—**Original**—

The Efficacy of Ununited Tibial Fracture Treatment Using Pulsing Electromagnetic Fields

Relation to Biological Activity on Nonunion Bone Ends

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Abstract

Thirty ununited tibial fractures with a median time since injury of 18 ± 9 months were treated by electrical stimulation using pulsing electromagnetic field therapy. Union was achieved in 25 cases (83.3%) in a median interval of 8.6 ± 3.2 months. Patient age and gender, the presence of surgical hardware, length of disability, and the number of surgical procedures did not affect the outcome. Ununited fractures that appeared to be hypertrophic or sclerotic type radiographically, indicating a good blood supply to the bone ends, all healed. Treatment failures occurred only among lesions with a poor blood supply, and in necrotic or defective radiopraphic types. Pulsing electromagnetic field therapy is an effective treatment for ununited tibial fractures with good blood supply to the bone ends. (J Nippon Med Sch 2001: 68: 149—153)

Key words: ununited fracture, tibia, pulsing electromagnetic field therapy, nonunion

Introduction

Bassett et al[1] first described the use of inductively coupled electromagnetic fields to facilitate bone repair, and later these investigators used them in the treatment of unuited fractures. Since then, many reports have documented the beneficial effects of this method and other methods of electrical stimulation[2-4]. Methods of electrical stimulation can be classified into three types based on the degree of invasiveness: implanted stimulators to treat failed posterior spinal fusion[5], semiinvasive devices, which utilize direct current[6,7], and non invasive types, which generate an electromagnetic energy field around the bony discontinuity[8].

This article reports the clinical efficacy of pulsing electromagnetic field (PEMF) therapy in treating ununited tibial fractures. Factors associated with the success or failure of this method are discussed.

Meterials and Methods

Thirty patients, (24 men and 6 women), with an average age of 42.6 years (range, 23 to 71 years) were enrolled in the study (**Table 1**). The patients were classified as having a delayed union or nonunion according to the criteria of the American Orthopedic (AO) Group. About 80% of the nonunion cases were the result of motor vehicle accidents, and 16 fractures were originally open. Eight patients (28%) had previous osteomyelitis at the fracture site. The duration of disability ranged from 6 months to 8 years and 3 months (average, 1 year and 6 months). The peak of

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Table 1 Demographics and clinical characteriatics of 30 patients with ununited tibial fractures treated by PEMF

Men	24
Women	6
Average Age	42.6 ± 10.5 yrs
Closed Fractures	14(57%)
Open Fractures	16(53%)
Prior Infection	8(27%)
Average umber of previous operations	1.8(0—5)

Table 2 Backgrounds and clinical outcomes of 30 patients with ununited tibial fractures

No.	Case	Age (y)	Sex	Number of previous operations	Presence of surgical hardware	Disability time (months)	Radiographic classification	Bony union
1	S K	32	Male	1	(−)	7	Necrotic	No
2	A K	60	Male	3	(+)	49	Hypertrophic	Union
3	H S	34	Male	0	(−)	6	Hypertrophic	Union
4	K S	50	Male	3	(+)	26	Screlotic	Union
5	N K	34	Male	0	(−)	6	Hypertrophic	Union
6	H N	60	Female	1	(+)	7	Screlotic	Union
7	T S	45	Male	0	(−)	8	Screlotic	Union
8	I M	68	Male	2	(+)	9	Screlotic	Union
9	M K	32	Male	0	(−)	21	Screlotic	Union
10	W K	31	Male	1	(+)	7	Hypertrophic	Union
11	O T	71	Male	0	(−)	19	Necrotic	No
12	F K	69	Male	5	(−)	99	Screlotic	Union
13	O K	33	Male	2	(+)	17	Necrotic	Union
14	Y M	51	Male	3	(−)	21	Screlotic	Union
15	O Y	33	Male	2	(+)	23	Necrotic	No
16	T F	36	Female	1	(+)	7	Screlotic	Union
17	K T	25	Male	2	(+)	16	Screlotic	Union
18	M T	42	Male	2	(+)	14	Screlotic	Union
19	O I	22	Female	0	(−)	23	Hypertrophic	Union
20	Y H	35	Male	1	(−)	9	Screlotic	Union
21	N S	46	Female	3	(+)	23	Necrotic	No
22	S Y	43	Male	2	(+)	8	Screlotic	Union
23	K T	41	Male	4	(+)	42	Screlotic	Union
24	I S	54	Female	0	(−)	15	Screlotic	Union
25	K T	48	Male	5	(+)	25	Defective	No
26	S Y	37	Male	2	(+)	12	Hypertrophic	Union
27	E M	40	Male	1	(−)	6	Necrotic	Union
28	N J	36	Male	3	(+)	15	Hypertrophic	Union
29	Y Y	48	Female	3	(+)	20	Hypertrophic	Union
30	I K	23	Male	1	(+)	6	Screlotic	Union

the distribution of disability period in the 30 patients was between 10 and 24 months. Almost 80% of the patients had at least one surgical procedure related to the fracture. The average number of operations was 1.8, and 2 patients were operated on 5 times.

The system used was similar to the one described by Bassett et al[9]. An electric current of highly specific shape, magnitude and frequency rate was generated in the bone by a pair of externally placed, oval, air-cored electromagnets driven by a generator. This generator produced a 5-m sec burst of quasi-rectangular, asymmetrical pulses at 15 Hz. The driving voltage to the coils was set to produce 1 to 15 my of induced current in the bone for any prescribed distance between the coils, which varied with the width of the plaster cast. The tibia was immobilized via a long leg plaster cast with the knee flexed at 30 degrees. The square locator block, whose position was checked radiographically, fitted into a female fitting on one of the coils. The other coil was then placed on the opposite side of the plaster, parallel and at 180 degree to the locator coil. All patients were instructed to use the equipment for 8 hours per day and not to bear weight until told to do so. The treatment was on an outpatient basis, and the apparatus was used at the patient's home, mainly during sleep.

A clinical and radiological assessment out of plaster was made every 6 weeks. More frequent clinical examinations out of plaster were avoided to prevent disrupting any early tenuous union. Immobilization was changed to PTB cast and brace as clinically indicated. Electromagnetic treatment was discontinued when there was no clinical mobility at the site of the nonunion, no pain on stress, and not more than slight tenderness over the fracture site. Radiographic confirmation in two planes showing bony trabecular crossing at least half the width of the defect was required before the fracture was considered united.

Results

Bony union was achieved in 25 of 30 cases (83.3%) of ununited tibial fractures by pulsing electromagnetic fields. The median time to reach union among patients in whom healing occurred was 8.6 ± 3.2 months (range, 4 to 16 months). The healing rate did not correlate with patient age or gender, the presence of surgical hardware, length of disability, or the number of previous operations (**Table 2**). Treatment failures included patients in whom no healing was observed and dropouts. No side effects or complications from PEMF were recorded.

The orientation of the nonunion, whether transverse, oblique or very oblique, did not affect the results, but the radiologic appearance of pseudarthrosis did correlate with the outcome (**Table 3**). All 8 hypertrophic nonunions healed, as did all 15 sclerotic non-unions. Four of 6 patients with a necrotic nonunion, and the 1 patient with a defective nonunion failed to heal with PEMF and immobilization.

Table 3 Correlation between radiographic appearance and outcome of ununited tibial fractures treated by PEMF therapy

Radiographic type	Non-union	Union	Persistent non-union
Hypertrophic	8	8	0
Screlotic	15	15	0
Necrotic	6	2	4
Avascular	0	0	0
Defective	1	0	1
Total	30	25	5

Discussion

No universally accepted definition of "fracture nonunion" exists. Some authors define nonunion as a state that exists when union of the fracture will not occur without surgical intervention. Nicoll[10] defined nonunion as a condition in which, in the opinion of the surgeon, the fragments will not unite with further conservative treatment. However, fractures which have otherwise failed to heal with nonsurgical treatment and have been diagnosed as nonunions can be induced to heal with the administration of electrical stimulation. Electrical methods have assumed an increasing role in the clinical management of ununited fractures since 1981[9]. Exposure of the fracture site to a pulsing electromagnetic field by external coils applied to the cast or skin induces a weak current in bone. Pulsing electromagnetic fields were found to augment repair of fibular osteotomies[1]. Although clinical experience has accumulated using pulsing electromagnetic fields with ununited discontinuities of bone[9,11], increasing attention has been focused on the mechanisms of their action. Simultaneously, other experimental studies have demontrated that the calcium content of isolated chondrocytes can be increased or decreased by altering the pulse design[12], the cyclic AMP, collagen, proteoglycan, and calcium content of chick-limb rudiments can be modified selectively[13]; and DNA synthesis can be changed with a high level of specificity[14]. Furthermore, pulsing electromagnetic fields were characterized by more extensive calcification of fibrocartilage and its replacement by fibrous bone[15]. Clinically, success using this non invasive, outpatient method has been described in 1,007 ununited fractures worldwide[16]. The overall success rate reported by Bassett[16] was 81%; the internationally reported success rate is 79%, and it is 76% in other centers in the United States. Bassett reported that PEMF was effective in 75% of 332 patients with an average disability duration of 4.7 years, an average of 3.4 previous operations and a 35% rate of infection. Heckman et al[17] reported healing in 64.4% of 149 patients using PEMF, and that the healing rate was higher for the tibia than for the femur or humerus. They also reported that combined electro-stimulation and bone grafting was more effective than either measure alone in some cases. Finally, Heckman et al[17] found that young patients healed more rapidly than older patients, and that electro-stimulation is more effective when instituted within 2 years of the original fracture than when started thereafter. Our series, failed to confirm any of these findings, and we do not recommend withholding treatment based on the presence of these factors: plates or nails, disability periods, or the number of previous operations.

The intimate proof of any treatment's worth is variation in a double-blind trial. Double-blind trials of fracture treatment are especially difficult to perform because variation in the degree and extent of injury makes it problematic to define comparable treatment groups. Sharrard[18] conducted one double-blind trial comparing treatment of similar fractures by immobilization: one group was given a dummy stimulator and the other group used a generator that produced pulsed electromagnetic fields. PEMF increased the rate of healing in tibial fractures with delayed union. Capanna et al[19] studied the effect of PEMF on the healing rate and the time-to-union of host-graft junctions in patients with bone tumors. The patients underwent bone resection followed by massive allografts. In that double-blind study, PEMF decreased the time-to-union of the host-graft junction in patients who did not receive postoperative chemotherapy. Taken together, these studies provide compelling evidence that PEMF promotes bonyunion of ununited fractures.

Our success rate of 83.3% for tibial union in almost identical to that reported in other series[9,16,17]. Weber et al[20] have classified nonunions into two types based on biological activity or inactivity, and whether the blood supply of the bone ends was adequate or compromised. This classification system is valid for aseptic as well as infected nonunions. Biologically active nonunions with good blood supply appear hypertrophic or sclerotic radiologically, and biologically inactive nonunionns that are necrotic, avascular and defective reflect an inadequate blood supply. The treatment failures in this study were all necrotic or defective nonunions, and 4 of 6 necrotic cases failed to unite. We conclude that PEMF to treat ununited tibial fractures is likely to be successful only when blood supply to the bone ends is good.

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