



The Effect of Pulsed Electromagnetic Fields Stimulation in Percutaneous Surgery for Hallux valgus and Metatarsalgia

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Abstract

Objective: To evaluate the effect of PEMFs on bone and soft tissues healing time after percutaneous osteotomies for hallux valgus and metatarsalgia in terms of bone union rate, edema resorption and pain relief.

Methods: Sixty patients percutaneously treated for hallux valgus and metatarsalgia were divided into a treated group when stimulated with PEMFs and a control group of untreated patients. At baseline and during follow-up, pain, edema, use of analgesics were evaluated. Radiographic follow-up was also performed.

Results: The early use of PEMFs gained pain relief, edema reduction and functional recovering in a shorter time course with no complications when compared with the untreated group. The VAS score in the treated group decreased significantly from 8.6 (range, 4-7) before treatment to 2.5 (range, 0-3.8) at the last follow-up. The mean AOFAS score improved from 30.4 (range, 20-66) before treatment to 95 (range, 82-100) at the last follow-up. Pain and edema were constantly lower at 45, 90 and 180 days.

Conclusion: Treatment with PEMFs is demanding because it requires an external device and long-lasting daily stimulation. However, the early application of PEMFs would be beneficial to selected patients with high activity levels by reducing the suffering time after surgery. Accelerated postoperative rehabilitation due to positive PEMFs effects could be more effective.

Keywords: Pulsed electromagnetic fields (PEMFs); Hallux valgus; Metatarsalgia; Percutaneous surgery; Bone healing

Background

The increasingly-common practice of minimally invasive surgery of the forefoot significantly reduces surgical time and hospital stay, leading to a shorter recovery time, rapid esthetic and functional results [1,2]. An immediate and full restoration of weight bearing and early return to work activities are expected with percutaneous forefoot surgery, especially in fully-active adult patients. Despite the forefoot tissue sparing, postoperative disorders such as early or late edema, pain or delayed osteotomy repair can have an unfavourable effect on the final outcome [2]. Postoperative management includes analgesic coverage and the treatment of swelling with dressings and medical shoes. Controlling the postoperative inflammatory microenvironment in the operated foot, by targeting both pain and bone metabolism, can be important for the success of the percutaneous technique.

Pulsed low-frequency Electromagnetic Fields (PEMFs) have been increasingly applied over the last 50 years to promote endogenous osteogenesis and to enhance fracture bone healing. In the USA and Europe, the research on the use of PEMFs for bone repair processes has continued throughout the last century. Every year, tens of thousands of patients undergo treatment all over the world.

In vitro and *in vivo* preclinical studies have shown that PEMFs are able to enhance osteoblast proliferation, the inhibition of osteoclastogenesis and angiogenesis, hematoma resorption and osteoblast differentiation [3-8]. In clinical settings, treatment with PEMFs has been seen to accelerate slow bone turnover, to control inflammation and local osteoporosis, to promote tissue healing and relieve pain [9-12]. Since their first clinical application, as described by Bassett et al. [13,14] and Sharrard [15], PEMFs have been considered as adjuvant therapy for both conservative treatment with or without immobilization and in the postoperative management of at risk

fractures, stress or acute fractures, delayed unions, non-unions and osteotomies of the long bones [14-22]. Three randomized prospective double-blind studies have been conducted on the effect of PEMFs on human femoral intertrochanteric osteotomies [17], tibial osteotomies [18] and osteotomies in patients undergoing massive bone grafts [23] and showed a significantly shorter healing time (29%, $p < 0.05$), early bone callus mineralization and faster osteotomic line healing. As far as foot and ankle surgery is concerned, few randomized controlled trials describe the effects of bone electrical stimulation on bone: it is indicated primarily for difficult cases such as failed fusions, congenital pseudarthrosis and non-unions [24,25] or combined with a collagen scaffold seeded with bone marrow-derived cells in osteochondral lesions of the talus [26] or after arthroscopic debridement and microfractures for the treatment of osteochondral defects [27]. Several studies support the use of electromagnetic stimulation for acute metatarsal fractures. Holmes [19] treated 9 delayed unions and nonunion of Jones fractures with non-weight bearing cast combined with PEMFs, and successfully achieved union in all treated patients in a mean time of 4 months. Benazzo et al [28] treated 25 lower limb stress fractures in athletes, including fifth metatarsal fractures, by applying a sinusoidal waveform of alternating current and obtained 88% union rate. Streit et al [11] quantified the *in vivo* effect of PEMFs on growth factors expression

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and healing time in fifth metatarsal non-unions, finding a significant increase in local growth factors, higher levels of Bone Morphogenetic Proteins and, overall, a faster union rate than non-stimulated controls. Although they described a single case, Martinelli and colleagues [29] were the first authors to study the application of PEMFs after a successful surgical revision with a locking plate for a pseudarthrosis following percutaneous distal osteotomy for hallux valgus. However, this is a single case report and the actual adjuvant effect of PEMFs on final bone consolidation is not discussed [29].

The potential benefit of PEMFs in improving outpatient recovery after percutaneous surgery for hallux valgus and metatarsalgia has yet to be investigated. The aim of the study was to evaluate the effect of PEMFs on bone and soft tissue healing time after percutaneous osteotomies for hallux valgus and metatarsalgia in terms of bone union rate, edema resorption, and pain relief.

Methods

A series of 60 patients (52 women, 8 men) treated for hallux valgus and metatarsalgia between October 2015 and June 2018 was investigated and consecutively enrolled in the study. The inclusion criteria were: diagnosis of moderate to severe hallux valgus associated with central or lateral metatarsalgia, no metal implant or any other osteotomy maintenance devices percutaneous surgical technique. Percutaneous extra capsular osteotomy of the metatarsus and/or proximal phalanx of the first ray, associated with Distal Minimally Invasive Metatarsal Osteotomy in case of metatarsalgia, was performed by the same surgeon in all cases. In order to obtain a homogenous series for the analysis of outcomes in the first Author's experience with postoperative PEMFs in this kind of surgery, the following exclusion criteria were applied: pregnancy, hypertension, risk factors for bone healing in the subject's medical history such as peripheral arterial obstructive disease, heavy smoking, hyperlipidemia or hypercholesterolemia, leg edema. Patients with systemic diseases such as rheumatoid arthritis, diabetes mellitus, and patients on oral corticosteroids were excluded from the

study. Antibiotic prophylaxis was provided by administering 2 g of intravenous cefazolin 30 minutes before incision. The postoperative dressing was renewed every 15 days and maintained for 35 days. Immediate weight-bearing was allowed with hard-soled shoes for at least 30 days in all cases. Oral paracetamol or NSAIDs were suggested for pain control. In accordance with our Hospital's thromboembolic prophylaxis guidelines, 4000 IU of subcutaneous enoxaparin sodium were administered daily for 12 days [30].

Postoperative administration of PEMFs was offered to all operated patients, except those with heart pacemakers or a history of malignancy or with peripheral artery disease. The 30 patients who agreed to comply with the PEMFs stimulation regimen were included in the treated group, and retrospectively compared with the control group of 30 untreated patients.

Seven days after the surgical procedure all patients in the treated group were told to use the PEMFs medical device (Biostim[®], IGEA SpA, Carpi, Italy) for 8 hours a day overnight. Stimulation was discontinued at 42nd postoperative day (Figure 1). The device generated an electromagnetic signal with the following parameters: frequency of 75 Hz, peak magnetic field intensity of 2.5 mTesla, 10% duty cycle. The devices were fitted with a clock to memorize the treatment times, in order to monitor patients' compliance. Follow-up visits were scheduled for Days 45, 90 and 180 after surgery; radiographic and clinical data were collected at each programmed visit. Metatarsal osteotomy repair was graded into 4 categories using standard anteroposterior and laterolateral x-rays, using to the score proposed for tibial osteotomy in a previous study by Mammi et al. [18]: SCORE 1) the osteotomy line is still clearly visible at follow-up on both projections; SCORE 2) over 50% of the osteotomy line is visible SCORE 3) the bone bridging involves more than 50% of the osteotomy; SCORE 4) a complete bone union is achieved at the osteotomy site. Local edema was described as mild, moderate or severe based on a subjective observation of both foot-swelling (4 mm, 6 mm and 8 mm, respectively) and pitting time (5, 8, 10 seconds, respectively). Pain and functional recovery were recorded

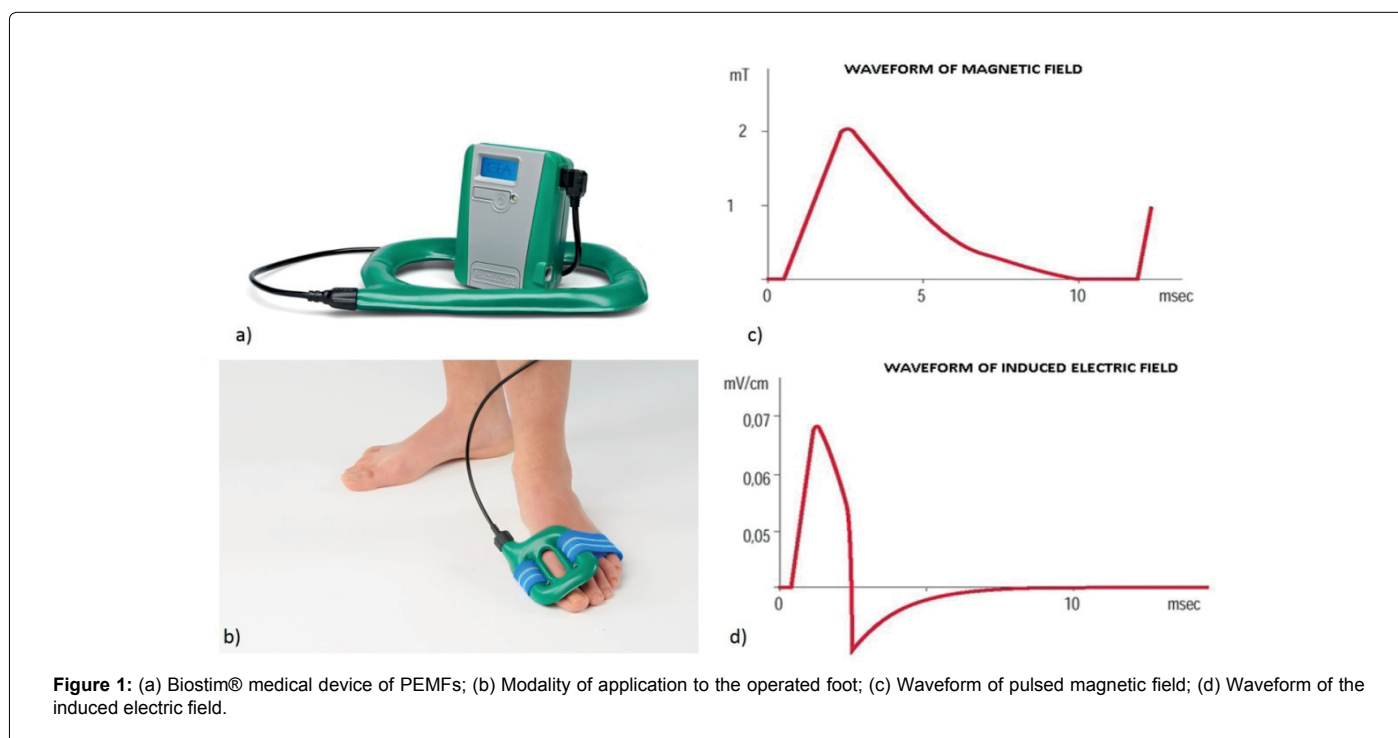


Figure 1: (a) Biostim[®] medical device of PEMFs; (b) Modality of application to the operated foot; (c) Waveform of pulsed magnetic field; (d) Waveform of the induced electric field.

using a visual analog scale (VAS) and the American Orthopaedic Foot and Ankle Score (AOFAS); preoperative versus postoperative use of analgesics was also investigated.

Statistical analyses were conducted using of NCSS9 software (Hintze, J. (2013). NCSS 9. NCSS, LLC. Kaysville, Utah, USA. www.ncss.com.). Mean values and standard deviation were obtained for the continuous variables. Paired and unpaired Student t-test was used for comparisons between the 2 groups at each study time-point. Comparisons between groups for categorical or ordinal variables were performed using a contingency table and the two-tailed Chi-square test of independence. $P=0.05$ was set as the minimum significance level.

Results

No patient was lost to periodic follow-up. No postoperative soft tissues complications such as thrombophlebitis, wound infections nor dehiscence, were encountered in the 2 groups. The postoperative weight-bearing regimen was followed as instructed in all cases. None of the stimulated patients complained of either discomfort or complications after PEMF application; their compliance with the PEMFs treatment was satisfactory in terms of the modality of application, hours and duration of administration.

As shown in Table 1, patients' demographics between the 2 groups were similar.

As regards comparisons in the x-ray score [18], the fracture healing rate was significantly higher in the treated group than in the control group at each radiographic follow-up (Figure 2).

The VAS score and AOFAS for the treated and control groups are provided in Figures 3 and 4, respectively. The VAS in the treated group decreased significantly from 8.6 (range, 4-7) before treatment

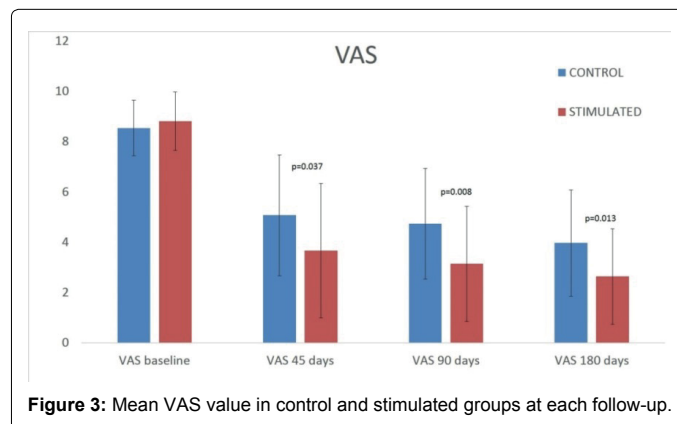


Figure 3: Mean VAS value in control and stimulated groups at each follow-up.

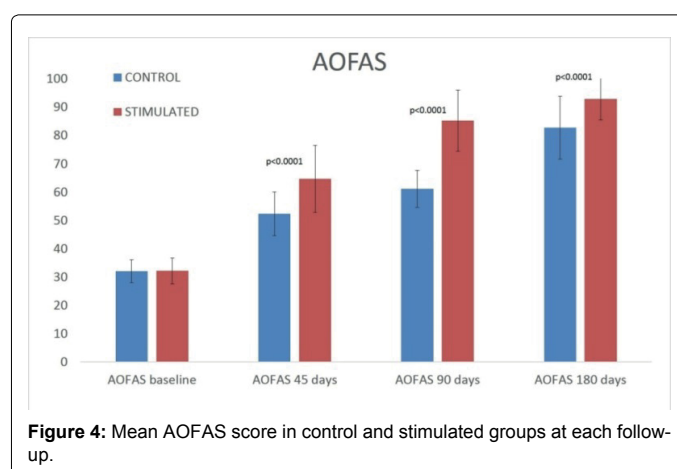


Figure 4: Mean AOFAS score in control and stimulated groups at each follow-up.

	Control	Stimulated	p-value
N° patients	30	30	1.000
Sex	4M, 26F	4M, 26F	1.000
Age	62.6 ± 8.7	64 ± 8.1	0.533
Weight	62.7 ± 5.9	61.9 ± 5.8	0.570
AOFAS score	32 ± 4.1	32.1 ± 4.6	0.929
Pain (VAS)	8.5 ± 1.1	8.8 ± 1.2	0.365
Analgesics use	20	18	0.789

Table 1: Preoperative characteristics of patients included in the control and stimulated groups.

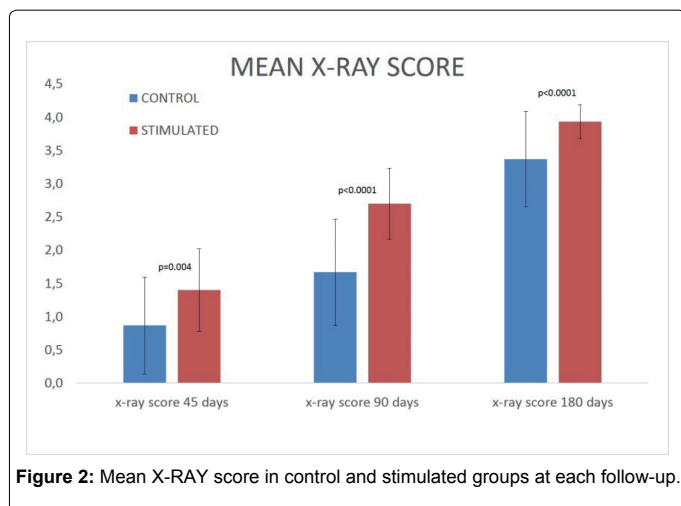


Figure 2: Mean X-RAY score in control and stimulated groups at each follow-up.

Follow up	Control			Stimulated			p-value
	Severe	Mild	Moderate	Severe	Mild	Moderate	
45 days	57%	16%	27%	4%	64%	32%	<0.0001
90 days	47%	26%	27%	0	73%	27%	<0.0001
180 days	33%	55%	12%	0	83%	17%	$p=0,002$

Table 2: Incidence of postoperative edema in control and stimulated groups.

to 2.5 (range, 0-3.8) at the last follow-up. Their mean AOFAS score improved from 30.4 (range, 20-66) before treatment to 95 (range, 82-100) at the last follow-up. A statistically significant reduction in pain and better AOFAS score were reported in the treated group at each follow-up visit. There was a lower incidence of severe postoperative edema amongst treated patients (Table 2).

The use of analgesics was lower during the postoperative recovery period for patients in the treated group (10% in treated group vs 33% in the control group, $p=0.014$).

Discussion

Skeletal complications after percutaneous forefoot surgery such as osteonecrosis, nonunion, malunion and recurrence are quite rare (1% to 3%) [1,2,31,32]. Delayed or non-unions mainly concern lateral metatarsal osteotomies; they are usually not related to pain or stiffness, except in the case of secondary joint instability and metatarsalgia. Some non-unions can result in significant pain and disability and are frequently observed in patients with comorbidities at high-risk of failed fusion, such as rheumatoid arthritis, vascular diseases, diabetes or smokers. Early or late postoperative edema is a very common

complication (1% to 22%) and its etiology is multifactorial, depending on the impairment of venous and lymphatic circulation, metabolic disorders, osteodystrophy, hyperalgesia, etc. [31,33]. Its prevention is achieved by leaving the percutaneous accesses unsutured, venous drainage and stiff-soled shoes allowing immediate weight bearing. The edema usually resolves after a few months with no sequelae; lymph drainage and mud bath therapy are suggested for irresolvable cases. Complex regional pain syndrome is uncommon (2% to 6%); however, it mainly occurs in case of inaccurate or unstabilized osteotomies [31].

As reported by Yuan et al. [34] biophysical stimulation, as a prospective, non-invasive and safe physical therapy strategy for accelerating bone and soft tissues healing, has received special attention in recent decades.

Although PEMFs treatment indications and protocols vary greatly in Literature, very few studies have addressed their early application on acute fractures or soon after the clinical or radiographic suspicion of a delayed union at 12-16 weeks after a fresh fracture [10,15,20,22,35]. In their prospective randomized double-blind study, Faldini et al. [20] applied PEMFs 7 days after minimally-invasive surgery with screws for femoral neck fracture, in an attempt to demonstrate whether PEMF stimulation affects the incidence of postoperative osteonecrosis. Very few studies have documented the effectiveness of using PEMFs to reduce extravascular edema after a simple fracture, although the addition of electromagnetic stimulation would seem to gain better overall outcomes than ice therapy alone after a prolonged immobilization for scaphoid and wrist fractures [10,35]. The effect of PEMF therapy was studied in patients with spontaneous osteonecrosis of the knee in the early stage, and showed a significant reduction in pain and functional recovery and prevented 86% of knees from prosthetic surgery [36]. The use of PEMFs has been successfully promoted needing to increase the union rate of forefoot fractures at high risk of failed fusion (i.e. proximal fifth metatarsal fractures, Jones fractures, and diaphyseal stress fractures), without the complications and morbidity typically associated with revision surgery [11].

Unlike the majority of relevant studies that promote bone healing stimulation as a salvage treatment for failed fusions and/or established pseudarthrosis (6 months after trauma or later), our study aimed to evaluate the efficacy of early-applied PEMFs in postoperative recovery from a type of surgery that is per se highly demanding and elective. Clinically, our results show a trend towards an earlier healing time in the PEMFs stimulation group after percutaneous forefoot surgery. None of the stimulated patients presented failures or complications, or required surgical revision for recurrence or postoperative shoe modifications. The early use of PEMFs led to pain relief, edema resolution and accelerated functional recovery with no complications when compared with the untreated group. Pain and edema were significantly lower at 45, 90 and 180 postoperative days confirming a that PEMFs have a long lasting anti-inflammatory effect mediated by the agonist action of adenosine A_{2A} receptors [12,20,37,38].

This comparative retrospective study presents some limitations: it is not a prospective randomized, double-blind placebo-controlled trial and was conducted on a small sample size treatment population. The control group is limited to patients participating in the study who refused the postoperative PEMFs application. However, the selection of patients included was as homogeneous as possible in terms of clinical presentation and surgical procedure. It could be argued that many risk factors for bone and soft tissues healing have not been considered in the study, such as diabetes or peripheral artery disease [39], but the aim was firstly to gather a valuable effect of bone electrical

stimulation after this specific surgical technique, avoiding any bias or confounding factors on final results. There is no doubt that further studies could be conducted to reinforce the hypothesis of PEMFs efficacy after corrective forefoot surgery in improving not only bone healing but also angiogenesis and soft tissue postsurgical recovery. It is important, in our opinion, to focus on the potential advantages of early PEMF use after an elective outpatient surgery such as percutaneous osteotomies for hallux valgus and metatarsalgia, providing its adjuvant role after an appropriate surgical technique. It could be argued that PEMF application is demanding, as it requires the positioning of an external device for long-lasting daily stimulation on the foot. Since correct outpatient management is essential to assessing the efficacy of electromagnetic stimulation of the bone, its use should be restricted to patients who can guarantee adequate treatment compliance. The overall cost per patient of the PEMF device should also be considered. However, the treated group showed better radiographic healing rates and pain control with less edema: therefore, accelerating recovery time could be more cost effective because it reduces the immobility period and minimizes the time off work. It is interesting to note that, similarly to their valuable role in both acute fractures and delayed fusions, PEMFs also effective in the treatment of acute and chronic inflammatory disorders, making this approach broadly applicable to several clinical presentations. As in several previous studies advocating the electrical stimulation of bone for other ankle and foot bone healing disorders and its role in improving symptoms in patients affected by limb ischemia, the early application of a noninvasive electromagnetic treatment after percutaneous surgery for forefoot deformities may be particularly beneficial for reduction in pain and functional demanding high-functioning young-adult patients, or smokers, patients with diabetes or rheumatoid arthritis or those on corticosteroid therapy, who are at a high risk of delayed or non-unions [24,25,39].

Conclusion

To our knowledge, this is the first experience with early PEMF application after percutaneous forefoot surgery for hallux valgus and metatarsalgia to be reported in literature. A larger caseload prospective randomized controlled trial is required to confirm our results.

In clinical practice, the early application of PEMFs would appear particularly beneficial to selected patients with high activity levels by reducing pain, walking disability, convalescence time and abstention from work activities after surgery. An accelerated rehabilitation program after surgery for hallux valgus and metatarsalgia could be a cost-saving and clinically more efficacious option, due to the positive effects of PEMFs on bone healing and pain.

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