Reprinted from: «ITALIAN JOURNAL OF ORTHOPAEDICS AND TRAUMATOLOGY»
Volume IX - Number 3 - September 1983

Glaser

TREATMENT OF DELAYED UNION AND PSEUDARTHROSIS BY LOW FREQUENCY PULSING ELECTROMAGNETIC STIMULATION

Study of 35 cases.

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This is a study of 35 cases of delayed union or established fibrous union (« pseudarthrosis ») treated by pulsing electromagnetic stimulation. The treatment, applied up to 12 hours per day, can be carried out at home, with clinical and radiological control every 60 days. The average time of healing was 6 months. Consolidation occurred in 88.5 % of cases, usually without the production of excessive periosteal callus.

The method was particularly useful and effective in infected fractures ,failed bone grafts, revascularisation of fragments showing signs of necrosis, and fractures with associated skin lesions.

The possibility of accelerating fractures healing by artificial means has always been an aspiration of the traumatologist, and from the end of the 18th century electrical stimulation has been used without, until recently, any success (Galvani, 1791;Hartshorne, 1841; Lente, 1850). The first important advance was by the researches of Japanese and American surgeons (Yasuda, 1953; Fukada & Yasuda, 1957; Bassett & Becker, 1962) who showed that in a segment of bone subjected to a deforming load, positive electrical charges are induced along the convex (tension) side and negative charges along the concave (compression) side (Fig. 1).

Recent studies (Shamos & Levine, 1967; Eriksson, 1974 & 1976) attribute this difference of potential to deformation of the macromolecules of collagen and to ionic movements in the interstitial fluid (« streaming potentials ») which cause resorption on the electropositive side and deposition on the electronegative side (Yasuda, 1953; Bassett *et al.*, 1964).

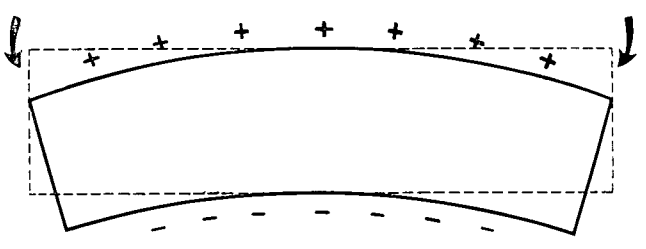

FIG. 1. - Piezoelectric phenomenon in bone: A skeletal segment subjected to deformation is positively charged on the convex (tension) side and negatively charged on the concave (compression) side.

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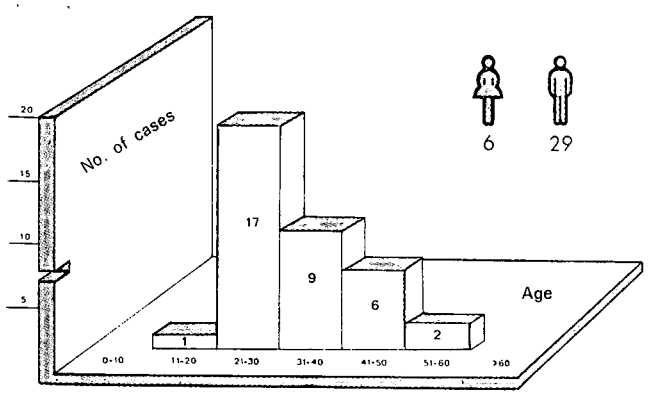

FIG. 2. - Distribution according to sex and age in 35 cases. There is a marked preponderance of males and also of the third decade.

These and other observations gave rise to the thought that electrical stimulation could exert reparative effects on bone as well as on the soft tissues.

This led to various techniques of osteogenetic stimulation; direct implantation of the electrodes into the fracture focus (Becker *et al.*, 1977; Brighton *et al.*, 1975, 1977, 1981; Friedenberg *et al.*, 1974; Friedenberg & Brighton, 1974; Jorgensen, 1972, 1977; Lavine *et al.*, 1972; Masureik & Eriksson, 1977; Rowley *et al.*, 1974; Zichner, 1981); the use of implanted electrodes supplemented by pulsing electromagnetic fields (Kraus & Lechner, 1972; Lechner *et al.*, 1981); and finally to pulsing electromagnetic stimulation as a completely non-invasive procedure (Bassett *et al.*, 1977; Watson, 1979; De Haas *et al.*, 1980; Sedel *et al.*, 1981; De Bastiani *et al.*, 1981; Sharrard *et al.*, 1982).

These studies demonstrated that an electromagnetic field with suitable characteristics could induce

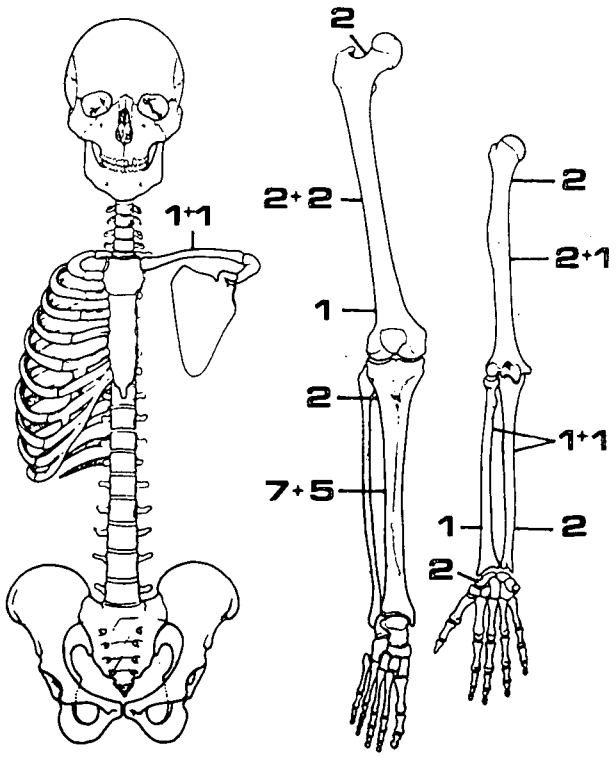

FIG. 3. - Localisation according to closed fractures (black) and open infected fractures (red). The most frequent site is the tibia.

biological changes conducive to osteogenetic stimulation. The magnetic field, as in the case of mechanical deformation, induces tension on the cell membrane which depends on the voltage (Luben *et al.*, 1982). It also acts on the vascular system. The stimulus to union is exerted through the accelerating or retarding effects on all the phases of calcification — vascular invasion, mineralisation, remodelling — but above all on the early stages in which new vascular formation leading to markedly increased local vascularity has been demonstrated (Weigert & Werhahn, 1977; Bassett *et al.*, 1979; Zichner, 1981).

The object of the present paper is to make a critical evaluation of our own experience in the use of pulsing low frequency electromagnetic stimulation (PES) in the treatment of delayed union and established pseudarthrosis in adults.

MATERIAL AND METHODS

The present study comprises 33 adult patients with a total of 35 fractures affected by delayed union or established pseudarthrosis, treated by PES between October 1979 and October 1981. All were followed up for a minimum of 6 months, either to cure or to the termination of treatment.

The distribution according to sex and age is reported in Fig. 3. Fifty-one per cent of cases were in the third decade and there was a male predominance of 83 %. The sites and levels of fractures are shown in Fig. 3. The tibia was most affected (40 %) but there was a wide distribution of both site and level.

Delayed Union (11 cases) was characterised by scarcity of callus formation and poor alignment of the fragments about 5 months after injury (Ruggieri *et al.*, 1977). Seven of these were closed fractures and 4 open fractures, none of which were associated with infection.

The initial treatment of these fractures was:

Closed fractures 7	Plaster cast	3	(neck of humerus; carpal navicular; distal ulna)
	Küntscher nail	1	(distal tibia)
	Screws and plaster .	3	(neck of femur; upper tibia; clavicle)
Open fractures . 4	Plaster cast	3	(shaft of humerus; radius and ulna; shaft of tibia)
	Kirschner nail	1	(clavicle)

In the latter group, in accordance with our usual procedure, we removed 2 plates and screws from the femur and tibia.

Established pseudarthrosis (24 cases - no infection) was diagnosed on the basis of no evidence of union at least 10 months after injury (Rug-

gieri *et al.*, 1977). There were 24 cases, 14 of which showed hypertrophic sclerosis with malalignment, and 10 showed atrophic changes. In 5 of the latter there was a loss of substance more than 2.5 cms. There were 19 closed fractures and 5 open fractures.

Fifteen closed fractures in this group were initially treated as follows:

Closed fractures 15	Plaster cast 7	(neck & shaft of humerus; fracture both bones of forearm; shaft of ulna; shaft of femur; upper & mid shaft tibia)
	Plaster and screw fixation 6	(shaft of humerus; neck, shaft and supracondylar fracture femur; shaft of tibia)
	Küntscher nail 1	(tibia)
	Screw fixation 1	(navicular)

Four open fractures were treated as follows:

Open fractures . 4	Plaster fixation . . . 3	(radius 1, tibia 2)
	External fixation . . 1	(femoral shaft)

In the latter group, in addition to electromagnetic stimulation, we removed 2 femoral plates and substituted external fixation for 4 months. In 2 cases (radius and tibia) there was loss of substance due to failure of autoplastic grafts.

Infected open fractures (5 cases) which resulted in pseudarthrosis comprised 3 tibial fractures with severe open wounds, 2 of which were initially treated by external fixation and the third in plaster. The other 2 cases involved the femoral shaft (one of which also involved the tibia) in which plate fixation was used. In both cases the plates and screws were removed and replaced by external fixation. In one of the tibial fractures there was sequestration after 4 months. This was removed and an autoplastic graft applied with further fixation in plaster.

We used autoplastic grafts in 4 cases in which there was loss of bone substance and sclerosis of the fragments.

Stabilisation of the fracture is an essential part of electromagnetic treatment. It was achieved by conventional plaster fixation in 16 cases, in 10 cases with « functional » plaster, in 5 cases by external fixation, and in the remaining 4 cases by internal fixation (2 Küntscher nails, 2 compression plates).

The chances of union occurring were evaluated case by case. Weight bearing was allowed in cases of non-union with good contact between the fragments and in which the plaster or internal fixation ensured stability. On the other hand, it was forbidden in cases where the site or other features of the pseudarthrosis made stable fixation questionable.

The interval between injury and the application of electromagnetic treatment was an average of 15 months, ranging from a minimum of 5 months to a maximum of 2 years.

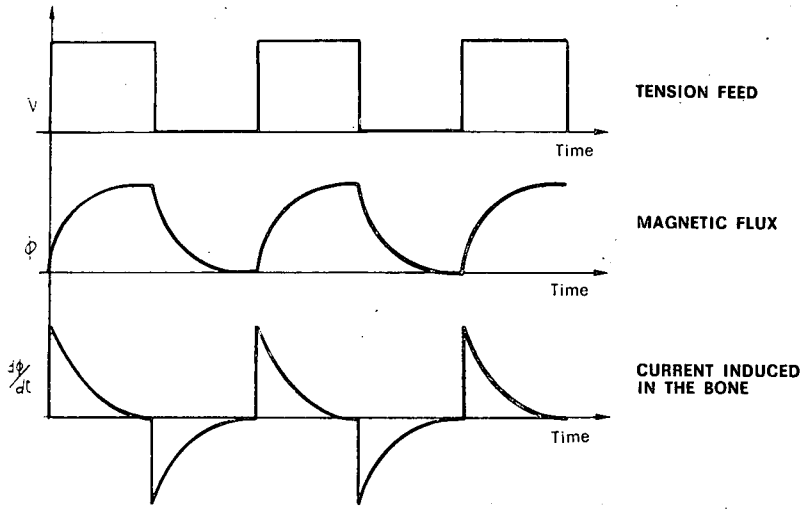

FIG. 4. - Diagram of the tension feed (50 % cycle), magnetic flux and current induced in the bone.

The equipment used (« BIOSTIM ») is supplemented by mains current. The electromagnetic field was generated by two 1500 coil solenoids producing a current of 100-200 volts, regulated by the distance between the solenoids to induce in the bone a voltage of biological significance (Bassett *et al.*, 1974 and 1977) (Fig. 4). The frequency was 75 Hertz and the duration of single impulses 1.3 milliseconds.

The stimulation was for a minimum of 12 hours a day continued for at least 60 days. Most patients did it during the night in their own homes.

The solenoids were positioned over the centre of the pseudarthrosis parallel to and opposite each other (Fig. 5). This was controlled by A.P. and lateral radiographs to ensure that the lines of force of the magnetic field were perpendicular to the axis of the segment of bone involved. The solenoids were maintained in position by elastic bandages (Fig. 6). The pre-requisites for successful treatment are: good stabilisation of the fracture site; loss of bone substance not in excess of 2.5 cms. Treatment is not contraindicated by infection with secretion, by sequestration if the necrotic fragments do not exceed 3 cm in the main axis of the long bones, by the site of the pseudarthrosis or the length of time it has been present, or by the presence of metallic internal fixation provided this is non-magnetic material (stainless steel 3161, chrome-cobalt-molibdenum alloy, titanium).

The patient is recalled every 60th day for clinical and radiological assessment.

RESULTS

Union was obtained in 31 cases (88.5 %) in all of which the clinical and radiological tests were unequivocal. The average time to achieve union was 6 months, with a range of 4-13 months.

There were 3 re-fractures, all of which occurred within 3 months of union and showed the typical characteristics of fatigue fractures. They

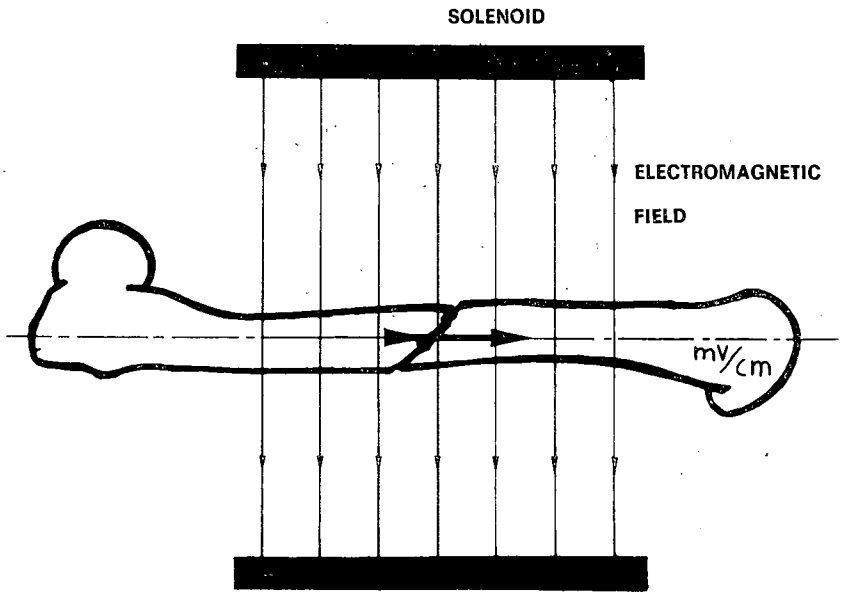

FIG. 5. - The pseudarthrosis must be centred exactly between the two solenoids, which must be parallel and exactly opposite to each other. They must also be aligned along the axis of the bone.

were all cured by a further period of plaster fixation and electromagnetic stimulation for 35 days. In one of these cases a high tibial osteotomy was performed to correct malalignment. In the whole series, there were 4 failures, the reasons for which were analysed.

1. **Male aged 20.** Closed fracture of the tibia treated by Küntscher nail fixation which was too short and too slender, allowing so much movement that non-union was inevitable (this was demonstrated radiologically by movement at the lower pole of the nail). The persistence of this instability was also responsible for the failure of electromagnetic treatment (Fig. 12). In spite of this, the patient was able to walk without support and without pain, no doubt due to compensatory thickening of the fibula.

2. **Male aged 36.** Atrophic type of pseudarthrosis of the upper

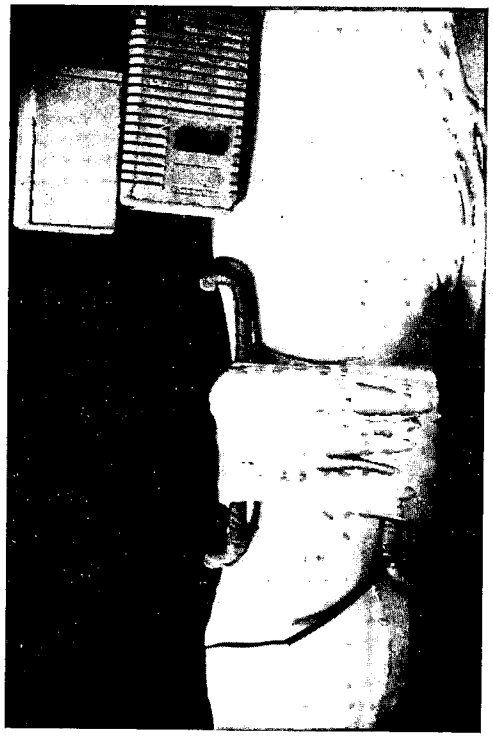

FIG. 6. - The solenoids are secured in position by encircling plaster or elastic bandages. The pilot lamp ensures that the apparatus is functioning correctly.

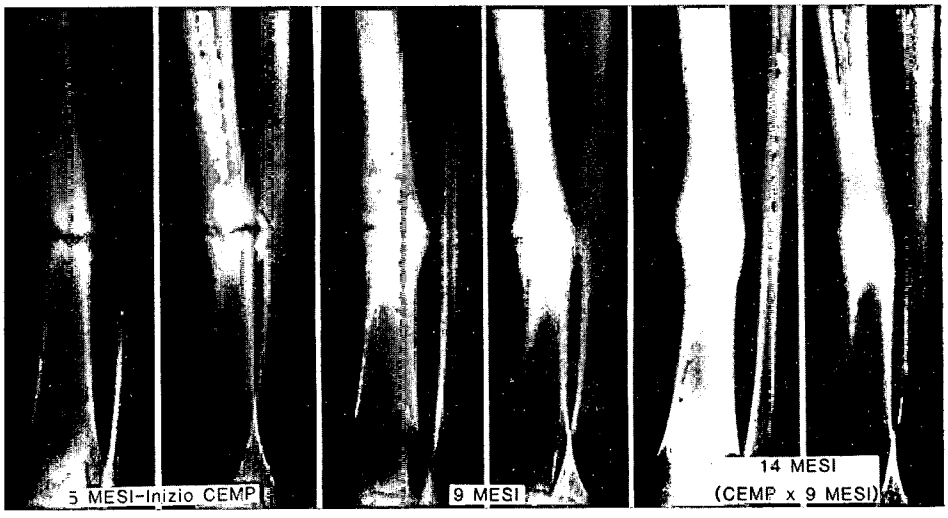

FIG. 7. - Male aged 24. Delayed union with sclerosis 5 months after a closed fracture. Consolidation occurred at 9 months following electromagnetic therapy and further plaster fixation. From the commencement of treatment it seemed obvious that pseudarthrosis of the hypertrophic type would develop. The cure after 9 months was in our view attributable to the use of electromagnetic therapy.

third of the femur with loss of bone substance. The initial treatment was by Küntscher nail which became infected (*Pseudomonas aeruginosa*). The nail was then removed and after surgical cleansing of the wound and antibiotic drainage, external fixation was applied and the sepsis was brought under control. After 7 weeks of electromagnetic therapy infection recurred with multiple sequestra which necessitated surgical intervention.

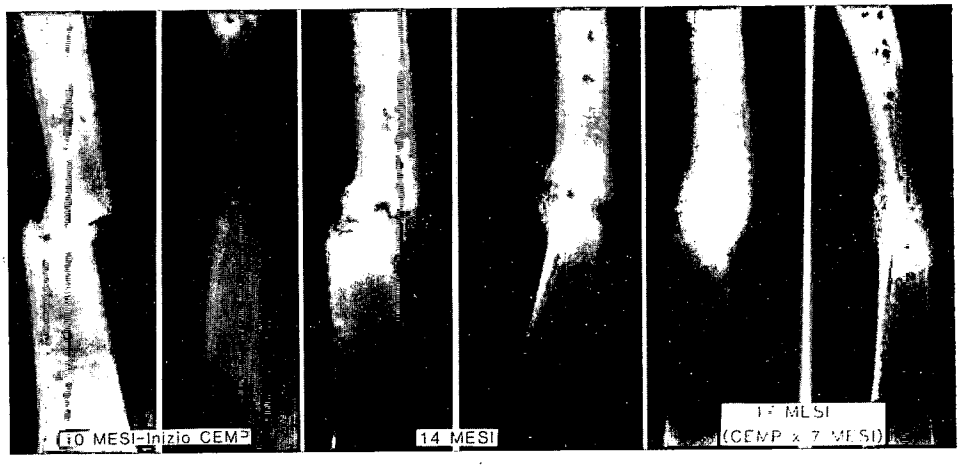

FIG. 8. - Male aged 26. Loose pseudarthrosis 10 months after an infected open fracture (E. coli). The external fixation was removed and replaced by plaster with electromagnetic therapy. 4 months later there was lysis of the bone ends with commencing periosteal callus. 3 months later union was complete. The infection subsided after 6 weeks. The cure of the pseudarthrosis and the subsidence of infection after 7 months electromagnetic therapy is in our opinion clear evidence of the effectiveness of electromagnetic therapy. This is based on our experience of similar cases treated simply by further immobilisation in plaster.

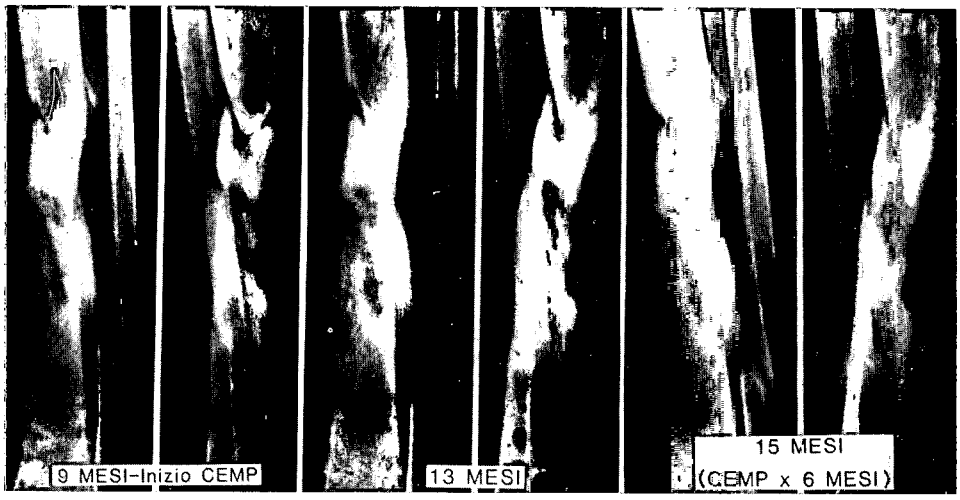

FIG. 9. - Male aged 23. Atrophic type of pseudarthrosis 9 months after an open fracture with marked loss of skin due to secondary necrosis. This was followed by persistent infection with discharging sinuses (Pseudomonas). The external fixators were removed and substituted by plaster and electromagnetic therapy. Clinical and radiological union was achieved after 6 months. Skin cover was complete. Note the progressive incorporation and revascularisation of the middle fragment which was showing signs of ischaemic necrosis when electromagnetic treatment was commenced.

3. **Female aged 38.** Atrophic pseudarthrosis of a closed tibial fracture with a trapezoidal third fragment which became necrotic and formed a sequestrum (confirmed histologically after removal). The gap after removal of the sequestrum was such that electromagnetic therapy was never likely to succeed.

4. **Male aged 27.** Atrophic pseudarthrosis of an open but non-infected fracture of the femur. After 3 months of electromagnetic therapy compression plate fixation was performed. At operation it was found that failure of union was due to the interposition of soft tissues between the fragments.

Successful results were achieved in 93 % of firm pseudarthroses and 60 % of loose pseudarthroses, which corresponds with those reported by

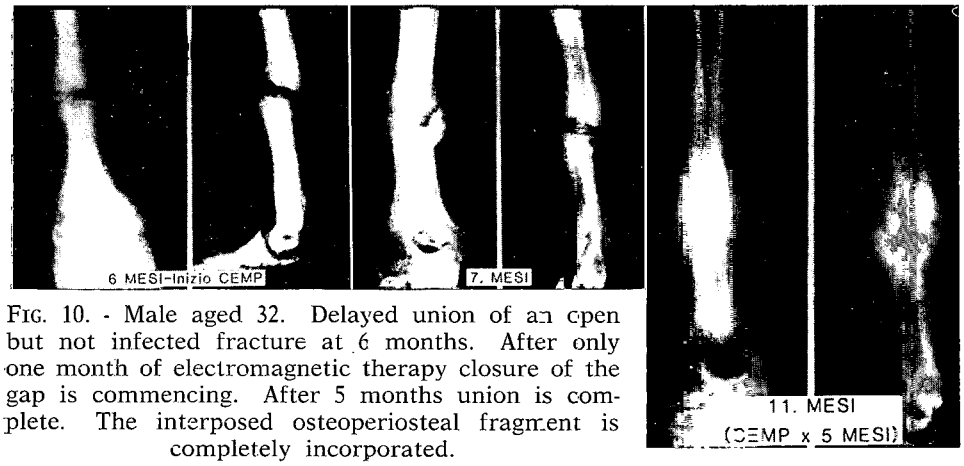

FIG. 10. - Male aged 32. Delayed union of an open but not infected fracture at 6 months. After only one month of electromagnetic therapy closure of the gap is commencing. After 5 months union is complete. The interposed osteoperiosteal fragment is completely incorporated.

FIG. 11. - Male aged 24. Atrophic infected pseudarthrosis (Staph. aureus) at 2 years after injury. The initial treatment was internal plate fixation by the posterior approach after surgical cleansing. When this failed, it was followed by external fixation, sequestrectomy, skin grafting and autoplastic cancellous bone grafts, supplemented by electromagnetic therapy. After 2 months the bone grafts show evidence of incorporation. The skin grafts also succeded and the secreting fistulae closed. At 6 months there was complete radiological and clinical union. This case illustrates the beneficial effects of electromagnetic therapy on the bone grafts, which became incorporated in 2 months.

other authors (Bassett *et al.*, 76 % in 2552 cases, 1982; Brighton *et al.*, 81 % in 382 cases, 1982). Of the unsuccessful results in our series, 1.8 % were attributable to uncontrolled sepsis or to gaps in the bone beyond acceptable limits. In the latter cases, the problem was solved by filling the gap with a cancellous graft supplemented by electromagnetic therapy which always accelerated the incorporation of the graft at both ends.

Our results were at variance with those of other authors (Bassett *et al.*, 1978; Sedel *et al.*, 1981; Sharrard *et al.*, 1982) in that we did not note any significant variation between different bones, different levels of fracture, or the influence of the patient's age or the duration of the pseudar-

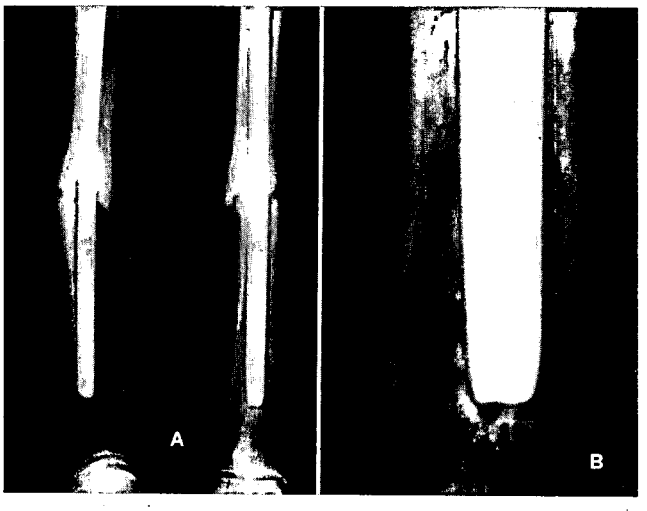

FIG. 12. - Male aged 20. Hypertrophic type of pseudarthrosis in an open fracture treated 4 months after injury by Küntscher nail fixation. (*A*) after 5 months of electromagnetic therapy, which was started 10 months after injury, there is no evidence of union. The failure in this case is attributable to the inadequate fixation of the fracture, which is clearly demonstrated (*B*) by the rarefaction around the lower end of the nail.

throsis. However, firm pseudarthroses always healed more quickly and with less periosteal callus.

In our opinion, the results depend on scrupulous observance of the technical use of the apparatus, namely, correct voltage, correct duration of application and correct positioning combined with good stability and continuous orthopaedic surveillance.

DISCUSSION

Low frequency pulsing electromagnetic stimulation has proved to be of great value in the treatment of retarded union and established pseudarthrosis, particularly in fractures initially associated with skin, vascular or nerve lesions (Bassett *et al.*, 1978; Cacciatore *et al.*, 1980; Marchetti *et al.*, 1981).

We would stress that in achieving our results we have used an original technique as regards the electromagnetic field, and that our cases have been selected on data that are orthopaedically impeccable.

In the literature we noted only 2 cases in which the apparatus used was similar to that used by us. In one of these cases (Bassett) the solenoids were of low impedence but induced a high current for a very short period. Most authors used successive impulses similar to the initial impulse, but Watson used solenoids with a ferrous nucleus which induced an intense electromagnetic field but with a low intensity current of longer duration. These systems all had a frequency of less than 1 Hertz. The technique we used differed in that the solenoids had a high impedence (without a ferrous nuclues) which induced a current of biological significance for a sufficient period of time (1.3 seconds) at a frequency of 75 Hertz.

In our cases, union appeared to be due to the stimulation of periosteal callus, which is more physiological than the interfragmentary calcification described by other authors (Bassett *et al.*, 1977). This periosteal stimulation is interpreted as the effect of the increased vascularity already described.

CONCLUSIONS

From a study of our material we arrived at certain conclusions:

1. **Immobilisation** of the fracture is essential and must be quite firm, wheather achieved by internal or external fixation or by plaster. In our opinion, movement at the fracture site, particularly torsional movement, in one of the causes of failure.

2. **Weight bearing** should be forbidden in all cases of loose pseudarthrosis. In firm pseudarthrosis it is permissible only if radiological examination shows it to be stable on weight bearing.

3. **Deformity.** The fragments should be in good axial and rotational alignment. Malalignment should be corrected by osteotomy remote from the site of non-union before P.E.S. is commenced.

4. **Bone grafts.** The incorporation and fusion of bone grafts is greatly accelerated by electromagnetic therapy, particularly in the case of cancellous grafts which rapidly become « corticalised » after fusion.

5. **Infection.** Infection at the site of pseudarthrosis is a positive indication for the use of electromagnetic therapy, not only because there is no other alternative, but because the vascular stimulus induced may have a positive effect in resolving the infection.

6. **The apparatus** must be adapted to individual cases according to the type and morphology of the fracture. The distance between the solenoids and the fracture must take account of the thickness of the plaster and any intervening material. The apparatus includes a pilot lamp to ensure that it is working properly.

7. **Contraindications.** The only contraindications are gaps in the bone exceeding 2.5 cms and skin defects that require grafting before commencing electromagnetic therapy.

8. **Side effects** are unknown. Very rarely a patient may complain of a deep burning sensation which disappears immediately if the frequency is adjusted.

9. **Causes of failure.** The main causes of failure are inadequate fixation of the fracture, incorrect use of the apparatus, and soft tissue interposition between the fragments. Necrosis of the bone ends or of intermediate fragments is not necessarily a cause of failure because the treatment often causes revascularisation and sometimes even resorption with the substitution of new bone.

10. **The advantages** of the method are obvious: The natural distrust and unwillingness of patients to undergo further surgery, particularly in cases of previous failure. Electromagnetic therapy is completely non-invasive and can be carried out in the patients home with a marked saving in cost and hospital beds. The success rate, indeed, is very high and capable of still further improvement if the indications and technique are faithfully observed. We would not pretend, however, that all cases can be cured.

It is difficult to judge how much credit to attach to the electromagnetic therapy and how much to the more traditional orthopaedic procedures that necessarily accompany it, but it is surely significant that since adopting this treatment we have had far fewer occasions to intervene surgically in the treatment of established pseudarthrosis. We have good reason to believe, however, that in the treatment of pseudarthrosis, infected or otherwise, electromagnetic therapy produces positive results more quickly and with much less surgical intervention. Our experience over many years in the treatment of delayed union and established non-union confirms this belief, but this should, of course, be confirmed by more extensive studies in many centres, compared with the results of the more traditional methods.

It has been demonstrated that electromagnetic therapy can favourably influence reparative processes in all tissues — bone, cartilage, nerve, vascular — and this opens up new prospects for the future use of this method in a variety of fields — epiphyseal necrosis, osteochondritis, prosthetic loosening, neoplasia, and above all in the treatment of fresh injuries.

Finally, we would hope that in the future more research will be directed towards the fundamental scientific basis of this new treatment. It should be approached not merely empirically, or even less so as a « miracle cure », but with the cautious, scientific and rational attitude which this new science of « electrobiology » deserves. Although recently revived, it has its roots in antiquity and with all the sophisticated modern methods of investigation now at our disposal, it should be possible to place it on a sure scientific foundation. Otherwise, it is in danger of becoming yet another example of evanescent charlatanism.

SUMMARY

Thirty-five cases of retarded union or established non-union were treated by low frequency pulsing electromagnetic stimulation.

Consolidation was obtained in 31 cases (88.5 %) in an average period of 6 months. There were failures, the reasons for which are analysed.

The history, development, and present technique of electromagnetic therapy are described. Our results show that it is an effective method of treatment in cases with or without infection, in cases in which previous bone grafts have failed, and in cases with associated soft tissue lesions.

A fundamental requisite of treatment is that the fracture should be efficiently immobilised. The duration of the pseudarthrosis, its site and pathological characteristics do not appear to have significant effect on the outcome of treatment.

We did not observe any significant side effects.

In the opinion of the authors, this method of treatment may have application in wider fields, particularly in the treatment of fresh fractures.

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