Treatment of non-unions by electromagnetic stimulation

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I. Introduction

Since 1974, we have studied on electromagnetic stimulation of bone growth and repair in the Interdisciplinary Center of Bone Biomechanics. It was necessary to realize a rigorous scientific approach of the fundamental mechanisms and of the clinical data of treatments which were prematurely sold throughout the European countries under different forms, devices and distributors. Moreover, the conception and the biological effects of some stimulators distributed in our country had no scientific base at all.

In the United States, the application of electric stimulation to non-union repair seemed to be successful although the sampling of the published clinical series was quite heterogeneous.

An interdisciplinary collaboration allowed us to investigate different aspects of electric stimulation :

— the topographical distribution of the electric parameters induced by the stimulation device (Dierickx, 1982);

— the electric characteristics of the living tissues (Hinsenkamp, 1978 ; Dierickx, 1978 ; Georges, 1979 ; Pegoff, 1979);

— the cellular mechanisms involved in transcription and response to the electrical « message » (Hinsenkamp, 1978 ; Chiabrera, 1979, 1980);

— the influence of this stimulation on osteogenesis (Rooze, 1979), on fresh fractures repair (Hinsenkamp, 1978) and non-unions.

II. Historical summary

The principle of therapeutical use of some electric properties is not recent in traumatology. We mention the thesis of the Belgian surgeon Van Helmont (1621) entitled « De magnetica vulnerum naturali et legitima curatione ».

In the 19th century, casual attempts of electrical stimulation of non-unions were realized by some searchers, like Lente (1850) who related three cases of successful healing and Berenger-Feraud (1871) who defined a technique called « electropuncture ».

The first rational hypothesis explaining the effect of electric stimulation on bone tissue was initiated by the discovery of two properties of bone :

1° Bone apposition is increased in the area of mechanical strain concentration. This observation was analysed by Wolff (1892).

2° Piezoelectric properties of the bone were observed by Yasuda (1953).

The association of these two properties allowed Bassett to make the following hypothesis in 1971 : « It is clear that bone converts mechanical energy to an electric signal, and changes in the electric environment of mesenchymal cells may control, to a large degree, their mitotic and functional activity ».

Although the effective mechanism at a cellular level is not explained, the electric stimulation was rapidly applied in clinics to the treatment of non-unions.

One technique uses implanted electrodes to apply the electric stimulation to bone tissues. The disadvantages are :

— a surgical implantation of foreign bodies in a pathological tissue with a previous septic result in 30 % of the cases ;

— electrolysis phenomena observed after application of some devices conceived in ignorance of the fundamental laws of electrochemistry (Hinsenkamp, 1978);

— an electric activity restricted to the vicinity of the electrode requiring the implantation of 4 electrodes in the same non-union site.

The second technique — the more recent one — uses electromagnetic fields. The disadvantages due to electrode implantation are avoided. Two induction coils are disposed on each side of the non-union, the device is removable and does not produce any contact reaction.

The disadvantages are :

— the ignorance of the active parameter which can be the magnetic field itself, the electric field or the induced current ;

— the relative imprecision of the topography of the electric parameters between the induction coils ;

— the electric behavior of the living tissue.

Despite these unknown elements, the Anglo-Saxon series recording the data of these two methods have comparable results. We report the most representative.

Using the stimulation with electrodes, Brighton (1979) publish a serie of 168 cases of non-unions with a mean length of evolution of 2.8 years. He implants 4 cathodes in the non-union area and one skin anode. The associated treatment is a rest plastercast with stimulation during 3 months, followed by a walking plastercast during 3 months without stimulation. In the whole serie, including 25 % of a sepsis anamnesis, he obtains healing in 78.4 %. Bassett (1979), using electromagnetic stimulation, publishes a serie of 308 cases including non-unions, delayed unions and congenital non-unions with a mean length of evolution of 2.5 years. Thirty per cent of the cases have a previous anamnesis of sepsis. Healing is obtained in 80 % of the cases. Among these 308 cases, 50 are congenital non-unions with a lower success rate but still interesting (68 %). One hundred and ninety-six of these 308 cases are non-unions of the tibia for which the healing success rate is 83 %.

The results are very good in both methods but the composition of these series is quite heterogeneous.

III. **Material and method**

In our clinics, we chose the electromagnetic stimulation for its benignity and facility of use. The stimulation units are supplied by EBI*. Figure 1 shows the diagram of the stimulating current.

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* Electro Biology Inc., 300 Fairfield Road, Fairfield, New Jersey.

The stimulation is turned on 12 to 15 hours a day in one or more than one sequence and during a mean period of 6 months (table I). The treatment is applied at home by the patients themselves. A period of at least 6 months without modification of the treatment and without any surgical procedure was required before the beginning of the electric stimulation.

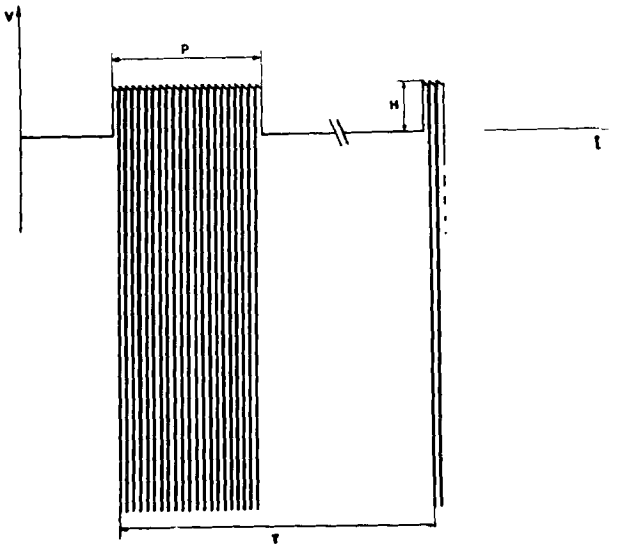


FIG. 1. — Characteristics of the electromagnetic signal : width P : 5 msec, positive potential amplitude H = 13.5 mV, period T : 66 msec (15 Hz).

Presently, cases of non-unions are treated with a multicenter collaboration including :

— the « Clinique du Parc » in Tubize (D[r] R. Dozinel),
— the « Hôpital Paul Brien » (D[r] G. Tondeur),
— the « Hôpital Universitaire Brugmann » (D[r] R. de Marneffe),
— the « Institut Edith Cavell-Marie Depage » (D[r] A. Danis),
— the « Institut Médico-Chirurgical d'Etterbeek » D[r] J.M. Baillon).

IV. **Results**

Case 1. — Mrs V. He. (42 y.o.) was sent to our department for an atrophic non-union of the middle third of the right humerus. We mention the most significant prior history.

TABLEAU

	Case 1	*Case 2*	*Case 3*	*Case 4*	*Case 5*	*Case 6*
Location	Humerus	Tibia	Femur	Scaphoid	Femur	Tibia
Non-union type . . .	Atrophic	Atrophic	Hypertrophic	Atrophic	Hypertrophic	—
Time period between the initial lesion and the treatment	14 months	12 months	29 months	17 months	24 months	66 months
Number of surgical procedures	2	3 (1 spongeous bone graft)	3 (1 spongeous bone graft)	1 (1 spongeous bone graft)	2	1
Lenght of the electric treatment	3 ½ months	5 months	6 months	4 ½ months	12 months	9 months
Modification of the associated contention	Plaster splint	Walking cast (4 months)	None	Wrist cast (2 months)	Hip spica (1 month)	Walking cast (5 months)

1970 : discovery of a proteinuria with progressive renal insufficiency.

1973 : beginning of hemodialysis.

1974 : kidney transplantation followed by three rejections and, after seven months, return to hemodialysis.

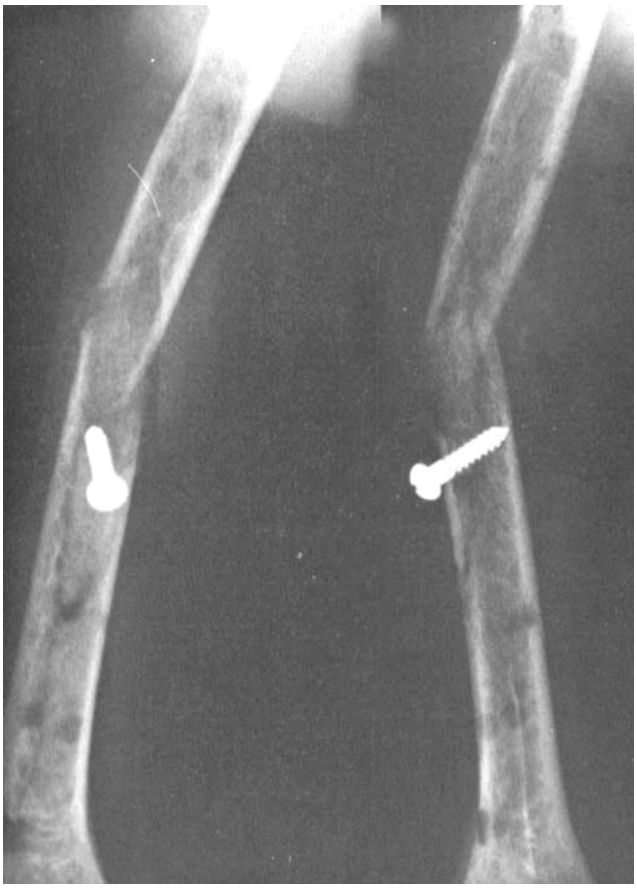


FIG. 2. — Humeral fracture after retrieval of the external fixation.

1977 : diagnosis of a hyperparathyroidy after spontaneous fracture of ribs and of pubic arch.

Subtotal parathyroidectomy ; complications requiring a right hemicolectomy followed by a pancreatitis.

1978 : normalisation of the biological parameters.

January 1979 : fall on the right arm with oblique fracture of the middle third of the right humerus treated by external fixation.
After one week, a displacement requires a second repositioning with associated screw for better stabilization of the fragments.

April 20 : retrieval of the external fixation after clinical and radiological healing.

April 30 : refracture of the humerus in the callus area (fig. 2), treated by hanging cast.

A B C

FIG. 3. — *Callus formation on frontal X-rays incidence.*

A. Beginning of the treatment, mobile fibrous callus.

B. 3 months after stimulation.

C. 4 months after stimulation.

August 7 : removal of the plaster cast and immobilization by a Dessault bandage.

September 6 : removal of the Dessault and replacement by a splint.
Diagnosis of a non-union.

The electromagnetic treatment starts 14 months after the initial injury. At the beginning, the non-union site is completely mobile and painless. A flexion of 70° is measured in some positions. The X-rays shows an atrophic non-union (fig. 3A). The humeral shaft shows a deep osteoporosis. A fibrouscallus connects the fragments. No bone trabecula bridges the non-union.

During the treatment we used a simple plaster cylinder around the arm, decreasing the motion in the non-union area without ed rigid immobilization. The plaster allow adequate and constant positioning of the coils. X-rays were taken each month. During the first two months, neither clinical nor radio-

logical modifications are observed. At the beginning of the fourth month, the non-union is rigid and the X-rays show a large callus (fig. 3 B and C). The earliest modifications of the callus begin by a peripheric bridging in the periosteal area, poorly calcified at the third month.

One month later, we observe an increasing density of the corteces with formation of well calcified bone trabeculae in the previous non-union area. A calcified medullary callus bridges the medial cortex. Active mobilization begins

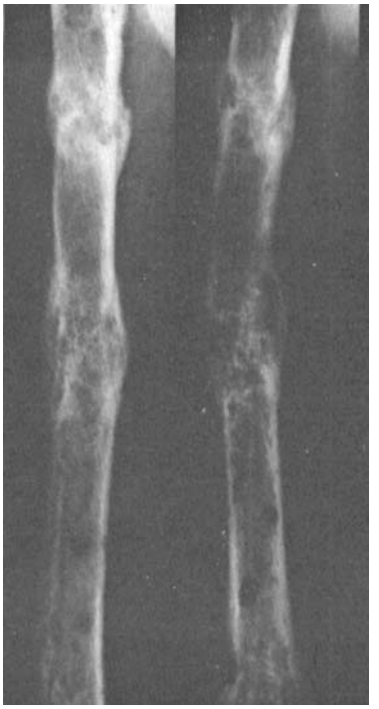


FIG. 4. — After a new fracture on a previous pin hole, rigid callus organization after 2 months stimulation without associated retention.

at that time. The hypothesis of a normalization of the phosphocalcic metabolism concomitant with bone repair is not possible considering a fracture of the right femur produced on the third month of treatment by a slight trauma. This new fracture attests a persisting bone fragility as well as the following clinical story of the patient. Considering the radiological fragility of the whole humerus (fig. 4), we recommend to pursue the electromagnetic treatment for a while. Two months later, waking up, the patient turns over her right arm and breaks her humerus on the edge of the inducing coils. The stimulating coils are then shifted facing the new fracture and the healing is obtained after two months without any associated retention (fig. 4).

Case 2. — Mr Bau. is a 46-years-old patient with an atrophic non-union of the distal third of the left tibia.

May 26, 1978 : open spiroid fracture of the left distal tibia and fibula, with a butterfly fragment on the tibia.

May 27 : external fixation, triangular frame bridging the ankle.

A B C D E

FIG. 5. — *X-rays evolution of the case 2.*

A. Mobile non-union at the beginning of the treatment.
B. After 5 months of stimulation.
C. After 6 months of stimulation.
D. After 9 months of stimulation.
E. 16 months after the beginning of the treatment.

June 19 : replacement of the triangular frame by a half-frame external fixation. Uncorrect reduction : diastasis, axis angulation of 10° and isolated butterfly fragment persisting.

September 6 : delayed union.
Spongeous bone graft with correction of the axis.

March 3, 1979 : removal of the external fixation.
Weight-bearing crutch, painful non-union.

We treat the patient with electromagnetic stimulation 12 months after the initial lesion. The pain persists. On the X-ray we measure a ten degree angulation of the bone axis with a fracture line still present (fig. 5 A). Clinically, the non-union is mobile. The stimulation is pursued during one month without any associated retention. Because of the mobility of the non-union, a plaster boot is prescribed during one month and replaced by a walking cast during three months. On the removal of the plaster, the non-union is clinically

rigid and the X-rays show a bridging callus (fig. 5 B). The full weight-bearing walk is allowed at that time and the old non-union site remains painless.

Case 3. — Mr Lyc. (56 y.o.) has a hypertrophic non-union of the right femur.

May 23, 1976 : fracture of the right femur and bifocal fracture of the left tibia after a car accident.
Treatment of the femur by a reversed nail-plate with 12 screws and of the tibia by external fixation.

FIG. 6. — X-rays before treatment showing well organized edges of the non-union line.

June 2 : bending of the femoral implant.

June 16 : a new plate replaces the old one and a tibial traction is associated.

July 5 : bending of the second plate.

October 10 : X-rays showing an angulation of 12° and no callus.

October 21, 1977 : non-union, removal of the nail-plate ; triangular external fixation associated with spongeous bone graft.

February 24, 1978 : satisfying evolution and removal of the external fixation.

March 20 : fatigue fracture of the callus ; plastic cruromalleolar splint.

Regarding the stature of the patient and the level of the non-union, the efficacity of the splint is hazardous and a rigid retention of the fragments is not realized. It is a new non-union evolution.

We begin the electromagnetic stimulation after 2.5 years of time since the initial fracture and after 8 months from the removal of the external fixation. The X-rays show a well organized hypertrophic non-union (fig. 6). Nothing is

FIG. 8. — After 6 months of stimulation, rigid and bridging callus.

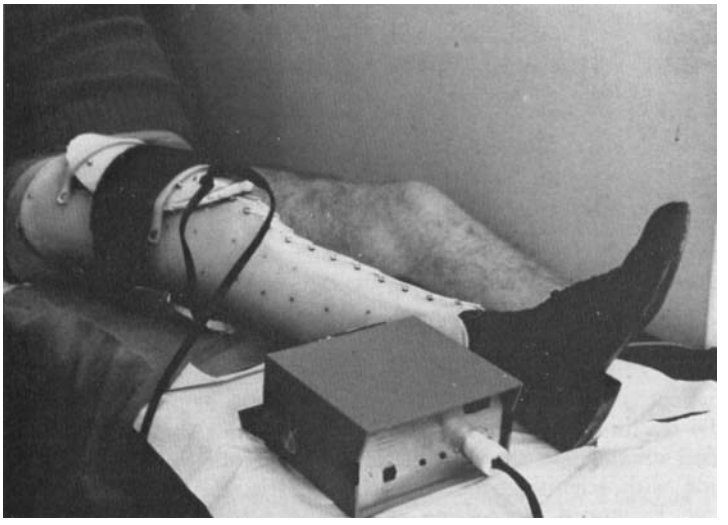


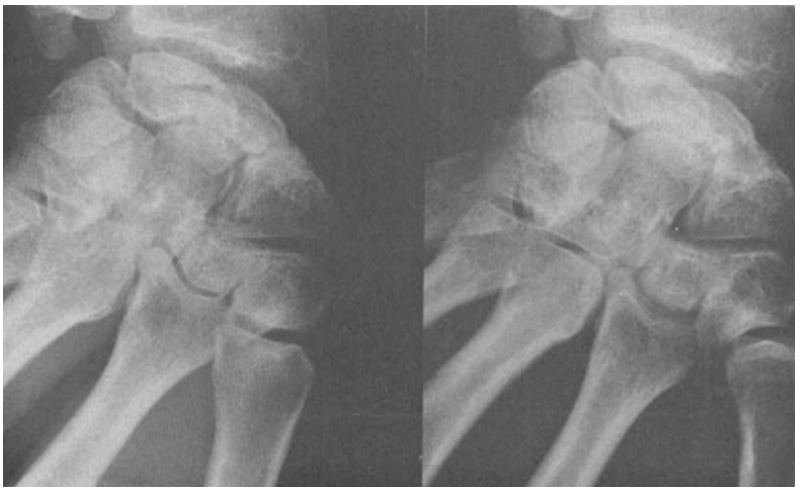
FIG. 7. — Induction coils fixed on the plastic splint.
The generator unit is in front.

changed regarding the retention and the coils are fixed on the plastic splint (fig. 7). After 5 months stimulation, the mobility is decreasing and a callus appears though the fracture line is still present. One month later, a callus bridges the previous non-union (fig. 8). The normal function of the left leg is allowed and the patient walks with a slight lameness. One year and a half after the stimulation, the healing is maintained with callus remodelling.

Case 4. — Mr Gof. (30 y.o.) has an atrophic non-union of the right scaphoid.

July 1979 : injury of the right wrist, untreated.

September 6, 1979 : X-rays diagnosis of a scaphoid non-union.



A B

FIG. 9. — *Radiological evolution of the case 4.*

A. Before treatment, non-union line in the scaphoid.
B. After 4 months of stimulation.

September 26 : surgical procedure on the non-union with spongeous bone grafting. Four months rigid immobilization.

January 22, 1980 : removal of the last plaster retention.
Non-union line still persisting on the X-rays.

October 13 : no modification of the non-union line on the X-rays. The wrist is painful and active mobilization is restricted.

The patient is taken in charge in our serie after 17 months of evolution since the initial fracture and after 14 months since the last surgical procedure. The radiological examination shows at the beginning of the treatment a clear non-union line with sclerotic bone on each side (fig. 9 A). The electromagnetic stimulation is applied during one month and a half without any associated treatment, afterwards a plaster cast is prescribed during two months. At the

removal of the plaster, the X-rays show a fuzziness replacing the sclerotic edges and a peripheral callus. The physiotherapeutic exercises are started one month later. At that time, four months and a half after the beginning of the treatment, the fracture line has almost completely disappeared (fig. 9 B) and a normal function is restored despite some arthrosic lesions of the scaphoid.

Case 5. — Mr Too. (21 y.o.) has hypertrophic non-union after an upper osteotomy of the right femur. His clinical story started when he was two and a half years old.

August, 1961 : frequent falls and pain in the hips.
Diagnosis of a congenital dislocation of the hip.
Treatment : abduction plaster cast.

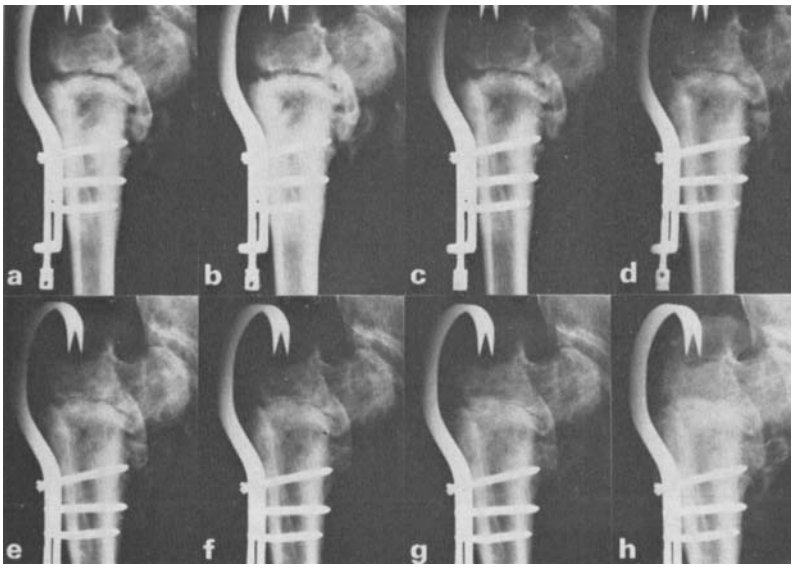


FIG. 10. — *Radiological evolution of the case 5.*

A. Before treatment.
B. After 2 months of stimulation.
C. After 4 months of stimulation.
D. After 5 months of stimulation.
E. After 7 months of stimulation.
F. After 9 months of stimulation.
G. After 11 months of stimulation.
H. After 12 months of stimulation.

April, 1962 : surgical correction with tibial bone graft, osteotomy and abduction plaster cast during 4 months.
Good evolution with recovery of a normal function.

January, 1977 : pain complains.
Radiologic alteration of the articular cartilage.

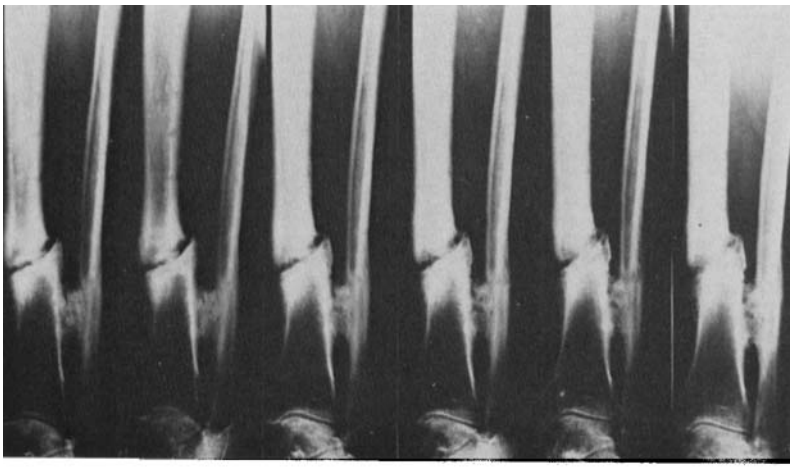
July 5, 1978 : Pauwels osteotomy fixed by nail-plate : loosening of the nail-plate.

April, 1979 : retrieval of the nail-plate and replacement by a « Maquet plate ».

October : organization of a non-union.

The non-union is treated by electromagnetic stimulation 2 years after the second osteotomy and 14 months after the last surgical procedure. The X-rays show a large non-union gap in the pertrochanteric area with an isolated small trochanter (fig. 10 A). The normal activity with full weight-bearing is allowed to the patient. Three months later the small trochanteric fragment is fixed by a calcified callus. At 5 months of stimulation the non-union gap is thinner (fig. 10 D) but an important loading and the mobility of the non-union requires the immobilization of the patient in a plaster cast during one month (fig. 10 F). At the removal of the plaster, partial weight-bearing is allowed. After eleven months of stimulation, only a thin non-union line persists (fig. 10 G) without motion around the non-union line. One month later, the X-rays show a callus bridging the non-union (fig. 10 H).

Case 6. — Mr And. (51 y.o.) has a non-union of the left tibia.



A B C D E F

FIG. 11. — *Radiological evolution of the case 6.*
A. Before treatment.
B. After 2 months of stimulation.
C. After 4 months of stimulation.
D. After 6 months of stimulation.
E. After 9 months of stimulation.
F. 12 months after the beginning of the treatment.

September 12, 1974 : oblique open fracture of the left tibia between the medial and the distal third.
Treated by a plaster splint.

September 18 : surgical treatment by external fixation.

March 1975 : retrieval of the external fixation.
Non-union formation. The non-union area is painful and two crutches are necessary for walking.

We begin the electromagnetic treatment five years and a half after the initial injury and five years after the last surgical procedure. The non-union

area is still painful and slightly mobile. The gait is impossible without crutches. The X-rays show a clean non-union line with a hypertrophic formation (fig. 11 A). The stimulation is started and pursued during four months without associated treatment. Because of the slow evolution of the non-union line (fig. 11 C), a walking cast is then prescribed during five other months. The non-union is clinically rigid after 6 months of stimulation. The X-rays show a bridging callus well calcified on the anterolateral shaft and a growing callus on the posterior aspect (fig. 11 D). The non-union line progressively disappears. The walking cast is still prescribed considering the persisting mechanical fragility of the non-union. At the removal of the plaster and at nine months of electric stimulation, the callus is rigid (fig. 11 E) and a normal function is progressively recovered.

V. **Conclusion**

The fundamental researches realized on cell cultures, on embryos or on animals show osteogenesis modification after electromagnetic stimulation. The effective mechanism involved in the translation of the electric signal by the cell and its functional answer are still unknown.

Some specific functions of synthesis in the studied cells seem to be activated as if some operons are derepressed by the electric signal. A possible hypothesis of the induction of cellular answer could be an alteration of the ionic exchanges at the cell membrane.

The results of the clinical series of non-unions treated by electromagnetic stimulation also show a modification of the osteogenic result in the non-union area.

Before the treatment, the six studied cases (table) had, at least, a 7 months period free from any surgical procedure while the non-union was irremediably in formation. In 3 of the 6 cases, a surgical procedure with spongeous bone graft apposition was previously realized. Except the cases 2 and 6, no satisfying contention with a modification of the previous status was made. During the treatment, the radiological evolution was the following :

— softening of the sclerotic edges of the non-union,

— increasing fuzziness in the non-union line,

— formation of trabecular bone bridges.

Among the 6 cases, 3 atrophic and 2 hypertrophic non-unions, the clinical evolution was faster than the radiologic healing. The rigidity of the non-union is obtained before an ossified callus.

Although we can not explain the active mechanisms of the stimulation by electromagnetic fields, we observed their action *in vitro* and *in vivo*.

The clinical results appear especially interesting in the treatment of the non-unions.

For the patients having undergone many unsuccessful surgical operations, when a surgical procedure is counter-indicated, or when the patient refuses an operation, this modality of treatment is definitely indicated.

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