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CA Bassett, SN Mitchell and SR Gaston
J Bone Joint Surg Am. 1981;63:511-523.

The Journal of Bone and Joint Surgery

American Volume

VOLUME 63-A, No. 4 APRIL 1981

Treatment of Ununited Tibial Diaphyseal Fractures with Pulsing Electromagnetic Fields*

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ABSTRACT: **One hundred and twenty-five patients with one hundred and twenty-seven ununited fractures of the tibial diaphysis were treated exclusively with pulsing electromagnetic fields. The over-all success rate in healing of the fracture with this surgically non-invasive out-patient method was 87 per cent. The success rate was not materially affected by the age or sex of the patient, the length of prior disability, the number of previous failed operations, or the presence of infection or metal fixation.**

Patients with an ununited fracture of the tibial diaphysis present the orthopaedic surgeon with a major therapeutic challenge, particularly when a history of prior infection is present or there is active drainage from the fracture site. A method for inducing weak electrical currents in bone by pulsing electromagnetic fields has been found to provide the orthopaedic surgeon with a surgically non-invasive modality in the management of this difficult problem[20,21,23].

The therapeutic use of asymmetrical pulsing electromagnetic fields in the treatment of ununited fractures is the result of a systematic twenty-five-year investigation of bioelectrical phenomena in the skeletal system and of their role in regulating its cellular elements[9]. In the 1950's, histotypic function by mesenchymal cells was found to be controlled by nutritional and biomechanical factors in the microenvironment[1-3,12]. A search for a mechanism to explain mechanical effects on the function of bone cells demonstrated that hydrated, living bone became electrically charged, piezoelectrically, when it was deformed[11]. Subsequently, a hypothetical link to Wolff's law was proposed for this effect[4-8,11,24]. Given this hypothesis, it was considered essential to establish the cellular effects of weak electrical currents in bone. It was demonstrated in the laboratory that such currents increased bone formation at the cathode (negative pole)[17]. This report was followed by a series of bioelectrical studies from Friedenberg and Brighton's group in Philadelphia[32-37] and from other investigators[39,43,51,55].

An ability to increase the rate and mass of bone formation on "command" appeared to have clinical importance in a variety of orthopaedic areas. Since the method required the insertion of electrodes, however, a number of problems were envisioned, including iatrogenic infection. Osteogenesis was limited to the immediate vicinity of the cathode, and therefore multiple electrodes would be required for large bones. For generalized conditions such as osteoporosis, this approach clearly was not practical. However, this method has subsequently been applied clinically for non-unions[25-27,34,40,42,52].

In the search for a non-invasive method of changing the electrical environment of cells, cultures of fibroblasts[13] and later rabbit fibular osteotomies[14] were subjected to constant and time-varying capacitative fields of 100 to 1000 volts per centimeter. Both the *in vitro* and *in vivo* experiments were successful and were later confirmed by other laboratories[44,45,49,50]. Although it was demonstrated that cell function could be changed at a distance, an unacceptably high level of voltage was needed and electri-

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cal safety could not be assured.

Investigations were begun in 1970 to determine whether asymmetrical pulsing electromagnetic fields could induce biologically active currents in bone. Pulses similar to those described previously for hydrated bone[11,28] were induced by means of external coils. The hypotheses, principles, and experimental steps leading to clinical application were documented elsewhere[9,10]. The success of the animal studies[18,19] led to cooperative clinical trials in selected patients for whom the use of pulsing electromagnetic fields offered high benefits and a low risk of complications. A significant number of these patients had been disabled for more than two years and many faced amputation[20,21,23]. The 127 ununited tibial diaphyseal fractures reported here were managed by us personally. The group is part of a larger pool of 1,000 patients who reached a final result but were managed by more than 300 individual orthopaedic surgeons, with an over-all success rate of 80 per cent. Unlike the present group, the larger group included non-unions of other bones as well as the tibia, failed arthrodeses, and congenital pseudarthroses[15].

Patient Population and Methods

Nearly equal numbers of ununited fractures of the tibial diaphysis were treated at the New York Orthopaedic Hospital and at other centers or private offices in the United States, operating under a standard protocol of treatment. The 125 patients with 127 tibial lesions whose cases are presented here were all selected and treated under our supervision since 1974. In the first three years most patients in the study had a history of multiple surgical failures — either infection or drainage, or both, and long-term disability (more than two years). Often, amputation had been recommended. During the last two years of this study less complicated cases were accepted, including a few patients with delayed union. Only two patients (1.6 per cent) had surgical procedures while being treated with the coils, and these were at the beginning of the treatment. The surgical procedure in both patients consisted of a fibular osteotomy to permit manipulative correction of the tibial deformity. In all patients, the clinical and radiographic features of the non-union had not changed for a minimum of four months prior to starting treatment.

The patients were classified as having a delayed union or non-union according to the criteria of the AO Group[48,56]. A delayed union was defined as no clinical or radiographic evidence of union at four to nine months after fracture. A non-union was defined as a fracture that had not united by nine months after fracture. In both non-unions and delayed unions either fibrocartilage or fibrous tissue, or both, was postulated to occupy the gap between the bone ends. Generally, these patients had neither gross motion in all planes nor radiographic evidence of a gap in excess of one centimeter. Both "hypertrophic" and "atrophic" non-unions were accepted for treatment. Active drainage or a history of infection were not considered to be contraindictions to treatment by this method. The term

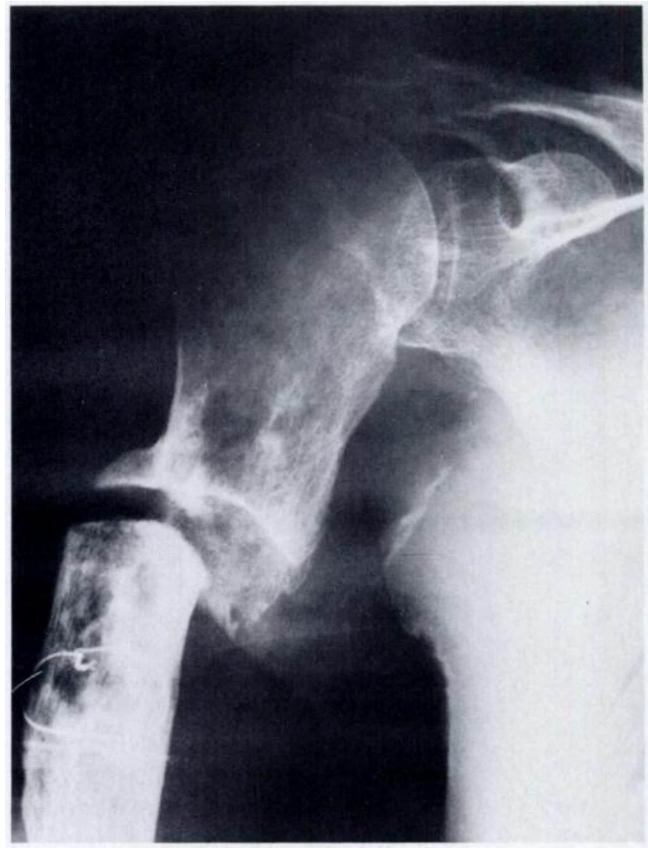

FIG. 1

Long-standing synovial pseudarthrosis of the proximal part of the humeral shaft. Note the smooth, concentric "joint" surfaces flanking the gap, with marginal sclerosis of bone mimicking subchondral bone. There was gross motion in all planes. Lesions with these clinical characteristics were not accepted for treatment.

pseudarthrosis was reserved for ununited fractures that demonstrated gross instability in all planes and usually showed smooth eburnated bone covering the fracture ends (Fig. 1). The present pulses are ineffective in treating such pseudarthroses with a fluid-filled gap, and such lesions were not accepted for treatment.

All patients whose fractures met these clinical and radiographic criteria followed similar therapeutic regimens, although over the course of the first five years we placed increasing emphasis on adequate plaster-cast immobilization, non-weight-bearing, and an organized post-treatment rehabilitation program. The majority of patients were treated in the past two years and the protocol has become standardized. The current treatment program is as follows.

As the pulse-shaping circuits and coils are provided by the manufacturer* on prescription for each patient, an accurate measurement of the *final* intercoil distance (within $\pm$ 0.25 inch [0.6 centimeter]) is necessary. This step determines the size (diameter) of the coils and the voltage applied to the coils. Cast thickness (diameter, not circumference) is measured with calipers at the level of the

* EBI (Electro-Biology, Inc.), 300 Fairfield Road, Fairfield, New Jersey 07006. Bi-Osteogen System 204.

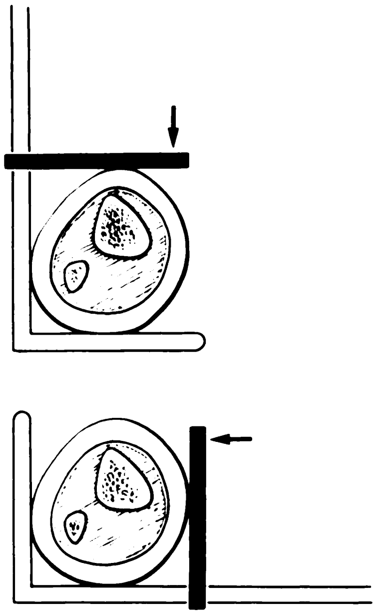

FIG. 2

Diagram demonstrating the use of calipers to determine intercoil distance (diameter of the extremity and cast at the level of the non-union).

ununited fracture (Fig. 2). The technical and physical principles were described in detail elsewhere[9,21].

After calibration by the manufacturer, the equipment is delivered to the orthopaedic surgeon for application to the cast. In patients with clinically acceptable alignment, a well molded, tight, long plaster cast is applied over a single layer of padding with the knee in 40 degrees of flexion. When instability at the non-union site and axial malalignment are present, the best reduction obtainable is attempted by manipulation without anesthesia. Internal metallic devices such as screws, wires, nails, or plates are not removed before treatment, since 316L stainless-steel and cobalt-chromium alloys are not significantly permeable to magnetic flux and therefore are reasonably compatible with the electromagnetic field.

A coil-placement block then is temporarily fixed to the cast surface by adhesive tape. The block is positioned directly over the non-union site by so-called dead-reckoning, and its position is marked on the cast. If the site is at or proximal to the middle third of the tibia, the block is placed anteriorly. Otherwise, the block is placed laterally and is offset anteriorly to center over the tibia, which is eccentrically placed in the leg.

Anteroposterior and lateral radiographs are then made with the center of the x-ray beam aimed at the block. If positioning is adequate (that is, the non-union is centered within the confines of the block), the block is fixed finally to the cast surface with a thin layer of plaster. When its position is not satisfactory, an adjustment is made using the block outlines on the cast as a guide. The final diameter of the cast, from the base of the block (not its summit), is compared with the intercoil distances supplied by the manufacturer. This is to assure the induction of a therapeutic voltage across the fracture site. If the diameter is within 0.5 ± 0.25 inch (1.3 ± 0.6 centimeter) of the specifications, coils are fitted to the coil-placement block and adjusted so that each coil in the pair is at 180 degrees and they are generally parallel to one another on opposite sides of the cast. Care is taken to prevent skewing of the coil either proximally or distally, as well as medially or laterally. Adjustment of the Velcro strap link between the pair of coils accommodates variations of cast circumference (not diameter). The final assembly is held in place by tension in an encircling elasticized Velcro strap.

Utilizing the enclosed manufacturer's instructions, the physician can instruct the patient in the use of the uncomplicated equipment (Fig. 3). The pulse-shaping unit is inserted into a standard electrical wall outlet and the coils are attached to the front of the unit with a special plug. The timing clock on the front panel is a check, for both the patient and the surgeon, on the number of hours of daily use. The necessary daily ten hours of treatment can be cumulative, as long as no one exposure time is less than one hour. Interruptions not exceeding five to ten minutes are permitted. Both audible and visual alarm features signalling circuit or cord failures are demonstrated to the patient. An alarm is needed since the active fields cannot be sensed by the patient and pulse characteristics must be reasonably accurate for effective treatment. The ten volts of current applied to the coils, however, is non-hazardous even if the coils are inadvertently immersed in water.

Non-weight-bearing is a *critically* important feature of the management program, and the patients are admonished not to support or steady themselves with the limb. The well molded long plaster cast, with the knee flexed to 40 degrees, is hypothesized not to apply significant tensile load to the non-union site during walking, as the major weight of the cast is carried by the distal part of the thigh and the knee. Furthermore, the position minimizes the chance for significant weight-bearing with resultant application of bending or torque forces to the soft tissues in the gap. These forces (mainly tensile) are thought to be counterproductive to the first step (Stage I) of healing of the non-union, during which the fibrocartilage in the discontinuity is calcified. This instruction often runs counter to the patient's previous experience with full weight-bearing in a patellar tendon-bearing cast, and therefore it requires thorough explanation and persistence on the part of the orthopaedic surgeon in order to ensure the patient's compliance. Radiographs are made at four to six-week intervals *without removing the plaster cast.* When possible, standardized anteroposterior and lateral radiographs are made with the *tube centered* on the *block.* The amperage, kilovoltage, and development times should be as constant as possible each time radiographs are made. These steps ensure radiographs in which densities in the non-union site and surrounding sclerotic bone can be compared with some accuracy, even through plaster. The approach also alleviates rotational or projectional deviations. For more accurate assessment of fracture gaps with compound planes, tomograms are made.

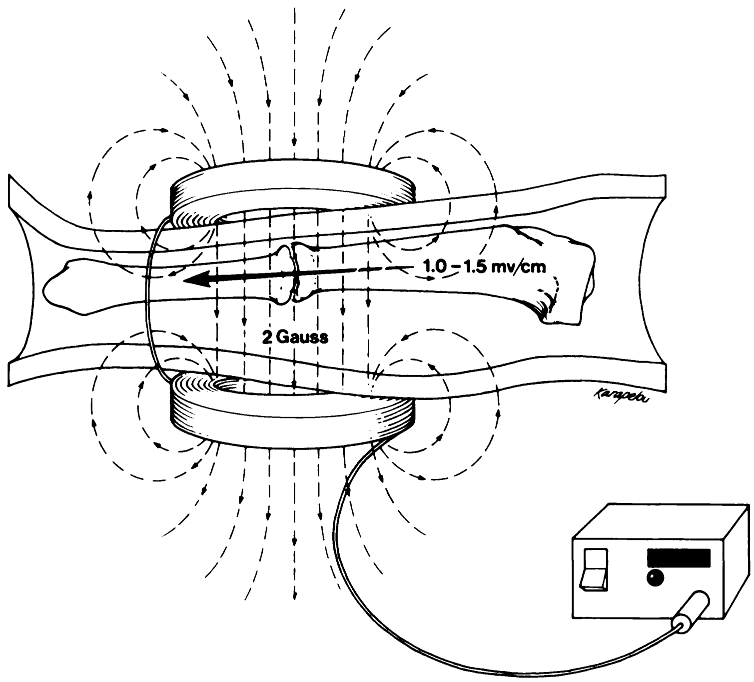

FIG. 3

The pair of coils is mounted anteriorly and posteriorly on the surface of the cast and is plugged into the pulse generator. The generator, which is attached to the 110-volt line, "drives" the coils with ten to eighteen volts, depending in part on the distance between the coils. As current flows in the coils, a pulsing electromagnetic field is established between the pair, penetrating the cast and soft tissues. The field is weak (average, two gauss) and the magnetic flux lines (B field), which are at right angles to the bone in this configuration, induce a voltage drop (E field, at a right cycle to the B field) along the long axis of the tibia of one to 1.5 millivolts per centimeter.

Evidence of healing is not based on the appearance of external callus, which rarely occurs, but on changes in the fracture gap and the dense bone flanking it. When an increase in radiographic density (fuzziness) in the tissues in the gap and a patchy loss of density in the sclerotic bone (sclerolysis) can be documented (often at one to three months after the onset of treatment), a coil effect is established (Stage-I healing) (Fig. 4). The microanatomical details of this process have been published[22]. When these changes are seen, the leg is placed in a short cast and impactive axial compression exercises (heel-strike) are begun. In this exercise, the heel is brought down forcibly on a bathroom scale to the prescribed level of load. The rate of loading (impactive) approximates that of heel-strike on the floor during brisk walking. The load and number of strikes, which can be done at intervals of one to several seconds, are described here for several conditions of stability. In some patients with either large fracture gaps or drainage, or both, the interval from the start of treatment until the end of Stage-I healing (fuzziness in the gap and sclerolysis) exceeded the one to three-month interval. Under these circumstances, axial compression exercises are not commenced until the radiographic signs of coil effect are present. Again, patients are admonished to remain totally *non-weight-bearing* until otherwise instructed.

The axial compression exercises take advantage of experimental data indicating that adequate impactive loading rates are required to produce maximum endogenous voltages in the bone (piezoelectrically)[11,28]. The amount of loading is adjusted by the stage of healing and the orientation of the non-union gap in space. If the fracture is transverse and hypertrophic and there is radiographic evidence of advanced healing at one to three months, the patient is instructed to repetitively *strike* the heel on a bathroom scale to a maximum pressure of twenty-five to thirty pounds (eleven to fourteen kilograms) fifty times, three times a day, for three weeks. If there is aching at the fracture site, the amount of the load or the number of repetitions is decreased until the ache disappears. If no ache develops, the load is doubled for an additional three weeks before progressive partial weight-bearing (within ache tolerance) in a plaster cast is permitted. For oblique or comminuted fractures, the schedule consists of ten to fifteen pounds (five to seven kilograms) of heel *strike* done fifty times, three times a day, for three weeks, advancing to twenty to thirty pounds (nine to fourteen kilograms) for three weeks and then forty to sixty pounds (eighteen to twenty-seven kilograms) for three weeks, preceding partial weight-bearing. In patients with a fixed equinus deformity (in or out of the plaster cast), the heel of the cast is elevated to avoid weight-bearing or pressure through the distal parts of the metatarsal shafts or in the metatarsophalangeal joints. All patients are instructed to be certain that the fore part of the foot of the cast projects beyond the edge of the scale and to strike only with the heel.

Stage-II healing usually occurs at or before the time of partial weight-bearing and is indicated by the appearance of consolidated bone-stress lines that bridge the fracture gap in at least three distinct locations on the anteroposterior and lateral radiographs. The cast, coils, and

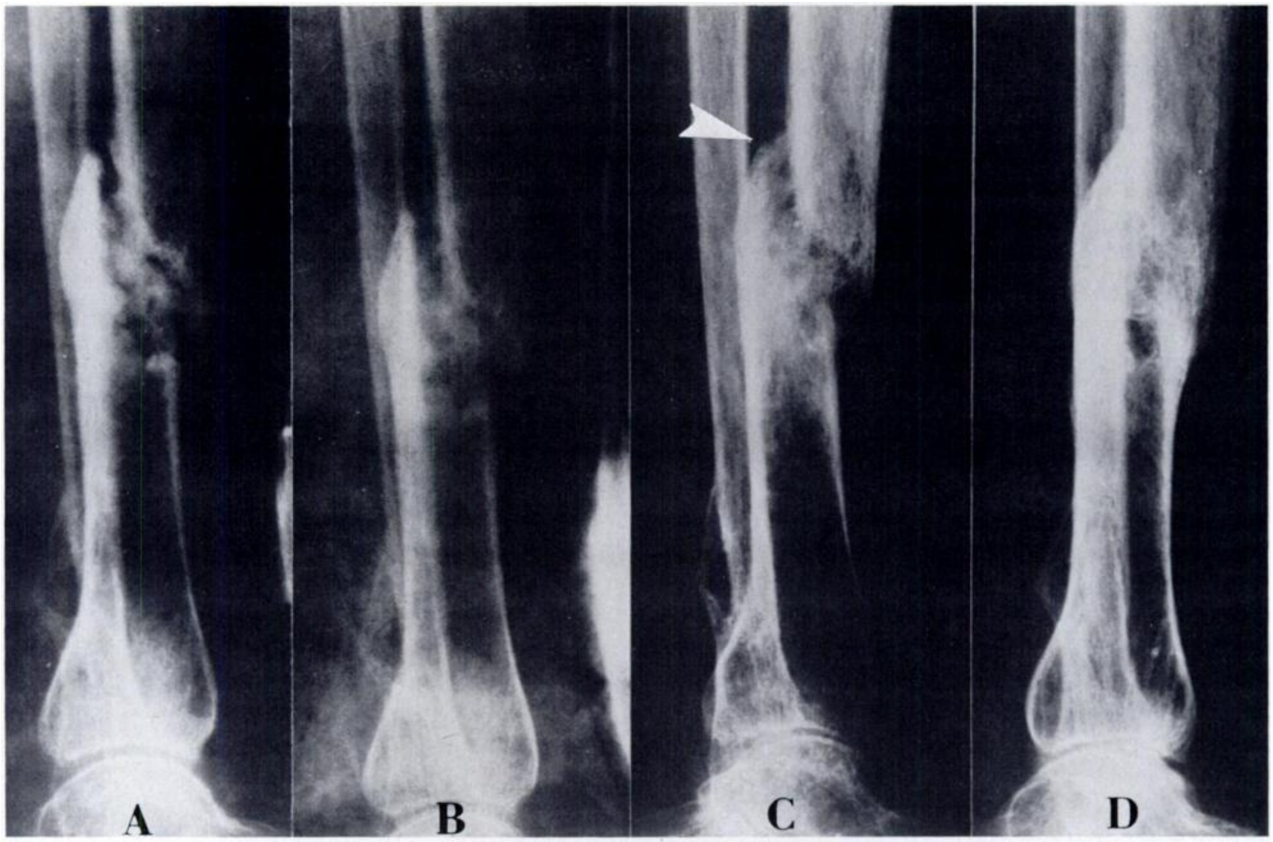

FIG. 4

Sequential lateral radiographs of the tibia of a woman, forty-two years old, with one previous failed attempt at surgical repair. She had been disabled for twenty-seven months. The timing in this patient (and in Figs. 6 and 7) represents a nominal rate of progress. Healing stages may not follow this rate in some patients, particularly those with wide gaps or drainage, or both.

A, June 30, 1978 — in a plaster cast at time of coil application.

B, August 4, 1978 — after four and one-half weeks of treatment. In comparison with *A*, the gap is irregularly clouded (mineralization) and the sclerotic bone flanking the gap is less radiodense (sclerolysis, probably secondary to active hyperemia). This is Stage-I healing. Axial compression exercises are begun, in the plaster cast, one month later.

C, December 14, 1978 — pulsing electromagnetic fields were discontinued two months ago. Now the patient is fully weight-bearing in a clam-shell support, without crutches. Note the trabecular bridging of the gap (Stage-II healing) and early cortical condensations (early Stage-III healing) (arrow).

D, October 18, 1979 — one year and four months after institution of pulsing electromagnetic fields. Remedullarization is well advanced (Stage-IV healing). The patient has a full range of unprotected activity and is asymptomatic.

crutches are then discontinued. The cast is replaced with a molded fiberglass or Orthoplast support (so-called clam-shell puttee), which extends from below the knee to above the ankle for mid-shaft lesions. For fractures of the distal third of the tibia, support includes a plantar extension on the posterior part of the shell to fix the ankle. In fractures of the proximal third, a long cylinder of the same composition is used to fix the knee and protect against bending movements. All external support is removed when continuity of the medullary canal across the non-union site is evident (Stage-III healing). At this time the fracture is considered to be healed, although radiographic evidence of further remodeling (Stage-IV healing) may be present for an additional two years. To re-emphasize, the amount and rate of graded progressive function are tailored to avoid aching in the region of the ununited fracture.

Results

The over-all success rate in the achievement of bone union for this series of 127 fractures of the tibial diaphysis was 87 per cent. The failure rate of 13 per cent includes all fractures in which healing did not occur, regardless of the cause for the failure (technical or management inadequacies, lack of adequate patient cooperation, and so on). Male patients outnumbered female patients in the total group by 2.7 to one. The average age was thirty-six years, with a range from fifteen to seventy-six years. There was an average of 2.4 failed surgical procedures per patient (range, zero to twelve) and an average pre-treatment duration of disability of twenty-eight months (range, four months to eighteen years).

The average duration of treatment of 5.2 months (range, two to twenty-two months) reflects longer exposure times during the early trial-and-error period when coil treatment was continued at least until partial weight-bearing was begun. The average duration of immobilization in a long cast was four months and in a short cast, 1.5 months. No major restriction in the range of motion of the knee was found after three months, assuming no prior knee injury.

TABLE I

DURATION OF DISABILITY

	No. of Patients	< 9 Mos.	9-24 Mos.	24-48 Mos.	> 48 Mos.
Total	125	28	56	19	22
Healed	109 (87%)	24 (86%)	49 (87%)	18 (94%)	18 (82%)
Failed	16	4	7	1	4

Forty-nine (39 per cent) of the 125 patients had a history of infection (prior or actively draining), but these still had an over-all rate of successful union of 82 per cent. Fifteen (79 per cent) of the nineteen patients with active drainage and twenty-five (83 per cent) of thirty patients with quiescent infection achieved bone union and returned to full activity. All fifteen patients with active drainage whose fractures united noted cessation of drainage prior to or concomitant with the establishment of union, and none has had a recurrence of drainage. In none did the infection become more active either during or after treatment. Characteristically, in the patients with active drainage the quantity and nature of the drainage altered within three to five weeks after the coils were applied. The drainage progressively changed from grossly purulent to serosanguineous to serous, and then stopped. Sinuses closed by granulating at the base and then epithelializing. No surgery was necessary for the base of the sinus or its margins. These results were obtained in the absence of any specific change (antibiotics or improved drainage) in antibacterial therapy.

The important findings of this study are summarized in Tables I and II. The success rate, as a function of the number of previously failed operations, is shown in Chart I and is not materially different for any number of prior operations from zero to more than five. The duration of treatment required to achieve fracture-healing is plotted against the year of treatment in Chart II and against pretreatment disability time in Chart III. The percentage of success as a function of the year when the patient was treated is presented in Chart IV and durations of pretreatment disability for each year are in Chart V.

Five refractures occurred after union had been achieved (Table III). All are listed as successes since each ultimately achieved union using pulsing electromagnetic fields without surgical intervention. Refracture was associated with a specific reinjury, an overzealous rehabilitation program, or failure to use external support during the early phases of increasing weight-bearing in patients with stress-risers.

TABLE II

REASONS FOR SIXTEEN FAILURES

Cause	No. of Cases
Inadequate patient cooperation	4
Gaucher's disease (pathological fracture)	1
Interposition of soft tissues proved at operative repair	5
Operative repair alone	2*
Operative repair and pulsing electromagnetic fields	3†
Gap more than 1 cm wide	5
Operative repair alone	3*
Operative repair and pulsing electromagnetic fields	2†
Large sequestrum with active drainage (sequestrectomy and pulsing electromagnetic fields)	1

* Failed.
† Healed.

Discussion

Ununited fractures that have not progressed to synovial pseudarthrosis often can be healed effectively and

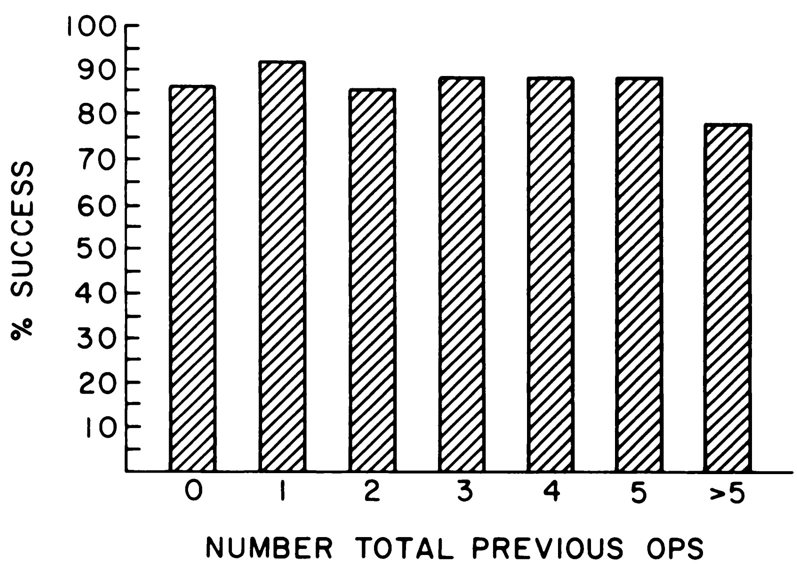

CHART I

Bar graph comparing the success rate (vertical axis) with the number of previous failed surgical attempts to gain union. There is a variation of only a few percentage points between these different categories.

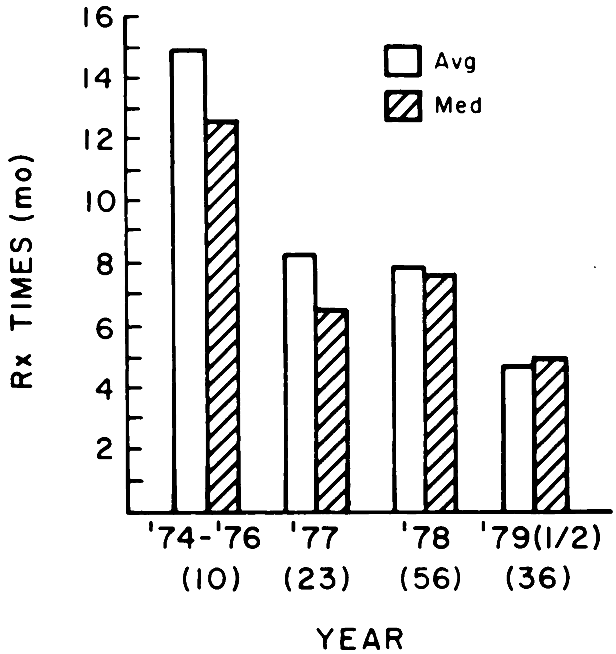

CHART II

Bar graph depicting the average (open) and median (hatched) treatment times as a function of the year of treatment. The year 1979 includes patients from the first six months only. The numbers in parentheses refer to the numbers of patients treated in each year. Note the progressive reduction in both average and median treatment times.

safely with pulsing electromagnetic fields, which induce weak electrical currents in bone. This statement is based on an extensive accumulation of basic, applied, and clinical data assembled during the past quarter of a century. Orthopaedic research has played a dominant role in opening this new area of cellular control mechanisms and the principles have far-reaching implications. Even at this early stage of development, this new non-invasive method for modifying cell behavior in the skeletal system has expanded our ability to care for complex and challenging non-unions, failed arthrodeses, and congenital pseudarthroses. The United States Food and Drug Administration has approved the method as safe and effective for the treatment of appropriate fracture non-unions, failed arthrodeses, and congenital pseudarthroses. The total clinical investigations have spanned seven years and are supported by toxicology and teratology studies.

The obvious advantages to the patient are the low to non-existent risk and treatment on an out-patient basis. The only disadvantage to this mode of treatment is the fact that the equipment must be plugged into a wall outlet for ten hours a day. Most patients do not see this as an insurmountable inconvenience.

Of particular interest is the group of twenty-two patients with a cumulative disability time of 167 years — an average of 7.6 years per patient. Twelve (55 per cent) had been or were actively infected. The success rate in this challenging group was 82 per cent, despite eighty-eight previous surgical failures. These operations included every common surgical approach for such lesions — grafts of many diverse types, internal or external fixation, and combinations. Many methods of post-fracture and post-operative management had been used: non-weight-bearing, a cast-brace, and ischial weight-bearing calipers, among others. In each individual, the chance of spontaneous healing was almost non-existent. The same statement probably is true for most of the nineteen patients with two to four

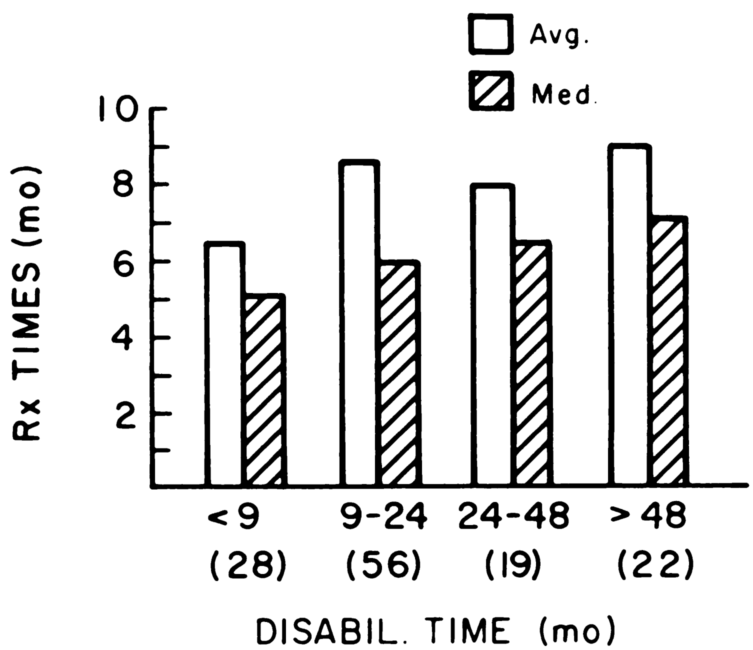

CHART III

Bar graph detailing average (open) and median (hatched) treatment times in each of the months-of-disability categories. The numbers in parentheses refer to the numbers of patients in each category. Note that there are no major differences in duration of treatment, but there is a trend toward longer times with increasing length of disability.

TABLE III

REFRACTURES

Case	Age (Yrs.)	Sex	Cause of Refracture	Time to Refracture (Mos.)	Time to Healing (Mos.) Non-Union	Time to Healing (Mos.) Refracture	Total Time to Final Result (Mos.)
1	32	M	Fell; acute fract.	5	12	3	15
2	17	F	Fell; acute fract.	4	11	4	15
3	22	M	Overactive; bilat. tibial stress fract.	8	10	8	18
4	26	M	Fell; acute fract.	3	6	4	10
5	27	M	Overactive; stress fract.	4	6	6	12

years of disability and for many of the fifty-six patients in the nine-month to two-year category. In the course of our broader study of non-unions, various "controls" have occurred, such as the one in the fractured fibula shown in Figure 5. In this patient, the only variable in treatment was an 0.75-inch (1.9-centimeter) spacer added to increase the distance between coil and bone, thereby reducing the induced voltage to a therapeutic level. This step, taken after little radiographic progress had occurred after three months of treatment, resulted in a prompt improvement in the radiographic appearance within one month. Some patients failed to receive their equipment immediately, and after four months or more of no radiographic progress in a non-weight-bearing plaster cast their non-unions went on to demonstrate changes within one month after the coils were added to the cast (Fig. 6). All of these fractures progressed to union.

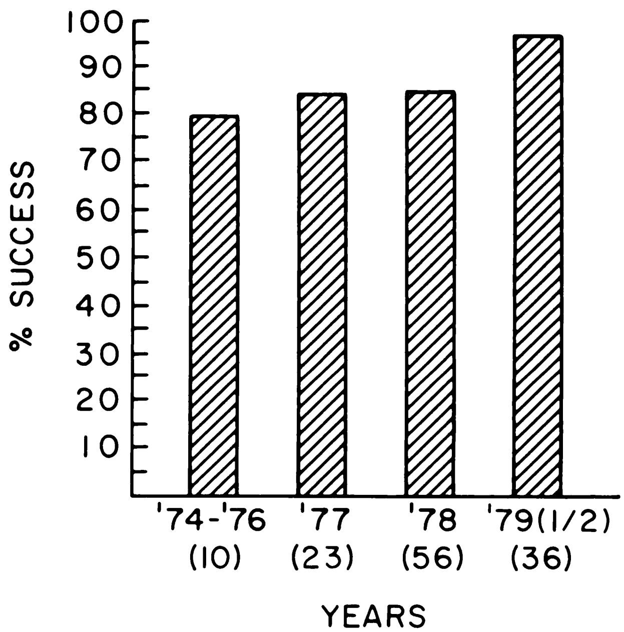

CHART IV

Bar graph demonstrating the percentage of success as a function of the year of treatment. Numbers in parentheses refer to numbers of patients treated. There is a trend toward an improving rate of success, with a level of 97 per cent for the thirty-six patients treated during the first half of 1979.

Although pulsing electromagnetic fields were essential to success, well organized orthopaedic care and cooperation of the patient (non-weight-bearing and use of coils for ten hours a day) were required for the usual progress to occur. This is not to say that union did not occur occasionally despite continued weight-bearing, treatment times of less than ten hours a day, suboptimum plaster casts, and marginal induced voltages. Healing in such patients, however, required treatment times significantly in excess of the median. In fact, the statistics are skewed in this direction because they include patients from the first three years, when important orthopaedic and technical features of management were being determined by trial and error.

The value of pulsing electromagnetic fields is evident in the group of failures (Table II), in which this method was combined with a bone-grafting procedure in six frac-

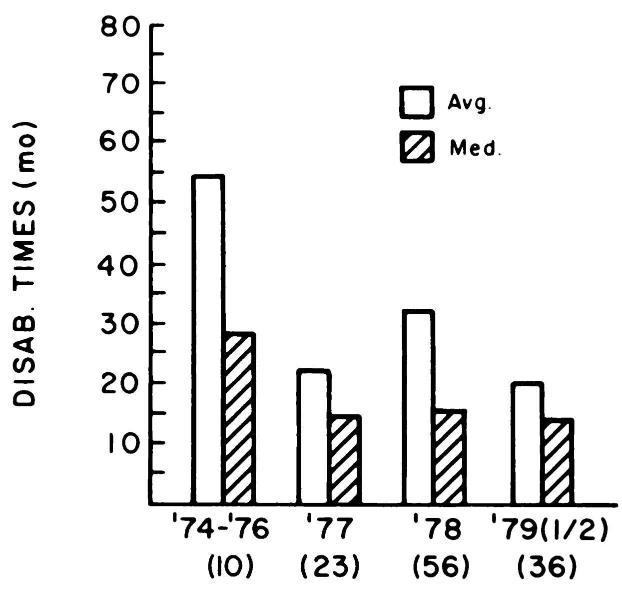

CHART V

Bar graph depicting the average (open) and median (hatched) duration of disability as a function of the year of treatment. Numbers in parentheses designate the number of patients in each year. From 1974 to 1979 the average duration of disability decreased, but the median time was fifteen months from 1977 to 1979. This pattern reflects improved confidence in the safety of the method and an increasing conviction that pulsing electromagnetic fields should not be viewed as a salvage treatment but should be used early in the course of treatment of an ununited fracture.

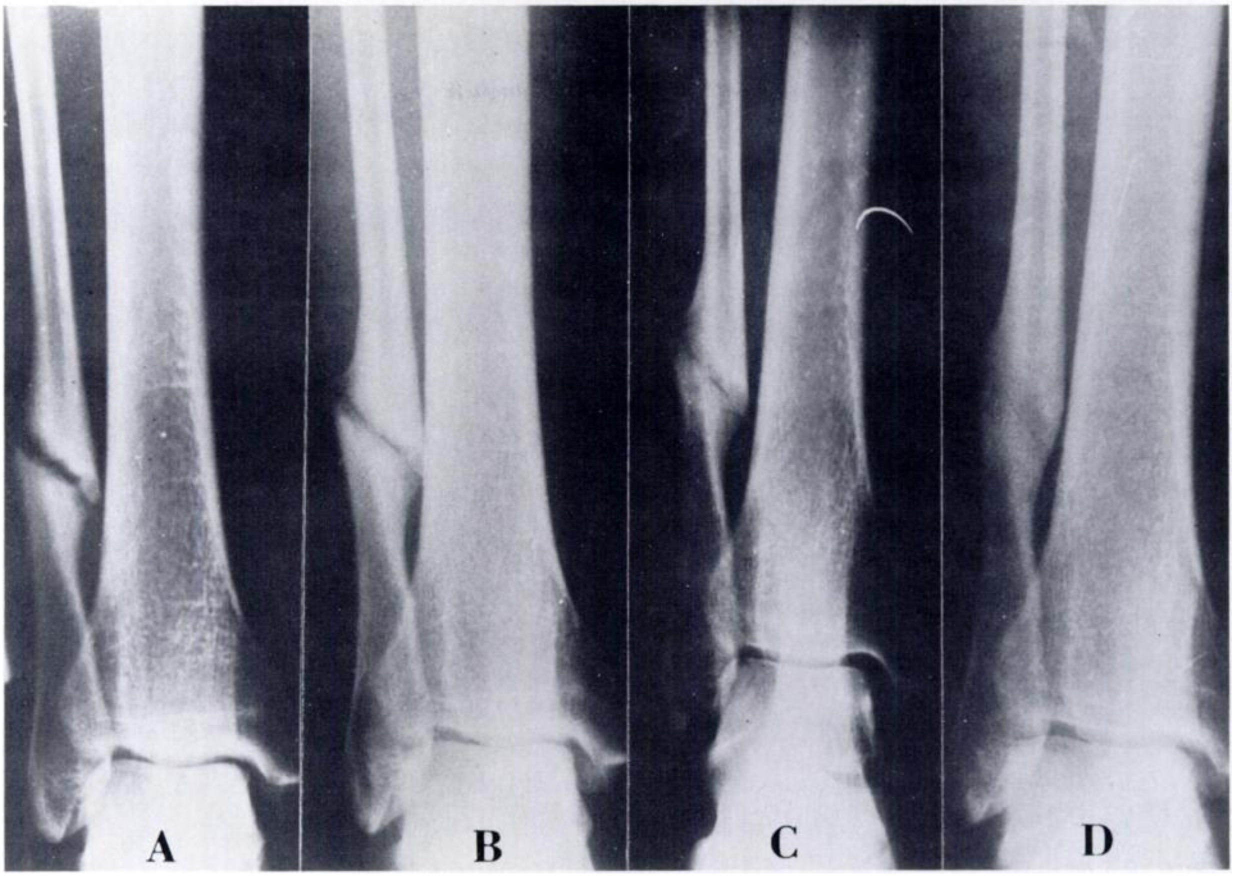

FIG. 5

Radiographs of the lesion in a woman, forty-five years old, two years after a fracture of the distal end of the fibula. Formerly an active sportswoman, she was unable to participate in sports because of pain. (This woman was in the larger series of patients, included here for illustration.)

A, February 9, 1976 — application of a single coil.

B, May 24, 1976 — after three months of treatment with pulsing electromagnetic fields, there is a small amount of clouding in the gap medially (at the farthest distance from the face of the coil).

C, June 25, 1976 — one month after the coil was moved laterally from the fibula by an 0.75-inch (1.9-centimeter) spacer, decreasing the induced voltage (the only change in management). Note the marked radiographic change in the entire width of the gap.

D, March 30, 1977 — the lesion has healed. The patient participates in full sports activity without limitation.

tures. All united, while five fractures that were bone-grafted without pulsing electromagnetic fields failed to unite. In these latter five fractures, however, detrimental circumstances were identified, such as inadequate fixation, segmental loss, vascular compromise, or electrode-induced necrosis. When they are used immediately after grafting, it is our impression that the incorporation and remodeling of bone grafts are accelerated. The possibility that bone grafts and pulsing electromagnetic fields may perform synergistically is currently under study.

A few words of caution should be added about patient selection. Synovial pseudarthrosis and uncontrollable motion are absolute contraindications. Furthermore, with unreduced interposition of soft parts between the fragments, a radiographic gap more than one centimeter wide in any projection, or an uncooperative patient, progress may not occur at the usual rate.

A distinct pattern of radiographic progress may be expected with proper management, and many patients start their axial compression exercises in a short cast by one to three months after the onset of treatment. If the anticipated radiographic changes have not appeared by that time, a review of the management procedure may reveal an error or errors whose correction will resume or speed progress. If no change ensues within an additional month or two, operative repair is undertaken, the coils often being used postoperatively.

The most common errors that were found to impede rapid healing were as follows:

1. The final distance between the coils mounted on the cast varied more than ± 0.25 inch (0.6 centimeter) from the orthopaedic surgeon's original prescription.

2. Placement of the block was inaccurate; it did not center on the non-union and include the *entire* non-union site.

3. Coils were not properly mounted. Either they were not exactly opposite one another (skewed proximally or distally) or they were not parallel.

4. Motion at the non-union site was inadequately controlled by the cast. Casts were removed prematurely, prior to Stage I, for radiographs and stress-testing in the office.

5. The patient did not maintain a strict non-weight-bearing status.

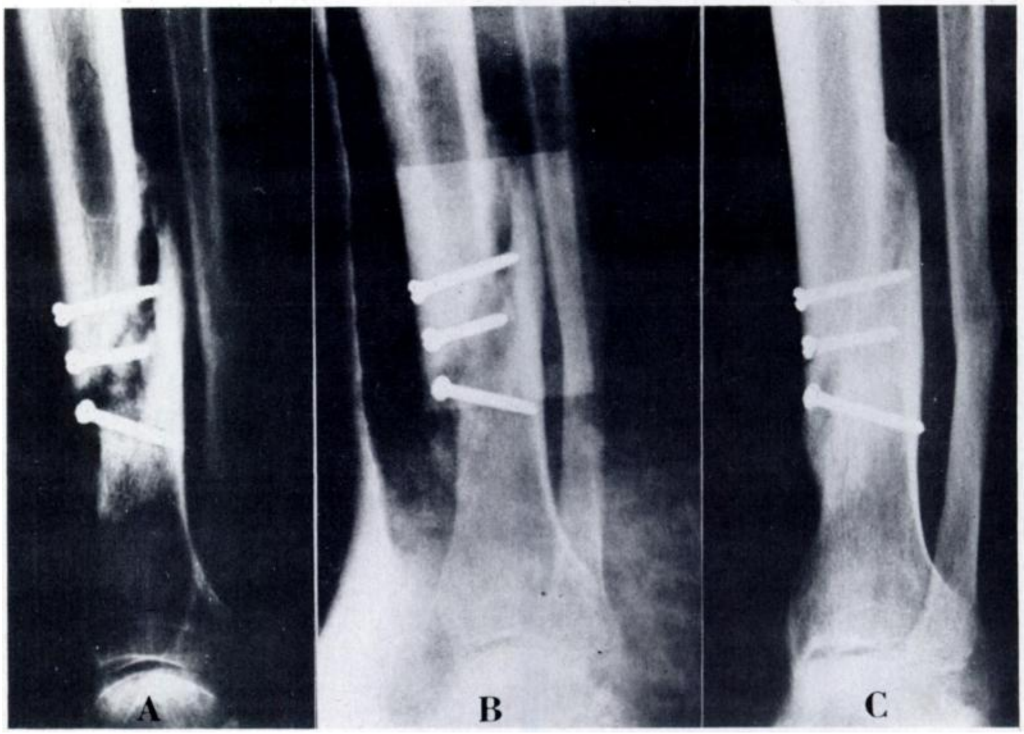

FIG. 6

Sequential lateral radiographs of an atrophic non-union in a man, seventy years old. He had had one failed operative repair and had been disabled for eleven months. Note the presence of metal screws (cobalt-chromium, compatible with field).

A, May 10, 1978 — immediately before coil application, after four months in a plaster cast and using crutches.

B, June 6, 1978 — Stage-I healing.

C, October 9, 1979 — Stage-IV healing. The patient is asymptomatic, with full unprotected activity.

6. Equipment was used for less than ten hours a day.

7. Onset of graded function (axial compression exercises) was mistimed. If started before Stage-I healing (fuzziness of gap and sclerolysis), at about one to three months, function seemed to be counterproductive. Individuals with either wide gaps or active drainage, or both, frequently required longer intervals of treatment with the coils before progressive loading. When exercises were delayed beyond completion of Stage-I healing, however, in anticipation of further progress with pulsing electromagnetic fields, maturation of the bridging process appeared to be slower and disability (total immobilization and non-weight-bearing) time was increased.

8. In lesions of the distal third of the tibia, if the foot was in equinus angulation in the cast, the heel was not built up, so that the metatarsals and toes were striking instead of the heel.

9. Partial weight-bearing was not preceded by an adequate program of controlled-impact axial compression exercises, without weight-bearing.

10. Patients did not stop or lessen activities when they had an ache in the maturing non-union site.

11. External support (a light plaster cast or molded orthosis) was removed prematurely (particularly in the presence of residual focal bone discontinuities or stress-risers). Such patients were at risk of refracture from a fall or from an inappropriately rapid increase in use which exceeded ache tolerance.

In the beginning, the essential role of management of the patient was not fully understood, and too much emphasis was placed on the equipment and its ability to induce healing and produce a *mature* bridge of bone. The data in Chart III support this view, although technical improvements also occurred. In 1974 to 1976, the median duration of treatment was nearly thirteen months and the average was fifteen months. By 1979, the median and average treatment times were five months.

Chart IV suggests that these differences are not related to changes in duration of disability.

The rationale behind management is based, in part, on the sequence of events that have been observed during healing of non-unions induced by pulsing electromagnetic fields, together with their biomechanical implications. These events have been studied in the canine radius using the hypertrophic non-union model of Müller et al.[47]. The results were presented elsewhere[22]. Basically, pulsing electromagnetic fields produce a bone-healing pattern almost identical to that of so-called rigid internal fixation with an AO plate. Gap tissues progressively calcify and are invaded by vessels from the flanking bone margins, producing a picture very similar to that of normal endochondral ossification. The electrical fields do not stimulate osteogenesis directly, but rather appear to modify fibrochondrocyte function so that any soft-tissue impediment to bridging by bone is eliminated. Gap tissues were biopsied routinely when a surgical repair followed an unsuccessful course of treatment with pulsing electromagnetic fields. These tissues demonstrated patchy areas of mineralized fibrocartilage and endochondral ossification similar to those observed more uniformly in the canine model.

The implications of healing induced by pulsing electromagnetic fields at the clinical level are clearly evident in the serial radiographs, which demonstrated increasing radiodensity in the gap region as calcification of fibrocartilage progressed. A patchy pattern is observed because of the frequent non-uniform distribution of fibrocartilage in the non-union site. As vascular penetration of the calcified fibrocartilage proceeds, the local vascular bed is increasingly fed by vessels in the sclerotic bone flanking the gap. Active hyperemia in these areas leads to resorption of bone and a decrease in the radiographic density (sclerolysis).

Biomechanical correlates of the biological process dictate a graded pattern of function. Calcified cartilage, which unites the bone fragments for the first to third months, is not very strong and requires support if it is not to fail as function of the extremity begins. Fortunately, during the interval from one to six months it is progressively replaced by the stronger fiber and lamellar bone. Nonetheless, with the relatively more rigid lever arms of the tibial fragments flanking the fracture gap, this newly formed bone may undergo stress failure if bending or torque moments are excessive in amount or frequency. Protected and graded function is achieved with the axial impact exercise, a method based on fundamental observations[11,32] which we have used for twelve years[7]. The impact during axial compression exercises is designed to approximate the loading rate of heel-strike in a normally rapid gait. The amount of load is controlled by the bathroom scale. These exercises are employed until stress-induced patterns of trabecular bridging begin to restructure the area at about four months (Fig. 7). Even then, high-impact situations such as may occur during football, skiing, or soccer should be avoided until nearly full osteonal remodeling has occurred. This process may take two years or more in some individuals. Management of the patient after union is established does not differ significantly from the usual management after successful fracture-healing or bone-grafting. Before early union is achieved, the early non-weight-bearing regimen may appear to be at odds with the present practice of treating fresh fractures by the cast-brace method. The results in this study, however, were obtained in patients who were largely prevented from premature weight-bearing. When this part of the treatment

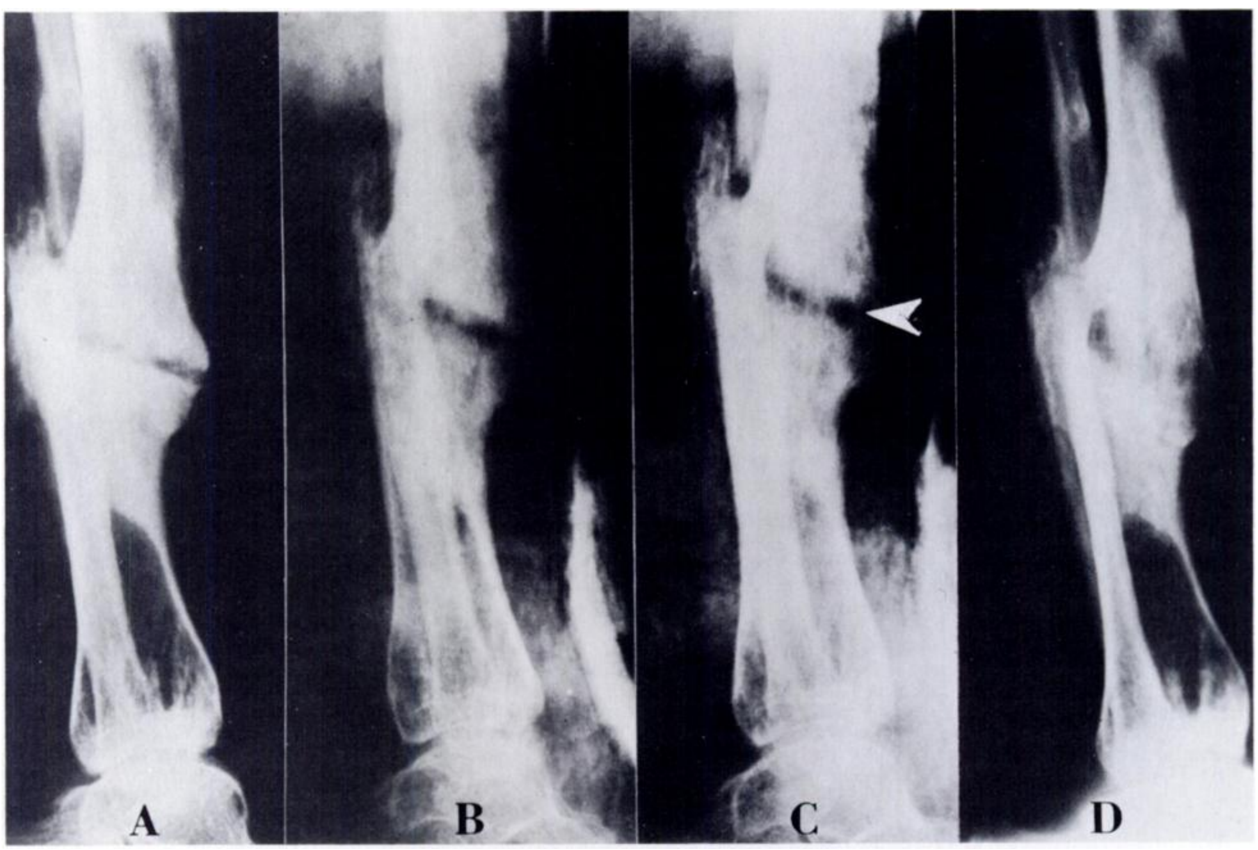

FIG. 7

Sequential lateral radiographs of the lesion in a thirty-two-year-old man who had had four failed attempts at surgical repair. He had been disabled for fifty months.

A, December 20, 1977 — at the time of coil application.
B, February 14, 1978 — Stage-I healing (see Fig. 4 for description). Axial compression exercises were begun at this time.
C, March 16, 1978 — Stage-II healing. Note the trabecular bridging (arrow).
D, February 6, 1979 — Stage-IV healing. The patient has full unprotected activity.

protocol was ignored, the progress toward fracture union was slower than normal or did not occur. Although the deleterious effects of premature weight-bearing in this system are documented, their mechanism is not. There are data to suggest, however, that cyclic tensile loading of collagen controls the pattern of extracellular matrix synthesis[30,31]. Since collagen is both electrically charged (an electret)[46] and piezoelectric[38], continual function (tensile loading) may produce an endogenous electric pulse which is counterproductive. With the extremity at rest, cells respond only to the "message" contained in the pulse induced by the coils.

No untoward results or hazards were observed during this study. Several apparently beneficial side-effects have been noted, most of which have been substantiated in animal studies during the past two years. For example, we have already noted the improvement that occurred in actively draining non-unions. Clinical evidence suggests a beneficial effect on infection beyond that expected from immobilization and increasing bone stability. Furthermore, radiographic evidence of healing of avascular necrosis has been obtained in patients being treated for femoral neck non-unions, and laboratory studies have demonstrated increased uptake of technetium polyphosphate in devascularized femoral heads in rabbits[54]. Increased rates of wound-healing have been documented in patients with a chronic soft-tissue wound associated with an ununited fracture. Reports of increases in sensation and pseudomotor function in chronically insensate skin (degloved, flaps, and pedicle grafts) in patients with ununited fractures have prompted a renewed[16] laboratory investigation of the effects of pulsing electromagnetic fields on peripheral nerve regeneration[41].

The possible mechanisms behind these bioelectrical and field effects have been given a considerable amount of attention and were documented in detail elsewhere[5,6,8-10,53]. Suffice it to say that physical mechanisms are more clear, at this stage, than are *fundamental* cellular mechanisms. Currents can be produced in tissues by inductively coupling a time-varying electromagnetic field. In this situation, the tissue is analogous to the secondary element of a transformer. Furthermore, the pulse shape of the current in the coils determines the induced current in the tissues. If the final pulsing current has certain similarities to a pulse occurring in whole bone during deformation[5,8,11,28], it appears to be "understood" by certain cellular components of the skeletal system, which modify their behavior[29]. It is also clear that the cellular effects cannot be ascribed to heating (which occurs with other electromagnetic systems such as radio and microwave frequencies). The field strengths used in this clinical study produced 10^{-10} watts per square centimeter, which will cause a change of only 0.001 degree Celsius at nominal tissue impedances.

This report documents the effectiveness of surgically non-invasive pulsing electromagnetic fields in treating 125 patients with 127 ununited fractures of the tibial diaphysis. The over-all success rate was 87 per cent, which compares favorably with results of surgical repair and which, unlike an operative procedure, is unaffected by age, the duration of disability, the presence of infection, or the number of previously failed operations. In view of these correlations and the fact that the technique can be applied on an out-patient basis, with little or no risk, it should be given strong consideration as a method of choice for patients with the proper indications.

NOTE: The authors wish to thank R. J. Pawluk, Assistant Professor of Orthopaedics (Biomechanics), and A. A. Pilla, Senior Research Associate (Orthopaedic Surgery), for their help in the early phases of this study, and Electro-Biology, Inc., Dr. Thomas A. Duerden, and John P. Ryaby for a continuing program of equipment improvements to facilitate patient care.

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