A Prospective, Double-Blind Trial of Electrical Capacitive Coupling in the Treatment of Non-Union of Long Bones*

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ABSTRACT: Twenty-three patients who had an established non-union of a long bone were entered into a prospective, double-blind trial in which electrical capacitive coupling was used for treatment. Twenty-one patients completed the study: ten who were actively managed and eleven who were managed with a placebo unit. The non-union healed in six of the ten patients who had been managed actively but in none of the patients who had been managed with the placebo unit. This difference in the rates of healing between the actively managed and the placebo groups is highly significant (p = 0.004).

Electrical phenomena in bone were first reported, to our knowledge, by Fukada and Yasuda, in 1957. They originally called these potentials piezoelectric, since they were able to demonstrate a classic linear relationship between bone deformation and polarization at high rates of deformation.

Not long after the discovery of electricity by Faraday, the medical community began attempting to apply it in a therapeutic manner[16]. Geddes gave credit for the use of electricity in the treatment of fractures to Boyer, with his reference being to Stevens' English translation of Boyer's work[5]. We reviewed Boyer's original text[4] and could not find any reference to electrical treatment of fractures. It is therefore unclear when electricity was first applied to fracture-healing.

Many subsequent papers have reflected the effort that has been expended on understanding how these and other bioelectrical phenomena may affect the growth and healing of bone. The literature is now extensive and has been well reviewed[3,13,20].

Brighton and Pollock reported a longitudinal study of twenty-two non-unions that had been treated with electrical stimulation delivered by capacitive coupling; the rate of union was 77 per cent[6]. The authors believed that it would be difficult to perform a randomized, double-blind study in the United States because patients would not accept the possibility of being treated with a placebo unit for as long as six months.

In 1979, the senior one of us (J. B. K.) began a longitudinal (unpublished) study of direct-current stimulation in twenty-nine patients who had an established non-union. The average duration from the time of the fracture to the commencement of treatment was twenty-one months. The male:female ratio was eighteen to eleven, the age range was nineteen to sixty-three years, and the mean age was forty years. Nineteen (66 per cent) of the patients had healing. Between 1979 and 1984, an additional seventeen patients were managed with a variety of pulsed electromagnetic-stimulation devices; in thirteen, the bone united after five to eighteen months.

In 1986, we performed a longitudinal study of capacitive coupling in a similar population of eighteen patients. The male:female ratio was thirteen to five, the age range was nineteen to seventy-five years, and the mean age was forty-one years. The bone healed in thirteen patients.

Lavine and Grodzinsky stated that, despite the publication of encouraging longitudinal clinical studies, the proper clinical role of electrical stimulation in the treatment of established non-unions cannot be determined until randomized trials have been undertaken.

In the current study, the capacitively coupled bone-stimulation device was totally non-invasive and completely portable. It consisted of two stainless-steel disks, which were applied to the skin on either side of the limb in the approximate position of the non-union. These were connected to an electronic unit that delivered a five-to-ten volt peak-to-peak sine wave at sixty kilohertz between the disks.

In view of the apparent efficacy, non-invasiveness, and portability of capacitive coupling, approval was obtained from the hospital's Ethics Committee for a double-blind, randomized study with use of this technique. In this paper, we report the results of that study.

Material and Methods

Sixty-four non-unions in the immediate population served by our hospital had been treated in three previous (unpublished) studies; however, adequate numbers of patients subsequently ceased to be available

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locally. Therefore, in the last quarter of 1987, a postal appeal for suitable patients was made to members of The British Orthopaedic Association who were practicing in the United Kingdom. Twenty-three patients who met our criteria for inclusion in the study and who were willing to give informed consent to participate (with the knowledge that a placebo stimulator might be used) were thus recruited from the beginning of 1988 until the first quarter of 1989.

The definition of a non-union in this trial was that at least nine months had elapsed since the injury and there had been no clinical or radiographic signs of progress toward healing, at the site of the fracture, for at least three months before the patient was entered into the study. An anteroposterior radiograph, a lateral radiograph, and two oblique radiographs were used to determine the radiographic status at the site of the fracture. The same radiographic criteria had been used in the earlier (unpublished) studies in our hospital, in a multicenter trial of direct-current stimulation[7], and in a trial of capacitive coupling[6].

For a patient to be entered into the study nine months after the injury, there had to have been continuous immobilization from the time of the original injury, with no other form of treatment directed to the site of the injury during this period. For a patient to be entered into the study after more than nine months, the immobilization had to have been continuous for the three months preceding the commencement of the capacitive coupling. Again, no additional form of therapy, operative or non-operative, could have been applied to the site of the injury during that three-month period. Previous operations, the presence of metal implants (broken or intact), or previous electrical stimulation were not grounds for exclusion provided that the treatment had been given more than three months before the patient was entered into the study. An infection at the site of the fracture also did not preclude entry into the study.

Other criteria for exclusion included an established synovial pseudarthrosis or a gap or bone defect of more than one-half the width of the bone at the location of the fracture; both of these conditions have been found to render a fracture unsuitable for electrical stimulation[7]. A synovial pseudarthrosis was recognized by excessive mobility of the fracture site or by a cold cleft between hot fragments on a technetium methylene-diphosphonate bone scan[10]. Generalized disorders of bone metabolism were also grounds for exclusion.

No upper age limit was applied; however, all patients had reached skeletal maturity.

The electrical current was delivered with the use of commercially available Orthopak bone-growth stimulators (Biolectron, Hackensack, New Jersey), which were modified to accomplish double-blinding. These modifications did not affect the designated active units. The placebo units were adjusted to give no electrical output across the electrodes while being used by the patient except during the brief (less than thirty-second) daily check of the equipment and the battery. During these brief periods, the level of the current was about one milliampere root-mean-square, compared with the therapeutic range of five to ten milliamperes in the active units. The placebo also delivered a small signal when monitored momentarily by the investigators during the patient's clinical visits. This ensured that the investigator could not distinguish between the active and the placebo units. It was assumed that the extremely short duration and the low amplitude of the current would be unlikely to have a therapeutic effect.

The units were powered by a nine-volt transistor-radio battery, which was renewed daily. The active units continuously delivered a five-to-ten-volt peak-to-peak sine wave at sixty kilohertz.

Externally, all units appeared identical but were marked with individual code numbers. The key to the code was concealed from the investigators and kept by the manufacturer. The manufacturer took no part in the allocation of the numbered units to the patients, nor was the manufacturer informed of the patients' outcomes when the code was eventually broken. After we had been informed whether a unit was active or a placebo, we tested it ourselves to ensure that the information was correct.

Each potential patient was examined by the senior one of us (J. B. K.) to ensure that the criteria for entrance into the study had been met. If the criteria had been fulfilled, the patient was then referred to the junior one of us (G. S.), who allocated the stimulator units randomly as they arrived after having been processed for importation by Her Majesty's Customs and Excise. The patient was managed conventionally (with a plaster cast or a brace), as was appropriate for the specific fracture, by the junior one of us, but with the addition of the electrical stimulator. Holes were cut into the plaster cast to permit the application of surface electrodes. The precise form of external support was a continuation of that which had been used in the three preceding months, to ensure that the addition of the electrical stimulation was the only new variable.

Similarly, even when we considered that a period of non-weight-bearing was advisable at the beginning of capacitive coupling, this judgment was not enforced. Most of the patients had previously been encouraged to bear weight on the extremity, and we thought it inappropriate to change this behavior because of the risk of introducing an additional variable.

The patients were familiarized with the apparatus, instructed in its use and in the daily cleaning of the sites of the electrodes, and supplied with all necessary batteries. The evaluations were performed at intervals of three months (or sooner, if problems had arisen with the apparatus or the cast), at which time new radiographs were also made.

The protocol provided for an initial period of treat-

TABLE I

DATA ON THE TWENTY-ONE PATIENTS

Case	Sex, Age (Yrs.)	Mean Duration of Non-Union (Mos.)	Site of Fracture	Type of Fracture	Type of Non-Union	Previous Operations	Presence of Metallic Fixation Device	Motion*	Ext. Support	Duration of Treatment (Wks.)	Healing
Actively managed group											
1	M, 27	11	Dist. part of tibia	Commin., open	Atrophic	Débrid., skin-grafting	No	+	Brace	18	Yes
2	M, 31	23	Dist. part of ulna	Transverse, closed	Hypertrophic	—	No	+	Plaster cast	18	Yes
3	M, 54	16	Mid-part of tibial shaft	Oblique, open	Atrophic	Débrid., screws, myocut. flap	Yes	+	Plaster cast	21	Yes
4	M, 50	83	Mid-part of fem. shaft	Transverse, closed	Oligotrophic	Intramed. nailing ×2	Yes	–		26	No
5	M, 33	41	Mid-part of tibial shaft	Oblique, open	Hypertrophic	Débrid., plate and screws; débrid., bone-grafting, ext. fixat.	No	+	Plaster cast	28	Yes
6	M, 28	11	Mid-part of tibial shaft	Oblique, closed	Atrophic	Traction	No	+	Plaster cast	37	No
7	M, 36	17	Mid-part of tibial shaft	Commin., closed	Atrophic	Plate and screws; bone-grafting, ext. fixat.	No	+	Brace	30	No
8	M, 31	20	Prox. part of femur	Commin., open	Hypertrophic	Débrid., plate and screws; débrid., removal of fixat.	No	+	Brace	26	Yes
9	F, 55	59	Prox. part of femur	Oblique, open	Hypertrophic	Plate and screws; débrid., removal of fixat.; bone-grafting	No	+	Brace	26	No
10	F, 51	28	Prox. part of femur	Oblique, closed	Oligotrophic	Intramed. nailing	Yes	–		17	Yes
Placebo group											
11	M, 38	32	Mid-part of tibial shaft	Oblique, open	Hypertrophic	Débrid., ext. fixat.	No	+	Brace	26	No
12	M, 29	18	Mid-part of tibial shaft	Commin., open	Oligotrophic	Plate and screws; removal of fixat.	No	+	Brace	26	No
13	M, 49	31	Mid-part of tibial shaft	Commin., open	Oligotrophic	Screws; ext. fixat.; myocut. flap	Yes	+	Plaster cast	26	No
14	M, 35	33	Mid-part of ulnar shaft	Oblique, closed	Hypertrophic	Plate and screws; bone-grafting ×2	No	–	Brace	26	No
15	M, 23	13	Mid-part of tibial shaft	Transverse, closed	Oligotrophic	Intramed. nailing; removal of fixat.; débrid.	No	+	Plaster cast	26	No
16	F, 87	43	Dist. part of tibia	Commin., closed	Atrophic	Plate and screws; bone-grafting	No	+	Brace	26	No
17	F, 58	20	Mid-part of tibial shaft	Commin., closed	Oligotrophic	Plate and screws; ext. fixat., bone-grafting	Yes	+	Brace	26	No
18	M, 34	12	Prox. part of tibia	Oblique, open	Oligotrophic	Débrid.	No	+	Brace	26	No
19	M, 23	23	Mid-part of tibial shaft	Commin., open	Atrophic	Débrid., ext. fixat.; bone-grafting	No	+	Brace	26	No
20	M, 68	33	Dist. part of tibia	Commin., closed	Oligotrophic	Plate and screws	Yes	+	Brace	26	No
21	F, 60	28	Prox. part of tibia	Oblique, closed	Oligotrophic	Plate and screws; bone-grafting	Yes	+	Brace	26	No

*Estimated clinically, as absent (–), jog (+), or obvious (++).

ment of six months. Any patient in whom the non-union had healed before six months was withdrawn from treatment but continued to be evaluated at appropriate intervals until the end of the study. If no healing had taken place by six months, the patient was withdrawn from the study and was offered an alternative form of treatment. If the patient wanted to continue to receive or to begin electrical treatment, the code was then broken, and those who were using a placebo unit were offered electrical stimulation. If a non-union was healing but had not completely healed at six months, the treatment was continued, with the patient unaware of whether the unit was active or a placebo, for a maximum of nine months.

At the conclusion of the study, the non-union was blinded with regard to any other information relative to the patients.

Both the clinical assessment by the junior one of us (G. S.) and the radiographic assessment by the senior one of us were performed before the assignment of the units was decoded; the junior one of us had used the radiographs regularly in the treatment of the fractures.

Compliance with the use of the device was assessed according to a readout from the unit that showed the number of days of usage.

All patients were seen a minimum of six months after the treatment had been discontinued, to verify that late failure had not occurred.

The outcome was analyzed by application of a two-tailed Fisher exact test. The level of significance was

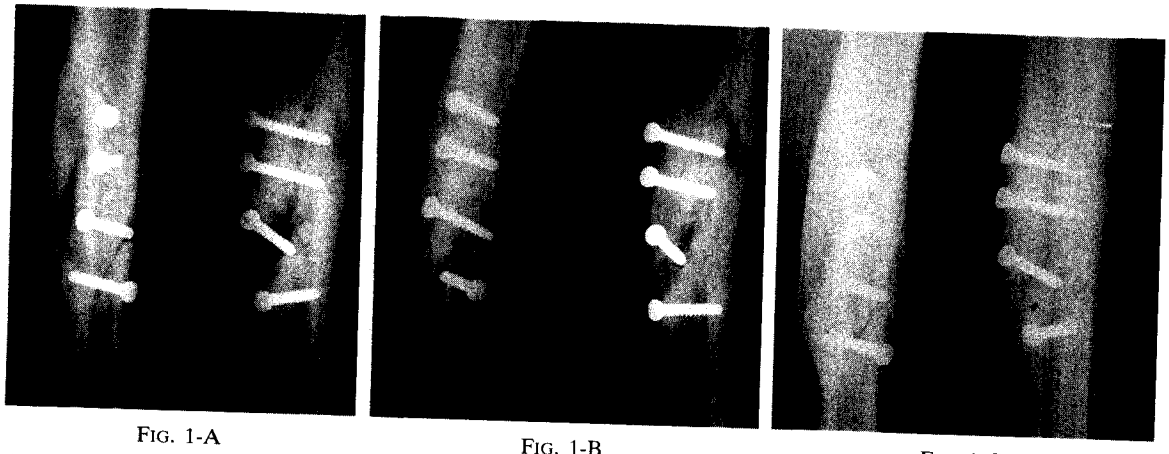

FIG. 1-A FIG. 1-B FIG. 1-C

Figs. 1-A, 1-B, and 1-C: Case 3. Anteroposterior and lateral radiographs of the tibia of a fifty-four-year-old man who had sustained multiple injuries in a vehicular accident, including an open fracture of the tibial diaphysis and a closed fracture of the medial malleolus. The malleolar fracture healed after screw fixation. The diaphyseal fracture was debrided and stabilized with interfragmentary screws before a myocutaneous flap was mobilized for closure. The soft tissues healed, but after sixteen months of immobilization in a plaster cast, the diaphyseal fracture remained painful and mobile during examination. There had been no radiographic evidence of progress toward union in the three months before the patient was entered into the study.

Fig. 1-A: Radiographs made at the time of entry into the study, before electrical capacitive coupling.

Fig. 1-B: After six months of active electrical capacitive coupling, there was no pain or motion clinically when the fracture was stressed. Trabecular bridging is visible.

Fig. 1-C: Six months after the end of electrical treatment, the fracture had united, with remodeling of bone.

assigned to one of two categories: healed or not healed. At six months, union was considered present when trabecular bridging could be seen on all four radiographs, there was no apparent movement at the site of the fracture clinically, and there was no pain when the site was stressed. A non-union was defined as healing (although not yet healed) if, in comparison with the findings at the previous visit, there was less pain, less motion clinically at the site of the fracture, and a definite increase of callus radiographically. A lack of healing was defined as the absence, or cessation before union, of any clinical or radiographic improvement. A non-union that was still healing at nine months was classified as not having healed.

At the end of the period of treatment, the senior one of us (J. B. K.), who had not been involved in the management of the patients, reviewed the radiographs while

0.05. In view of the five comparisons, the experiment-wise chance of a spurious significant difference[18] is 23 per cent ($1 - [1 - 0.05]^5$).

Results

Of the twenty-three patients, two (one from each group) were excluded from the study for a persistent failure to comply with use of the device. The patient from the placebo group did not use the device for repeated long periods. The patient from the actively managed group was in the habit of removing parts of the brace that he considered superfluous and, occasionally, the entire brace. He had a mobile yet painless non-union that was thus uncontrolled.

The demographic data for the two groups were comparable (Table I). The mean duration of non-union before the study was thirty-one months (range, eleven to

eighty-three months) for the actively managed group compared with twenty-six months (range, twelve to forty-three months) for the placebo group. The age range in the actively managed group was twenty-seven to fifty-five years (mean, forty years; median, thirty-six years) compared with twenty-three to eighty-seven years (mean, forty-six years; median, thirty-five years) for the placebo group. The mean age in the placebo group was skewed by the presence of two patients, who were eighty-seven and sixty-eight years old.

At the most recent follow-up evaluation, ten patients in the actively managed group and eleven in the placebo group had completed the course of treatment.

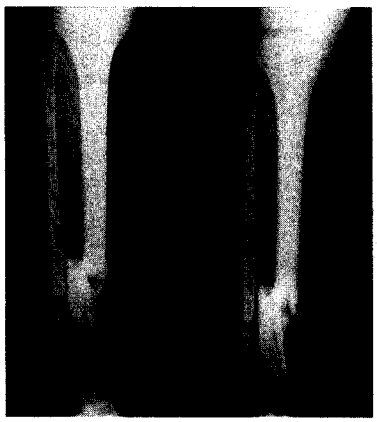

FIG. 2-A

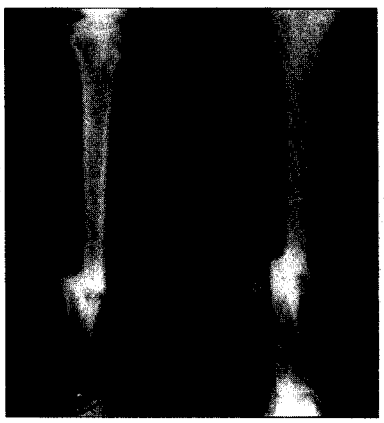

FIG. 2-B

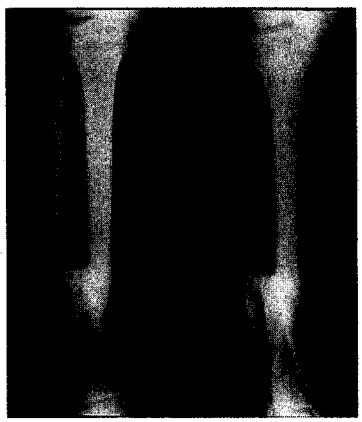

FIG. 2-C

Figs. 2-A, 2-B, and 2-C: Case 15. Anteroposterior and oblique radiographs of the tibia of a twenty-three-year-old man who had sustained a closed fracture of the tibial diaphysis while playing soccer. He had had closed intramedullary nailing of the tibia on the day of the injury, but an infection developed at the site of the fixation within a few months, with formation of an abscess. The fixation device was removed and the abscess was drained; *Staphylococcus epidermidis* grew on culture. He was managed with flucloxacillin and a plaster cast. The discharge from the wound lessened but did not stop. After thirteen months, the patient was entered into the study. The fracture was mobile and tender. A small amount of pus discharged daily, but there was no surrounding inflammation. He did not receive additional antibiotics.

Fig. 2-A: Radiographs made at the beginning of treatment with a placebo unit.

Fig. 2-B: After nine months of treatment with the placebo unit, the fracture site was still mobile clinically, painful, and discharging pus. No progress toward healing was seen.

Fig. 2-C: Six months after a fourteen-week period of electrical capacitive coupling, there was no longer any discharge, and the fracture had united.

Six of the ten patients in the actively managed group had a solid union (Figs. 1-A, 1-B, and 1-C), compared with none of the patients in the placebo group.

We compared the data for the patients in whom an actively treated fracture had united with those for the patients in whom an actively treated fracture had failed to unite. The mean duration of capacitive coupling in the six patients who had healing was twenty-one weeks, compared with thirty weeks in the four who did not have healing. The mean duration of nonunion before the study in the patients who had healing was twenty-three months (range, eleven to forty-one months), compared with forty-three months (range, eleven to eighty-three months) in the patients who did not have healing.

We were unable to demonstrate any relationship between a history of an open fracture and an eventual satisfactory union in the actively managed group. The skin had healed in all five patients who had had an open fracture in this group by the time that the patients were entered into the study. The three tibial fractures that united had been open, and the two ununited tibial fractures had been closed. The ulnar fracture that united had been closed. Of the two femoral fractures that united, one had been open and the other had been closed. Of the two femoral fractures that did not unite, one had been open and one had been closed.

A metallic fixation device was present in three patients in the actively managed group. These devices included a Küntscher nail in a femoral fracture that failed to unite after treatment with capacitive coupling, a locked intramedullary nail in a femoral fracture that united, and interfragmentary screws in a tibial fracture that united.

Two patients (Cases 5 and 8) had an allergic reaction to the electrode disks on the skin, but this resolved after treatment with hydrocortisone ointment and adjustment of the position of the disks.

In one patient (Case 6), a tibial fracture failed to unite despite thirty-seven weeks of active treatment, but an accompanying fibular fracture healed. Although there was a mass of new callus on the tibia, union did not occur. Because of the strict end-point in this study, the outcome was classified as a failure.

None of the fractures in the eleven patients in the placebo group united. Ten of these patients had a tibial fracture; five of the fractures were open and five, closed. The eleventh patient had a closed ulnar fracture. The skin had healed, by the time that the patients were entered into the study, in all but one of the patients who had had an open fracture. The patient in whom the skin

had not healed (Case 15) had originally had a closed fracture, but infection and drainage had developed after internal fixation. Residual metal was present in four of the patients who had had a tibial fracture: a broken plate and screws in one and screws alone in the others.

Outside of the scope of this double-blind study, six patients who had been managed with a placebo later chose to have treatment with an active unit. The fracture subsequently united in two of these patients: very rapidly (after six weeks) in one (Case 18) and after fourteen weeks in the other (Case 15). The latter patient was the only one who had an infection with active drainage from the bone (Figs. 2-A, 2-B, and 2-C). *Staphylococcus epidermidis* grew on culture of specimens of the discharge. No antibiotic was administered during the study period. The drainage stopped once union had occurred.

In one patient (Case 19) who had been managed with a placebo unit and subsequently chose active treatment, after nine months of active treatment the fibular fracture had united and the proximal, previously grafted section of a segmental non-union of the tibia had become incorporated, but the distal part of the fracture remained ununited. In another patient (Case 12), the pain had resolved soon after he had switched to active treatment, and motion (tested clinically) at the site of the tibial fracture was later absent; however, trabecular bridging still could not be seen on any of the four radiographs after nine months of active treatment. Two patients (Cases 11 and 13) had no apparent change at the site of the fracture despite their having switched to active treatment.

The results of the double-blind study were analyzed with the Fisher exact test for small sample size. There was a significant association ($p = 0.004$) between the use of capacitive coupling and eventual union. It may be considered that this statistical analysis is not acceptable because of the exclusion of the two patients who did not follow the protocol. If the data for these two patients are taken into account (the fracture in the patient in the placebo group united while the fracture in the patient in the actively managed group did not), there is still a significant association ($p = 0.02$) between the use of capacitive coupling and union.

We also considered the confounding influence of the two oldest patients in the placebo group, both of whom had had a tibial fracture. If the data for these two patients are excluded, the mean age of the patients in this group is thirty-nine years (median, thirty-five years; range, twenty-three to sixty years). The association between the use of capacitive coupling and union is still significant ($p = 0.01$).

Our results may also be subject to criticism because of the mixture of fracture sites that were included. It is unfortunate that all of the femoral fractures were assigned by chance to the actively managed group. A separate analysis of only the tibial fractures was performed. Of the five tibial fractures in the actively managed group, three united. Of the ten tibial fractures in the placebo group, none united. The Fisher exact test, if applied only to the tibial fractures, shows that the difference in the results between the actively managed and the placebo groups is still significant ($p = 0.02$), even if the data for the two oldest patients in the placebo group are excluded ($p = 0.04$).

Discussion

The evidence that has been accumulating from double-blind studies supports the view that electrical treatment can bring about healing in patients who have a non-union of a fracture. The use of pulsed electromagnetic fields was reported to have a significant effect ($p = 0.03$) in a double-blind study of thirty-four non-unions of the tibia[17]. However, all of the patients in that study had additional treatment consisting of external fixation and a fibular osteotomy.

To our knowledge, Sharrard reported the largest double-blind study in which electrical treatment was used at the sites of fractures. Forty-five patients who had a fracture of the tibial shaft were managed with pulsed electromagnetic fields, without any additional treatment other than immobilization of the limb in a cast. Sharrard found a significant relationship between the use of pulsed electromagnetic fields and enhanced fracture-healing; however, his study was concerned with delayed union, which was defined as a lack of healing sixteen to thirty-two weeks after the injury.

Barker et al. reported the results of a double-blind study of the use of pulsed electromagnetic fields for the treatment of tibial non-unions of at least fifty-two weeks' duration. Sixteen patients used either an active or a placebo apparatus for twenty-four weeks while the limb was immobilized in a plaster cast. No significant difference in the rates of union was demonstrated. However, it was subsequently reported that the control group had received a very small pulsed electromagnetic field[15]. In the light of recently published work on the effect of low-frequency electrical fields on osteogenesis, use of the placebo unit may have had a profound influence on the stimulation of bone formation[14].

We want to emphasize that the patients in the present study had an established non-union, not a delayed union, and that the definition of non-union that we used was also employed in previous studies of non-unions that were treated by other means[2,9].

We concede that we know of no large longitudinal study in which the very short, low-intensity signal that we used in the placebo unit during the daily battery check was employed; however, there was no evidence of progress to union in any of the eleven patients who were thus managed, three of whom subsequently had a change in the status of the non-union after active electrical treatment.

It will be questioned why this study was ended after only twenty-three patients had been recruited. It has

become more and more difficult to find patients who have a non-union of a long bone. We believe that this is partly because other centers in the United Kingdom are studying various forms of electrical stimulation, and partly because of a progressive change in the treatment of fractures of the lower limbs. The use of locked intramedullary nailing, even in certain open fractures, has now been established[8], and there has also been increased emphasis on restorative soft-tissue operations to improve blood flow adjacent to the fracture.

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