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Long-Term Pulsed Electromagnetic Field (PEMF) Results in Congenital Pseudarthrosis

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Summary. Ninety-one patients with congenital pseudarthrosis of the tibia have been treated with pulsed electromagnetic fields (PEMFs) since 1973 and all except 4 followed to puberty. Lesions were stratified by roentgenographic appearance. Type I and type II had gaps less than 5 mm in width. Type III were atrophic, spindled, and had gaps in excess of 5 mm. Overall success in type I and II lesions was 43 of 60 (72%). Of those 28 patients seen before operative repair had been attempted, 7 of 8 type I lesions healed (88%), whereas 16 of 20 type II lesions healed (80%) on PEMFs and immobilization alone. Only 19% (6 of 31) type III lesions united, only one of which did not require surgery. Sixteen of 91 limbs (18%) were ultimately amputated, most before treatment principles were fully defined in 1980. Fourteen of these 16 patients (88%) had type III lesions. Refracture occurred in 22 patients, most as the result of significant trauma, in the absence of external brace support. Twelve of the 19 refractures, retreated with PEMFs and casts, healed on this regime. Episodic use of PEMFs proved effective in controlling stress fractures in several patients until they reached puberty. PEMFs, which are associated with no known risk, appear to be an effective, conservative adjunct in the management of this therapeutically challenging, congenital lesions.

Key words: Congenital Pseudarthrosis – Pulsed electromagnetic fields.

Congenital pseudarthrosis of the tibia continues to present orthopedic surgeons with a major therapeutic challenge. The condition, more accurately termed infantile nonunion, is characterized by fractures that are exceedingly recalcitrant in their healing [1–7]. Classically, many surgical procedures, using bone grafts and/or skeletal fixation, have been employed for this problem [4, 7, 8]. In the past, repeated operations have failed to secure an overall success of more than 50% and this rate often diminishes if patients are followed through puberty [9]. Recently, microsurgical techniques have made it possible to transplant bone with an "intact" blood supply [10, 11]. Initial evidence supports an improvement in the success rate, but only a small number of patients have been followed to maturity. Furthermore, the method may be accompanied by iatrogenic problems in the normal, donor extremity (e.g., ankle valgus).

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Following publication in 1964 of the first controlled study showing that weak electric currents could trigger osteogenesis [12], a number of groups began clinical application of the method. One of the first of these involved congenital pseudarthrosis [13–16]. In 1973, pulsed electromagnetic fields (PEMFs) also were applied first in the clinic for this condition and proved to be promising [17].

Methods and Materials

This analysis includes 59 patients previously reported in 1982 who were treated under an I.R.B.-approved protocol at Columbia, together with 32 additional patients who entered the protocol since 1980. In all cases outside Columbia, clinical records and serial roentgenograms were available to the authors who aided in management by direct consultation with the responsible orthopedic surgeon. Details of equipment, protocols, and biophysical principles have appeared elsewhere [18–20]. Basically, patients were treated 10–12 hours a day with a "Helmholtz" coil pair, mounted on casts or orthoses, over the lesion. A repetitive single pulse pattern was used. The amplitude of the field was set by the manufacturer Electro-Biology, Inc., Parsippany, NJ on prescription to produce 1.5 mV/cm for normal cortical bone with periosteum.

In the early phases of the study, a molded, long-leg, bent-knee plaster cast was used for immobilization. Later, a 1½ spica was employed during the initial 3–6 months of treatment. When sufficient roentgenographic evidence of early bony union was present (e.g., beginning corticalization), protected weight bearing was allowed in a closely fitted, fiberglass orthosis with snug, circumferential Velcro strapping. Protection was maintained until medularization of the bony union was nearly complete in a reasonably well-aligned tibia. In those patients who required a surgical procedure, PEMFs were begun as soon as possible, usually within the first 2 weeks.

Results

General

Table 1 documents results of PEMF treatment in 91 patients ranked by type [19] and management pattern. Fifty-seven were treated at Columbia and 34 in other locales. There were 37 successes and 30 failures (47% success rate) at Columbia; 22 patients healed and 12 failed (65% success rate) in other parts of the country. Table 2 shows the age distribution of all patients, grouped by type and healed/failed categories. Type III patients fractured first at a younger age than types I or II, whether they healed or failed. Furthermore, PEMF treatment generally was instituted at an earlier age in this group. Tables 3 and 4 give the overall characteristics of healed/

Table 1. Results of PEMF treatment in 91 patients

Roentgenographic type	No.	% Total	Management	Healed	Failed[a]	% Success	Group success (%)
			Coils alone	7	1	88	
I	19	21	Coils + 1 op	4	3	57	69
			Coils + multi-op	2	2	50	
			Coils alone	16	4	80	
II	41	45	Coils + 1 op	11	2	85	73
			Coils + multi-op	3	5	38	
			Coils alone	1	12	7	
III	31	34	Coils + 1 op	2	6	25	19
			Coils + multi-op	3	7	30	
Total	91			49	42		54

[a] Healed includes only those cases with bony union, unrestricted function, and no requirement for any form of exoskeleton

Table 2. Age and type of all patients

Type	Healed		Failed	
Average	Age at fracture (yr)	Age at Rx (yr)	Age at fracture (yr)	Age at Rx (yr)
I	5	7.6	5	6.7
II	4.9	7.7	2.9	4.8
III	1.3	2.4	1.2	3.9

Table 3. Healed case characteristics (averages)

Age at fracture	4.2 yr	(range 1 mo–13.5 yr)
Disability time before PEMFs	3.0 yr	(1 mo–14 yr)
Number ops before PEMFs	1.6	(0–6)
Age at start of PEMFs	7.3 yr	(range 5 mo–15 yr)
Length of PEMF Rx	1.4 yr	(4 mo–4.1 yr)
Age at most recent analysis	Av. 15 yr	(4.5–26 yr)
Length of follow-up	Av. 6.5 yr	(2–12 yr)

Table 4. Failed case characteristics (Averages)

Age at fracture	1.8 years	(2 mo–11.5 yr)
Disability time before PEMFs	2 years	(1 mo–14 yr)
Number ops before PEMFs	1.4	(0–8)
Age at start of PEMFs	4 years	(6 mo–14.9 yr)
Length of PEMF Rx	1.5 years	(3 mo–4.1 yr)
Age at most recent analysis	N.A.	N.A.
Length of follow-up	N.A.	N.A.

N.A. = not applicable

failed groups, respectively. In this study, the term "healed" was applied only to patients with unrestricted function, without need for external support.

Amputation

Sixteen of the 42 patients listed as failures underwent amputation (38% of failures, 18% of the total patient population). Fourteen of these 16 amputations occurred in the 25 type III failures initially treated prior to 1980 when use of a 1½ spica and pulses with a 7:1 ratio for "positive" versus "negative" phases became routine. Furthermore, prior to 1980, PEMF failures were not treated routinely with a Boyd dual only grafting method (Fig. 1) or with microvascular fibular grafts.

Refracture

Twenty-two patients refractured after having united with PEMFs while actively engaged in childhood pursuits, with significant trauma and in the absence of an external support. Sixteen of these involved the original fracture site, an average of 13 months after PEMFs had been terminated (range: 2 weeks–51 months). Nineteen of the 22 refractures were retreated with PEMFs, with casting, and 12 healed a second time after an average of 13 months. Nine of these 12 remained united through puberty. The refracture group accounted for 9 of the overall 42 failures (21%). Patients who developed roentgenographic and clinical evidence of stress fracture that did not progress to a complete bony discontinuity were not included as refractures. In several cases with stress fracture, reinstitution of PEMFs resulted in subsidence of the lesion, some on multiple occasions, before reaching puberty (Fig. 2).

Discussion

PEMFs have proven to be a useful adjunct in the long-term management of patients with congenital pseudarthrosis of the tibia. First used in 1973, the method has produced success rates ranging from a low of 20% for aggressive, hypermobile, spindled, type III lesions with long gaps to 70% or more for type I and II lesions [19]. In two subgroups of 28 of type I and II patients unoperated on, the present healing rate equals or exceeds 82%, with PEMFs and plaster immobilization as the sole treatment regimen. Ninety-six percent of the patients in this series have passed puberty, a time when the orthopedic consensus indicates that the pathologic process is less active and refracture more remote [4].

Fourteen of the 16 amputations—the ultimate failure, occurred prior to 1980. They partly reflect both a "learning curve" and, at Columbia, a large concentration of the more challenging type III lesions. In fact, 40% of the 57 patients [21] cared for at Columbia had type III pseudarthroses. As specific details of pulse parameters emerged and concomitant management methods improved, the need for amputation lessened. Furthermore, Boyd dual on-lay and microvascular fibular grafts changed the dismal prognosis for the ex-

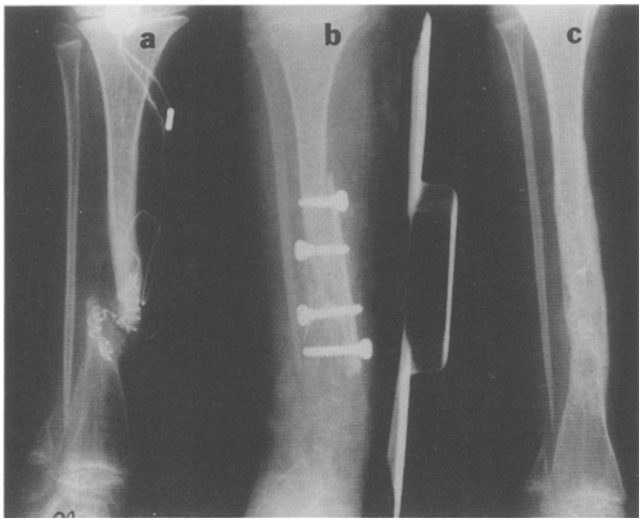

Fig. 1. (**a**) AP x-ray demonstrating a type III lesion in a 6-year-old male in June 1980, following three failed surgical attempts to produce union. Note broken electrodes of implanted D.C. "stimulator," the last of the surgical failures. (**b**) AP x-ray in April 1981, 7 weeks after a Boyd dual onlay graft and PEMFs, immediately postoperatively. Note lateral cortical onlay graft almost completely remodeled. (**c**) AP x-ray, May 1982. Patient has union and is fully functional in a "clam-shell" puttee. Refracture occurred in November 1985, following a severe injury. Patient was immediately regrafted and stimulated with PEMFs and has remained united through puberty.

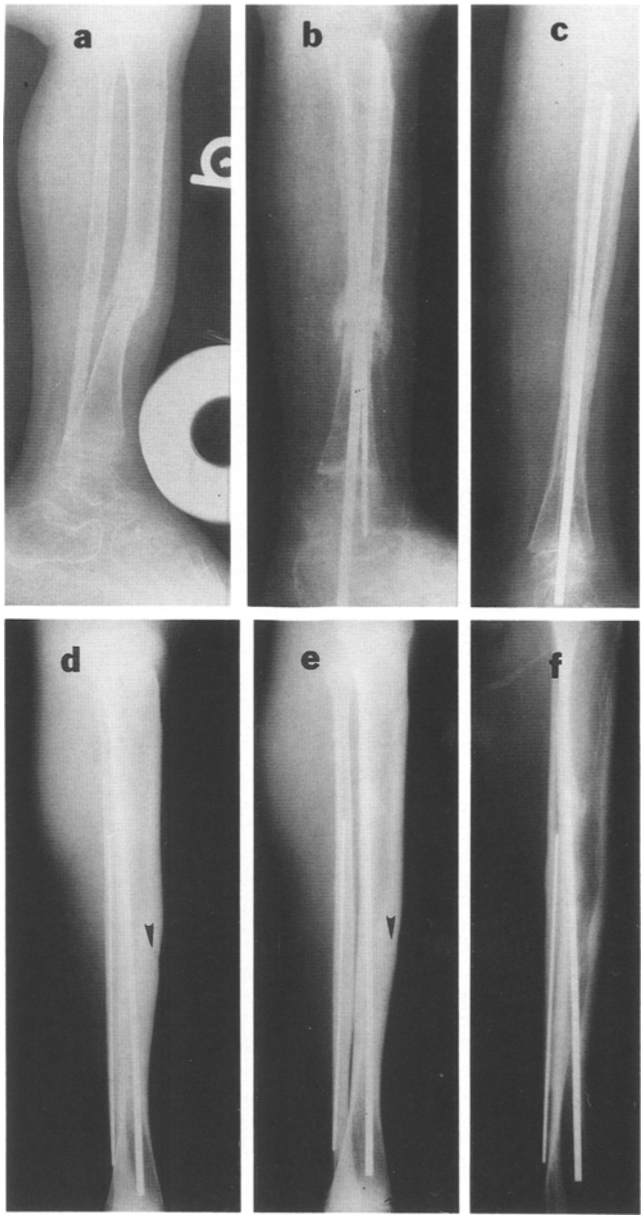

Fig. 2. (**a**) Lateral x-ray taken in January 1974 of a 3½-year-old female whose initial fracture occurred a year and a half previously. Note lack of bony union. (**b**) Lateral x-ray of July 1977, 2 months after IM rodding and grafting. Non-union persists. (**c**) Lateral x-ray taken in February 1979, 6 months after cast and PEMFs were applied in August 1977 for continuing motion and lack of radiographic progress at the fracture site. Patient has union and advanced remodeling of the old fracture. (**d**) Lateral x-ray, October 1982. Patient at 11 years of age developed pain and tenderness in anterior tibia at the site of her previous non-union. Radiographic signs of a stress fracture in the anterior tibial cortex (arrow). PEMFs restarted at night. (**e**) Lateral x-ray taken in July 1983. Patient has been asymptomatic for 4 months and the stress fracture signs are resolving (arrow). PEMFs discontinued. (**f**) Lateral x-ray, September 1986. Patient has remained asymptomatic for 3 years, is now 16 years of age and fully functional without an exoskeleton.

tremely recalcitrant type III lesions, which characteristically occurred in children at a younger age than type I and II lesions.

From experience thus far, several recommendations appear to be justified, assuming a lesion is functionally aligned. The first is based on 8 patients not reported herein who were treated between 7 months and 7 years of age, before any evidence of fracture was present (Fig. 3). Five of these avoided fracture and 1 of the remaining 3 who did not, healed on PEMFs alone; another 1 of the 3 united after surgery. In view of the safety record of this therapeutic method in more than 200,000 cases of all types over the past 17 years, very early treatment should be given consideration. Optimally, it consists of appropriate bracing and use of PEMFs until remedularization and remodeling of the lesion is well advanced.

Second, if fracture occurs in type I and II lesions, PEMFs combined with a 1½ spica during initial phases of treatment can lead to a success rate in the 80% range.

Third, following union, bracing should be continued, probably until puberty or until remodeling has obliterated major roentgenographic stigmata of the process (i.e., a medullary canal is reestablished).

Fourth, evidence of stress fracture or refracture calls for reinstitution of PEMFs and an appropriate exo-skeleton (cast or brace) until bony repair is established. In some patients, episodic use of PEMFs has been continued for up to 9 years before puberty occurred.

Fifth, if a functional union has not resulted after a year of adequate treatment or if the refracture rate is excessive, operative repair must be given strong consideration. Two methods have proven useful for those patients who have failed to respond to the more conservative PEMF approach: (1) the Boyd dual on-lay technique uses stout, cortical allografts with fresh autologus iliac chips combined with PEMFs, immediately postoperatively, and a 1½ spica; (2) the use of a microvascular fibular graft from the opposite extremity, an increasingly popular method. These latter ap-

Fig. 3. **(a)** Lateral x-ray of a 20-month-old female taken in May 1980 with a pre-type II tibial lesion. Note thinning of anterior tibial cortex, hypertrophy posteriorly, and fibular bowing. PEMFs begun at night, with a daytime caliper brace and continued for 5 years. **(b)** Lateral x-ray in February 1983. Patient last seen in follow-up in October 1989, at which time the tibial lesion had completely disappeared and the patient was fully functional.

proaches generally are required for the majority of aggressive, hypermobile type III lesions (with spindling and a wide gap) before union can be secured.

Leg length inequality has not been a significant problem in those children whose fractures united where function was maintained. Although there is anecdotal evidence in some patients that PEMFs may have stimulated longitudinal growth, definitive data are not available. Restoration of bony integrity to a weight-bearing extremity would, in itself, be expected to have a salutory effect on growth.

It has been suggested by Sutcliffe and Goldberg [21] that an unsuccessful result of PEMF treatment, initially, may modify the nonunion site by increasing vascularity and setting the stage for an improved chance of surgical success. It is clear from experimental studies that selected PEMFs have a strong angiogenic effect [22–24]. Their ability to modify the progressive nature of collapse in osteonecrosis and their synergistic behavior with viable bone grafts argue in favor of their use, at least in postgrafting phases if not earlier in the most challenging forms of sclerotic nonunions [25–29].

Scientific understanding of the biological effects of PEMFs has expanded, exponentially in the past decade, since the protocol for treating patients with congenital pseudarthrosis was standardized in 1980. Their mechanisms of action appear to have a rational basis in this pathological setting. Perhaps the most direct of these derive from their demonstrated ability to limit bone resorption, to affect calcification of fibrocartilage, and in favoring angiogenesis [20, 24, 30–35]. Alternatively, it is known that this specific form of electromagnetic energy affects both neural function and regeneration [36, 37]. In view of the documented association between neurofibromatosis and congenital lesions such as these, it is conceivable that further investigation may establish a neurological link for PEMF effects in this condition.

Regardless of appropriate mechanisms, this study affirms the clinical efficacy of PEMFs in a setting in which "spontaneous" healing and union from simple cast immobilization are exceedingly remote. The success rates, particularly in those cases treated without surgery, are consonant with earlier controlled studies of adult nonunions and more recent double-blind studies that establish PEMF effects on clinical bone healing, beyond a doubt [38, 39]. With efficacy issues now buttressed with more substantive data and with rational mechanisms demonstrated at the cellular level, it is to be hoped that PEMFs will assume a broader role in the orthopedic surgeon's armamentarium, particularly those faced with the challenge of congenital pseudarthrosis.

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