PULSED ELECTROMAGNETIC FIELDS "PEMF" CTU – MEDICAL DEVICE PERISO sa, for the TREATMENT OF THE

Abstract

PATIENTS WITH ACUTE ANKLE INJURIES

Background:

Ankle Sprain is a common problem in acute medical care and it is characterized by PAIN, intermitted swelling mechanical instability and stiffness.

Study Objective:

the purpose of this study was to evaluate the efficacy of PEMF (Pulsed Electromagnetic Field, CTU Medical Device - Periso sa) for the treatment of **Edema**, **Range of Motion (ROM)**, and **Pain** in patients with **ACUTE ANKLE INJURIES**.

Methods:

patients aged 18 years and older with unilateral ankle sprains were randomly assigned either to a PEMF treatment study group or a control group. Independent outcome variables included **EDEMA, RANGE OF MOTION (ROM),** and PAIN. Both groups received the current standard of care for ankle sprains and were instructed to return for a follow-up examination. Patients in the PEMF study group also received one session of treatment.

Results

patients in the PEMF study group had a statistically significant (F = 5.92, P = 0.02) improvement in EDEMA and pain and a trend toward increased ROM immediately following intervention with PEMF. Although at follow-up both study groups demonstrated significant improvement, patients in the PEMF study group had a statistically significant improvement in ROM when compared with patients in the control group.

Search strategy:

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

Conclusions:

data clearly demonstrate that a single session of PEMF can have a significant effect in the management of acute ankle injuries.

Keywords:

ankle, sprain, injuries, acute trauma, PEMF, radiographic evidence, ankle x-rays. No language limit was applied.

MD. Pietro Romeo (Annex







Introduction

Ankle sprain is an injury of the lateral ligament complex of the ankle joint. The injury is graded on the basis of severity. Grade 1 is a mild stretching of the ligament complex without joint instability; grade 2 is a partial rupture of the ligament complex with mild instability of the joint (such as isolated rupture of the anterior talofibular ligament); and grade 3 involves complete rupture of the ligament complex with instability of the joint. This gradation has limited practical consequences because both grade 2 and 3 injuries are treated similarly, and grade 1 injuries need no specific treatment after diagnosis.

Ankle sprain is a common problem in acute medical care, occurring at a rate of about one injury per 10,000 people per day. Injuries of the lateral ligament complex of the ankle form a quarter of all sports injuries. The usual mechanism of injury is inversion and adduction (usually referred to as supination) of the plantar flexed foot. Predisposing factors are a history of ankle sprains, ligament hyperlaxity syndrome, and specific mal-alignment, such as crus varum and pes cavo-varus. Some sports (e.g., basketball, football/soccer, volleyball) are associated with a particularly high incidence of ankle injuries. Pain and intermittent swelling are the most frequent residual problems, often localized on the lateral side of the ankle. Other residual complaints include mechanical instability and stiffness. People with more extensive cartilage damage have a higher incidence of residual complaints. In the long term, the initial traumatic cartilage damage can lead to degenerative changes, especially if there is persistent or recurrent instability. Every further sprain has the potential to add new damage. The current standard of care for acute ankle sprains includes resting the ankle, cryotherapy, compression dressings, elevation of the affected ankle, analgesia (specifically, nonsteroidal anti-inflammatory drugs [NSAIDs]), and early mobilization

Despite this current practice, 25% to 40% of ankle sprains are associated with recurrent injury or prolonged disability. The primary objective of this study was to evaluate quantitatively the effect of PEMF on patients with acute ankle injuries. The specific aim of this study was to assess the immediate effects of a single session of PEMF, as well as determining what additional benefit patients may receive when PEMF is added to the current standard of care for acute ankle sprains.

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 (Fig. 1), 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).

Fig. 1









SEARCH STRATEGY

Medline, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched from the inception of each database to 18 January 2013 The Medline and Embase databases were searched together via www.embase.com

The search was conducted using the keywords ankle, sprain, injuries, acute trauma, PEMF, radiographic evidence, ankle x-rays. No language limit was applied.

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

- 1 'ankle' OR 'tibia'/exp
- 2 'sprain' OR 'sprain'/exp
- 3 'injuries' OR 'injuries'/exp
- 4 'ankle x-rays' OR 'ankle x-rays'/exp
- 5 'fractures' OR 'fractures'/exp
- 6 #1 OR #2 OR #3 OR #4 OR #5

7 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'/exp 2 #3 #4 AND #5.

MATERIALS AND **M**ETHODS

This is a prospective, randomized, controlled, nonconsecutive clinical trial of adult patients presenting acute ankle injury.

STUDY SELECTION CRITERIA

Types of Studies, Participants and Interventions Included

Patients with an ED diagnosis of acute unilateral first or second degree ankle sprain by ED history, physical examination, and radiographic interpretation were considered for study inclusion.

The ED presentation was maintained in our intention-to-treat analysis. After providing informed consent for participation in the study, patients were randomly assigned as subjects in either the PEMF study group or in the control group.

The treatment commenced immediately after enrollment.

- Group 1: patients treated with PEMF (Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session).

 The Pulsed Electromagnetic Field was delivered through a coil centered over the injured ankle site.
- Group 2: control group

EXCLUSION CRITERIA

Patients were excluded if they were younger than 18 years, had a positive ankle drawer test (indicating ankle instability and a third-degree sprain), had a chronic ankle injury on the contralateral side, or if they were drunk or otherwise had an altered mental status when presenting to the ED. If the official radiographic interpretation was significant for a fracture missed by the ED physician, the patient was removed from the follow-up analysis. 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.

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

Patients in both groups were evaluated for **Edema**, **Range of Motion** (**ROM**), and **Pain**. Edema was measured in centimeters as the maximal circumference about the medial and lateral malleoli and was compared with measurements taken of the uninjured ankle (i.e., delta circumference). Using a goniometer placed at the lateral malleolus with the approximate axis of motion at an imaginary line between the medial and lateral malleoli, investigators measured patients ROM as the degrees of motion from full, patient-active plantar flexion to dorsiflexion. Investigators compared these results with the same measurement in the uninjured ankle (i.e., delta range). Patients were then asked to quantify their pain using a 1 to 10 visual analog pain scale.

METHODS

Patients in both groups received the current standard of care for acute ankle sprains: RICE therapy (Rest, Ice, Compression, Elevate). Patients were advised to rest and ice the ankle for 20-minute intervals.

Patients' injured ankles were then placed in a Jones compression dressing (i.e., alternating layers of elastic bandages and compression bandages) and they were instructed to elevate the ankle.

Patients were also instructed on the safe and proper use of crutches. Each patient was further instructed to return in 5 to 7 days for a follow-up examination.

At follow-up, a research assistant repeated the aforementioned measurements on the sprained and on the uninjured ankle.

Patients were offered continued follow-up in the outpatient clinics.

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. In Group 1, the patients received a PEMF treatment commenced immediately after enrollment.

Immediately following the treatment session, the sprained ankle was reevaluated for Edema, ROM, and Pain.

STATISTIC **A**NALISY

STATISTICAL METHODS

This study used repeated observations of each patient in the PEMF study group and in the control group. Observations were made on both the injured ankle and on the uninjured ankle. In this study, several analyses were used: (1) a 2-way repeated analysis of variance (ANOVA) was used with each measure; (2) repeated measures analysis of covariance to determine whether use of the uninjured ankle as a covariate would improve the analysis; and (3) repeated measures ANOVA and the Student t test on the PEMF study group to assess the immediate

Another way of adjusting for initial difference is to use percentages using the normal, uninjured ankle as the denominator.

This procedure has been used in analogous studies.

The covariance analyses were conducted with these percentages as well.

effectiveness of the additional intervention (i.e., the PEMF session).







Characteristic	Treatment, No. (%) (n = 28)	Control, No. (%) (n = 27)	P
✓ Age, y	29.9 ± 9.8	32.8 ± 13.3	
✓ Sex # Male # Female	11 (39) 17 (61)	10 (37) 17 (63)	
Race or ethnicity# Caucasoid	28 (100)	27 (100)	
Baseline Outcome Variable ✓ Edema (cm) # Delta circumference:	26.95 ± 2.5 2.07 ± 1.3	26.83 ± 1.8 1.67 ± 0.8	0.15
injured-contralateral (degrees) ✓ Range of motion (degrees) # Delta range: injured-contralateral (degrees)	2.07 ± 1.3 28.21 ± 19.9 -31.24 ± 12.4	1.67 ± 0.8 22.41 ± 13.3 -28.85 ± 16.1	0.15
✓ Pain scale (1 to 10)‡	6.50 ± 2	7.25 ± 2.5	0.22

RESULTS

A total of 55 patients were enrolled in this study: 28 in the PEMF study group and 27 in the control group. The mean age was 31 years, and 62% of participants were women. Table 1 summarizes the demographic characteristics of the patient population for this study and outlines the means for each observation and outcome measure. There were no statistically significant differences between the delta ankle circumference (as a measure to evaluate Edema), mean ROM, or the patients' subjective evaluations of their levels of pain at the baseline measure.

Results of a single session of PEMF provided in an ED are presented in Tables 1 through 3. To assess the effectiveness of PEMF in this setting, Student t tests were conducted on the means of each measure between the initial sprain and after PEMF was provided (Table 2) and subsequently at 1-week follow- up (Table 3).

The repeated ANOVA for each of the measures yielded a significant within-subjects effect, indicating that one PEMF intervention session was effective with respect to reducing edema and pain. Although there was a trend in improved PEMF (11 degrees), this finding was not statistically significant. Similar results were found in the analyses of the percentages, except that a significant interaction was found for ROM (F = 5.92, P = 0.02). Analyses run with the uninjured ankle as a covariate did not change these findings. Seventy-three percent of the patients enrolled returned for follow-up evaluation. The 15 patients lost to follow-up did not differ with regard to baseline characteristics. All patients had a statistically significant improvement in all three outcome measures at follow-up. Comparison of the two study groups at follow-up revealed a statistically significant improvement in ROM in the group that received PEMF in addition to the current standard of care for acute ankle sprains.







Table 2 PEMF: Outcome Measures Before and After One Session in Emergency Department, N = 28*					
Variable	Before Treatment	AfterTreatment	P		
✓ Edema (cm) # Delta circumference:	26.95 ± 2.5	24.79 ± 1.2			
injured-contra lateral (cm)	2.57 ± 1.3	0.81 ± 1.0	<0.001		
✓ Range of motion (degrees)# Delta range:	28.21 ± 19.9	43.23 ± 10.3			
injured-contra lateral (degrees)	-31.24 ± 12.4	-16.22 ± 27.7	0.08		
✓ Pain scale (1 to 10)†	6.50 ± 2	2.1 ± 1.7	<0.001		
* All values are expressed as mean \pm SD for continuous variables. † Patients were asked to quantify their pain using a 1 to 10 visual analog pain scale.					

DISCUSSION

An ankle sprain is a traumatic, ligamentous injury at the level of the ankle mortise. Three levels of ankle sprain severity are commonly described. Multiple studies have confirmed that the majority of ankle sprains occur from a foot inversion mechanism, with as many as 85% of inversion injuries causing isolated anterior talofibular ligament tears. The second most commonly affected structure is the calcaneofibular ligament at the fibular origin most often an accompanying injury to an anterior talofibular ligament sprain. The traumatic vector of force occurs with ankle inversion, internal rotation, and plantar flexion of the foot relative to the leg. This force exceeds the ROM of the lateral ligaments and results in injury to them. For clinicians treating patients with such injuries, two general treatment goals exist: the restoration of functional anatomy and a decrease in Edema. When these goals are accomplished, an increased ROM and patient comfort will follow. Additionally, restoring functional anatomy will allow for easier drainage of excess fluids, or Edema. It is important to reduce the accumulation of fluids surrounding the injury because fluid around the joint increases pain. Obviously, the more pain a patient has, the less likely he or she is to attempt mobilization. Also, tissue swelling increases the likelihood of adhesions that can delay healing and decrease ROM. Simko et al state that the recovery rate for ankle function following an inversion sprain may be related to the effectiveness of edema control at the injury site. Fluids must be mobilized back into the lymphatic system for optimal healing to occur. Our results imply that there is both an immediate advantage and a delayed benefit to adding PEMF in the acute care setting of ankle injuries. After a brief PEMF session in the ED, patients will have a significant reduction in swelling and, consequently a reduction in their level of pain. Patients who receive PEMF as an adjunct to traditional pain management will have greater ROM.

In addition, other studies involving PEMF have used sham treatments. Our study design did not include such a placebo control. In the design phase of the trial, we decided that the PEMF session would be tested against what is currently practiced in the ED.

Finally, we report preliminary data regarding the immediate and short-term impact of PEMF in ED patients with acute ankle injury.

Conclusion

The results of our study indicate statistically significant reductions in edema and pain and a trend toward increased ROM immediately following one PEMF intervention session.







Although both groups had significant improvement at follow-up, the PEMF study group had a statistically significant improvement in ROM when compared with the control group. The efficacy of PEMF has been demonstrated in multiple settings. Our data clearly demonstrate that a single session of PEMF in the ED can have a significant effect on the management of acute ankle injuries. Future research should include the investigation of the role of PEMF as provided in the ED in long-term outcome measures, including prevention of recurrent injury and long- term disability.

Table 3 One-Week Follow Up: Outcome Measures for Patients Who Received PEMF CTU - PERISO sa, Treatment and Control Subjects, N = 40*						
Variable	Treatment (n = 20)†	Control (n = 20)†	P			
✓ Edema (cm)# Delta circumference:injured-contra lateral (cm)	25.75 ± 2.0 0.77 ± 1.1	25.45 ± 1.9 0.57 ± 1.0	0.48			
✓ Range of motion (degrees)# Delta range:injured-contra lateral (degree	42.5 ± 14.4 s) -5.25 ± 8.8	39.0 ± 15.4 -13.5 ± 12.4	0.01			
✓ Pain scale (1 to 10)‡	3.15 ± 1.4	3.5 ± 2.8	0.61			
* All values are expressed as mean ± SD for continuous variables. † Fifteen patients (27%) were lost to follow-up. The 8 patients in the treatment group and the 7 patients in the control group did not differ with regard to baseline characteristics. ‡ Patients were asked to quantify their pain using a 1 to 10 visual analog pain scale.						

CONFLICTS OF INTEREST

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

Confidentiality Warning

All the data and information in this documents are reserved and under Confidentiality Warning. You are hereby notified that any dissemination, copy or distribution of this information is prohibited without the prior written consent of PERISO sa Swiss Company.

References:

- 1. Wedmore IS, Charette J. Emergency department evaluation and treatment of ankle and foot injuries [review]. *Emerg Med Clin North Am.* 2000;18:85-113,vi.
- $\textbf{2.}\ \ Packer GJ, Goring CC, Gayner AD, Crax ford AD. Audit of ankle in juries in an accident and emergency department. \textit{BMJ}. 1991; 302:885-887.$
- **3.** Birrer RB, Fani-Salek MH, Totten VY, Herman LM, Politi V. Managing ankle injuries in the emergency department [review]. *J Emerg Med.* 1999;17:651-660.
- **4.** Wilkerson GB, Horn-Kingery HM. Treatment of the inversion ankle sprain: comparison of different modes of compression and cryotherapy. *J Orthop Sports Phys Ther.* 1993;17:240-246.
- **5.** Higgins G. Towards evidence based emergency medicine: best BETs from the Manchester Royal Infirmary. Mobilisation of lateral ligament ankle sprains. *J Accid Emerg Med*. 1999;16:217-218.
- **6.** MascaroTB,SwansonLE.Rehabilitationofthefootandankle[review]. *Orthop Clin North Am.* 1994;25:147-160.







- 7. de BieRA, de VetHC, van den Wildenberg FA, Lenssen T, Knipschild PG. The prognosis of ankle sprains. Int J Sports Med. 1997;18:285-289.
- **8.** Han KH, Muwanga CL. The incidence of recurrent soft tissue ankle injuries. *Br J Clin Pract*. 1990;44:609-611.
- 9. Blood SD. Treatment of the sprained ankle. JAm Osteopath Assoc. 1980;79:680-692.
- $\textbf{10.} \ \ Pennington GM, Danley DL, Sumko MH, Bucknell A, Nelson JH. Pulsed, non-thermal, high-frequency electromagnetic energy (DIAPULSE) in the treat-ment of grade II and grade II ankle sprains. \\ \textit{MilMed.} 1993;158:101-104.$
- **11.** Diebschlag W, Nocker W, Bullingham R. A double-blind study of the efficacy of topical ketorolac tromethamine gel in the treatment of ankle sprain, in comparison toplace bo and et of enamate. *J Clin Pharmacol*. 1990;30:82-89.
- 12. Kaufman D, Leung J. Evaluation of the patient with extremity trauma: an evidence based approach. Emerg Med Clin North Am. 1999;17:77-95 viii
- 13. Hamilton WC. Injuries of the ankle and foot [review]. Emerg Med Clin North Am. 1984;2:361-389.
- **14.** Vitale TD, Fallat LM. Lateral ankle sprains: evaluation and treatment [published correction appears in *J Foot Surg.* 1988;27:315]. *J Foot Surg.* 1988;27:248-258.
- 15. Fallat L, Grimm DJ, Saracco JA. Sprained ankle syndrome: prevalence and analysis of 639 acutein juries. J Foot Ankle Surg. 1998;37:280-285.
- Simko M, Deslarzes C, Andrieu R. Hydrostatic pressure therapy in the treat- ment of edema [in French]. Rev Med Suisse Romande. 1987;107:935-939.
- 17. Haren K, Backman C, Wiberg M. Effect of manual lymph drainage as described by Vodder on oedema of the hand after fracture of the distal radius: a prospective clinical study. Scand J Plast Reconstr Surg Hand Surg. 2000; 34:367-372.

DEVICE REFERENCES

1b Rubik B.: Bioelectromagnetics & the Future of Medicine.

Administrative Radiology Journal, 16, 8, 1997, pp. 38-46.

2b Bassett C.A.: Fundamental and Practical Aspects of Therapeutic Uses of Pulsed Electromagnetic Fields (PEMFs). Critical Reviews in Biomedical Engineering, 17, 5, 1989, pp. 451-529.

3b Bassett C.A.L.: Beneficial Effects of Electromagnetic Fields.

Journal of Cellular Biochemistry, 51, 1993, pp. 387-393.

4b Heckman J.D., Ingram A.J., Loyd R.D., Luck J.V. Jr., Mayer P.W.: *Nonunion Treatment with Pulsed Electromagnetic Fields*. Clinical Orthopaedics and Related Research, 161, 1981, pp. 58-66.

5b Hulme J., Robinson V., DeBie R., Wells G., Judd M., Tugwell P.: *Electromagnetic Fields for the Treatment of Osteoarthritis*. (Cochrane Review), Cochrane Library, 3, Oxford, Update Software, 2002.

6b Luben R.A.: Effects of Low-energy Electromagnetic Fields (pulsed and DC) on Membrane Signal Transduction Processes in Biological Systems. Health Physics, 61, 1, 1991, pp. 15-28.

7b Ichioka S., Minegishi M., Iwasaka M., Shibata M., Nakatsuka T., Harii K., Kamiya A., Ueno S.: *High-intensity static magnetic fields modulate skin microcirculation and temperature in vivo.* Bioelectromagnetics JID - 8008281 21: 183-188, 2000.

8b Rubik B., Becker R.O., Flower R.G., Hazlewood C.F., Liboff A.R., Walleczek J.: *Bioelectromagnetics: Applications in medicine*. In: B.M. Berman, D.B. Larson, *et al.*, "Alternative Medicine, Expanding Medical Horizons", NIH Publication No. 94-066, Washington, DC, US Government Printing Office, 1994.

9b Glazer P.A., Heilmann M.R., Lotz J.C., Bradford D.S.: *Use of Electromagnetic Fields in a Spinal Fusion: A Rabbit Model*. Spine, 22, 1997, pp. 2351-2356.

10b Stiller M.J., Pak G.H., Shupack J.L., Thaler S., Kenny C., Jondreau L.: A portable pulsed electromagnetic field (PEMF) device to enhance healing of recalcitrant venous ulcers: a double-blind, placebo-controlled clinical trial. Br. J. Dermatol. 127: 147-154, 1992.

11b Wilson D.H., Jagadeesh P.: Experimental Regeneration in Peripheral Nerves and the Spinal Cord in Laboratory Animals Exposed to a Pulsed Electromagnetic Field. Paraplegia, 14, 1976, pp. 12-20.

12b Miller J.A. *et al.*: *Control of extracellular fluid volume and the pathophisiology of edema formation.* Philadelphia, Saunders, 2000, pp. 795-865.







Pagina 10 di 16

13b Yen-Patton G.P., Patton W.F., Beer D.M. et al.: Endothelial cell response to pulsed electromagnetic fields: stimulation of growth rate and angiogenesis in vitro. J. Cell. Physiol., 1988; 134: 37-39.

14b Pacini S., Gulisano M., Peruzzi B., Sgambati E., Gheri G., Gheri B.S., Vannucchi S., Polli G., Ruggiero M.: *Effects of 0.2 T static magnetic field on human skin fibroblasts.* Cancer Detect. Prev., 27: 327-332, 2003.

DATE: 21/02/2018

SIGNATURE: MD Pietro Romeo

Or. PIETRO ROBBEO

MEDICO CHIRURGO

Specialiste in Orionedia a Traumatologia:
via Cernusciu, 59 - 21100 VARESE.

Codice Piscale RMO PTR 5850S L/182X

Pantia IVX. 31727940122







ANNEX 1

FORMATO EUROPEO PER IL CURRICULUM



INFORMAZIONI PERSONALI

Nome Pietro Romeo

Indirizzo Via E. Cernuschi 59

21100, VARESE (VA), ITALIA.

(039) 0332.281099-347.6651575 Telefono

Fax

E-mail romeo.p@libero.it

Nazionalità Italiana Data di nascita 05/11/1958

ESPERIENZA LAVORATIVA

Aprile 2010 - oggi Date (da − a)

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)

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.Ili 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)

Dr. PIETRO RCHMEC

MEDIC CHRUNGO

Specialish er ar faller av 1700 vare
Collice Fiscale Millo PTR 58SD5 Lat.

Partita IVA. 01727340122

Curriculum Vitae Dott.Pietro Romeo







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	07/09/2017	

NOME E COGNOME (FIRMA)

Dr. PIETRO ROMEO MEDICO CHIRURGO MEDICO CHIRUMGO
Specialiste in Orionecia a Trasmatologic
via Cernusciu, 59 - 21100 VARESE.
Codice Piscale RMO PTR 58505 L452X
Panita IVA, 31727940122

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 piezoelettrica ,elettromagnetica apparecchiature focalizzate 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 **ALTRE LINGUE**

Italiano

Inglese Buona

 Capacità di lettura · Capacità di scrittura

· Capacità di espressione

Buona

Discreta

orale

Ha maturato negli anni capacità di lavoro individuale e in equipe

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.

Or PIETRO ROMEO MEDICO CHIRLIRGO specialisto in Originació a Traumatologo. ria Cemuschi, 59 adice Fiscale RIAD 1100 VARES

Curriculum Vitae Dott.Pietro Romeo









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.

DI. PIETRO REMISCO
MEDICO CHIROROD
Socialiste in Organicia a Traumatoko
Via Cernuscrii, 59 - 21100 VARE I.
Control Fiscale RMO PTR 58505146.
Partita IVA. 31727940122







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

Or PIETRO ROMEO

MEDICO CHIRURGO

Specialista in Oroniecta a Traumatologii.
Via Cemuschi, 59 - 21100 VARESI.
Codice Fiscale RMO PTR 58305 L452X.
Parlita IVA, 21727940122





