Results of non unions treatment by pulsed electromagnetic field stimulation

by L. SEDEL[1], P. CHRISTEL[1], J.DURIEZ[2], R. DURIEZ[2], J. EVRARD[3], C. FICAT[4], J. CAUCHOIX[4] and J. WITVOET[1]

This is a report of the results obtained by a multicenter study on the effects of pulsed electromagnetic field on bone non union. Four orthopaedic departments were involved : Hôpital Beaujon, Hôpital Cochin, Institut Calot and Hôpital Saint-Louis. The device is the one developed and manufactured by Electro-Biology Incorporated with the collaboration of C.A.L. Bassett. This work is the result of close cooperation by these teams (4).

I. Technique

The device which consists of two large Helmholtz coils connected to a generator, delivers a repetitive pulsed train type of signal. The voltage induced in bone by the electromagnetic field must be close 1 to 1.5 mv/cm with a average magnetic field of two gauss. In order to achieve this it is necessary that the coils be precisely placed on each side of the non union site. In reality it is difficult to insure the exact voltage to be induced into bone because of the insufficient knowledge on the conductivity of each bone component (5). Nevertheless experimental works performed principally at the orthopaedic research laboratory at Columbia University Medical School have demonstrated the importance of the amplitude, shape and frequency in the effectiveness of the pulses.

(1) From Service de Chirurgie Orthopédique, Hôpital Saint-Louis, Paris.
(2) From Institut Calot, Berck.
(3) From Service de Chirurgie Orthopédique, Hôpital Cochin, Paris.
(4) From Service de Chirurgie Orthopédique, Hôpital Beaujon, Paris.

II. Clinical application

The non union site has to be immobilized by a molded non weight bearing plaster cast. If any metallic material has been previously used it must be non-magnetic. All non unions with a los of substance of more than 1 cm and those misaligned are discarded.

Positionning of the coils is performed using a special gauge embedded in the plaster along with X-rays controls. The non union site must be exactly in the middle of the electromagnetic field. Application lasts 12 to 14 hours a day for a period of at least 2 months.

III. Material and methods

Thirty-nine cases were treated by this method. Ten females - 29 males. The age range is 7 to 81 years (mean : 29 years). Location of the non union (fig. 1) : tibia, 20 ; femur, 11 ; humerus, 4 ; radius and ulna, 2 ; ulna, 1 ; clavicle, 1. The delays between initial trauma and stimulation are from 2 months to 14 years (mean : 11 months). The number of previous operations were : 0 to 6 (mean : 2). The types of non union were atrophic, 17 ; hypertrophic, 5 ; congenital, 4 ; infected, 13.

IV. Results

Results are known for 37 patients, two were lost for follow-up.

Thirty-one healed and 6 failed. Let us first analyse the failures and then the successes.

Failures.

The first one (case 36) is a 78 years old woman who presented with an atrophic non union of the ulna 4 months after a fracture. A plaster cast was applied for two months with stimulation. After this delay union did not occur. The patient was operated upon where upon healing occurred.

The second one (case 32) is a 81 years old woman who sustained a comminuted fracture of the left upper-humerus. After 18 months there was a painful non union. She was immobilized in a thoraco-brachial cast which did not provide a strict immobilization. The stimulation was applied for 2 months without success. She was then lost for follow-up.

The third one (case 4) is a 24 years old man who presented a hypertrophic non union of the tibia lasting for 4 years. He accepted the sti-

mulation but refused the cast. Two months later the non union was still present. One year later he accepted to wear the plaster cast but then he was only stimulated during 5 weeks where upon he preferred to be operated on.

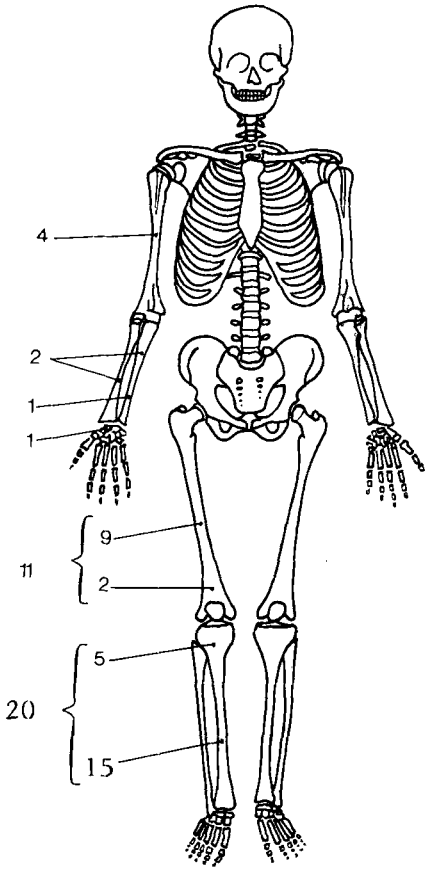

FIG. 1. — Location of non unions.

The fourth one (case 11) is a 69 years old man who presented with a severe non union of the femur after an osteosynthesis followed by an infection. He was then sent to Cochin hospital where he was operated on : excision of necrotic and infected tissues was performed as well as fixation with an external fixator. Two months later electrical stimulation was begun, but it was applied only 6 hours a day. Two months later the femur was still mobile and so a graft was then inserted. He is non completely healed.

Case no.	Sex	Age	Site	Type	Delay before stimulation	Number of previous procedu es	Stimulation time	Delay before union	Infected or not
1	M	7	Tibia	Congenital	4 years	2 (15 days before)	4 months ½	6 months	
2	M	40	Tibia ¼ superior	Atrophic + infection	2 years 4 months	5	3 months ½	5 months	
3	M	43	Tibia ¼ superior	Atrophic	10 months	3	6 months	6 months	
4	M	24	Tibia	Hypertrophic	3 years 3 months	2	3 months + weight bearing allowed	Failure Reoperated 2 years later	
5	M	22	Tibia	Bone crack	18 months	4	3 months	5 months	
6	M	28	Tibia	Sept. after Papineau	4 years	3	4 months + 2 ?	10 months	
7	M	70	Femur ¼ inferior	Atrophic + infection	10 months	4 (2 grafts)	2 + 2 (4 months)	10 months	++
8	M	32	Femur ¼ inferior	Atrophic + infection	6 years	6	3 months + 10 days	10 months	++
9	F	26	Femur diaph.	Atrophic + infection	3 years½	5 (spongious graft during stimulation)	6 months	9 months	+
10	M	13	Femur diaph.	Atrophic + infection	4 years	2	6 months ½	10 months	++
11	M	69	Femur	Atrophic	7 months	5	2 months ½ (6 h / day)	Failure Reoperated 2 months after healed	++

Case no.	Sex	Age	Site	Type	Delay before stimulation	Number of previous procedures	Stimulation time	Delay before union	Infected or not
12	M	41	Leg	Delayed union	6 months	1	3 months + 6 days	7 months	
13	M	38	Leg	Hypertrophic	14 years	3	3 months + 15 days	4 months	
14	M	20	Leg	Hypertrophic	15 months	1	2 months	3 months + 20 days	
15	F	57	Tibia metaph.	Iterativ osteotomy	5 months	2	2 months	3 months	
16	M	18	Leg	Atrophic (Papineau)	6 months	1	3 months ½	5 months	+
17	M	17	Leg	Atrophic	13 months	2	4 months + 20 days	6 months	
18	M	8	Leg	Congenital curvature osteotomized	6 months	1	2 months	4 months	
19	M	20	Leg	Crack at a screw hole site	2 months	2	2 months	4 months	
20	F	75	Leg	Delayed union	3 months ½	0	3 months	6 months	
21	M	57	Tibia metaph.	After valgus osteotomy	3 years	4	3 months ½	Weak at 4 months	
22	M	13	Tibia	Congenital	0	0	4 months	?	
23	F	15	Tibia	Congenital	12 years	3 or 4	3 months	7 months	
24	M	22	Femur diaph.	Atrophic + infection	10 months	2	5 months	6 months	++
25	F	16	Fracture on osteomyelitis	—	8 months	1	2 months 20 days	6 months	++
26	M	17	Femur diaph. + infection	Atrophic + infection	6 months	4	2 months	4 months	++

Case no.	*Sex*	*Age*	*Site*	*Type*	*Delay before stimulation*	*Number of previous procedures*	*Stimulation time*	*Delay before union*	*Infected or not*
27	M	17	Femur diaph. + infection	Atrophic + graft	8 months	4	3 months ½	Failure	++
28	M	29	Femur	Atrophic	1 year	1	4 months	6 months	0
29		22	Femur	Atrophic	2 years 10 months	5	1 month ½	8 months	++
30	F	63	Humerus	Hypertrophic	15 months	2	5 months	10 months	
31	F	60	Humerus	Hypertrophic	13 months	0	1 month 20 days	3 months	
32	F	81	Humerus	Atrophic	18 months	1	2 months	Failure	
33	M	50	Humerus	Atrophic	21 months	4	6 months + iterativ fracture + 3 months	10 months	
34	M	29	Radius Ulna	Atrophic + infection	7 months	2	3 months ½	4 months	
35	M	60	Navicular	—	25 years		4 months	Failure	
36	F	78	Ulna	Atrophic	4 months	0	2 months	Failure	
37	M	21	Radius Ulna	Atrophic	5 months	1	2 months ½	4 months	
38	M	45	Tibia	Atrophic	31 months	2	3 months	6 months	
39	F	27	Tibia	Atrophic	11 months	3	3 months	8 months	

The fifth one (case 35) is a 60 years old man who presented with a navicular non union lasting for 25 years. Plaster and stimulation were applied for four months. At the end of the treatment pain was diminished so he was considered as healed. But five months later the non union was still visible and pain reappeared. The patient blamed a recent trauma as the cause. In fact X-rays had never shown complete healing. Later he was lost for follow-up.

The sixth one (case 27) is a 17 years old man who presented with a severe non union of the femur infected and operated on four times for drainage, excision and then reconstruction of a 7 centimeters loss of substance. Eight months later there was gross mobility at the fracture site. An electrical stimulation was applied on a large cast extending from the iliac crest to toes. This lasted 5 months. At the end the non union was still mobile. He was reoperated on and grafted again which led to ultimate healing.

Finally, out of these 6 failures, we must consider that the treatment was incorrectly applied in 4 of them (in two cases the stimulation lasted less than 2 months and in two cases the immobilization was unsufficient).

V. **Successes' analysis** (fig. 2, 3, 4)

It is rather difficult to perform an accurate analysis of the successful cases.

Non union' site and type were different as were the initial and follow-up treatments. Nevertheless 31 stimulations achieved union. The mean time of stimulation was 3 months and 8 days with extremes from 50 days to 9 months. Healing occurred between 3 months to one year (mean : 6 months).

Let us discuss the quality of healing. Some unions were quite evident, strong with a large callus, while on the other hand, some were weak, with thin or curved bones, or as in the forearm, one bone healed, the other did not. These were grouped under the term weak union. Out of over 31 successes, 21 were strong and 10 were weak.

Those 10 represent : 3 congenital pseudarthroses, 3 healing after gross infection and graft, one supracondylar non union of the femur which healed with a severe varus deformity, one humerus healed after 9 months stimulation during which a refracture occurred ; actually still considered as weak, are two non unions of the forearm in which only one bone (ulna in one, radius in the other) healed. One of those has been operated upon.

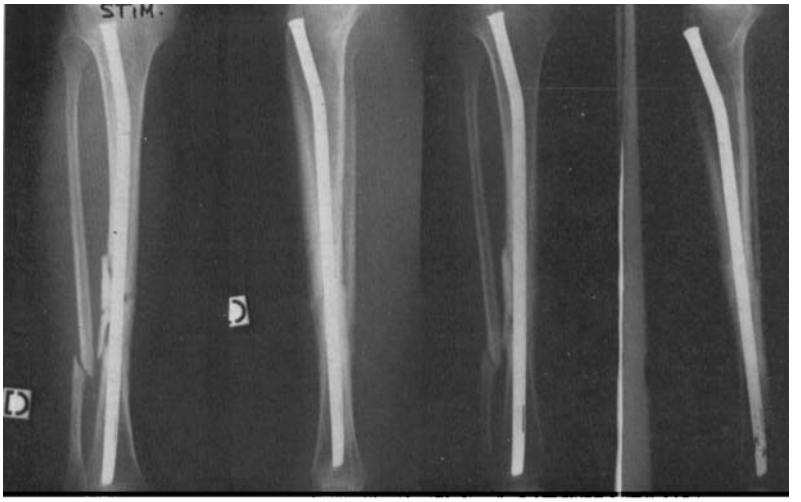

FIG. 2A. FIG. 2B.

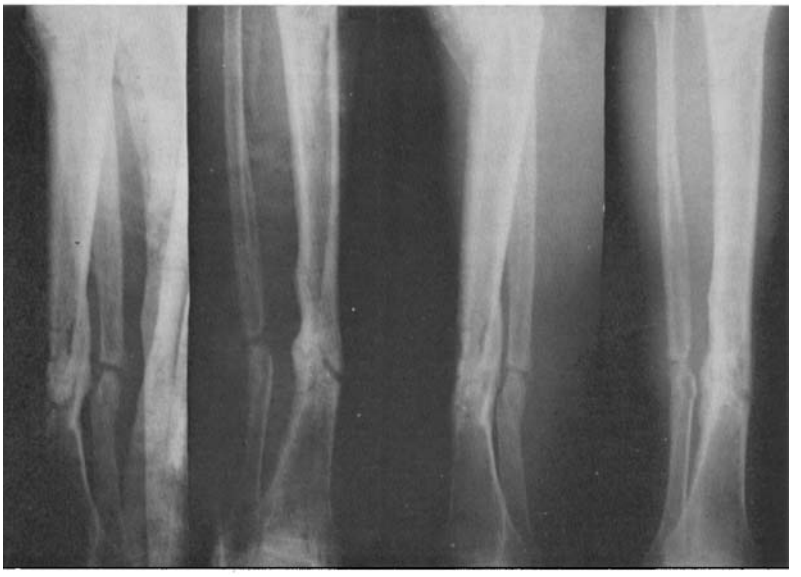

FIG. 3A. FIG. 3B. FIG. 3C. FIG. 3D.

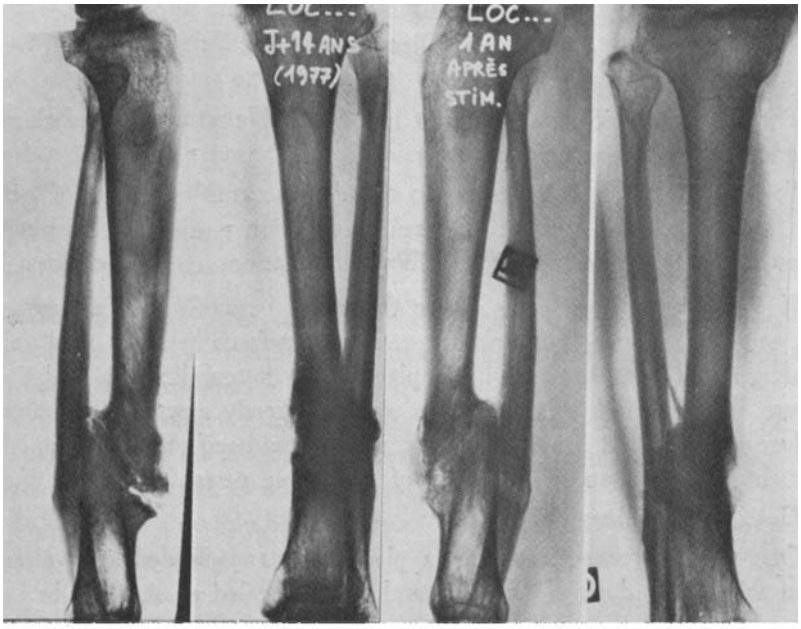

FIG. 4A. FIG. 4B.

FIG. 4A. 4B. — *Case 13*. This is a 38 years old man who sustained an opened compound fracture of the tibia treated by closed intramedullary nailing.

Thirteen years after he is presented with an hypertrophic non union, mobile but rather painful. He was operated upon in another department : scratching of the callus and plaster cast for 3 months. He did not heal.

We saw him 8 months later, he was still mobile. We applied electrical stimulation on a molded plaster cast for 3 months. At 4 months he was completely united.

FIG. 2A, 2B. — *Case 12*. This 41 years old man sustained an open fracture of the right leg. An emergency operation was performed with intramedullary nailing. Five months later he was rehospitalized for non union : the fracture site was painful and the X rays showed no sign of union. Electrical stimulation was started 6 months and a half after the injury and was applied with a molded plaster cast. This stimulation lasted 87 days. Weight bearing was allowed one month later. Healing was achieved at this time.

FIG. 2A. — X-ray before stimulation.

FIB. 2B. — X-ray one year later.

FIG. 3A, 3B, 3C, 3D. — *Case 38*. A 45 years old man sustained a compound fracture of his right tibia treated by an osteosynthesis with a plate.

Two years later the plate is removed and then the tibia refractured with skin opening. He is treated by a plaster cast for 7 months. But after this delay the bone is still mobile.

He came to us with a misaligned, mobile non union of the tibia.

We made a molded plaster cast with a good alignment and applied the external electro-magnetic stimulation for 4 months without weight bearing and during 13 hours per day.

He was then exercised during 2 months and is considered as healed 6 months after the beginning of the stimulation.

VI. **Discussion**

The question which arises is what is the possible role of pulsed electromagnetic field in non union healing.

To answer this, it is necessary to make an accurate selection of cases. We must take into account only real non union — so that disputable cases which might have healed without stimulation, should be discardel.

If we look at those cases where the delay between the fracture and the stimulation was short, where cracks or refracture after non union healing could have healed with a plaster cast immobilization, and those where the electrical treatment was applied shortly after a surgical procedure which could have healed the patient by itself, then we see that 9 such cases fall into this category of disputable cases.

Here are those cases :

One tibia fracture treated by a plaster cast, not healed at 3 months then stimulated during 3 months and finally healed at six months.

One very weak tibia callus after four procedures. Following three months of stimulation the callus got bigger and thus avoiding the need for any new procedure.

A crack at a hole site after plate removal. One patient had a spongious graft 15 days after the beginning of the stimulation which lasted 6 months.

Five patients were operated on with stabilization, drainage and bone graft less than 2 months before electrical stimulation.

After discarding those 9 cases, 22 cases apparently remain where the effects of electrical stimulation can be discussed.

We know that according to M. Urist and Watson-Jones that some non unions may heal after long term immobilization alone. So also be discarded those cases where electrical stimulation lasts more than 6 months should. Six such cases were immobilized more than 6 months before healing.

This leaves only 16 cases which can be considered undisputable. They non unions were located : at the tibia (11), the femur (1), the humerus (1), and the forearm (2).

The types were : congenital (2), hypertrophic (3), atrophic (8), after iterativ high tibia osteotomy (1).

For those 16 cases the role of electrical stimulation seems real. It must also be reported that during the delay before receiving the apparatus, two patients healed (one congenital non union of the radius in a five years old boy, and one tibia non union in a 25 years old man).

If we compare this short serie to the 220 cases published by Bassett (3), we may observe many similarities. Best results were those located at the tibia (88 % success), 25 congenital pseudarthroses healed but some were weak. The time of electrical stimulation is longer than in our series (5 months and a half) and he did not perform a critical analysis of his cases.

VII. **Conclusion**

Electromagnetic field stimulation of bone non union should only be applied in very well defined situations and should be carried out in a careful precise manner.

Results are difficult to evaluate. We achieved 31 successes out of 37 cases treated but a critical analysis shows that only 18 of these cases could be considered as undisputable.

In fact only a double blind study of real non union could determine the effectiveness of such a treatment.

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