Ossatec
Bone Growth Stimulator
Clinical Data

Clinical Description

Ossatec Clinical Evaluation/Study

IC-Type Electric stimulation for delayed bone healing: monocentric evaluation over eight years of experience.

Type of study: Monocentric Retrospective Study **No of patients:** 294

Objective

An important complication of fracture healing includes delayed union, defined in this study as inadequate or absent radiographic healing 3 months after the injury, with an incidence as high as 5 to 10%. The etiology of poor bone healing is often multifactorial and includes both patient dependent as well as external factors). The impact of a delayed union should not be underestimated as it can lead to a persistent loss of limb functionality, an inability to attain previous professional or sporting tasks, as well as have an economic impact on social healthcare systems.

Methods

Patients who received IC electrostimulation since 2011 over an 8-year period at our department were screened. Electrostimulation was applied with the use of the commercially available Ossatec device (Ossatechnics BV, Uden, The Netherlands).

Results

Our results showed a significant reduction in pain and increase in patient reported activity levels after electrostimulation. Although these finding are linked with fracture healing, 30% of patients with persistent delayed union reported a reduction of pain.

Conclusion

Our study confirms the results of prior publications that electrostimulation has a beneficial effect on the healing of delayed unions, whether after initial fracture treatment or osteotomies, and can thus lower the incidence of revision surgery. In addition, our results suggest the therapy can be used for all sexes, age groups and fracture locations.

References

1. Bhandari M, Guyatt GH, Swiontkowski MF, Tornetta P, Srpague S, Schemitsch EH. A lack of consensus in the assessment of fracture healing among orthopaedic surgeons. J Orthop Trauma. 2002;
2. Zura R, Mehta S, Della Rocca GJ, Steen RG. Biological risk factors for nonunion of bone fracture. JBJS Reviews. 2016.
3. Mills LA, Simpson AHRW. The relative incidence of fracture non-union in the Scottish population (5.17 million): a 5-year epidemiological study. BMJ Open. 2013;3(2):e002276.

Ossatec Clinical Evaluation/Study

Joint Replacements and Implanted Prosthetics.

Type of study: Clinical **No of patients:** 132

Objective

Since PEMF therapy has been shown to improve bone mass, decrease harmful inflammation, and stimulate circulation and the body's repair processes, it has been studied in conjunction with joint replacements with much success.

Methods

132 patients had PEMF therapy for advanced loosening of their prosthesis. Treatment was done 2-3 times a day for 40 minutes each time, for 20 weeks. Follow up was done over the course of 5 years. A revision procedure was no longer deemed necessary in 70% of patients.

Results

In one randomized double-blind study, 30 patients undergoing hip revision were treated for 6 hours per day for 90 days after surgery. Subjective improvement was higher in those receiving the PEMF treatments compared to the placebo.

Conclusion

Since PEMF therapy has been shown to improve bone mass, decrease harmful inflammation, and stimulate circulation and the body's repair processes, it has been studied in conjunction with joint replacements with much success. This study shows a positive clinical correlation between PEMF therapy and bone stock restoration after surgery. The studies show a strong correlation between PEMF therapy and successful treatment and longevity of joint replacement implants. There appears to be a dosing effect where longer treatment times or treatments at higher intensities have higher long-term success than shorter treatment times or lower intensity treatments.

Ossatec Clinical Evaluation/Study

Title: **Pulsed Electromagnetic Fields in the Treatment of Nonunions.**
Reference: B. J. Punt, P. T. den Hoed, and W. P. J. Fontijne

Type of study: Retrospective open non-blinded study **No of patients:** 415

Abstract

Background
Clinical application of electric stimulation and electromagnetic Weld stimulation include the treatment of delayed union and nonunion. In the literature success rates up to 90% are reported for the treatment of delayed union and nonunion with pulsed electromagnetic stimulation. We report our experience with pulsed electromagnetic stimulation in the treatment of nonunion.

Methods
All patients treated with pulsed electromagnetic stimulation for a nonunion between January 1996 and January 2000 were included.

Results
415 patients in more than 10 hospitals in the Netherlands were treated with Ossatec pulsed electromagnetic fields for a non-union from January 1996 to January 2000.

93 of the 415 patients fulfilled the required criteria: elapsed time since injury, no surgery 3 months before start of stimulation, and sufficient follow-up. One group was treated for long bone fractures (LBF) (64 patients). The other group consisted of patients treated for non-long bone fractures (NLBF). We evaluated our findings according to clinical and radiographic criteria.

The success rate of our treatment of a nonunion with pulsed electromagnetic Weld was 76% for the LBF group and 79% for the NLBF group.

Conclusion
Pulsed electromagnetic Weld stimulation of a nonunion showed to be an effective treatment in our study.

Ossatec Clinical Evaluation/Study

Early application of Ossatec pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures.

Type of study: Randomized Controlled Study **No of patients:** 92

Objective
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 6 months 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. In this study, the outcomes of postoperative delayed union of long-bone fractures treated with an early application of PEMF were evaluated as 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 16 weeks and 6 months, were randomly split into two groups and subjected to an early application of PEMF 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 4.8 months led to a success rate of 77.4%. This was significantly higher than the control, which had an average duration of 4.4 months and a success rate of 48.1%. The total time from operation to the end of the study was a mean of 9.6 months for patients in the PEMF group.

Conclusion
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 6 months or more of delayed union, as described by others.

Ossatec Clinical Evaluation/Study

Early application of Ossatec pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures.

References

1. Tseng SS, Lee MA, Reddi AH: Nonunions and the potential of stem cells in fracture-healing. J Bone Joint Surg Am 2008, 90(Suppl 1):92–98.
2. Einhorn TA, Laurencin CT, Lyons K: An AAOS-NIH symposium. Fracture repair: challenges, opportunities, and directions for future research. J Bone Joint Surg Am 2008, 90(2):438–442.
3. Calori GM, Mazza E, Colombo M, Ripamonti C, Tagliabue L: Treatment of long bone non-unions with polytherapy: Indications and clinical results. Injury 2011, 42(6):587–590.

Ossatec Clinical Evaluation/Study

The effect of pulsed electromagnetic fields and dehydroepiandrosterone on viability and osteo- induction of human mesenchymal stem cells.

Type of study: Research Article - Lab Cell

Objective
The hypothesis of this work was that human bone marrow-derived mesenchymal stem cells (MSCs) are regulated by pulsed electromagnetic fields (PEMFs) and by intracrine conversion of an adrenal prohormone to dihydrotestosterone. The effect of PEMF and dehydroepiandrosterone (DHEA) on viability and osteogenic differentiation of human MSCs and on the viability of osteoblastic SaOS-2 cells was evaluated. To examine how PEMF and DHEA affect the viability and osteo-induction of human MSCs.

Methods
Human osteogenic sarcoma SaOS-2 (ECACC 890500205) cells were cultured on 10 cm diameter Petri dishes (Corning, NY, USA), using McCoy's 5A culture medium containing GlutaMAXTM (Gibco BRL/Life Technologies, Gaithersburg, MD, USA) supplemented with 10% fetal calf serum (FCS), 100IU/ml penicillin and 100mg/ml streptomycin. Cells were grown to 80% confluence at 37 C in a humidified atmosphere containing 5% CO2. The culture medium was carefully decanted and the cell monolayer was washed twice in 140 mM phosphate-buffered saline (PBS; pH 7.4). Cells were removed from the plates by applying 1–2ml 2.5mg/ml trypsin in PBS–ethylenediaminetetraacetic acid (EDTA; 0.02%) solution at room temperature for 1min, after which most of the solution was removed and incuba- tion was continued for 5 min at 37C. The cells were pelleted by centrifugation at 500 g for 5 min, resuspended in culture medium and seeded onto tissue culture treated polystyrene 24-well plates (BD, Franklin Lakes, NJ, USA)
PEMFs were produced by an OSSATEC bone growth stimulation device (Ossatechnics, Uden, The Netherlands), continuously (24/7) stimulating with 15 Hz, 1 Gauss EM field, consisting of 5ms bursts with 1ms pulses. The stimulus was started 24 h after seeding.

Results
It stimulates the migration of the progenitor cells to the fracture site and help bone maturation and extracellular matrix synthesis.

Ossatec Clinical Evaluation/Study

The effect of pulsed electromagnetic fields and dehydroepiandrosterone on viability and osteo- induction of human mesenchymal stem cells.

Conclusion

PEMF and DHEA treatment might have potential use in preparation of tissue-engineered bone grafts in vitro and they could speed up the healing of tissue-engineered bone grafts in vivo.

References

1. Aaron RK, Ciombor DM. 1996; Acceleration of experimental endochondral ossification by biophysical stimulation of the progenitor cell pool.
2. J Orthop Res 14: 582–589. Bassett CA, Pawluk RJ, Pilla AA. 1974; Acceler- ation of fracture repair by electromagnetic fields. A surgically noninvasive method. Ann NY Acad Sci 238: 242–262.