedures, presence of infection, immobilization, weightbearing, fracture gap, prior disability time, and daily device usage.

The patient population of 181 subjects (193 fractures) was composed of 118 males with an average age of 38 years (range: 13-76 years), and 63 females with an average age of 49.2 years (range: 14-83 years). The injuries treated included 130 long bones, 35 short bones, and 28 failed fusions

TABLE I

Distribution by Bone Class

Bone Class	Number	Percent of Injuries
Long bone	130	67.4
Short bone	35	18.1
Failed fusion	28	14.5
Total	193	100%

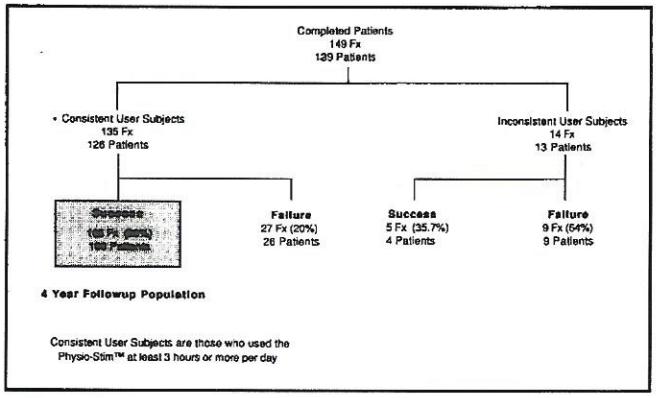

Fig. 3 Study overview.

(Table I). Prior surgical interventions had been performed on 81% (157/193) of the fractures, with an average of two procedures per fracture. Internal fixation and bone grafting were the principal surgical procedures previously used to effect repair.

A history of internal fixation was reported for 113 nonunions, while 68 had some type of internal fixation device in situ during the course of the trial. Twenty-six fractures had a history of external fixation. Infection was present in 19 nonunions. The elapsed time since fracture or surgery for arthrodesis was greater than nine months but less than 12 months in 78 nonunions and 12 months or longer in 115. The average duration of nonunion in this cohort was 2.6 years (range: nine months to 42 years).

An independent panel of three orthopaedists reviewed all radiographs at the termination of treatment. A successful rating indicated that at least two of the three panelists rated the subject's final radiographs as showing cortical bridging and/or trabecular bridging with major modification of the radiolucent gap on any radiographic view and that the overall callus showed progression from baseline. In addition to the rating of the panel of orthopaedists, investigators rated each subject for motion at the fracture site, tenderness, pain, and requirement for casting. Patients were determined to be clinically healed if they were noncasted, without motion at the fracture site, and had absent or minimal pain at the nonunion site.

To confirm long-term safety and effectiveness of PEMF treatment for ununited fractures, 100 subjects (108 fractures) who used the device an average of at least three hours daily and were classified as healed at the time of termination of treatment with the PEMF device underwent clinical and radiographic examination four years later (Fig. 3).

RESULTS

All 139 patients (149 fractures) who completed the 12-week minimum PEMF treatment were stratified according to average daily usage time to assess dose-response relationships (Fig. 4). No statistically significant differences in success rates were observed among the usage strata above three hours per day. In contrast, the success rate in the 13 patients (14 fractures) averaging less than three hours daily use (35.7%, 5/14) was significantly lower than that observed in the 126 patients (135 fractures) averaging more than three hours (80%, 108/135). Confidence interval tests indicate this difference to be statistically significant at $p < .05$. This difference implies a dosage threshold; subsequent analysis of study results therefore is confined to the 126 subjects (135 fractures) who averaged greater than three hours PEMF treatment per day.

Statistical analyses based on confidence interval estimate techniques also were conducted to determine what pretreatment and/or treatment factors had a significant effect on healing rate. None of the following parameters demonstrated a statistical difference: open versus closed fractures, nonunion of nine to 12 month duration com-

TABLE II

Results by Fracture Gap

Fracture Gap	Total Number	Number Healed	Success Rate
0-3 mm	59	52	88.1%
3-6 mm	40	34	85.0%
6-10	22	16	72.7%
>10 mm	8	4	50.0%
Not measurable	6	2	33.3%
Total	135	108	80.0%

TABLE III

Results by Bone Class

Bone Class	Total Number	Number Healed	Success Rate
Long bone	98	81	82.7%
Short bone	21	17	81.0%
Failed fusion	16	10	62.5%
Total	135	108	80.0%

TABLE IV

Results by Fracture Site

Fracture Site	Total Number	Number Healed	Success Rate
Tibia	50	37	74.0%
Fibula	8	7	87.5%
Femur, neck	2	2	100.0%
Femur, other	13	12	92.3%
Humerus	7	7	100.0%
Ulna	10	10	100.0%
Radius	6	5	83.3%
Scaphoid	13	10	76.9%
Metatarsal	5	4	80.0%
Ankle fusion	10	6	60.0%
Fusion, other	6	4	66.7%
Other	5	4	80.0%
Total	135	108	80.0%

pared to one to ten years, age of patient (whether less than or greater than 60 years), gender, recalcitrant versus first time treatment, infected versus noninfected nonunions, fracture gaps up to 1cm, long versus short bone, or weightbearing versus nonweightbearing.

The closed fracture union rate was 88% (61/69) compared to a 66% rate (35/53) for open fractures. In 13 fractures, the type of injury (open or closed) was not reported. The elapsed time since fracture or surgery for arthrodesis ranged from nine months to 42 years. Sixty fractures had nonunions of 12 months duration or less, with a healing rate of 83% (50/60). Sixty-six fractures had a nonunion duration between one to ten years and 82% (54/66) united. Union occurred in 44% (4/9) of nonunions of greater than ten years duration.

Union occurred in 90/107 (84%) subjects less than 60 years of age compared to 18/28 (64%) of those 60 years of age and older. The mean age of treated patients was 42 years. Females had a success rate similar to males, with healing in 41/53 nonunions (77%) compared to 67/82 (82%). Among recalcitrant nonunions, i.e., those that had undergone prior electrical stimulation or bone grafts, union occurred in 37/48 (77%) compared to 71/87 (82%) nonunions in which no such prior attempts to achieve union had been made. The rate of healing in infected nonunions was 79%, while in noninfected nonunions the success rate was 80%.

Among nonunions with gaps of 6mm or less, 87/99 (88%) healed with PEMF therapy compared to 20/30 (67%) with gaps greater than 6mm (Table II). Fractures with gaps of less than 1cm consolidated in 102/121 cases (84%); however, only a 50% success rate was observed with gaps more than 1cm (4/8). Six fracture gaps were too complex to be measured.

The overall success rate in healing long bones (Table III) was 83% (81/98); in short bones, the healing success rate was 81% (17/21). In this series, the tibia was the most prevalent fracture site treated (Table IV), and a 74% success rate was achieved (37/50). Scaphoids represented 62% of the short bones treated (13/21), and a healing rate of 77% was effected (10/13).

Subjects for whom weightbearing was a part of their treatment achieved an 87% success rate

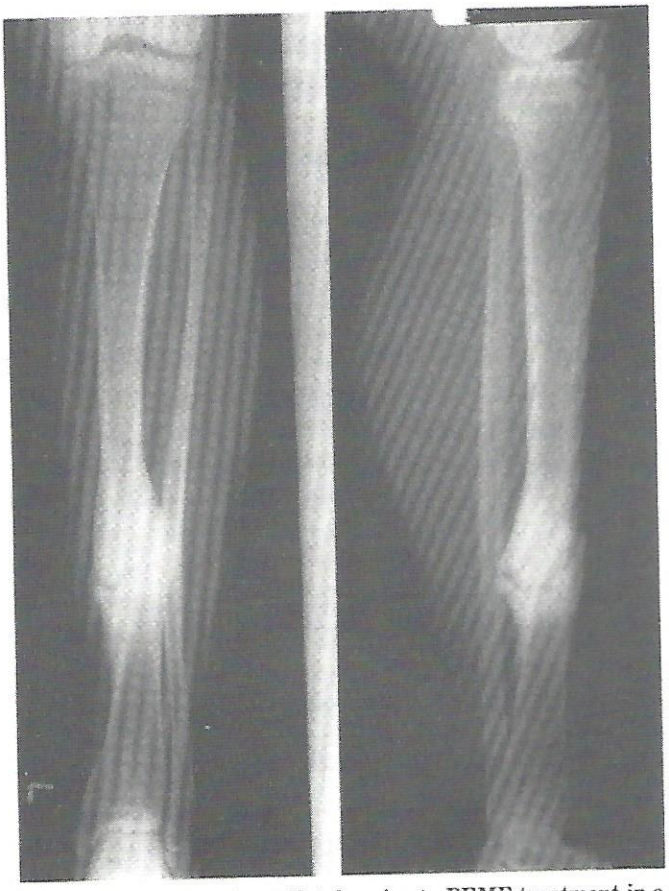

Fig. 6A X-ray taken immediately prior to PEMF treatment in a 15-year-old female with a slightly comminuted fracture of the left distal tibia reveals insufficient deposition of periosteal callus and fibrous clouding of the gap nine months following injury.

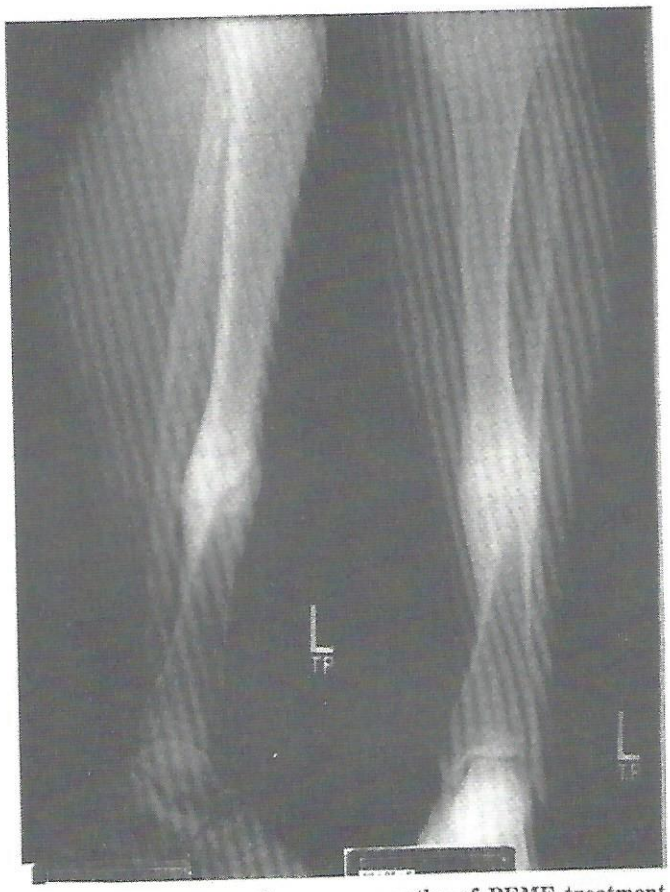

Fig. 6B X-ray taken after seven months of PEMF treatment reveals obliteration of fracture gap with dense trabecular bridging and solid bony union through periosteal and endosteal callus.

(41/47), versus 70% (18/26) in those without weightbearing (Fig. 5).

Four years after the conclusion of PEMF treatment, long-term follow-up was conducted on all subjects who averaged more than three hours of daily PEMF treatment and who had been classified as healed at the conclusion of the study. This group included 100 patients with 108 fractures. A 90% follow-up rate was achieved: 90/100 subjects (97/108 fractures) were examined and radiographs were obtained. All fracture sites and types were well-represented.

Of the nine subjects who were not examined, six refused to comply with the follow-up, while three had died of causes unrelated to treatment (one of whom had a double fracture). Only one subject was not contacted, having emigrated to Spain.

Among the patients evaluated at four years, healing was confirmed in 92% of fractures (89/97), while 8% presented with nonunion (8/97). Yates corrected chi-square analysis indicates no statistically significant difference between the four-year success rate and the original rate. There were no prognostic factors that significantly impacted long-term success, nor were any long-term complications or adverse effects attributable to PEMF therapy reported by either subjects or physicians.

DISCUSSION

The effectiveness of treatment of nonunions and failed arthrodeses with electrical stimulation, regardless of method, is similar.[4,6-14] Although Bassett recommended ten to 12 hours of PEMF therapy per day,[4] only one previous study by Pethica and Brownell has evaluated PEMF dosage

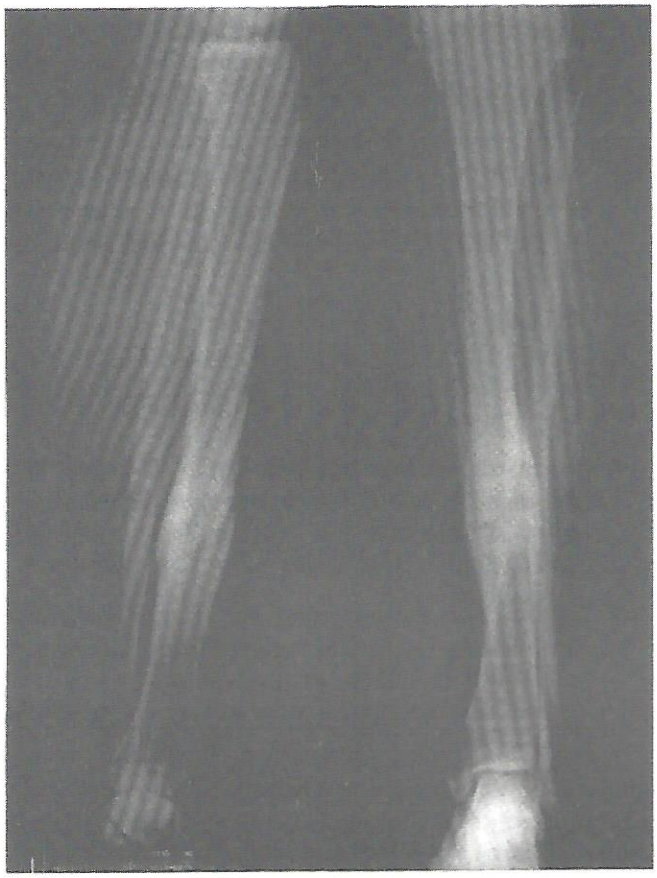

Fig. 6C X-ray four years after conclusion of treatment with PEMF reveals persistent solid union.

effects in the clinical setting.[5] Their study, however, reported dosage impact on healing times rather than on success rates. Our findings demonstrate that with the device used in this study, at least three hours of treatment time per day is necessary for successful union. No statistically significant difference was noted with increasing treatment times beyond three hours per day.

The incidence of tibial nonunions as a percentage of all long-bone nonunions has increased.[15] Moreover, tibial nonunions are currently the most common long-bone nonunion treated by the orthopaedic surgeon.[15] As previously indicated, tibial nonunions responded to PEMF treatment at a rate of 74% (Table IV). A representative case report is depicted in Figure 6.

While infected nonunions continue to be difficult treatment challenges, there was no statistical difference in the healing rate of infected versus noninfected nonunions in this series.

Previous protocols have recommended nonweightbearing with nonunions since weightbearing may cause unwanted motion at the fracture site. In addition, the endogenous piezoelectric potentials generated by weightbearing were speculated to possibly interfere with the exogenous signal induced by PEMF.[10] Data from this series indicate that weightbearing in conjunction with PEMF therapy may be acceptable if fracture motion is adequately controlled. The success rate in tibia/fibula nonunions appeared to be increased by weightbearing versus nonweightbearing.

Sharrard[11] attributed failures of PEMF therapy to fracture gaps of 5mm or greater. Fractures with gaps greater than 1cm or greater than one-half the diameter of the bone at the fracture site have been identified as poor candidates for PEMF therapy by Bassett.[4] Studies comparing success rates of PEMF therapy relative to the size of the fracture gap have not been reported. In our series, there was no statistically significant difference in the success rates of nonunions with fracture gaps up to 1cm.

SUMMARY

This study validates the long-term safety and efficacy of PEMF therapy for the treatment of fracture nonunions and failed arthrodeses and confirms its status as a viable alternative to operative procedures in their treatment. Variables such as the age of the patient (whether less than or greater than 60 years), gender, previous attempts to achieve union (recalcitrant versus first time treatment), infected versus noninfected nonunions, fracture gaps up to 1cm, weightbearing versus nonweightbearing, or duration of nonunion up to ten years did not significantly impact PEMF treatment success in this series.

This study further revealed a threshold dosage of three or more hours of daily PEMF treatment, documenting that ten to 12 hours of daily treatment is not necessary to effect union, as was previously thought. It also illustrated that weightbearing may be allowed in lower extremity nonunions if the nonunion is relatively stable or if the stability can be controlled by internal or external methods.

REFERENCES

1. Bassett CAL: Fundamental and practical aspects of therapeutic uses of pulsed electromagnetic fields (PEMFs). Crit Rev Biomed Eng 17:451-529, 1989.

2. Sharrard WJW: A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. J Bone Joint Surg 72B:347-355, 1990.

3. Mooney V: A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions. Spine 15:708-712, 1990.

4. Bassett CAL, Mitchell SN, Gaston SR: Pulsing electromagnetic field treatment in ununited fractures and failed arthrodeses. JAMA 247:623, 1982.

5. Pethica BA, Brownell J: The dose-response relationship in PEMF therapy of ununited fractures. BRAGS Transactions III:22, 1988.

6. Bassett CAL, Mitchell SN, Gaston SR: Treatment of ununited tibial diaphyseal fractures with pulsing electromagnetic field. J Bone Joint Surg 63: 511, 1981.

7. Brighton CT, Black J, Friedenberg ZB, Esterhai JL, Day LJ, Connolly JF: A multicenter study of the treatment of non-union with constant direct current. J Bone Joint Surg 63A:2, 1981.

8. Bassett CAL, Pilla AA, Pawluk RJ: A nonoperative salvage of surgically resistant pseudoarthroses and nonunions by pulsing electromagnetic fields. Clin Orthop 124:128, 1977.

9. Bassett CAL, Valdes MG, Hernandez E: Modification of fracture repair with selected pulsing electromagnetic fields. J Bone Joint Surg 64A:888, 1982.

10. Bassett CAL: The development and application of pulsed electromagnetic fields (PEMFs) for ununited fractures and arthrodeses. Orthop Clin North Am 15:61, 1984.

11. Sharrard WJW, Sutcliffe ML, Robson MJ, Maceachern AG: The treatment of fibrous nonunion of fractures by pulsing electromagnetic stimulation. J Bone Joint Surg 64B:189, 1982.

12. Bigliani LU, Rosenwasser MP, Caulo N, Schink MM, Bassett CAL: The use of pulsing electromagnetic fields to achieve arthrodesis of the knee following failed total knee arthroplasty. J Bone Joint Surg 65A:480, 1983.

13. Connolly JF: Electrical treatment of nonunions — its use in 100 consecutive fractures. Orthop Clin North Am 15:89, 1984.

14. Paterson DC, Lewis GN, Cass CA: Treatment of delayed union and nonunion with an implanted direct current stimulator. Clin Orthop 148:117, 1980.

15. Meister K, Segal D, Whitelaw GP: The role of bone grafting in the treatment of delayed and nonunions of the tibia. Orthop Rev 19(5):260-271, 1990. ■