PULSED ELECTROMAGNETIC FIELDS "PEMF"
CTU – MEDICAL DEVICE *PERISO sa*,
for the
TREATMENT OF POSTOPERATIVE DELAYED UNIONS OF LONG-BONE FRACTURES:
A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

Abstract

Background:
pulsed electromagnetic field (PEMF) is reported to be an effective adjunct for the management of nonunion long-bone fractures. Most studies implement PEMF treatment after 6months or longer of delayed union or nonunion following fracture treatment. Despite these variations in treatment, the early application of PEMF following a diagnosis of a postoperative delayed union has not been specifically analyzed.

Study Objective:
the purpose of this study was to evaluate the efficacy of the early application of PEMF in the bone healing of POSTOPERATIVE DELAYED UNIONS OF LONG-BONE FRACTURES, compared with a sham-treated control group.

Methods:
in this prospective, randomized controlled study, a total of 58 long-bone fracture patients, who presented with delayed union of between 16weeks and 6months, were randomly split into two groups and subjected to an early application of PEMF CTU – MEDICAL DEVICE – PERISO sa, or sham treatment. Clinical and radiological assessments were performed to evaluate the healing status. Treatment efficacy was assessed at three month intervals.

Results:
patients in the PEMF group showed a higher rate of union than those in the control group after the first three months of treatment, but this difference failed to achieve statistical significance. At the end of the study, PEMF treatment conducted for an average of 4.8months led to a success rate of 77.4%. This was significantly higher than the control, which had an average duration of 4.4months and a success rate of 48.1%. The total time from operation to the end of the study was a mean of 9.6months for patients in the PEMF group.

Search strategy:
databases used to identify studies for this clinical study include Medline, Embase and Cochrane.

Conclusions:
Fracture patients treated with an early application of PEMF achieved a significantly increased rate of union and an overall reduced suffering time compared with patients that receive PEMF after the 6months or more of delayed union, as described by others.

Keywords:
PEMF, Electromagnetic field, Delayed union, Fracture healing, Long-bone fracture.

MD. Pietro Romeo (Annex 1)

INTRODUCTION

Despite recent improvements in fracture management, delayed union and nonunion remain as intractable complications following surgical reduction and fixation of long-bone fractures. It is estimated that 5–10% of all fractures show impaired healing [1]. Surgical management is usually preferred in the treatment of an established nonunion, especially in those fractures that are accompanied by infection, deformity, shortening or bony defect. Otherwise, nonsurgical methods are considered for delayed union to facilitate osteogenesis, osteoinduction, as well as osteoconduction and thus stimulate the healing process [2, 3]. Among the reported therapeutic methods, the use of biophysical interventions, such as pulsed electromagnetic field (PEMF) therapy, has attracted the attention of clinicians in the past decades, because of their noninvasive characteristics [4, 5].

PEMF was introduced in the mid-1970s as a beneficial tool for fracture healing [6]. Although the mechanism remains poorly understood, PEMF provides an effective adjunct for the management of un-united long-bone fractures [7, 8, 9, 10]. However, the indication and treatment strategies for the use of PEMF vary within the literature. The majority of investigators do not start PEMF treatment until an established nonunion is diagnosed [11, 12, 13, 14], and others consider a late stage of delayed union (over 6months after fracture) as the indication for its use [15, 16, 17]. Very few studies have addressed the early application of PEMF immediately after diagnosis of a delayed union (at about 16weeks after fracture) [18], and no reports have specifically investigated the efficacy of the early application of PEMF. Long-bone fracture healing has been recognized as an orchestration of prompt hematoma formation, inflammatory response, cell proliferation and differentiation, followed by a long-term process of ossification and remodeling [19]. Since the healing process is not considered to be accomplished in the case of a delayed union in orthopedics terms, the early intervention of PEMF possesses the theoretical advantage of reactivating the biological process of bone repair, thereby facilitating fracture healing and possibly shortening the treatment duration. In the present study, the authors aimed to evaluate the efficacy of early- applied PEMF on postoperative delayed union of long-bone fractures. We hypothesized that the early application of PEMF in patients with delayed union might lead to an increased rate of fracture union compared with sham-treated patients. The outcomes of postoperative delayed union of long-bone fractures in patients treated with an early application of PEMF after the delayed union diagnosis were evaluated and compared with the placebo-treated controls.

DEVICE DESCRIPTION

PULSED LOW-FREQUENCY ELECTROMAGNETIC FIELDS: The pulsed low-frequency (< 50Hz; ~7Hz) electromagnetic fields (1b) belong to the class of non ionizing radiations, that is, they are characterized by an associated energy below 12 eV (electron-Volt). Such an energy is insufficient both to turn on ionization phenomena in molecules and to break even very weak chemical bonds. For this reason in the last decades these radiations have not been considered able to interact with biological systems and, as a consequence, the studies on this subject were scarce and information poor, especially when compared with the great amount of knowledge concerning the interactions among ionizing radiations and biological systems (2b). Only recently, due to the more and more common use of electromagnetic fields of different intensity and frequencies (3b), a vast research activity (4b-5b-6b-7b-8b-9b-10b-11b) has started, addresses to the definition of their main biological and therapeutic effects, on which are based the exposition thresholds currently recommended.

DIAMAGNETISM: The diamagnetism works on hydrogen atoms. Indeed, when a hydrogen atom is covalently bound to a strongly electronegative atom, as for example the oxygen, the bond electrons tend to move toward the latter. As a consequence, the H atom assumes a partial but consistent positive charge. This charge, distributed in a small volume, lead to a high electric charge density. At this point, the hydrogen atom tends to bind with a partially negatively charged atom (the oxygen atom of a different water molecule) in this way acquiring a greater stability neutralizing its electric charge.

A single water molecule does not feel any net force, since it is subject to the action of the

surrounding molecules that are uniformly distributed in any direction of the three-dimensional space. The liquid water consists in a disordered network of molecules, bound together by relatively weak chemical bonds. Such a network is continuously subject to fluctuations that randomly break and create new bonds among the molecules. Due to these characteristics the water does not have a proper dipole magnetic moment and it is repelled by an external magnetic field (diamagnetism). The PEMF - CTU PERISO sa, is a device of molecular diamagnetic acceleration. It uses an energy of up to 200 Joule, generating high power (2 Tesla), pulsating fields and developing a water-repulsive force with the following main therapeutic aims:

- liquids transport;
- tissue biostimulation.

Liquids transport: as a result of diamagnetic repulsion, the free water in the extracellular compartments is fiercely pushed away from the field application site. The transport of extracellular liquids helps the oedema and post-traumatic effusions reabsorption and the scoriae removal, and stimulate the lymphatic circulation and related phenomena also thanks to the vasodilatation draining action produced by the diathermia coupled with PEMF (CTU – PERISO sa). In addition, the magnetic field works on the intracellular liquids, increasing their mobility. The increase of the thermal molecular excitation supports the cells biochemical activity as well as the mitochondrial and phagic-lysosomal metabolic mechanisms. The result is a beneficial acceleration of all energetic, metabolic and cellular activities like ionic transport, scoriae removal and cellular breathing.

Tissue biostimulation: a variable magnetic field crossing a conductor induces an electric current. The human body is a conductor, that when it is crossed by a magnetic field the phenomenon of biostimulation occurs. The action of magnetic fields is well described in terms of bioelectric parallelisms existing among cells (12b), since it acts on the difference of electric potential on the membrane sides as well as on the orientation af the circulating atoms that behave as elementary magnetic dipoles (13b, 14b).

Materials and Methods

This was prospective, randomized controlled study; total of 58 long-bone fracture patients, who presented with delayed union of between 16 weeks and 6 months, were randomly split into two groups and subjected to an early application of PEMF CTU – MEDICAL DEVICE – PERISO sa, or sham treatment. Clinical and radiological assessments were performed to evaluate the healing status. Treatment efficacy was assessed at three month intervals.

Study Selection Criteria

Types of Studies, Participants and Interventions Included

Once included in the study, the patient was blindly assigned into the PEMF treatment group (Group 1) or the control group (Group 2) according to randomly generated numbers. The treatment commenced immediately after enrollment.

- In Group 1, PEMF using a real (Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session).
- In Group 2, the coil was applied for 30min/day with a sham signal generator from the same manufacturer (Fig.2).

Therefore, patients were blinded to the treatment. Protected weight bearing was encouraged unless it compromised the stability of the fractured area. All patients were requested to record their potential discomfort and the duration of the treatment. They were also asked to refrain from smoking, alcohol abuse, or additional forms of therapy during the study period. Biweekly contact through phone calls was performed by two research assistants to exclude patients with poor compliance.

Exclusion Criteria

The exclusion criteria consisted of implant loosening or failure, infection, established

nonunion (healing failure after more than 9months, without any clinical or radiographic sign of progression to union within the last 3months) [20], a fracture gap greater than 5mm, and the presence of the implant within the fracture gap [11]. Before performing the treatments with PEMF CTU Medical Device – PERISO sa, all the patients received a clinical evaluation to detect:

- Unsuitable physiological states
- Presence of ferromagnetic material within the areas of the body to be treated.

In addition the Patients with metabolic disorders were excluded as were those patients who received medications that could affect fracture healing [18, 20]. Patients with Open Physis, terminal illnesses/malignancies, pregnancy or lack of contraception use in women of childbearing age, and use of pacemaker or any implanted electrical device were excluded, and ferromagnetic parts

BENEFIT/RISK

No Risks, Dangers, Adverse Reactions have been associated with the use of the CTU Medical Device – PERISO sa, even outside the protocols used. The CTU Medical Device PERISO sa, respects all CLINICAL SAFETY Standards.

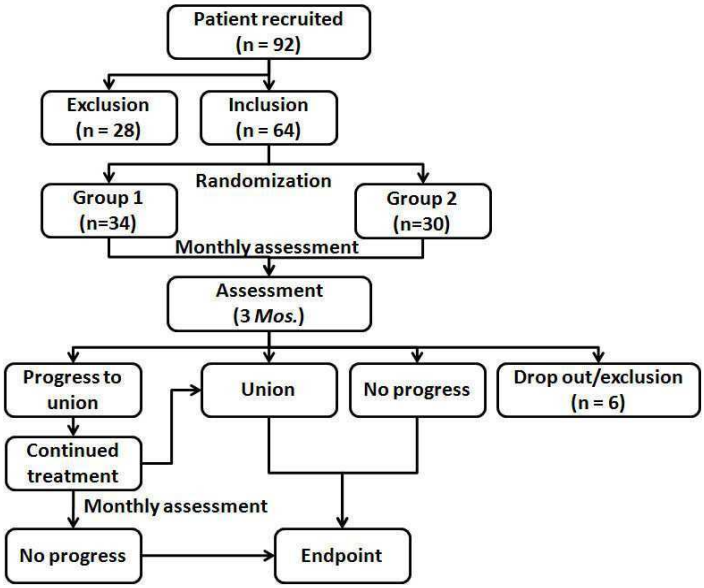
TYPES OF OUTCOME MEASURES

Clinical and radiological assessments were performed monthly following commencement of the treatment. Clinical evaluations of pain when stressed and motion at the fracture site were carried out by two senior surgeons independently, who were blinded to the grouping information. The consensus was derived from further discussion if necessary. Another two blinded surgeons reviewed the anteroposterior and lateral radiographs of the fracture to assess cortical bridging. Union was considered positive when there was no pain during joint stressing or during motion at the fracture site, and callus bridging was present for three out of four cortices on orthogonal radiographs [21]. Treatment was ceased in all patients when union was achieved or no radiographic progress to union was observed for a continuous three-month period (Figure1).

METHODS

Between April 2014 and September 2016, patients with postoperative delayed union of long-bone fracture were recruited from the outpatient clinic. A flowchart of the study is presented in Figure 1 (Fig. 1). During the baseline assessment, anteroposterior and lateral radiographs were taken to address the fracture healing status and the fixation method. Data on the demographic characteristics, co-morbidity, medication history, lifestyle habits, fracture type, soft tissue condition were collected, as was information on the surgery and postoperative rehabilitation. Delayed union was defined as a failure to heal after at least 16weeks and not more than 9months following surgical reduction and fixation of the fracture [12, 18]. Radiographically, healing failure was identified when callus bridging was not observed in more than three cortices on biplane radiographs.

Fig. 1
Flowchart of the study



The authors had intended to initiate intervention 16 weeks after fracture for each patient, but not all patients were referred to the clinic in time. Therefore, patients were included in the study if they were enrolled between 16 weeks and 6 months postoperatively. A power analysis was conducted to estimate the sample size, with reference to a previously reported randomized controlled trial that achieved a union rate of 89% in PEMF (CTU – PERISO sa) (Fig. 2) treated tibial nonunion cases compared with a 50% union rate in the sham-treated controls [13]. To detect the similar change in union rate with 80% power in our study, we required more than 48 patients

Fig. 2

Search Strategy

Medline, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched from the inception of each database to 05 September 2016. The Medline and Embase databases were searched together via www.embase.com. The search was conducted using the keywords tibial, union, non-union, delayed fractures, PEMF, radiographic evidence, bridging callus, tibial x-rays, and it was limited to RCTs (List 1). Additionally, all of the available reviews related to tibial fractures were manually screened for any additional possibly relevant studies. No language limit was applied.

List 1 Search Strategy used in www.embase.com (step by step):

1 'tibial' OR 'tibia'/exp
2 'Humerus'
3 'Ulna'
4 'Radius'
5 'Femur'
6 'union' OR 'union'/exp
7 'non-union' OR 'non-union'/exp
8 'nonunion' OR 'nonunion'/exp
9 #1 OR #2 OR #3 OR #4
10 fractures (7) #7 #5 AND #6
11 tibial union, nonunion/exp
12 #3 #4 OR #5 #6
13 random: ab,ti OR factorial: ab,ti OR crossver: ab,ti OR placebo :ab,ti OR control :ab,ti OR trial:ab,ti OR group: ab,ti OR 'crossover procedure'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'randomized controlled trial'/ex 3 #4 #5 AND #6 #7.

Statistic Analysis

Statistical Methods

Group demographics were compared using independent t-test or Fisher's exact test. The successful rate of fracture union was calculated after three months of treatment and at the end of the study in each group, with the difference between groups compared with Fisher's exact test. SPSS version 15.0 software (SPSS Inc, Chicago, IL) was used and the level of significance was set as 0.05.

Results

During the study period, 92 patients with delayed union were recruited, with 64 patients meeting our inclusion criteria for early PEMF or sham treatment initiated 16weeks and not more than 6months postoperatively (Figure1). Four patients dropped out after a short period of treatment, and another two patients, who received herbal supplements during the study, were excluded

	Treatment group	Control group	P Value
No. of patients	31	27	
Age (*Yr.*)*	41.1 ± 14.5 (range 19 to 68)	38.4 ± 11.6 (range 20 to 62)	0.450
Fracture Site (No. of patients)			0.439
Femur	10	14	
Tibia	16	9	
Humerus	3	2	
Radius and/or Ulna	2	2	
Methods of Fixation			0.430
Plate	18	12	
Intramedullary Nail	13	15	
Elapsed Time before Treatment (*Mo.*)*	4.8 ± 0.9 (range 4 to 6)	5.1 ± 0.8 (range 4 to 6)	0.238
Duration of Treatment (*Mo.*)*	4.8 ± 2.3 (range 2 to 12)	4.4 ± 1.6 (range 2 to 7)	0.489
Rate of fracture union (3 *Mo.*)	38.7%	22.2%	0.256
Rate of fracture union (Endpoint)	77.4%	48.1%	0.029
Total Time from Operation to Endpoint (*Mo.*)*	9.6 ± 2.3 (range 7 to 17)	9.5 ± 1.5 (range 7 to 12)	0.849

The remaining 58 patients were included for statistical analysis. Patient demographics (Table1) were comparable between the two groups, with no significant differences determined for patient age (P=0.450), fracture site (P=0.439), or method of fixation (P=0.430).

A total of 31 patients received PEMF CTU – MEDICAL DEVICE – PERISO sa treatment, while the remaining 27 cases were assigned to the control group (Table1). Before treatment, the average elapsed time since fracture operation were 4.8months and 5.1months in the two groups, respectively (P=0.238). Following three months of treatment, 12 cases achieved union with a success rate of 38.7% (95% confidence interval (CI), 0.21 to 0.57) in Group 1 (Figure3). Meanwhile, the fracture union success rate was 22.2% (6 out of 27, 95% CI, 0.08 to 0.42) for Group 2, which was slightly lower than that for Group 1 (P=0.256), but not statistically significant. The relative risk of fracture union was 1.74 (95% CI, 0.76 to 4.01). Radiographic progress to union was observed in 17 patients in each of the groups, who subsequently received extended PEMF or sham treatment. At the end of the study, the average lengths of treatment were 4.8months and 4.4months in the two groups (P=0.489), with a union rate of 77.4% (24 out of 31, 95% CI, 0.58 to 0.90) in Group 1 (Figure4) compared with a union rate of 48.1% (13 out of 27, 95% CI, 0.28 to 0.68) in Group 2 (P=0.029, Table1). The relative risk of fracture union was 1.61 (95% CI, 1.04 to 2.48). The total times from operation to the end of the study were averaged at 9.6months and 9.5months in Group 1 and Group 2 respectively (P=0.849). No discomfort was reported by the patients in either group during treatment.

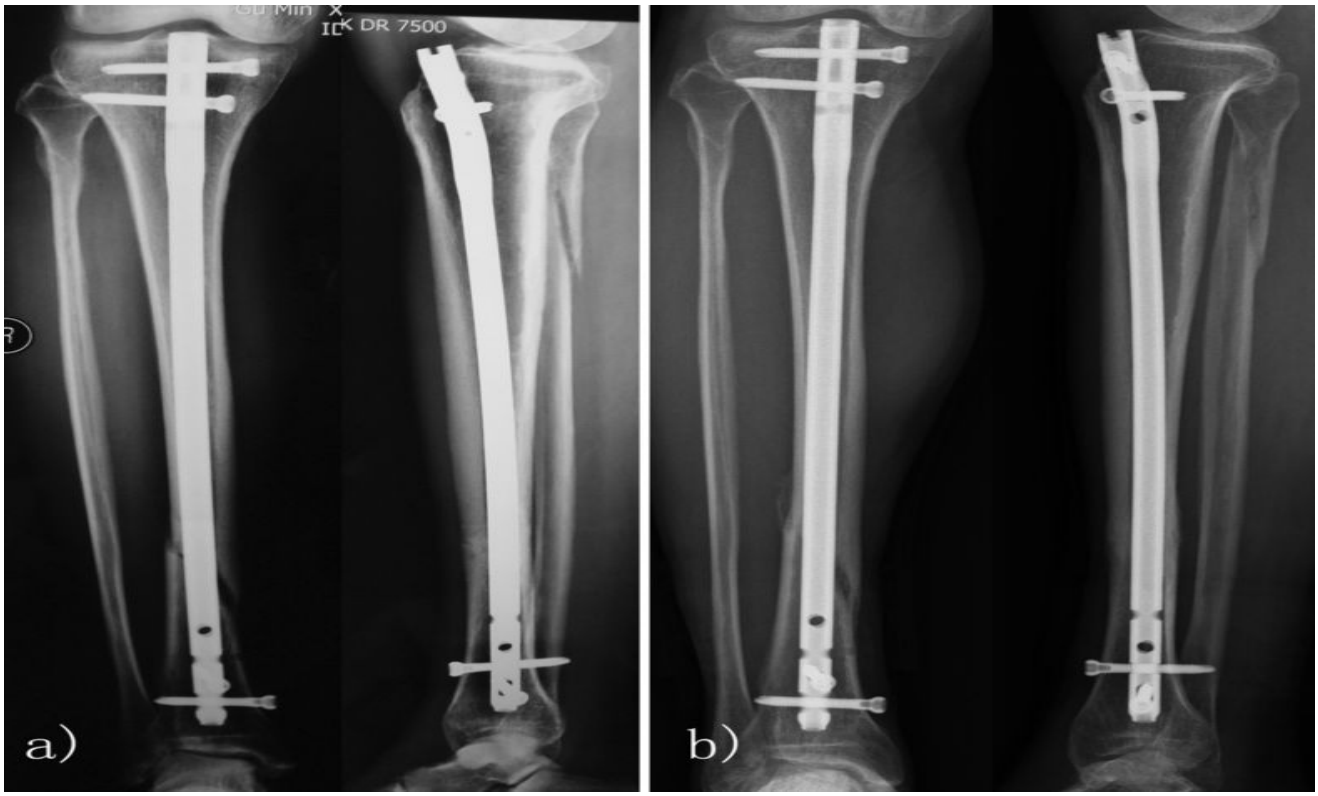


Figure 3
Delayed union of tibia fracture treated with PEMF. (**a**) A delayed union of tibia fracture was observed in a 65-year-old male patient following close reduction and intramedullary fixation 16weeks ago. PEMF treatment was initiated; (**b**) Fracture union was observed after 3months of treatment.

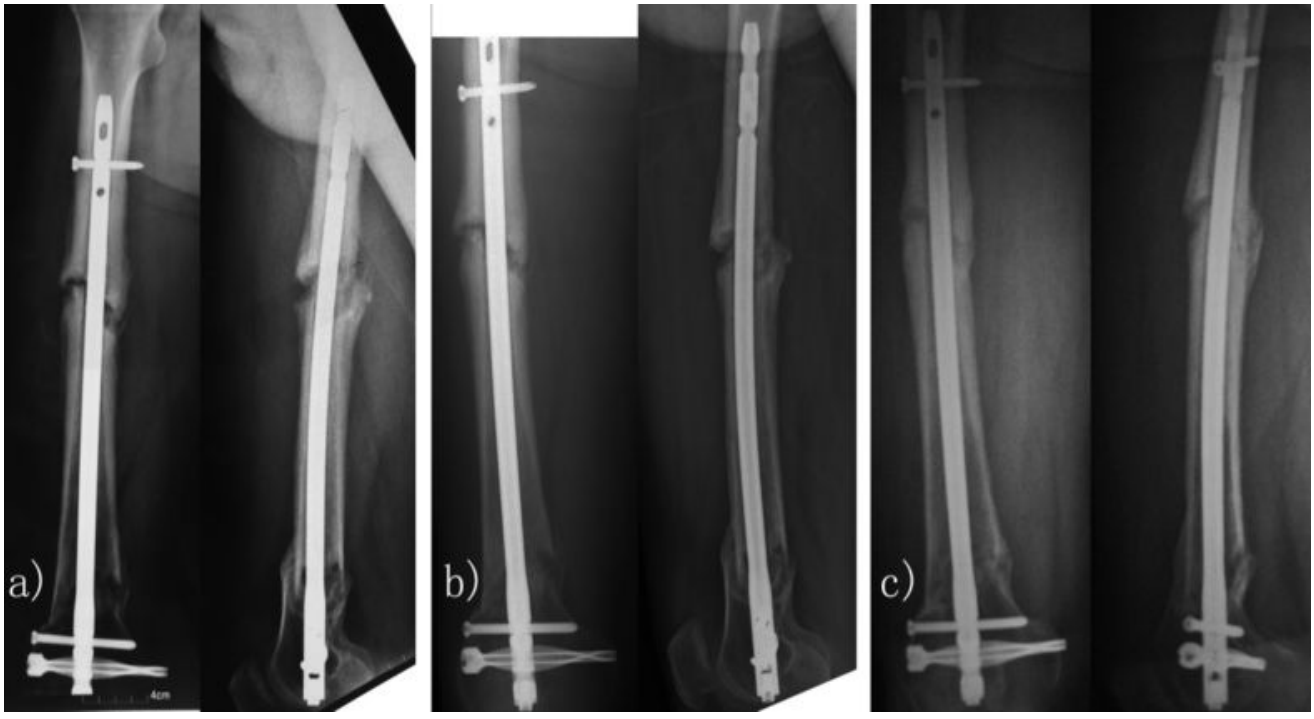


Figure 4
Delayed union of femoral fracture treated with PEMF. (**a**) PEMF treatment was started in a 59-year-old male patient who received reduction and intramedullary fixation 5months ago; (**b**) Radiographies showed progress to union following 3months of treatment; (**c**) Fracture united after 8months of treatment.

DISCUSSION

In this randomized controlled study, we investigated, for the first time, the clinical efficacy of the early application of PEMF CTU – MEDICAL DEVICE – PERISO sa treatment in postoperative delayed union of long-bone fractures. Following three months of PEMF treatment, patients showed a higher rate of union (38.7%) than the sham-treated patients (22.2%), but this difference failed to achieve statistical significance. At the end of the study, PEMF treatment, conducted for an average duration of 4.8months, led to a success rate of 77.4%, which is significantly higher than that in the control group (48.1%).

Clinically, the concepts and techniques surrounding the surgical management of long-bone fractures have evolved rapidly in recent decades. By comparison, the ensuing individual progress of fracture healing, in terms of biological and mechanical changes after surgery, has been poorly examined, despite the impaired healing rate of 5-10% in long-bone fracture patients. Among the multidisciplinary approaches explored to treat delayed union and nonunion fractures, the majority of studies employ the use of invasive procedures, such as surgical debridement, bone grafting and harvesting, or local injections [22, 23], and hence, these procedures have been primarily examined in established nonunions. For delayed unions, noninvasive interventions, such as PEMF, are preferred before further invasive procedures are considered [4, 24].

The original aim for this study was to instigate PEMF treatment immediately after the diagnosis of a postoperative delayed union (at 16weeks after fracture). In our opinion, an earlier intervention is likely to be more effective because of the potentially deteriorated state of the biological environment after 16weeks of delayed union or nonunion [25, 26]. However in most published trials, PEMF stimulation was deferred until 6months or later after fracture, with very few studies addressing the early application of PEMF in patients with delayed union. Sharrard conducted a randomized controlled trial with PEMF treatment initiated on patients with tibial delayed unions at 16 to 32weeks after fracture [18]. Although the results revealed a significantly higher rate of union than the control, the authors did not specify the information and outcomes pertaining to the patients who received earlier intervention. A case series by Bassett addressed the effect of PEMF on 125 cases of delayed union and nonunion [27], with the earliest intervention started at four months after fracture. However, here again, the author only presented the overall success rate of the patients treated with PEMF within the nine month study period, without clarifying the impact of an early application of PEMF treatment. Similarly, in a report by Colson, there was a lack of consideration of the early effects of PEMF amongst 33 cases of long-bone delayed union or nonunion with treatment commenced from 2 to 120months after fracture [28]. As such, our study provides pertinent evidence for the early application of PEMF on the delayed union of long-bone fractures.

The success rate following PEMF treatment in delayed union or nonunion varies dramatically (15.4–93.9%) across published studies due to different parametric settings and treatment strategies [28, 29]. Considering studies with more than 30 subjects enrolled for PEMF treatment (a total of 12 studies, as summarized by Griffin), the average success rate was 80.1% (ranging from 67.6% to 93.9%) [10]. Punt examined a case series on established nonunions and achieved a success rate of 76–79% [14]. These results are comparable with the final success rate in our study (77.4%), demonstrating the similar stimulative effect of PEMF on delayed union, despite its earlier application in the present study. Therefore, our “sooner rather than later” hypothesis did not necessarily prevail for the clinical efficacy of PEMF. A recent report by Adie on the negative effect of PEMF on acute tibial shaft fractures further supports this [30].

Considering the treatment duration, no significant difference was observed between the groups in our study. However, the total time from fracture surgery to the end of PEMF treatment was obviously shortened in our study (9.6months on average) compared with that in other studies who initiated PEMF stimulation after a postoperative window of 6months, or longer in some cases (over 17.1months in Heckman’s study, and 11.6months in de Haas’s study) [15, 16], not to mention the studies wherein PEMF treatment was applied in established nonunions. The early application of PEMF treatment, therefore, benefitted the

patients by reducing the fracture suffering time. In clinical practice, PEMF treatment for delayed unions should be considered and initiated as early as possible, making patients fully aware of the success rate but also the increased cost.
At present, a definitive reason for the occurrence of a delayed union remains far from conclusive [31]. Both systemic and local factors are believed to be involved [23, 32]. In our study, strict inclusion and exclusion criteria were set with reference to previously published clinical trials to rule out the interference of confounding variables such as metabolic disease, medication, smoking, alcohol abuse, infection, and unfavorable reduction or fixation from previous operations [11, 18, 20]. However, there were several factors constrained by practicality that may have influenced the outcome. For instance, the degree and extent of local damage caused by the accident or previous operation was difficult to trace. Further, patient activity levels, as a subject-related factor, could not be standardized during the study period, despite our recommendations for protected weight bearing. Another limitation of the present study was the relatively small numbers of patient for each fracture site or fixation method. We therefore could only draw an overall conclusion. Besides, serum biochemical markers were not measured in this study, which may potentially shed light on the biological mechanism of the early application of PEMF treatment.

Conclusion

In conclusion, within the limitations discussed above, the early application of PEMF CTU – MEDICAL DEVICE – PERISO sa treatment, promotes fracture healing and leads to a significantly increased rate of union compared with the sham treatment. Even though the final success rate in this study was not superior to that measured in other PEMF trials, we show that our patients benefitted from a reduced overall suffering time between fracture and repair.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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ANNEX 1

FORMATO EUROPEO PER IL CURRICULUM VITAE

INFORMAZIONI PERSONALI

Nome	Pietro Romeo
Indirizzo	Via E. Cernuschi 59 21100, VARESE (VA), ITALIA.
Telefono	(039) 0332.281099- 347.6651575
Fax	---
E-mail	romeo.p@libero.it
Nazionalità	Italiana
Data di nascita	05/11/1958

ESPERIENZA LAVORATIVA

• Date (da – a)

Aprile 2010 – oggi
Istituto Ortopedico Galeazzi – IRCCS – Via Riccardo Galeazzi 4, Milano.
Dipartimento di Clinica Ortopedica Università degli Studi Milano
(Direttore Prof. V. Sansone)
Dirigente Medico (Rapporto LP)

Ottobre 2004 - oggi
Eurocentro Polispecialistico – V.le Milano 18 - Varese
Convenzionato Servizio Sanitario Regione Lombardia
Specialista Ortopedico – Terapia con Onde d'Urto (Rapporto LP)

Da Aprile 2000 - Marzo 2015
INAIL – Istituto Nazionale Assicurazione Infortuni sul Lavoro
V.le Aguggiari, 6 . 21100 Varese
Specialista Ortopedico Convenzionato

Dal 1993 al 2000
Azienda Sanitaria Locale della Provincia di Varese- Via O. Rossi 9- Varese
Dirigente Medico - Organizzazione Servizi Sanitari di Base – Incarico in Ambulatorio Infortuni Traumatologia

Dal 1993 al 2000
Ministero di Grazia e Giustizia – Dipartimento dell'Amministrazione Penitenziaria- Casa Circondariale di Busto Arsizio (VA)
Specialista Ortopedico Convenzionato

1990
Azienda Sanitaria Locale della Provincia di Varese- Via O. Rossi 9- Varese
Ospedale Filippo Del Ponte
Assistente Medico Supplente – Chirurgia Generale (Incarico a Termine)

Dr. PIETRO ROMEO
MEDICO CHIRURGO
Specialista in Ortopedia e Traumatologia
Via E. Cernuschi, 59 - 21100 VARESE
Cod. Fiscale RMO PTR 58S05 L452X
Partita IVA 01227940122

Curriculum Vitae Dott.Pietro Romeo

	1990 Azienda Sanitaria Locale della Provincia di Varese- Via O. Rossi 9- Varese Igiene Pubblica Assistente Medico Supplente (Incarico a Termine)
• Nome e indirizzo del datore di lavoro	Dal 1988 al 1993 Ministero di Grazia e Giustizia – Dipartimento dell'Amministrazione Penitenziaria- Casa Circondariale di Busto Arsizio (VA) Medico del Servizio di Assistenza Sanitaria Integrativa
• Tipo di azienda o settore • Tipo di impiego • Principali mansioni e responsabilità	
ISTRUZIONE E FORMAZIONE • Date (da – a)	2008 Bologna – Scuola di Ecografia Muscolo Scheletrica Corso Avanzato 2006 e 2007 Bologna – Scuola di Ecografia Muscolo Scheletrica Corso Base 1992 Diploma di Specializzazione in Ortopedia e Traumatologia Università degli Studi di Milano 1984 Abilitazione Professionale Università degli Studi di Pavia 1984 Diploma di Laurea in Medicina e Chirurgia Università degli Studi di Pavia 1977 Diploma di Maturità Scientifica Liceo "F.lli Vianeo" Tropea (CZ)
• Nome e tipo di istituto di istruzione o formazione • Principali materie / abilità professionali oggetto dello studio • Qualifica conseguita • Livello nella classificazione nazionale (se pertinente)	

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CAPACITÀ E COMPETENZE ORGANIZZATIVE

ULTERIORI INFORMAZIONI

Affiliazione a società scientifiche
SIOT (Società Italiana Ortopedia e Traumatologia)
ASON (Associazione Specialisti Osteoarticolari Nazionale) – Referente regionale per la Lombardia biennio 2015-2017
SITOD (Società Italiana di Terapia con Onde d'Urto).
Componente del Consiglio Direttivo biennio 2008-2010, biennio 2010-2012 biennio 2012-2014 , biennio 2014-2016 , biennio 2016-2018
ISMST (International Society for Medical Shock Wave Treatment)

Il sottoscritto è a conoscenza che, ai sensi dell'art. 76 del DPR 445/2000, le dichiarazioni mendaci, la falsità negli atti e l'uso di atti falsi sono puniti ai sensi del codice penale e delle leggi speciali. Inoltre, il sottoscritto autorizza al trattamento dei dati personali, secondo quanto previsto dalla Legge 196/03.

CITTA' __Varese_____

DATA___07/08/2017 _____

NOME E COGNOME (FIRMA)

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Curriculum Vitae Dott. Pietro Romeo

CAPACITÀ E COMPETENZE PERSONALI

Acquisite nel corso della vita e della carriera ma non necessariamente riconosciute da certificati e diplomi ufficiali.

Italiano

Dal 1995 al 2016 interesse e competenze specifiche nel campo dell' Ortopedia applicata alla Medicina Legale quale consulente di compagnie assicurative (1995 – 2008) dell' Istituto Nazionale Assicurazione Infortuni sul Lavoro (INAIL) , consulente tecnico per la branca di Ortopedia presso il Tribunale di Varese sino al mese di ottobre 2015.

Dal 2004 interesse nella Terapia con Onde d'urto Extracorporee utilizzando apparecchiature focalizzate piezoelettrica ,elettromagnetica ed elettroidraulica . Esperto in trattamenti ecoguidati ed eco-assistiti *manu medica*, per il trattamento delle principali patologie muscolo scheletriche, inclusi i ritardi di consolidazione delle fratture , la patologia vascolare e metabolica dell'osso le osteocondropatie e il trattamento delle ulcere cutanee . Dal 2010 attività di ricerca clinica e sperimentale presso il Dipartimento di Ortopedia e Traumatologia dell'Università degli Studi di Milano dell' Istituto Ortopedico Galeazzi (Direttore prof V. Sansone) che riguardano l'impiego delle energie fisiche nella patologia metabolica , degenerativa e vascolare dell'osso , gli effetti su colture di cellulari (Centro di Ricerca Applicata sulla Stimolazione Biofisica dei Tessuti Muscolo-Scheletrici)

Coautore di pubblicazioni in materia su riveste nazionali e internazionali indicizzate . Relatore – moderatore in congressi e corsi di formazione

PRIMA LINGUA Italiano

ALTRE LINGUE

Inglese

- Capacità di lettura: Buona
- Capacità di scrittura: Buona
- Capacità di espressione orale: Discreta

CAPACITÀ E COMPETENZE RELAZIONALI

Vivere e lavorare con altre persone, in ambiente multiculturale, occupando posti in cui la comunicazione è importante e in situazioni in cui è essenziale lavorare in squadra (ad es. cultura e sport), ecc.

Ha maturato negli anni capacità di lavoro individuale e in equipe

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Partita IVA [illegible]

2012 TORINO XI CONGRESSO NAZIONALE SOCIETA' ITALIANA TERAPIA CON ONDE D'URTO EXTRACORPOREE (SITOD)
P. Romeo. La terapia con onde d'urto extracorporee. L'Operatore. Figure professionali coinvolte e specificità operative

2012 TORINO XI CONGRESSO NAZIONALE SOCIETA' ITALIANA TERAPIA CON ONDE D'URTO EXTRACORPOREE (SITOD) CONVEGNO SATELLITE: LE ONDE D'URTO IN PATOLOGIA ORTOPEDICA
P. Romeo. La Terapia con Onde d'Urto. Indicazioni Controindicazioni Aspetti Medico Legali.

2012 – ROMA 4° CONGRESSO NAZIONALE C.O.R.T.E
P. Romeo – MC D'Agostino, Onde d'Urto e Rigenerazione tissutale, il ruolo dell'Angiogenesi

2012- INNSBRUCK 2nd ISMST Basic Research Meeting
MC D'Agostino. P. Romeo. Early angiogenic response to shock waves in a three – dimensional model of microvascular endothelial cell culture (HMEC-1)

2011 - SANTA MERGHERITA LIGURE (GE) INDICAZIONI E LIMITI DELLA TERAPIA CON ONDE D'URTO: DAL MEDICO DI MEDICINA GENERALE ALLO SPECIALISTA.
- P. Romeo. Indicazioni Controindicazioni e modalità di somministrazione della terapia con onde d'urto. Linee guida

2011 VARESE AGGIORNAMENTO DEL MEDICO DI MEDICINA GENERALE
- L'Edema Osseo Midollare nelle patologie Osteoarticolare. Aspetti prognostici e Terapeutici

2011 BERGAMO TERAPIA CON ONDE D'URTO: DALLA RICERCA ALLA PRATICA CLINICA. INDICAZIONI
- P. Romeo Effetti Biologici delle Onde d'Urto Extracorporee. I Meccanismi della risposta cellulare.

2010/2011 MILANO – I CORSO AVANZATO SULL'UTILIZZO DELLE ONDE D'URTO EXTRACORPOREE IN ORTOPEDIA-FISIATRIA E MEDICINA RIGENERATIVA

-P. Romeo, V. Sansone Effetti Biologici della Stimolazione con Onde d'Urto. I meccanismi dell'azione terapeutica.
-P. Buselli, P. Romeo. Aspetti Medico Legali delle Terapia e raccolta del consenso informato.
- P. Romeo, V. Sansone. Onde d'Urto extracorporee e patologie vascolari dell'osso. Il razionale terapeutico
-P. Romeo, V. Sansone Le Onde d'Urto nella patologa dell'Achilleo. Dalla biologia alla pratica clinica.

2010 BARI. X CONGRESSO NAZIONALE SOCIETA' ITALIANA TERAPIA CON ONDE D'URTO EXTRACORPOREE (SITOD)
- P. Romeo, Indicazioni Controindicazioni, Utilità, Inutilità nelle applicazioni cliniche (o routinarie) delle onde d'urto focalizzate.

2010 SANTA MARGHERITA LIGURE (GE) NUOVE FRONTIERE NEL TRATTAMENTO DELLE PATOLOGIE ORTOPEDICHE CON ONDE D'URTO ED INGEGNERIA TISSUTALE ON LINE
- P. Romeo. V. Sansone. M.C. D'Agostino Onde d'Urto e Angiogenesi, Considerazioni clinico sperimentali.

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TREATMENT OF POSTOPERATIVE DELAYED UNIONS OF LONG-BONE FRACTURES:

A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

2010 VIENNA 1 th ISMST (International Society for Medical Shock Waves Treatments) BASIC RESEARCH MEETING
M.C. D'Agostino – P. Romeo. Osteogenesis and Bone Turnover

2009 CAMPOBASSO XXXVII SIMFER. SOCIETA' ITALIANA MEDICINA FISICA E RIABILITAZIONE
M. C. D'Agostino, P. Romeo. V. Sansone
Onde d'Urto Extracorporee dalla litotripsia alla rigenerazione tissutale. Sessione Poster

2007 VII CONGRESSO NAZIONALE SOCIETA' ITALIANA TERAPIA CON ONDE D'URTO EXTRACORPOREE (SITOD)
L. Polo – P. Romeo
Effetti secondari e applicazioni "off label "delle Onde d'urto. Sperimentazione e aspetti Medico Legali

Varese 07/08/2017

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