Comparative study of the use of electromagnetic fields in patients with pseudoarthrosis of tibia treated by intramedullary nailing

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Abstract We made a comparative cohort study in patients suffering from tibial pseudoarthrosis, all of whom were treated by intramedullary nailing. We divided patients into two groups: one treated by intramedullary nailing only (control group) and the other by intramedullary nailing combined with pulsed electromagnetic fields (PEMFs). The study included 57 cases of tibial pseudoarthrosis in 57 patients from February 1987 to February 2002. Pseudoarthrosis was treated surgically in all cases (Grosse-Kempf dynamic intramedullary nailing). This was combined with PEMFs in 22 cases. The average age was 38.3 years (range 14–89 years) and the average duration of follow-up was 27.2 months (range 12–48 months). Forty-nine fractures (86%) healed and eight (14%) did not. Of the group treated with PEMFs, 20 (91%) healed and two (9%) did not; from the group that did not receive PEMF (35), 29 (83%) healed compared to six (17%) that did not. The relationship between union and use of PEMFs, and between time to union and use of PEMFs was clinically relevant. PEMFs are useful when treating tibial pseudoarthrosis. Its noninvasive nature means that there are more complication-free unions.

Introduction

Tibial pseudoarthrosis is a common complication that increases the inactivity time of the patient and requires several surgical interventions with irregular results. The use of intramedullary nailing in delayed union is an accepted method, but it is not exempt from complications, mainly unhealed pseudoarthrosis [23].

The use of pulsed electromagnetic fields (PEMFs) has been studied and used in clinical practice for several years in delayed union and pseudoarthrosis [1, 2, 5–10, 12, 14–16, 20]. Its biochemical effect is a result of increased calcium transport through the cell membrane. This leads to a higher intracellular concentration of calcium and stimulates growth factors such as collagen and proteoglycans, thus accelerating the process of union [3, 4, 13, 17]. Electrical stimulation can specifically, selectively, and simultaneously upregulate the expression of a number of osteoconductive bone morphogenetic proteins [24].

The objective of this study was to compare the results of patients suffering from tibial pseudoarthrosis treated using intramedullary nailing with those of patients who were treated with intramedullary nailing and PEMFs.

Material and methods

We performed a retrospective cohort study of patients with tibial pseudoarthrosis treated using intramedullary nailing. The patients were divided into two groups: one group treated with intramedullary nailing and PEMFs, the other with only intramedullary nailing (control group).

We studied 57 fractures in 57 patients from February 1987 to February 2002. The average age was 38.3 years

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(range 14–89 years) and the average follow-up was 27.2 months (range 12–48). PEMF was added to the treatment in 22 patients.

The left side was affected in 30 patients and the right side in 27. The most frequent cause of fracture was traffic accident in 37 patients (65%), direct injury in 12 (21%), and falls in eight patients (14%). Seventeen were closed fractures and 40 were open fractures (Table 1).

The tibia was divided into five zones, and the most frequently affected areas were the medial-distal third in 25 patients, the medial third in 14, the distal third in 12, the medial-upper third in five cases, and the upper third in one patient. The fracture line was spiral in 15 patients (26%), comminuted in 13 patients (23%), transverse in nine (16%), short oblique in seven patients (12%), bifocal in seven patients (12%), and long oblique in six (11%).

Initial management of the fractures was conservative in 11 patients, reamed intramedullary nailing in 23 patients and external fixation in 23.

Pseudoarthrosis was established clinically and radiologically. The clinical criteria were pain and movement in the region of the fracture. The radiological criterion was absence of bone callus six months after the fracture, with no evidence of radiological changes in the previous three months. The patients included had a pseudoarthrosis defect of less than 1 cm. The average time until the diagnosis of pseudoarthrosis was 7.94 months (range 6–18 months), and the average time until the second intervention was 10.4 months (range 6–22 months). Pseudoarthrosis was hypertrophic in 27 cases and atrophic in 30 cases.

Treatment was surgical in all cases (reamed Grosse-Kempf intramedullary nailing). This was combined with electromagnetic stimulation in 22 of the 57 patients. Both groups were similar in terms of aetiology, type of previous fracture (Table 1), and type of pseudoarthrosis. Of the 27 cases of hypertrophic pseudoarthrosis, nine were treated by PEMF, and of the 30 cases of atrophic pseudoarthrosis, 14 were treated with PEMF.

The stimulator was used for an average of 5.6 months (range 3–10 months). Twenty-two patients used the

electromagnetic stimulator (Howmedica) at home for a minimum of eight hours per day coinciding with their night rest (low frequency, 75 Hz; intensity, 10–20 A/cm; time of pulse, 1.3 microseconds; voltage, 180–220 V).

Patients underwent monthly clinical and radiological follow-up (X-ray in two projections). The radiographic criterion of union used was bone trabeculae traversing the fracture in two radiological projections (anteroposterior and lateral).

The clinical and radiological results were classified as excellent (return to previous activity without clinical or radiological sequelae), good (return to previous activity, union of the fracture but some type of clinical or radiological sequelae), and poor (unable to return to previous activity and/or needed surgery before the union of the fracture). The statistical study was carried out using the program SPSS for Windows (SPSS Inc., Chicago, IL, USA). Qualitative variables were analysed using the Fisher test and quantitative variables using the Student's *t* test.

Results

Forty-nine cases of pseudoarthrosis (86%) healed and eight (14%) did not. Of the 22 fractures treated with stimulation, 20 (91%) healed and two (9%) did not (Table 2). Of the 35 fractures treated with intramedullary nailing only, 29 (83%) healed and six (17%) did not (Table 2). The global evaluation of the clinical results is shown in Table 2.

The average time until there was radiological evidence of union of the fractures was 3.3 months (range 2–7 months) with PEMF and 4.9 months (range 3–9 months) without.

The relationship between the union of the fracture and the Gustilo classification, and between time to union of the fracture and use of the stimulator was statistically significant ($P \leq 0.05$). The relationship between the percentage of union and the age, sex, aetiology of the fracture, location, and previous treatment of the fracture was not statistically significant ($P \geq 0.05$).

The relationship between union and the use of electromagnetic stimulation was not statistically significant, but was clinically significant (relative risk 0.53, which supposes a reduction of 47% in the appearance of events. If we obtain the value of the significance from the

Table 1 Gustilo classification

Classification	PEMF	No PEMF	Total
Closed	7	10	17
Open grade I	3	5	8
Open grade II	5	8	13
Open grade IIIA	4	2	6
Open grade IIIB	3	9	12
Open grade IIIC	0	1	1

PEMF pulsed electromagnetic field

Table 2 Consolidation of the fracture

Type	Consolidation	No consolidation	Total
PEMF	20 (91%)	2 (9%)	22
Non-PEMF	29 (83%)	6 (17%)	35

PEMF pulsed electromagnetic field

binomial distribution, p value is 0.08, which supposes a trend to significance).

The clinical complications were two deep infections, one superficial infection, nine cases of protrusion of material, and three breaks of proximal screws. The material was removed in 11 patients due to intolerance. X-ray revealed a shortening of between 0.5 cm and 1 cm in six patients, union in varus of 5° in two patients, union in valgus of 10° in two patients, and nonunion in eight patients. Of the eight fractures that did not heal, seven did so after several further surgical interventions and in one case it was necessary to amputate the leg.

Discussion

Pseudoarthrosis is a frequent complication in fractures of the tibia and its treatment constitutes a challenge for the surgeon, with the result that many processes have been described for the treatment of pseudoarthrosis of the tibia. Treatment by intramedullary nailing is a relatively simple procedure with low morbidity. Because the nonunion site is not exposed, blood loss is minimal and hospital stay is short [22, 23].

PEMFs present certain advantages: the technique is noninvasive, it can be administered as ambulatory therapy, it can be used early in risky fractures, infection rates are lower, and there are fewer vascular problems. There are few contraindications: pseudoarthrosis with uncontrollable mobility, separation of the fragments by more than 1 cm, pseudoarthrosis secondary to pathological fractures, pregnancy, noncollaborating patients, presence of pacemaker, and childhood.

Electrical stimulation has been shown experimentally to enhance bone formation and neovascularisation in addition to alteration of bone turnover [3, 11, 17]. Many previous studies have shown the effect of the signal on both bone and cartilage cells [2]. It can aid in the healing of nonunion and induce bone neoformation [3, 7, 8, 17, 21]. Electrical stimulation can specifically, selectively, and simultaneously upregulate the expression of a number of osteoconductive bone morphogenetic proteins [24].

Few comparative studies using this method have been performed with control groups [7, 19, 20]. The randomised double-blind study by Sharrard [19] in 1990 compared the results of 20 patients treated by immobilisation and electrostimulation and a control group of 25 patients in which the stimulator was not used. The results obtained were statistically significant—a large number of the fractures exposed to electrostimulation healed.

Brighton et al. [7] compared three different methods (direct current, 167 patients; capacitive coupling, 56 patients; and autograft, 48 patients) in tibial pseudoarthrosis

and concluded that, when there were no risk factors, the three methods would offer similar results. More recently, in 2003, Simonis et al. [20] published a prospective, randomized, double-blind study in which pseudoarthrosis of the tibia was treated by osteotomy of the fibula and external fixation. The results of 18 patients who also underwent stimulator therapy were compared with those of a control group of 16 patients who did not receive stimulator therapy. There was a statistically significant association between the union of the tibia and the use of the stimulator.

Our study compared two groups of patients who were similar in terms of population and treatment used (dynamic reamed intramedullary nailing), with the only differentiating factor being the use of PEMFs. The study patients had a defect of less than 1 cm; therefore, other techniques might be necessary for patients with major defects (grafting, transport, vascularised fibular graft, etc). We found 91% union in pseudoarthrosis patients who were treated by surgery and stimulator, compared with 83% in those who did not receive the stimulator. These results are clinically significant and favour the use of PEMFs.

A statistically significant relationship was found ($P \leq 0.05$) between the union of the fracture and Gustilo's classification, i.e. the greater the degree of soft tissue injury, the lower the percentage of union; and between the time to union of the fracture and use of PEMFs, i.e., fractures treated with PEMF took less time to heal. The relationship between the percentage of union and the age, sex, aetiology of the fracture, location, and previous treatment of the fracture was not statistically significant ($P \geq 0.05$).

The results obtained demonstrate that PEMFs exert a beneficial effect in union disorders and complement other therapeutic approaches, in this case intramedullary nailing. Therefore, we think that electromagnetic stimulation is a useful, risk-free technique for the treatment of tibial pseudoarthrosis.

References

1. Aaron RK, Ciombor DMcK, Simon BJ (2004) Treatment of nonunions with electric and electromagnetic fields. *Clin Orthop* 419:21–29
2. Aaron RK, Ciombor DMcK, Simon BJ (2004) Stimulation of growth factor synthesis by electric and electromagnetic fields. *Clin Orthop* 419:30–37
3. Adair RK (1991) Biological effects on the cellular level of electric field pulses. *Health Phys* 61:395–399
4. Anderson JC, Erikson C (1970) Piezoelectric properties of dry and wet bone. *Nature* 227:491–492
5. Bassett CAL, Valdés MG, Hernandez E (1982) Modification of fracture repair with selected pulsing electromagnetic fields. *J Bone Jt Surg* 64-A:888

6. Bassett CAL, Mitchell SN, Gaston SR (1981) Treatment of ununited tibial diaphyseal fractures with pulsing electromagnetic fields. *J Bone Jt Surg* 63-A:511–523
7. Brighton C, Shaman P, Heppenstall B (1995) Tibial nonunion treated with direct current; capacitive coupling or bone graft. *Clin Orthop* 321:223–234
8. Brighton CT, Pollack SR (1984) Treatment of nonunion of the tibia with a capacitively coupled electrical field. *J Trauma* 24:153–155
9. Brighton CT (1981) Treatment of nonunion of the tibia with constant direct current: *J Trauma* 21(3):189–195
10. Brighton CT, Pollack SR (1985) Treatment of recalcitrant nonunion of the tibia with capacitively coupled electric field. *J Bone Jt Surg* 67-A:577–585
11. Cooper MS (1995) Membrane potential perturbations induced in tissue cells by pulsed electric fields. *Bioelectromagnetic* 1995 (16):255–262
12. Friendenberg ZB, Brighton CT (1996) Bioelectric potentials in bone. *J Bone Jt Surg* 48-A:915–923
13. Fukada E, Yatsuda J (1957) On the piezoelectric effect of bone. *J Physio Soc Japan* 12:1158–1162
14. Heckman JD et al (1981) Nonunion treatment with pulsed electromagnetic fields. *Clin Orthop* 161:58–66
15. Heppenstall RB et al (1984) Prognostic factors in nonunion of the tibia: an evaluation of 185 cases treated with constant direct current. *J Trauma* 24(9):790–795
16. Lavine LS, Grodzinsky AJ (1987) Electrical Stimulation of repairs of bone. *J Bone Jt Surg* 69-A:626
17. López-Durán L, Yageya J (1980) Bioelectric potentials after fracture of the tibia. *Acta Orthop Scand* 51:601–605
18. Scott G, King JB (1994) A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bone. *J Bone Joint Surg* 76A:820–825
19. Sharrard WJW (1990) A doubled-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. *J Bone Joint Surg B* 72:347–355
20. Simonis RB, Parnell EJ, Ray PS, Peacock JL (2003) Electrical treatment of tibial non-union: a prospective, randomised, double-blind trial. *Injury* 34(5):357–362
21. Skerry TM, Pead MJ, Lanyon LE (1991) Modulation of bone loss during disuse by pulsed electromagnetic fields. *J Orthop Res* 9:600–608
22. Sledge S, Johnson KD, Henry MB, Watson JT (1989) Intramedullary nailing with reaming to treat non-union of the tibia. *J Bone Joint Surg* 71A:1004–1019
23. Templeman D, Thomas M, Varecka T, Kyle R (1995) Exchange reamed intramedullary nailing for delayed union and non-union of the tibia. *Clin Orthop* 315:169–175
24. Wang Z, Clark C, Brighton C (2006) Up-regulation of bone morphogenetic proteins in cultured murine bone cells with use of specific electric fields. *J Bone Joint Surg* 88-A:1053–1065