Electrical Stimulation of Human Femoral Intertrochanteric Osteotomies

Double-Blind Study

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Low-frequency pulsing electromagnetic fields (PEMF) are being used in nonunion healing at several centers around the world. Much debate exists about quantification of PEMF effects, especially in humans where no randomized studies have been performed. The results of a double-blind treatment of 32 consecutive patients treated with femoral intertrochanteric osteotomy for hip degenerative arthritis are reported. Roentgenographic evaluation and callus density measurements performed with an image analyzer showed a statistically significant difference between controls and stimulated patients ($p < 0.01$). In this extremely homogeneous patient population, PEMF stimulation favored osteotomy healing.

Several techniques are used to stimulate osteogenesis with pulsing electromagnetic fields (PEMF).[4,7,8] The authors have reported positive results in the treatment of delayed unions and nonunions.[12,16,17] The success rate is not significantly different from that obtained with surgical techniques.[19] PEMF stimulation has been shown in a double-blind study to be biologically effective in the management of chronic refractory tendinitis of the shoulder.[5]

It has been suggested that the effectiveness of electrical stimulation in nonunion should be demonstrated in double-blind studies.[2,10] However, such studies are extremely difficult to perform in nonunions. Without case matching, very large populations are required to control multiple variables. The only attempt made was with a very small series that did not allow statistical interpretation.[1,13,18] Moreover, patients in the control group may have received a field stimulation of lower intensity.[13]

Attempts have been made to demonstrate the effectiveness of electrical stimulation in promoting osteogenesis using more homogeneous patient populations, tibial fresh fractures,[9,11] and Colles' fractures.[21] In all of these studies, PEMF favored fracture healing; however, none of them was performed in a double-blind fashion and biological effects in fresh fractures may be quite different than in ununited fractures.[3]

The results of a study performed over the past three years in a series of 32 consecutive patients treated with femoral intertrochanteric osteotomy for hip osteoarthritis are reported. The choice of these patients for a double-blind study of PEMF effects on osseous

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repair was made according to the following rationale: (1) The patients' ages were relatively homogeneous. (2) The surgical fracture was always located in the same region of the same bone. (3) The osteotomy was performed by the same surgeon, and the synthesis plate used was uniform in type and application. (4) Immobilization and rehabilitation programs were standardized for all patients.

The osteogenesis model studied here does not necessarily imply a correlation with the use of electrical stimulation for nonunion healing. This report focuses on the healing of the osteotomy; the evaluations made are primarly roentgenographic and no clinical data are presented.

MATERIALS AND METHODS

Patients, both men and women, with degenerative osteoarthritis of the hip were admitted to the study. Patients were selected for the osteotomy only if they were aged less than 70 years.

Patients were assigned by blocks to the control or to the treatment group according to the order of admission to the hospital. A computer-generated schedule prepared by a biostatistician was used to maximize the randomization criteria. In this process a random number seed was entered into the computer to generate a list that assigned equal numbers of active and control stimulators (blocks of four, two active and two control units) for a total of 32 patients (16 in the control group and 16 in the treatment group).

There were 12 women and four men in the control group and 11 women and five men in the experimentally stimulated group. The mean age in the two groups was 55 years (range, 38–69 years) and 56 years (range, 36–70 years), respectively. The average weight of the patients was 66.5 kg (range, 52–90 kg) in the control group and 72.6 kg (range, 60–102 kg) in the stimulated group. All the patients were in good health; patients suffering from rheumatoid arthritis were not admitted to the study. Twelve patients in the control group and 13 in the treatment group had unilateral hip involvement. The remaining patients had bilateral involvement. The severity of involvement of the hips by the degenerative arthritis was objectively evaluated. The acetabulum and the femoral head were divided into four and eight areas, respectively. A mean of 8.2 ± 1.6 areas was involved by the degenerative arthritis in the control group and a mean of 8.3 ± 1.4 areas was involved in the treatment group.

The osteotomy in these patients was designed to change mechanical forces on the femoral head. Each patient was studied carefully to select the most appropriate surgical procedure. The choice of performing an extension, a varus extension, or a valgus extension osteotomy was based both on clinical and roentgenographic evaluations. If the patient experienced pain relief with hip flexion, flexion and abduction, or flexion and adduction, then an extension, a varus extension, or a valgus extension osteotomy, respectively, was scheduled.

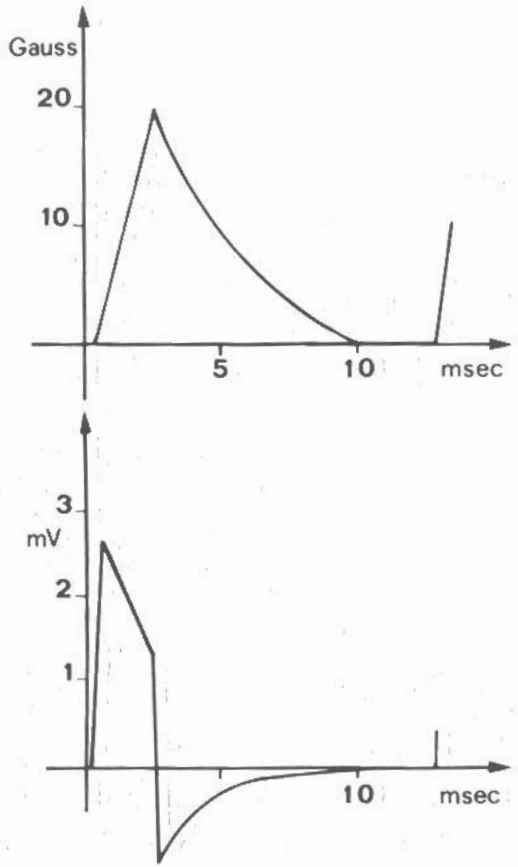
Roentgenographs were studied to determine how to release the load from the femoral head areas in which sclerosis was present and the articulation line was thin. A varus osteotomy was performed when anteroposterior (AP) roentgenographs showed an improvement in joint congruity when the hip was abducted and a valgus osteotomy was performed when AP roentgenographs showed an improvement in joint congruity when the hip was adducted. The same criteria were used for lateral roentgenographs to evaluate the need for extension.

Surgical Procedure

The patients were surgically treated according to a protocol published elsewhere for intertrochanteric osteotomy.[6,14] Bone wedges were removed from the posterior cortex and the lateral cortex during extension osteotomies and valgus extension osteotomies, respectively. During varus extension osteotomies, bone wedges were removed from the medial cortex in addition to the posterior cortex.

All osteotomies were fixed with the same type of intertrochanteric osteotomy plate (ACP 90° plate, Osteo AG, Selzach, Switzerland). Screws with a diameter of 4.5 mm were used. Four (30–40 mm long) were placed into the diaphysis and one (60–80 mm long) in the epiphysis. All patients were surgically treated by the senior author. Thirteen patients in the control group and seven in the stimulated group had a valgus extension osteotomy, one in the control group and two in the stimulated group had a varus extension osteotomy, and the remaining had an extension osteotomy (Table 1).

The postoperative roentgenographs were evaluated the day after surgery by the surgeon to confirm the positions of the femoral head, the acetabulum, and the fixation plate. The osteotomy was rated from 0 to 4 according to the results. In addition, the percent of bone contact between the two osteotomy edges with respect to the femur diameter was determined. This calculation was made on the roentgenograph taken on Day 0 by dividing the length of bone contact by the length of the whole osteotomy.



FIGS. 1A AND 1B. (A) Waveform of the magnetic field. (B) Waveform of electrical tension induced in a standard coil probe by the electromagnetic field.

All patients were discharged from the hospital between Days 10 and 14 after surgery. The postoperative management was the same for all patients. The patients were nonweightbearing up to Day 40, partial weightbearing (50%) from Days 40 to 90, and then full weightbearing. This postoperative weight-bearing protocol is satisfactorily and routinely used in the first author's department. Nonsteroidal antiinflammatory drugs were used similarly by both groups of patients within three days after surgery, after which they were not used.

STIMULATION TECHNIQUE

The third day after osteotomy, all patients were given either a control or active unit (Igeastimulator, Igea, Carpi, Italy) on a randomized, blind schedule. Patients were carefully instructed to use the stimulator for eight hours during daytime. The electromagnetic field was generated by means of a single coil positioned on the lateral side of the femur over the osteotomy and maintained in place by means of a Velcro (Velcro USA, Manchester, Ohio) strip; patients usually performed the stimulation lying on the opposite side. The electrical voltage supplying the coil induced the desired electric field in the osteotomy area. The induced electric field was monitored with a standard coil probe (Fig. 1). The stimulation parameters for active units were the following: 75 Hz, 1.3 milliseconds impulse width, 2.5 mV electric field amplitude, and 18 Gauss magnetic field amplitude recorded by a Hall probe (912 Gaussmeter, RFL, Boonton, New Jersey). The most significant differences between the waveform here employed and the single-pulse waveform used by others are the electric field amplitude and the impulse width that are lower and longer, respectively, than those described.[4] This was made possible by the use of a relatively high impedance coil. Control stimulators were indistinguishable from the active ones in weight, shape, and directions for use. The electrical circuit only supplied indicator lights. Current delivered by a pulse generator, usually supplying a blinking light coupled with the coil, was bypassed by means of a resistor. In this way, it was possible to completely disconnect coil leads, thus bringing the current flowing within them to 0. When performing a double-check control, no induction was detected in a pick-up coil connected with an oscilloscope with a sensitivity of 100 μV/cm.

All patients used the stimulators for three months. Patients were asked at each visit about the proper use of the stimulator and compliance with instructions. At each visit, the authors ascertained that the yellow light on the front of the unit was blinking, indicating proper functioning of the stimulator. At the end of the three-month period, the stimulator was sent back to the factory and the output checked. All stimulators worked properly.

ROENTGENOGRAPHIC ASSESSMENT

Roentgenographs were taken 40 and 90 days after osteotomy. For the purpose of this study on osteotomy healing, only AP roentgenographs were considered.

The presence of periosteal bone callus on the medial cortex was evaluated and assigned a value from 0 to 3. When osteotomy edges were well-defined and no osteogenetic image could be observed in the area proximal to the edges, a value of 0 was assigned. When edges revealed bone remodeling and osteotomy fragments appeared to be linked by a tissue presenting a low mineral content compared with the adjacent bone tissue, a value of 1

TABLE 1. Clinical Data of Patients Treated with Electrical Stimulation for Osteotomy Healing

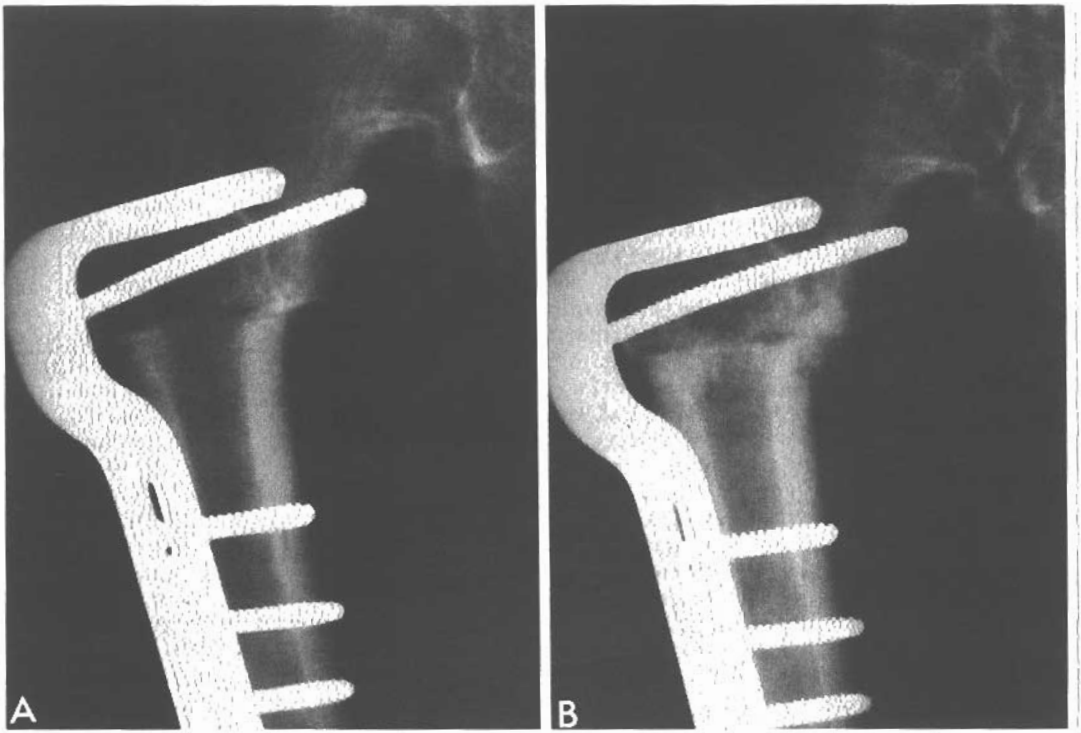
Control Group			*Treatment Group*		
Age	*Sex*	*Osteotomy Type*	*Age*	*Sex*	*Osteotomy Type*
47	F	Valgus Ext.	60	M	Valgus Ext.
59	F	Valgus Ext.	57	M	Valgus Ext.
38	M	Valgus Ext.	65	F	Valgus Ext.
55	F	Valgus Ext.	50	F	Extension
57	F	Valgus Ext.	48	F	Varus Ext.
52	F	Valgus Ext.	55	M	Extension
54	F	Valgus Ext.	61	F	Valgus Ext.
63	M	Extension	52	F	Extension
64	F	Valgus Ext.	46	F	Valgus Ext.
53	F	Varus Ext.	60	F	Extension
62	M	Valgus Ext.	36	F	Extension
45	F	Valgus Ext.	63	F	Valgus Ext.
68	F	Valgus Ext.	60	M	Extension
57	M	Valgus Ext.	65	F	Extension
62	M	Extension	70	F	Valgus Ext.
45	F	Valgus Ext.			

was given. When the osteotomy fragments were linked by a tissue whose mineral content was comparable to that of the femoral bone tissue, but no bone trabeculae were present, a value of 2 was assigned. Finally, a value of 3 was assigned when the osteotomy fragments were linked by a tissue whose mineral content was analogous to that of the femoral bone tissue and when longitudinal trabeculae were observed within it.

In an attempt to quantify calcification and maturity of the callus, callus relative density compared to the density of the iliac bone was measured. This last measurement was performed with an image analyzer (Tesak, Florence, Italy).[20] The roentgenographs of each patient were recorded and digitized by a camera connected to a computer. In the recorded image, 256 different gray colors, from 0 (black) to 256 (white), could be recognized. The software allowed normalization of the roentgenographs of each patient according to the density of the iliac bone and the soft tissue in the ischiopubic foramen. Once the roentgenographs taken at Days 40 and 90 are normalized, the callus image can be circumscribed on the video with an electronic pencil and its density read by the computer. The average density within the same area on the osteotomy site was measured each time. This technique did not allow a direct comparison between roentgenographic density of different patients. It did allow comparison of roentgenographs from the same patient taken at different times. The osteotomy line was evaluated in medial and lateral sections, divided by an imaginary line crossing the middle of the medullary canal.

The presence of trabecular bridging at the osteotomy site in the medial and lateral cortices was checked and a value from 0 to 3 was assigned as follows: (1) When none of the visible trabeculae in the proximal section linked to trabeculae of the distal section, 0 was assigned. (2) When fewer than 25% of the visible trabeculae showing an axial direction continued from the distal to the proximal fragment, 1 was assigned. (3) When 25% to 50% of visible trabeculae with an axial direction linked the two fragments of the osteotomy, 2 was assigned. (4) When more than 50% of visible trabeculae with an axial direction linked the two fragments of osteotomy, 3 was assigned. An example of how these values were determined is given in Figures 2 and 3 for control patients and in Figures 4 and 5 for actively stimulated patients. All evaluations and measurements were made by three orthopedic surgeons who had no knowledge of whether a patient was assigned to the control or treatment group.

The statistical analysis of the data was made by calculating the log likelihood chi-square test. For the results of the density analysis, the Student's t-test was used. The p values lower than 0.05 were considered statistically significant.



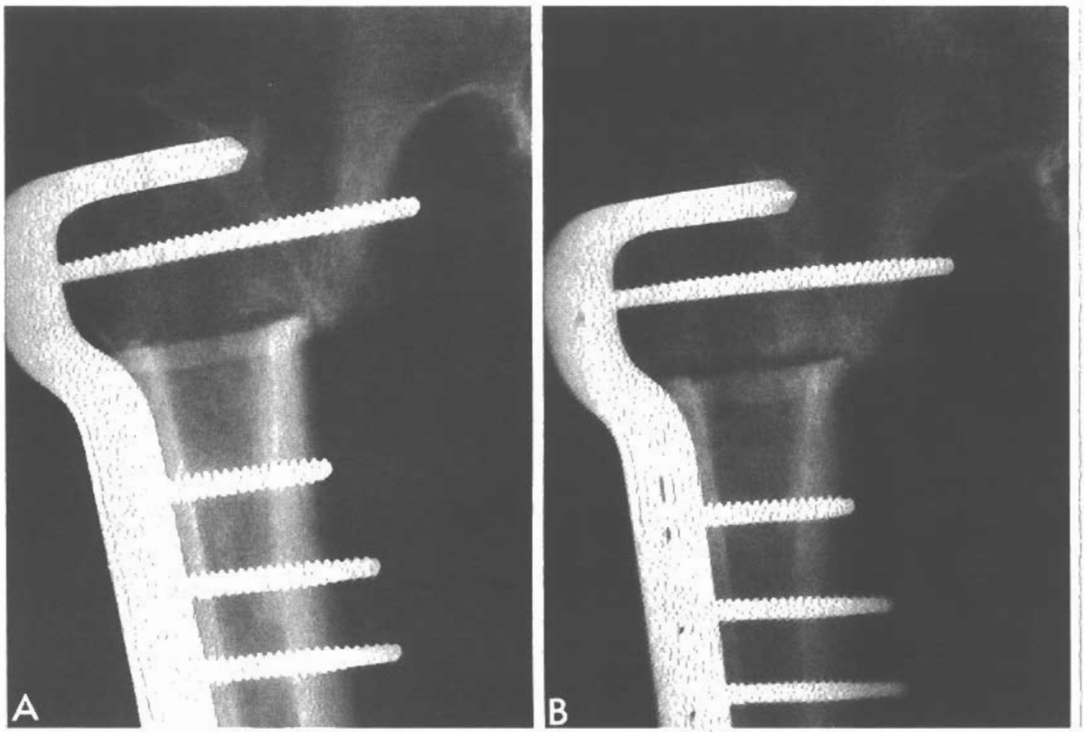
FIGS. 2A AND 2B. Control patient. (A) At 40 days the bone callus was graded 1 and trabecular bridging was graded 0. (B) At 90 days the bone callus was graded 2 and the trabecular bridging 1 on both cortices.

RESULTS

One patient in the treatment group treated with a varus extension osteotomy stopped stimulation 15 days after the osteotomy. On analysis, this unit was active and the patient was excluded from the study, leaving 16 patients in the control group and 15 in the stimulated group.

The control and treatment groups received the following scores: (1) judgment on the surgical procedure (control, 3.2 ± 0.9; treatment 3.5 ± 0.8, n.s.) and (2) percentage of bone contact (control, 81 ± 14.6; treatment, 85.9 ± 12.0, n.s.). Roentgenographic analysis at Day 40 showed that bone callus presence was more pronounced in the stimulated group (0.8 ± 0.67; $p < 0.02$) than in the control group (0.31 ± 0.4). The bone callus relative density was higher among actively stimulated patients (29.5 ± 28.0) *versus* control patients (18.9 ± 14.3), but no statistical differences were observed ($p < 0.1$, n.s.). The presence of trabecular bridging in the lateral cortex (control, 0.5 ± 0.5; treatment, 1.06 ± 0.59) was significantly higher among patients in the treatment group ($p < 0.02$). Similarly, the trabecular bridging at the medial cortex scored 0.5 ± 0.5 in the control group and 1.06 ± 0.7 in the treatment group ($p < 0.02$).

At Day 90, the roentgenographs showed a difference in the periosteal bone callus on the medial cortex: 1.37 ± 0.61 in the control group *versus* 1.93 ± 1.09 in the treatment group ($p < 0.05$). The bone callus was more calcified according to the density measured with the image analyzer: 22.5 ± 15.2 in the control group *versus* 34.8 ± 21.5 in the treatment group ($p < 0.05$). The presence of trabecular bridging at the lateral cortex was



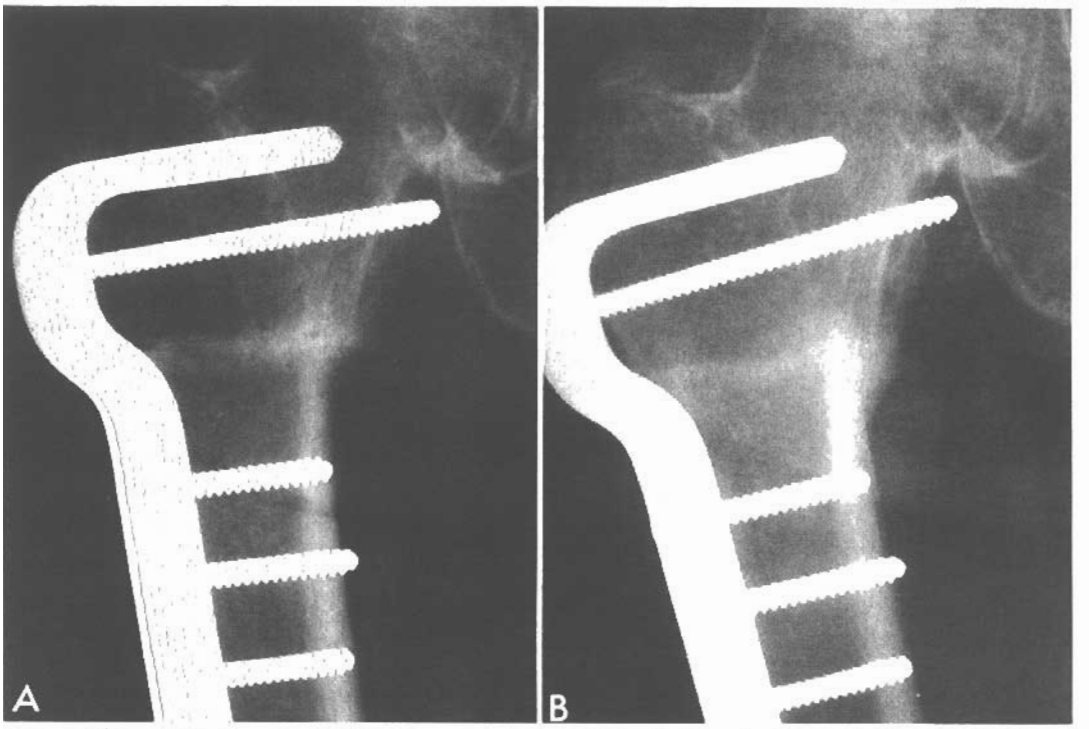
FIGS. 3A AND 3B. A patient in the treatment group. (A) At 40 days the bone callus was graded 1 and trabecular bridging was graded 0. (B) At Day 90 the bone callus was graded 2 and trabecular bridging 1 on both cortices.

more pronounced in the stimulated group. Patients in the control group scored 1.44 ± 0.61 *versus* 2.47 ± 0.63 for the treatment group ($p < 0.001$). At the medial cortex 1.56 ± 0.62 was the value obtained by the control group and 2.4 ± 1.56 by the treatment group ($p < 0.001$). All the patients recovered and no further surgery was required.

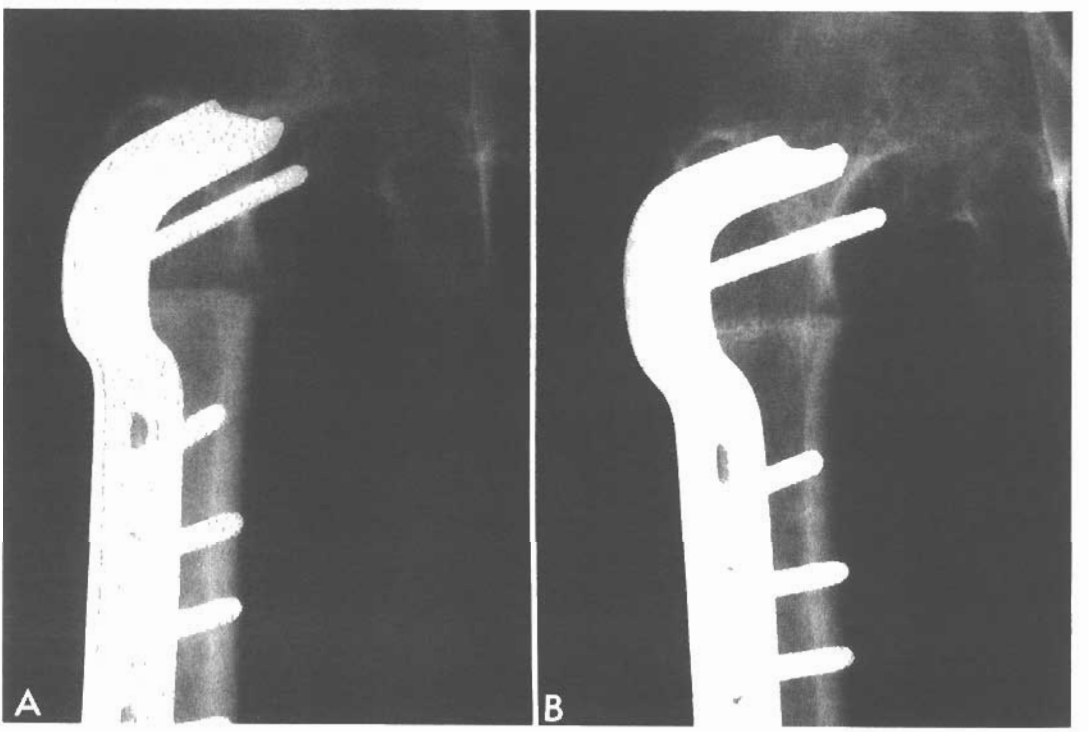
DISCUSSION

These data were obtained in an extremely homogeneous population of patients treated with femoral intertrochanteric osteotomy performed by the same surgeon and fixed with the same type of plate. This uniformity offered a unique opportunity to investigate the osteogenetic effect of PEMF stimulation in humans in a double-blind study. The study revealed that PEMF stimulation increased callus formation and trabecular bone bridging at the osteotomy level.

Although it is not easy to monitor the effects of electrical stimulation in humans, the authors observed no difference between the control and treatment groups at time 0 (indicating good randomization) and a statistically significant difference between the two groups by Days 40 and 90. These observations are in agreement with the reports of other authors who observed some effects of PEMF stimulation in nonrandomized studies.[9,11,15,21] The data in this study do not apply to fresh fractures and cannot support the use of PEMF stimulation for these injuries. Similarly, these findings do not necessarily apply to the nonunions in which spontaneous osteogenetic activity is expected to be much different.



FIGS. 4A AND 4B. A patient in the treatment group. (A) At 40 days the bone callus was graded 2 and trabecular bridging 2 (medial cortex) and 1 (lateral cortex). (B) At Day 90 the bone callus was graded 3 and trabecular bridging 3 on both cortices.



FIGS. 5A AND 5B. A patient in the treatment group. (A) At 40 days the bone callus was graded 1 and trabecular bridging 1 on both cortices. (B) At Day 90 the bone callus was graded 3 and trabecular bridging 3 on both cortices.

Attempts to quantify bone healing by callus patterns and trabecular bridging are more subjective than densitometric methods. Nonetheless, observer bias is restricted by the double-blind approach. The results obtained in this study were completely consonant with the more objective values produced by the image analyzer. In fact, statistically significant results were produced by both methods. The data demonstrate, at least for the specific population studied here, that PEMF increases osteogenesis in humans.

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