Is There Still A Role For Pulsed Electromagnetic Field in the Treatment of Delayed Unions and Nonunions

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Abstract

Objective: To examine the results of pulsed electromagnetic field stimulation (PEMF) in the treatment of delayed union and nonunion as well as on regenerate bone following distraction osteogenesis.

Method: Thirteen patients were treated for delayed union with PEMF therapy. One patient was treated for a nonunion. Three of the 13 patients had poor regenerate following distraction osteogenesis using the Ilizarov fixator. Demographics were collected by reviewing the medical records of each patient.

Results: Of 14 patients, eight (57%) were males. Average age was 45 years (range 15 - 67 years). Complete bony union occurred in 11 patients. Of the three patients with poor regenerate, two achieved complete consolidation. The average duration of PEMF treatment was 2.9 months (range 2 - 4 months).

Conclusion: PEMF is a useful non-surgical adjunct in the treatment of delayed union and nonunion. It may have a role in the stimulation of poor regenerate following distaction osteogenesis.

INTRODUCTION

Since the early 1980's, there have been numerous reports with claims of high success rates of the use of pulsed electromagnetic field (PEMF) for the treatment of delayed union and nonunion of fractures ($_{1,2,3,4,5}$). Opponents of electrical stimulation claim that prolonged immobilization, meticulous treatment and possibly surgical intervention account for the high success rate rather than electrical stimulation ($_6$). In addition, there are conflicting interpretations of whether PEMF exhibits clinically significant improvements in new born formation ($_{7, 8}$). However, two double-blind studies have demonstrated that PEMF treatment accelerated the healing of bone trauma ($_{9}$, $_{10}$).

This paper reports our experience with PEMF in the treatment of delayed union and nonunion. The authors also report on the use of PEMF stimulation on regenerate following distraction osteogenesis.

PATIENTS AND METHODS

For the purposes of clinical investigations, a nonunion was

defined as a fracture that is at least nine months old and has not shown any signs of progression to healing for three consecutive months $(_{11})$. Delayed union was defined as a fracture that at a minimum of three months showed slower progression to healing (11). This is a retrospective review of 13 patients who were treated for delayed union with PEMF therapy. One patient was treated for a nonunion. The study period was from November 1995 to June 2008. The prerequisites for the use of PEMF were as follows: delayed union or nonunion, axial alignment with reduction of the fragments, fracture gap less than one centimeter, no pseudarthrosis and immobilization of the fragments. In cases 12, 13 and 14, PEMF was used to stimulate the poor regenerate following distraction osteogenesis using the Ilizarov fixator. Demographics were collected by reviewing the medical records of each patient.

The patients were delivered a pulsed electric current by two large external coils applied directly over the fracture site at 180 degrees to each other. The magnetopulse system consisted of a control module and two treatment coils contained in a padded applicator. The pulsing electromagnetic field so developed expands outward in space at right angles from the faces of the coils and penetrates the fracture site. The magnitude of the current is determined, in part, by the driving voltage of the coil's pulsed generator and the magnetic field thereby produced. The magnetopulse generator produces positive halfcycle 50 Hz pulses of the sinusoidal nature. The intensity of the magnetic pulse is regulated by phase control of the 50 Hz base frequency pulsation applied to the coils.

All patients were initially offered a four week course of therapy consisting of four consecutive treatments each week followed by three days off. The course of treatment was extended where improvement though present, was deemed unsatisfactory. Pre-treatment and post-treatment radiographs were taken of each patient. Completion of healing was determined by radiographic evidence of trabecular bridging across the fracture site and consolidation of the regenerate. Restricted weight bearing was allowed in patients whose delayed union and nonunion were in the lower limbs.

RESULTS

Of the 14 patients, eight (57%) were males and six (43%)were females. The average age was 45 years (range 15 - 67years). There were 13 delayed union and one nonunion. Three patients with poor regenerate were included in the 13 delayed unions. The average duration of treatment prior to the use of PEMF was 5.6 months (range 3 – 21 months), and average duration of PEMF treatment (healing time) was 2.9 months (range 2 - 4 months). In cases 12, 13 and 14, the duration of initial treatment refers to the period following bone transport and lengthening. This is referred to as the consolidation phase. In case 12, there was no change in the quality of the regenerate. The Ilizarov fixator was maintained and the patient was started on bisphosphonates. In cases 13 and 14, there was good consolidation to allow full weight bearing. Bony union occurred in 11 of the 14 patients.

At following up, there were no recurrences of symptoms or refractures in 11 patients who had achieved complete bony union (Table 1). The average period of follow-up was 8.6 months (range 3 - 24 months).

Figure 1

Table 1: Patient Data

CASE	AGE (TEARS) /GENDER	DIAGNOSIS	TREATMENT	DURATION OF TREAT- MENT (MONTHS)	PRACTURE TYPE	DURATION OF PEMF (MONTHS)	HEALED	FOLLOW-UP (MONTHS)
			Cart					
			immobilisa-tion					
		Grade I open fracture distal	initially.DCP and bone		Delayed			
1	37 / M	uina	grafting	5	union	4	YES	6
		Streas						
		fracture of	Compression		Delayed			
2	67 / F	femoral neck	9016899	4	union	3	NO	24
			Cast					
		Open fracture	inmobilisation initially. DCP					
		distal tibia	and bone		Delayed			
3	39 / M	and fibula	grafting	5	union	3	YES	12
		Weber Type						
		B and medial malleolar	Open reduction and internal		Delayed			
4	47 / F	fracture	fication	3 1/2	union	3	YES	6
		Closed	Provide State					
		fracture	K-nail initially. DCP and bone					
5	49 / F	femoral shaft	grafting	21	Non-union	4	YES	24
		Closed						
		fracture			Delayed			
6	55 / M	femoral shaft	DCP	6	union	4	YES	12
7		Fracture base	Compression		Delayed			
	57 / M	femoral neck	ecteme	3	union	3	YES	12
8		Fracture shaft			Delayed			
	47 / M	of humerus	DCP	3	union	2	YES	6
			Cast		Delayed			
9	60 / M	Jones fracture	immobilisa-tion	3	union	2	YES	3
			ORIF.					
		Closed	Replating and bone grafting.					
		fracture shaft	Injection with		Delayed			
10	53 / M	of ulna	bone marrow	6	union	3	NO	12
		Matunion						
11	42 / F	shaft of ferror	Ostsotomy and plating	3	Delayed	3	YES	6
	4477	Terme	brannel		diada		120	u
			Excision and autogenous					
			conticancel-loss					
			iliac graft. Oraft removed					
			due to					
		~	infection. Bone		P. 4			
		Giant cell tuncur distal	transport using the Ilizarov		Delayed union (Poor			
12	43 / F	1/3 tibia	frame	8	regenerate)	2	NO	6
			ORIF.					
			Osteomyelitis					
			at the fracture site. Plate and		Delayed			
		Closed	infected bone		union		Good	
13	18/M	fracture tibial shaft	removed. Bone transport	6	(Pour regenerate)	2	Consolida -tion	4
13	10.144	all the second s			references()		-1011	-
			Femoral lengthening					
			lengthening using the					
			lizarov		Delayed			
			fixation Frame removed Non-		Union (Incomplete		Good	
		Lower limb	weight bearing		Consolida-		Consolida	
14	15/F	inequality	with crutches	-4	tion)	2	-tion	4

DISCUSSION

In our study, 11 (78.5%) of the 14 patients achieved complete bony union following PEMF treatment. Our success rate is similar to that reported for delayed union and nonunions using PEMF stimulation ($_1$, $_5$, $_{12}$). The successful sites of union included: two tibial shafts, one bimalleolar, one base of neck of femur, four femoral shafts, one humeral shaft, one fifth metatarsal and one distal ulna.

There was one patient with a Jones fracture (a fracture at the base of the fifth metatarsal distal to and within 1.5cm of the tuberosity). The Jones fracture is distinguished from fractures through the tuberosity by its propensity for recurrence, delayed union and nonunion ($_{13}$). The patient with the Jones fracture was immobilized in a below-knee cast and was allowed partial weight bearing. Successful union occurred after receiving PEMF stimulation for two

months. Holmes $(_{13})$ successfully treated five delayed unions and four nonunions of the proximal fifth metatarsal with PEMF. All fractures healed in the mean time of four months (range 2 – 8 months).

Of the two patients who were initially classified as having delayed unions of the ulna, only one healed. Despite three surgical procedures which included the initial open reduction and internal fixation, infiltration of the fracture site with bone marrow aspirated from the iliac crest, replating along with autogenous bone graft and an above-elbow cast, bony union did not occur (case 10). This patient received 75 PEMF treatments over a six month period. Clinically, this patient was treated as a nonunion but for the purposes of clinical investigations was classified as a delayed union. Union finally occurred after excision of the sclerotic bony ends and interposition of an allograft.

Three patients (cases 12, 13, 14) had distraction osteogenesis using the Ilizarov fixator. Case 12 had bone transport and lengthening following excision of 6cm of the distal tibia for a giant cell tumour. Case 13 had bone transport and lengthening after resection of 5cm of infected bone following plating of the tibia. Case 14 had femoral lengthening for 9cm limb discrepancy secondary to a growth arrest. All three patients (cases 12, 3, 14) had poor regenerate after eight, six and four months respectively. These months refer to the consolidation phases. Case 12 had "callus massage" at the regenerate site in an attempt to improve the quality of the regenerate. The "callus massage" consisted of alternating short periods of progressive distraction with periods of compression (0.5mm of distraction per day for seven days followed by 1mm compression a day for seven days over a four week period) $(_{14})$. Very little improvement in the quality of the regenerate was noticed after "callus massage". A two month course of PEMF did not improve the quality of the regenerate. The patient is presently on bisphosphonates. Cases 13 and 14 showed good consolidation after two months of PEMF stimulation respectively.

The current data on the beneficial effects of PEMF in distraction osteogenesis is not clear-cut. PEMF was found to have no effect on regenerate mineralization in a randomized study, however, catabolic effects on surrounding bone were reduced ($_{15}$). In 1991, a study in rabbits revealed no effects ($_{16}$). However, another study in rabbits in 2003, demonstrated that short daily PEMF exposures accelerated consolidation of the regenerate ($_{17}$). The authors stated that the current data

cannot be used to recommend electrical stimulation in distraction osteogenesis without further high-level trials being performed.

PEMF is used to treat recalcitrant ununited long bone fractures (12, 18, 19). Our study showed that 11 of 14 patients with delayed unions and a nonunion healed with the use of PEMF. A double-blind study showed that PEMF fields significantly influence healing in tibial fractures with delayed union (4). A prospective, randomized double-blind trial demonstrated a statistically significant positive association between tibial union and electrical stimulation $(_{12})$. A study by Midura et al $(_{10})$ suggested that PEMF treatment accelerated bone healing, and significant increases in callus volume were observed over native healing only within the first three weeks of treatment. In a published study by Ibiwoye et al (₉), PEMF treatments were started after nonunion was confirmed after 28 days. The bone formation responses in that model system of the 28 days had already become quiescent, and the effectiveness of PEMF treatment at that time was deemed marginal. Despite an overall positive clinical consensus, there still exists lingering doubts in the orthopaedic community regarding the effectiveness in PEMF to stimulate bone formation (10). Much of this uncertainty is ascribed to contradictory conclusions resulting from subjective data interpretation $(_{10})$. Many more concerns such as lack of standardization of interpretations, the timing of PEMF treatment and the type of waveform used, must be addressed before PEMF is universally accepted.

The authors of this study will continue to use PEMF as an adjunct to standard fracture care for delayed unions and nonunions.

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