

# The Electrical Stimulation of Tibial Osteotomies

## Double-Blind Study

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The effect of electromagnetic field stimulation was investigated in a group of 40 consecutive patients treated with valgus tibial osteotomy for degenerative arthrosis of the knee. All patients were operated on by the same author and followed the same postoperative program. After surgery, patients were randomly assigned to a control group (dummy stimulators) or to a stimulated one (active stimulators). Four orthopedic surgeons, unaware of the experimental conditions, were asked to evaluate the roentgenograms taken 60 days postoperatively and to rate the osteotomy healing according to four categories (the fourth category being the most advanced stage of healing). In the control group, 73.6% of the patients were included in the first and second category. In the stimulated group, 72.2% of the patients were included in the third and fourth category. On a homogeneous group of patients, electromagnetic field stimulation had positive effects on the healing of tibial osteotomies.

The biologic effects of electrical stimulation with pulsing electromagnetic fields (PEMFs) have long been debated.<sup>1,9</sup> During the last few years, PEMFs have been demon-

strated to favor *in vitro* cell proliferation<sup>5,8</sup> and *in vivo* to promote the healing of skin ulcers in humans.<sup>10</sup> More recently, studies conducted on the horse have clearly proved that the effect of PEMF on osteogenesis depends on the metabolism of the skeletal segment under study.<sup>4</sup> In the presence of slow bone turnover, the PEMF effect is particularly marked, so much so that it may lead to a 100% increase in the amount of newly deposited bone tissue.

Clinically, the lack of double-blind studies has long hindered researchers from quantifying the effect of electrical stimulation as opposed to other variables that might have modified healing during treatment: for instance, in the case of pseudarthroses, modification of the immobilization technique.<sup>2,7,14,16</sup>

Other investigators stimulated a group of congenital<sup>13</sup> and acquired pseudarthroses<sup>17</sup> while taking care not to introduce variables other than stimulation in the treatment; unions were achieved in more than 80% of the cases. Even if researchers had no bias, it was still difficult to quantify the effect of stimulation. The most adequate method to cope with the question of the effect of PEMF on a pseudarthrosis would certainly be a double-blind study.<sup>6,11</sup> This approach, however, has proven to be impractical. It is almost impossible to get an informed patient's consent to this type of study; also, it is clear that orthopedic surgeons themselves are unenthusiastic about taking part in such a study of chronically disabled patients.

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For these reasons, a number of researchers have focused their attention on less severe bone injury as a model for quantifying the effects of PEMF on the osteogenesis in humans. Over the last few years, a series of double-blind studies has enabled investigators to demonstrate that electrical stimulation unquestionably exerts a positive effect and promotes osteogenesis in humans. In particular, it has been demonstrated that electromagnetic fields are capable of promoting the union of femoral intertrochanteric osteotomies,<sup>3</sup> the healing of delayed unions,<sup>15</sup> and spinal fusions.<sup>12</sup>

In this study, the authors evaluate the effect of electrical stimulation in a consecutive series of 40 patients who had been treated with tibial osteotomy. They were selected by the following criteria: homogeneous surgical procedure, use of the same osteosynthesis device to stabilize the osteotomy, and a homogeneous postoperative rehabilitation program. The study also allowed the authors to determine whether the effects on femoral osteotomies that some of the authors had already described could be confirmed in another anatomic site. This study is exclusively based on a roentgenographic evaluation; no clinical data will be submitted.

#### MATERIALS AND METHODS

Forty consecutive male and female patients (Table 1) requiring a tibial reduction osteotomy were entered into this study. The maximum age was 80 years. Patients generally had to be in good health (consistent with their age). Patients suffering autoimmune disease or patients suffering from metabolic or neoplastic diseases were excluded. Likewise, patients who were administered steroids were not included.

The patients were placed either in a control or in a stimulated group according to their order of admission to the hospital. A random seed number was entered into the computer to generate a list that assigned equal numbers of active and control stimulators (block of four, two active and two control units) for a total of 40 patients (20 in the control group and 20 in the active group). The control (nonactive) group included 16 women and four men, whereas the experimental, active group included 15 women and five men. The patients'

TABLE 1. Characteristics of the Patients Treated

Control patients			Active Stimulated Patients *		
Age	Gender	Site	Age	Gender	Site
63	F	L	73	F	R
78	F	R	60	F	L
63	F	L	70	F	R
68	F	L	49	F	R
64	F	R	64	F	R
67	M	L	58	F	R
63	F	L	57	F	L
33	M	L	74	F	R
69	F	R	59*	F	L
57	F	R	64	M	R
71	F	L	52	M	R
58	M	R	54	M	R
57	F	R	73	F	L
56	F	L	56	F	L
57	F	R	77	F	L
70	F	L	61	F	R
47	F	L	62	F	L
61	F	L	71	F	L
59	F	L	59	M	L
61*	M	R	65*	M	R

L, left tibia; R, right tibia.

\* Patients excluded.

average age in the two groups was 61 years of age (range, 33-78 years of age) for the control group and 62 years of age (range, 49-77 years) for the active group, respectively. No significant differences were recorded with regard to the weight of the patients in the two groups.

The authors performed reduction osteotomies in all patients to reestablish the knee weight-bearing axis and, in particular, to restore the alignment between the femur and the tibia. The patients' roentgenograms, taken while standing on one foot, were carefully examined and analyzed before the surgical procedure, so as to determine how much correction had to be performed and hence how much wedge-shaped bone had to be removed.

#### SURGICAL PROCEDURE

All the patients were operated on by the same author, who used a technique that has been employed for ten years at the hospital. One centimeter of fibular bone is removed, between the medial third and the distal third of the fibula. The proximal metaphysis of the tibia is exposed through a

skin incision that extends laterally toward the anterior face of the tibia. Under roentgenogram control, Kirschner wires (K-wires) are used to identify the bone wedge to be removed and the osteotomy is performed. The bone edges are fixed by means of a blade staple made of Cr-Co-Mo (Hit Medica, Rimini, Italy). This guarantees the fixation of the osteotomy and is well tolerated. Soft tissues are sutured and a drain maintained in place for 48 hours.

The day after the surgical procedure, a control roentgenogram is used to assess the correction and the proper position of the fixation device. The result of the osteotomy was rated from 0 to 4. Four was assigned to an osteotomy where the correction equalled the desired degree, *i.e.*, there was an ideal contact between the bone ends over the whole length of the osteotomy and the immobilization device was adequately positioned. Furthermore, the percentage of contact between the osteotomy ends was calculated by dividing the osteotomy length by the length of the contact between the two bone ends.

Over the postoperative period, all the patients were given antithrombotic prophylaxis. Unless there were complications, the patients were discharged from the hospital seven to 14 days after the surgical procedure. All patients had a long nonweight-bearing plaster cast over the first 30 days and then a short weight-bearing plaster cast for the next 30 days. Patients were asked to carefully comply with this treatment regimen, which is routinely used at the hospital.

Over the postoperative period, the most frequent complication has been the occurrence of a deep venous thrombosis. This was diagnosed in eight patients by means of Doppler investigation with continuous-wave ultrasound.

#### STIMULATION TECHNIQUE

Three days after the surgical procedure the patients were instructed to begin using the stimulator, either an active or a control device, for eight hours a day. Stimulation was discontinued at Day 60, when the second plaster cast was removed.

The electromagnetic field was generated by two inductively coupled solenoid coils, which were positioned outside the cast and held in that position with a Velcro strap (Velcro USA, Manchester, Ohio). The generator of the electromagnetic field (IGEAsimulator, Igea, Carpi, Italy) drove the coils with single voltage pulses at a frequency of 75 Hz, each lasting 1.3 milliseconds. The electric field induced in the osteotomy site, as measured by means of a standard coil, equalled  $3.0 \pm 0.5$  mV; the signal waveform is illustrated in Figure 1.

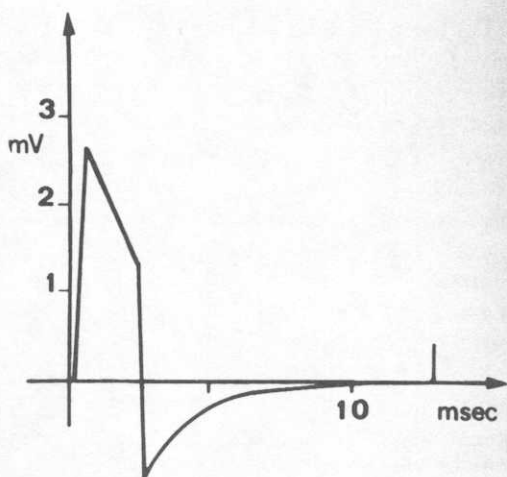


FIG. 1. Waveform of the electric field induced in a standard coil probe.<sup>3</sup>

Control (dummy) units did not differ from active stimulators, either in shape, weight, or by their operation. When using the dummy stimulators, it was impossible to record any induced electrical field in the probe placed on the osteotomy site.

A clock built into the dummy and active stimulators recorded the hours during which the stimulator was used; the patient was not informed about the presence of the clock. After the 60 days of stimulation all the stimulators were sent back to the manufacturer to check their operation. A final roentgenogram examination was performed for all patients 180 days after the surgical procedure.

#### ROENTGENOGRAPHIC ANALYSIS

All patients had roentgenograms taken at Days 30 and 60 postoperatively. The roentgenogram taken at Day 30, often with the plaster cast on, allowed no exact evaluation of the osteotomy. The time elapsed from surgery is too short and the repair process is not well advanced at 30 days. The roentgenogram at Day 30 was more specifically aimed at checking whether a good alignment and bone contact at the osteotomy site still existed.

The roentgenogram at Day 60 provides much more evidence about the osteotomy repair process. At this stage, a much clearer picture can be analyzed and, therefore, the authors decided to base their roentgenogram assessment on this image. Osteotomies were assessed roentgenographically both in the anteroposterior (AP) and the lateromedial views. The roentgenograms, obtained 60 days postoperatively were rated and fell into one of four categories.

- Score 1. The osteotomy line is still clearly evident at Day 60 on both views. The bone margins of the osteotomy line show a given degree of sclerosis (greater radiodensity). It is an osteotomy in which the course of healing is very slow and which can be seen even six months later. (Fig. 2; control group's osteotomy rated 1).
- Score 2. At Day 60 the two standard AP and lateromedial views show the osteotomy for over 50% of its length, with some signs of bridging but with no signs of sclerosis on either side of the osteotomy. (Fig. 3; control group's osteotomy rated 2.)
- Score 3. The two views still show the osteotomy site; however, bridging involves more than 50% of the osteotomy. (Fig. 4; control group's osteotomy rated 3).
- Score 4. A complete union of the osteotomy site has been achieved with bridging all over its length in the AP and lateral views. (Fig. 5; control group's osteotomy rated 4.)

The roentgenograms were independently evaluated on a double-blind basis by four different orthopedists. Whenever the osteotomy ratings disagreed with one another, the score assigned by the

majority was selected. In the event of an equal score (two patients, one per group), the case was jointly rediscussed so as to create a majority. The statistical analysis of the data was carried out by using the chi-squared test.

## RESULTS

One patient in the active group and one in the control group excluded themselves from the study. One patient in the active group was excluded because he did not meet the criteria to be admitted to the study, having had a delayed union of a previous osteotomy. Therefore, this study consists of 19 patients in the control group and 18 patients in the stimulated group. In both groups the score given for the osteotomy procedure was  $2.8 \pm 0.7$  SD. The percentage of contact exceeded 90% in both groups.

Five patients in the control group and three in the active group developed thrombophlebitis. In one female patient per group the

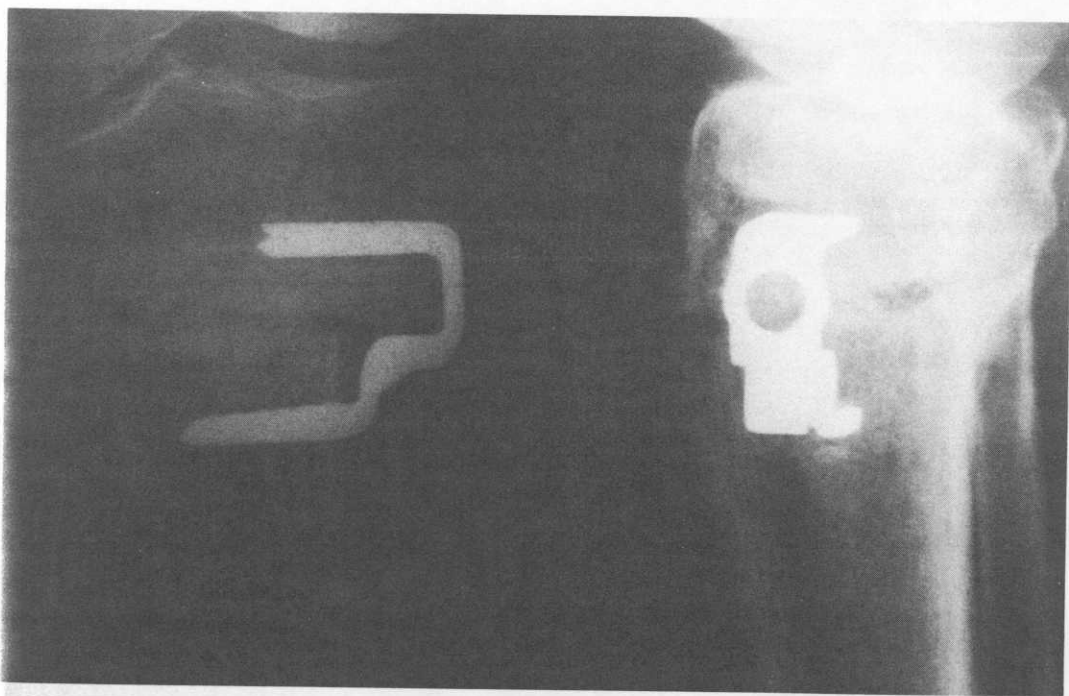


FIG. 2. Osteotomy of the left tibia of a 70-year-old woman after 60 days of placebo stimulation; rated 1.

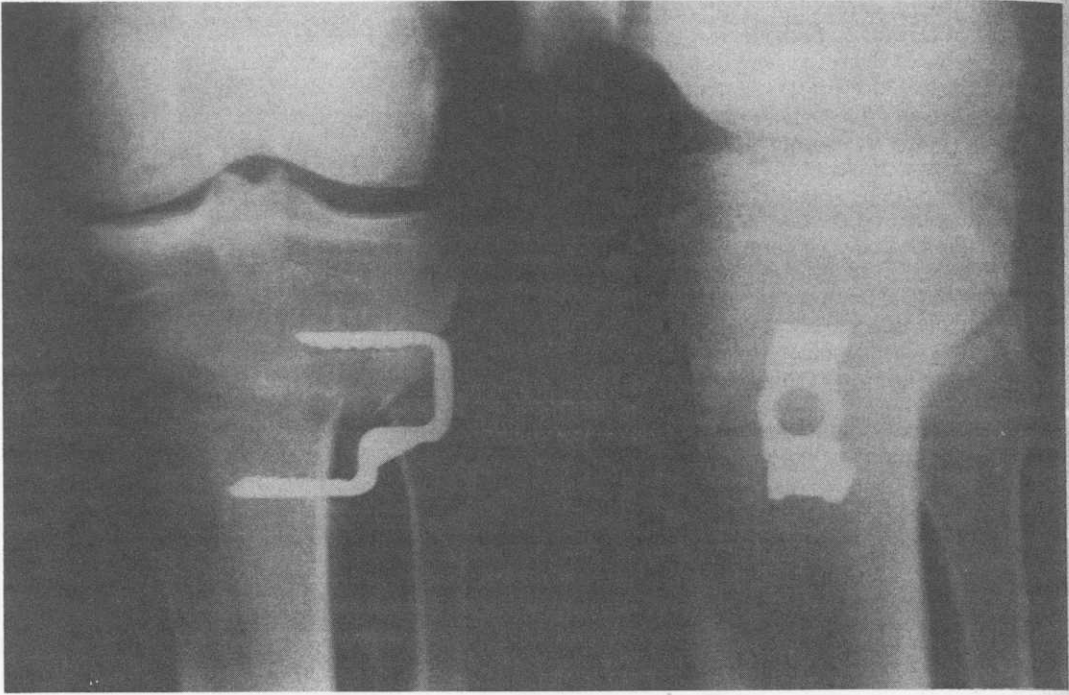


FIG. 3. Osteotomy of the left tibia of a 67-year-old man after 60 days of placebo stimulation; rated 2.

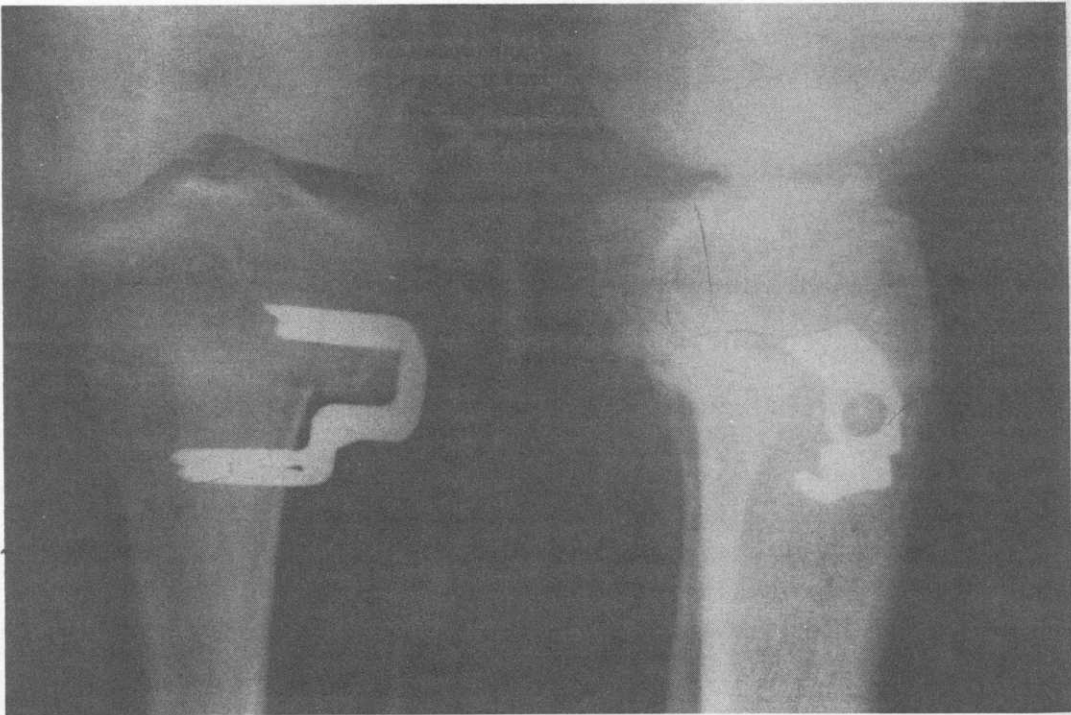


FIG. 4. Osteotomy of the left tibia of a 63-year-old woman after 60 days of placebo stimulation; rated 3.



FIG. 5. Osteotomy of the right tibia of a 69-year-old woman after 60 days of placebo stimulation; rated 4.

thrombophlebitis worsened into a pulmonary embolism; they both recovered.

All patients reported that they followed the postoperative weight-bearing regimen as instructed. On average, the stimulator was applied  $7.3 \pm 3.3$  SD hours per day in the control group and  $7.0$  ( $2.6$ , SD) hours in the stimulated group. The patients' compliance for device use was satisfactory.

This study was not aimed at determining whether the time of PEMF treatment could be correlated with the result; the purpose of the built-in timer was to monitor the patients' compliance. The analysis of the results as a function of the average hours of stimulation, however, suggests that the minimum time of daily, effective application is five hours per day. Within the control group, varying the stimulation time involved no change in the average score. In contrast, within the active group, the average score obtained by

patients applying the stimulator for less than five hours was  $2.3$ , whereas for those who applied the stimulator longer than five hours it was  $3.1$ . This observation suggests a dose-related effect of PEMF exposure; however, the small number of cases does not allow a significant statistical analysis. The roentgenogram analysis was conducted at Day 60. On average, roentgenograms at 57 ( $5$ , SD) days for the control group and 58 ( $6$ , SD) days for the stimulated group were available.

Figure 6 illustrates the rating of the roentgenograms in the two groups of patients. In particular, it is interesting to note the difference of distribution between the control and the active group, which proved to be statistically significant by chi-squared analysis ( $p < 0.04$ ). In the control group, 14 patients ( $73.7\%$ ) were included in the first and second categories as compared with five patients ( $27.8\%$ ) in the active group. Five of the con-

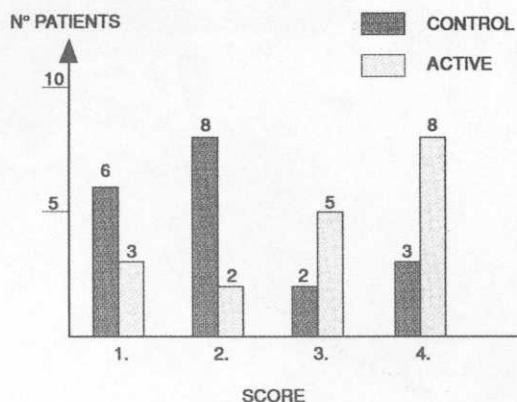


FIG. 6. Score values assigned to the osteotomy on the basis of roentgenographic evaluation. The distribution between control and active patients is significantly different:  $p < 0.04$ .

control group's patients (26.3%) and 13 of the active group's patients (72.2%) are included in the third and fourth categories. This difference is statistically significant, as determined

by the Fisher's exact test ( $p < 0.006$ ). On average, the score achieved by the osteotomies in the control group is 2.1 versus 3 in the active group.

## DISCUSSION

The data reported in this double-blind study confirm what was previously observed for femoral osteotomies, *i.e.*, a positive PEMF's effect on osteotomy union. This correlation with the study of femoral osteotomies has become much more evident in the remarkable similarity between the bridging images observed in the femur and those observed in this study, in particular for the fourth category (Fig. 7). The reader will find it interesting to review some of the figures that were reproduced in the previous paper.<sup>3</sup>

The score of 2 for an osteotomy at 60 days after operation can be considered normal for roentgenographic evolution. In the control

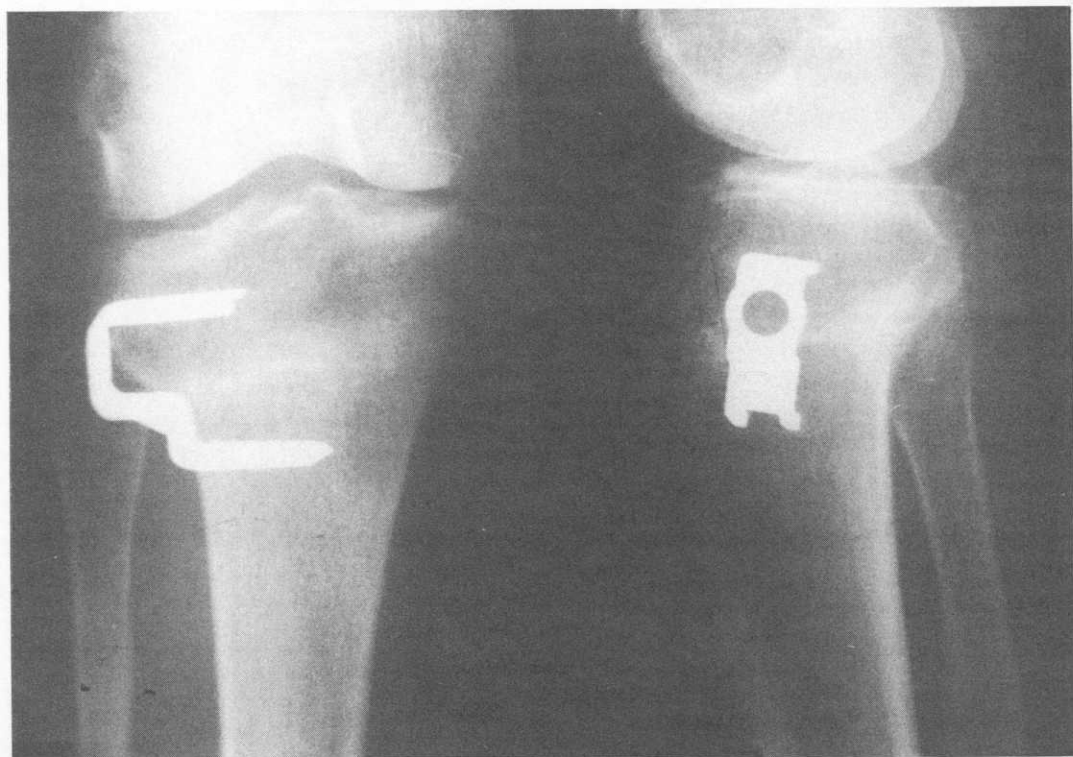


FIG. 7. Osteotomy of the right tibia of a 64-year-old woman after 60 days of active stimulation; rated 4.

group, the distribution of cases around the score 2 is symmetric, with six cases on the left (slower) and five cases on the right (faster). By contrast, when the sole variable, the magnetic field, is introduced, the distribution is clearly modified and loses its symmetry, with most of the cases (13) being positioned to the right of Group 2.

The data clearly demonstrate that electrical stimulation with PEMFs is capable of enhancing the rate of union of a tibial osteotomy in humans. Finally, they also confirm what was previously observed for femoral osteotomies, namely a positive effect exerted by the magnetic fields on osteogenesis.

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