

Clinical Effects of Electromagnetic Stimulation as an Adjunct to Periodontal Therapy*

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THE CLINICAL EFFECTS OF ELECTROMAGNETIC STIMULATION (EMS) on periodontal soft tissues and alveolar bone level were studied among 23 patients. The sides of the arch to receive EMS were randomly selected and exposed for a period of eight weeks following periodontal surgery. The contralateral control sides received surgery only. The electromagnetic signal was a multiple pulse signal with 21 asymmetrical quasirectangular pulses per burst and a burst frequency of 16.9 Hz. The peak magnetic field strength reached 0.46 Gauss. Changes from baseline in clinical attachment level, probing depth, and radiographic alveolar bone level were assessed at six, 12, and 18 months postsurgically.

A greater gain of clinical attachment level following EMS was observed only for pockets with initial depth of 1 to 3 mm. There were no consistent differences between test (EMS) and control sides in the change of clinical attachment level or probing depth for pockets deeper than 4 mm. Radiographically, the test sides demonstrated statistically significant gain of alveolar bone level compared with the control sides at six months following surgery. Hereafter, the rates of change were similar in the stimulated and unstimulated sides, and the total gain of alveolar bone level remained greater in the test side throughout the observation period.

Within the limitations of this study, it was concluded that electromagnetic stimulation does not promote gains in clinical attachment or alveolar bone level to the extent that it can be recommended as an adjunct to conventional periodontal therapy.

The interest in electrical stimulation for repair and regeneration was initiated by the discovery that piezoelectrical currents were produced in long bones when placed under tension.^{1,2} Such currents have also been observed in bone of the mandible in dogs³ as well as in humans.⁴ Later it was demonstrated in rabbits that electrical stimulation by electrodes² or charged Teflon films⁵ induced formation of bone around the charged element. Likewise, bone formation was found to be enhanced around cathodes placed in experimental fractures or wounds of beagle dog femora as a result of an increase in the rate of osteoblast mitosis.⁶ Several investigators have subsequently studied the effects of electrical currents on osteogenesis in animals using different electrical modalities such as direct current,⁷ pulsed voltage sources,⁸ constant-current sources,⁹ and alternating currents.¹⁰ Application of electrical stimu-

lation by electrodes to amputated limbs of frogs¹¹ and rats¹² resulted in partial regeneration, a process that does not normally take place.

Clinical studies in humans have reported enhanced healing and bone reorganization of nonunion fractures and pseudoarthroses by electrical stimulation following long-term unsuccessful conventional treatments.¹³⁻¹⁷ Although a major part of these results are derived from uncontrolled studies or case reports, there seems to be evidence of a positive effect of the electrical impulses.^{18,19}

Several investigators have reported that alveolar bone responds to electrical stimuli in a manner similar to long bone,^{3,4,20} and electrical stimulation has been proposed to facilitate tooth movements^{21,22} and to support healing following surgical procedures for cleft palate repair.²¹ In studies of electrical stimulation in periodontal therapy,²³⁻²⁵ electrodes or galvanic elements were placed into interproximal or furcation defects caused by naturally occurring periodontitis in beagle dogs. Although this treatment resulted in enhanced endosteal bone apposition around the electrodes, no clinically or

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radiographically significant changes in the depth of the defects were observed.

The main risks of placing electrodes into the defects are electrolysis and infection. Noninvasive bioelectrical therapies, i.e., electromagnetic or electrostatic fields, have been introduced to eliminate these side effects. Results from controlled studies in rats²⁶ and beagle dogs^{13,27} and from clinical treatment of pseudoarthroses and nonunion fractures in humans¹⁵ have indicated that such noninvasive electrical fields can stimulate bone regeneration as well.

During previous studies in our laboratories, a non-invasive electromagnetic signal was developed and tested. When exposed to stimulation with this electromagnetic field, subcultures of periosteal cells from fetal rat calvaria increased their rate of DNA and protein synthesis.²⁸⁻³⁰ In addition, stimulation with this signal enhanced the formation of bone in experimental wounds in rats³¹ and beagle dogs.^{32,33} Based upon these preliminary findings, it was the aim of the present study to test the clinical effects of electromagnetic stimulation (EMS) on human periodontal soft tissue and alveolar bone during a postsurgical healing period.

MATERIALS AND METHODS

Twenty-four patients (13 female, 11 male) with a mean age of 49 years (range 24-67 years) were selected for the study at the School of Dentistry, University of Michigan. Having received oral hygiene instruction, scaling, and root planing, these patients were still in need of periodontal surgery in two contralateral quadrants of the mandible or maxilla. Criteria for selection were pocket probing depths of 5 to 6 mm and associated radiographic bony defects on two pairs of contralateral teeth (molars or premolars). The patients were appraised of the study, and written consents were obtained consistent with the policies of the University of Michigan and the National Institutes of Health.

One side was randomly assigned as test side, while the contralateral side served as control side. Modified Widman flap surgery³⁴ without bone correction was performed on both sides at the same appointment. Following the surgery, all patients received biweekly polishing for two months and were then seen every three months for prophylaxis. The test sides were, in addition, exposed to an electromagnetic field during a period of two months starting on the day of the surgery. This electromagnetic field was created between a pair of coils (28 mm × 12 mm, 150 turns of No. 40 trifilar wire) that were placed parallel, buccally and lingually, along the two test teeth on a bite plane splint (Fig. 1). The patients were instructed to wear this modified splint for at least eight hours per day, to clean it meticulously, and to report any malfunction immediately. The signal that generated the electromagnetic field came from a pocket-sized, battery driven (9 V)

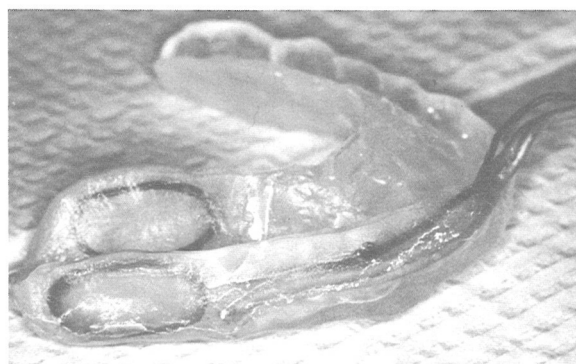


Figure 1. The modified bite plane splint, on which the coils were mounted. The cord connects these coils with the extraoral signal generator.

extraoral device and was transmitted to the coils through a cord connection. This signal was a multiple pulse signal with 21 quasirectangular pulses per burst, and with a burst frequency of 16.9 Hz. The amplitude across the field coils was 5900 mV (P-P) and 83 mV (P-P) when measured between the field coils with a search coil (Fig. 2). The peak magnetic force was approximately 0.46 Gauss. The signal characteristics were tested and calibrated biweekly during the two-month stimulation period.

At six, 12, and 18 months postsurgery, the probing depth and clinical attachment level from the cemento-enamel junction were measured at six well-defined sites for each test and control tooth. One examiner performed all clinical measurements while other investigators performed the clinical treatment procedures in a blind study design. The changes of these parameters from baseline per side, as well as the differences in changes between experimental and control sides, were determined for each reevaluation interval. The statistical analyses of these data were based upon total mean values per side and also on three presurgical probing depth categories (1-3 mm, 4-5 mm, larger than 6 mm) using the paired *t* test.

Radiographs of the two test teeth (EMS) and of the two contralateral control teeth were obtained prior to surgery and at six, 12, and 18 months. These radiographs were exposed with a system developed to produce identical images³⁵ using individual bite blocks and a cone-guiding device. This system has previously been shown to produce angulation errors within three degrees, resulting in a standard deviation of 0.1 mm when measuring alveolar crest levels.³⁵ All exposures were made at 70 kVP and 15 mA with similar exposure times, and the films* were developed, fixed, and rinsed under identical conditions. All radiographs were evaluated by one examiner at a magnification seven times normal on a modified Schei ruler.³⁶ The height of the alveolar periodontal bone was expressed in percentage of the root length at 5% increments. The cementoena-

* Ektaspeed EP21, Eastman Kodak Co, Rochester, NY.

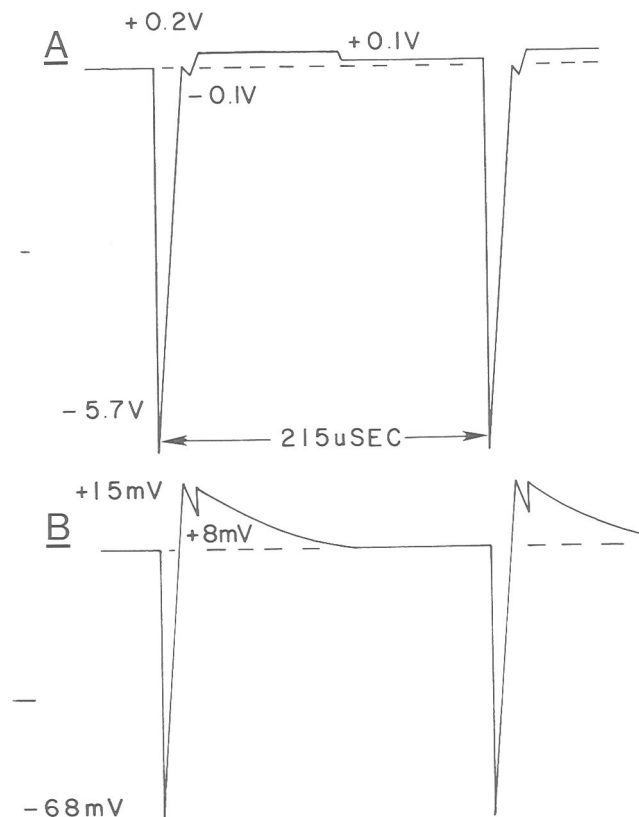


Figure 2. Drawing illustrating the characteristics of the signal, which generates the electromagnetic field as measured across the field coils (A) and between the field coils with a search coil (B).

mel junction (CEJ) or the margin of any covering restoration served as the coronal, and the root tip as the apical reference point, respectively. In angular defects, the most apical point was defined by the presence of a normal lamina dura and normal width of the periodontal membrane space. For analysis, the alveolar bone level was determined for each side as the average of the changes at four interproximal measurement sites. The radiographic changes from baseline were calculated for each reevaluation interval, and the differences between test and control sides were compared. These proportional data were analyzed by the nonparametric Wilcoxon rank sum test.

In the analysis of both soft tissue and alveolar bone level data, the patient served as the statistical unit and a significance level of $P < 0.05$ was applied. Only baseline values with corresponding reevaluation data were used for the analyses.

RESULTS

At the time of the data evaluation, twenty-three patients had been maintained in the study for six months, 18 for 12 months, and ten patients for 18 months following the electromagnetic stimulation period. The decrease in number of patients with time does not indicate "drop-outs," but reflects the varying length of time that the patients have been in the study.

Probing Depth and Clinical Attachment Level

Both test and control sides showed statistically significant probing depth reduction from baseline at all reevaluation intervals within each initial probing depth category (Table 1, Fig. 3). Although not statistically significantly different, the probing depth reduction of shallow pockets (1–3 mm) was larger on the test side, while the reduction of the pockets over 4 mm was greater on the control side. Likewise, the differences in total mean changes between test and control sides were not statistically significantly different.

There was a consistent gain of clinical attachment level from baseline in both test and control sites with an initial probing depth of 4 mm or deeper (Table 2, Fig. 4). This gain was, however, only statistically significant for pockets over 6 mm. Control sites of initially 1 to 3 mm showed a statistically significant loss of attachment at 6, 12, and 18 months while the changes in the experimental sites were insignificant for this probing depth category.

Evaluation of the changes in clinical attachment level, when based upon total mean values per side, demonstrated statistically significantly more gain in the test sides than the control sides at six and 12 months (Table 2, Fig. 4). However, additional analyses, when based upon the presurgical probing depth categories (1–3, 4–5, or over 6 mm), revealed that such a difference was limited to the sites with initial depths of 1 to 3 mm. This difference among the shallow pockets, although only statistically significant at 6 months, remained consistent throughout the 18-month observation period (Table 2, Fig. 4).

Alveolar Bone Level

The test sides demonstrated at six, 12, and 18 months an average gain of alveolar bone level (Table 3, Fig. 5), the size of which increased from 6 to 18 months of the reevaluation period. The control sides, in contrast, showed a loss of alveolar bone height at six and 12 months postsurgery. However, the magnitude of this loss decreased from six to 12 months and at 18 months a gain in alveolar bone level was demonstrated.

Although the gain of alveolar bone at all reevaluation intervals was larger on the test side than on the control side, the difference was only statistically significant at six months after the surgery (Table 3, Fig. 5).

DISCUSSION

In the present study an electromagnetic signal that had been developed and tested previously in our laboratories was applied and evaluated clinically as an adjunct to surgery in the periodontium.

In the test sides that received EMS, a consistently larger gain of clinical attachment was observed for only sites with an initial probing depth of 1 to 3 mm. However, it has previously been shown that surgical

Table 1
*Mean Reduction of Pocket Probing Depth from Baseline at the Various Examination Intervals Described for Three Initial Probing Depth Categories and for Total Means per Side**

Initial probing depth		6-Month examination				12-Month examination				18-Month examination			
		N	Change	MD	SD	N	Change	MD	SD	N	Change	MD	SD
1-3 mm	Test	22	0.27†	0.15	0.63	16	0.49†	0.30	0.63	9	0.69†	0.16	0.43
	Control		0.12				0.19				0.53†		
4-5 mm	Test	23	1.38†	0.08	0.82	17	1.31†	0.02	0.79	10	1.30†	-0.15	0.79
	Control		1.30†				1.28†				1.46†		
≥6 mm	Test	12	2.11†	-0.55	1.27	9	1.71†	-0.63	1.41	7	2.16†	-0.47	1.11
	Control		2.66†				2.35†				2.63†		
Total means per side	Test	23	0.89†	0.09	0.70	18	1.08†	0.11	0.70	10	1.21†	-0.07	0.81
	Control		0.83†				0.97†				1.28†		

* MD = mean difference; N = number of subjects.
† Statistically significantly different from baseline ($P < 0.05$).
§ Statistically significant difference ($P < 0.05$).

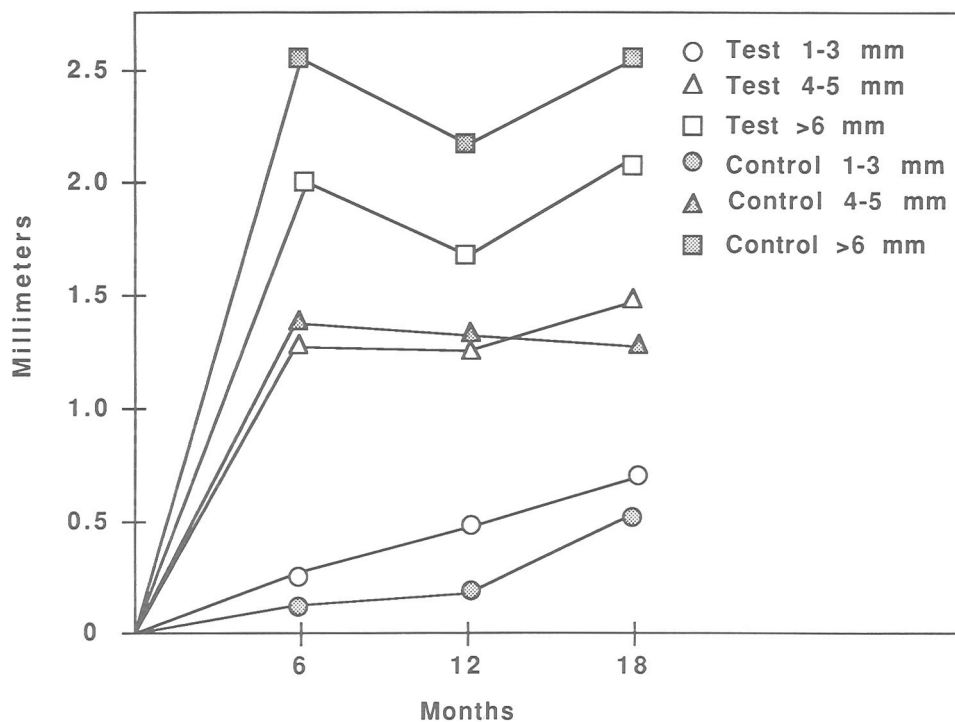


Figure 3. Reduction in pocket probing depth from baseline at six, 12, and 18 months reevaluation for each initial probing depth category.

procedures in pockets of this depth are not indicated since they do not promote better treatment results than nonsurgical therapy.³⁷ In the present study, these shallow sites were only approached surgically to gain access to areas of more severe disease involvement. Among the initially deeper pockets, no consistent differences between electromagnetically stimulated and control sites were detected. The control side changes in clinical attachment level and probing depth were observed to be comparable with results from previous studies of periodontal surgical procedures.³⁷⁻⁴⁰

These limited clinical effects of EMS on the periodontal soft tissues appeared to be in contrast to results of studies performed prior to this clinical application. Thus, increased DNA and protein synthesis had been

demonstrated among fetal rat calvarium cell application of an identical electromagnetic signal.²⁸⁻³⁰ Other investigators^{18,41} had shown similar findings in fibroblast cultures following exposure to electrical stimulation. In addition, well-developed collagen fibers and a significantly greater gain of connective tissue attachment had been demonstrated histologically in naturally occurring periodontal disease sites in beagle dogs that received EMS for 14 or 28 days compared with unstimulated control sites (unpublished). Also these results were in agreement with previous studies that had shown that electrical stimulation in beagle dog femora promoted an increased rate of mitosis among mesenchymal and bone cells around experimental fractures.⁶

Radiographically, at all reevaluation intervals there

Table 2
*Mean Changes of Probing Attachment Level from Baseline at the Various Examination Intervals Described for Three Initial Probing Depth Categories and for Total Means per Side**

Initial probing depth		6-Month examination				12-Month examination				18-Month examination			
		N	Change	MD	SD	N	Change	MD	SD	N	Change	MD	SD
1-3 mm	Test	22	-0.14	0.44†	0.81	16	-0.007	0.39	0.99	9	0.17	0.62	1.08
	Control		-0.58§				-0.40§				-0.45§		
4-5 mm	Test	23	0.39	0.29	0.94	17	0.37	0.14	0.99	10	0.51	0.07	0.77
	Control		0.10				0.24				0.44		
≥6 mm	Test	12	1.72§	0.09	1.41	9	1.09§	-0.28	1.90	7	1.87§	0.23	1.59
	Control		1.63§				1.36				1.63		
Total means per side	Test	23	0.17	0.30†	0.50	18	0.38§	0.33†	0.42	10	0.63§	0.27	0.50
	Control		-0.13				0.09				0.36		

* MD = mean difference; N = number of subjects.
† Statistically significant difference ($P < 0.05$).
§ Statistically significantly different from baseline value ($P < 0.05$).

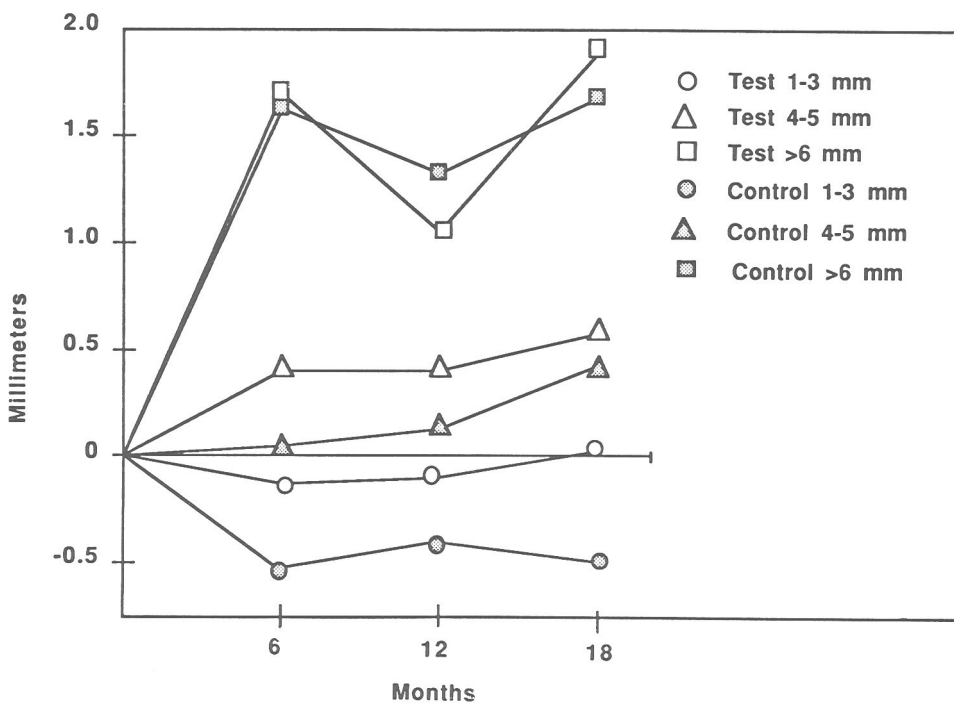


Figure 4. Changes in clinical attachment level from baseline at six, 12, and 18 months reevaluation for each initial probing depth category.

Table 3
*Mean Changes of Alveolar Bone Level in Per Cent of Root Length from Baseline at the Various Examination Intervals Described for Total Means per Side**

		6-Month examination				12-Month examination				18-Month examination			
		N	Change	MD	SD	N	Change	MD	SD	N	Change	MD	SD
Total means per side	Test	23	1.62	2.75†	3.35	16	2.39	2.94	3.21	10	3.42	2.49	2.83
	Control		-1.13				-0.55				0.93		

* MD = mean difference; N = number of subjects.
† Statistically significant difference ($P < 0.05$).

was consistently a larger gain of alveolar bone level on the sides that received EMS than on the control sides. Since the control side treatment, the modified Widman flap surgical design with no bone correction, previously has been shown to promote the most favorable post-

surgical healing in bony defects,⁴² it is noteworthy that the gain of alveolar bone level in the test sides consistently was larger than that of the control sides. The continuing long-term gains in alveolar bone level in both test and control sides during the whole observation

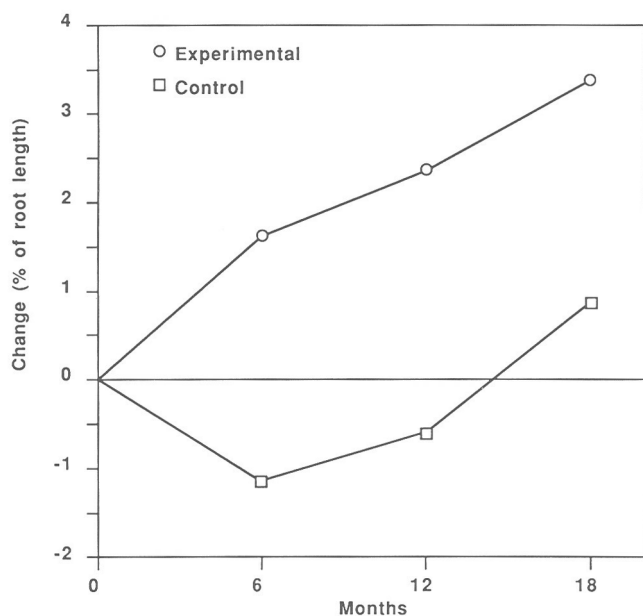


Figure 5. Mean changes in radiographic alveolar bone level from baseline at six, 12, and 18 months reevaluation expressed in per cent of root length.

period apparently reflect the slow processes of bone regeneration.

Another determinant to consider is the oral hygiene status that also has been shown to affect the amount of regeneration in bony defects.⁴³ In the present study, the patients received prophylaxis biweekly during the initial two months and thereafter once every three months. This schedule of prophylaxis visits may explain, in part, why the gain of alveolar bone level in the control sides was less than that observed in other studies.^{42,43} Thus in these studies, patients who were placed on a biweekly prophylaxis schedule demonstrated almost complete bone fill of intrabony defects following periodontal surgery.⁴³

The numerical expressions of the gains in alveolar bone level may have been affected by inclusion of defects of varying morphology into this study, although it was attempted to select angular type defects primarily. Since the changes of bone level were expressed as the averages per side of the alterations at several interproximal measurement sites along the study teeth, the magnitudes of the changes were, as expected, lower than those seen in studies of angular defects exclusively.^{42,43} This variation of healing patterns of different types of defects also seemed to be reflected in a large standard deviation of the alveolar bone level changes (Table 3). In spite of these considerations, the selected approach was considered to give the best impression of the EMS effect.

The absence of major clinical effects of EMS on both periodontal soft tissues and alveolar bone do not, however, exclude possible intratissue effects such as altered rates of fibroblast mitosis or collagen production. The complexity of chronically inflamed periodontal tissues

that may have caused yet unexplained alterations of bone and tooth substance as well as inhibitory factors for cell growth might have influenced the ability of the cells to respond to the electromagnetic field. Also, previous evidence of an effect of electrical stimulation in extraction wounds³³ but not in periodontal defects^{24,25} suggest differences in the response to electrical stimulation between cells of experimentally created wounds and naturally occurring periodontal defects.

In spite of the promising findings of laboratory studies, the present clinical study in humans did not confirm the effects of electromagnetic stimulation in periodontal defects during a postsurgical healing period. Within the limits of this study, the magnitude of the alveolar bone level gains and the clinical soft tissue response do not seem to justify the use of electromagnetic stimulation on a regular basis in periodontal therapy.

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