

Adie S, Harris IA, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. JBJS Am 2011;93:1569-76.

Design: Randomized clinical trial

Purpose of study: to estimate the effectiveness of pulsed electromagnetic field stimulation (PEMF) on the healing of acute tibial fractures

Population/sample size/setting:

- 218 patients (179 men, 39 women, mean age 39) treated for acute tibial fractures at six university-affiliated teaching hospital trauma centers in New South Wales
- Eligibility criteria were age over 18 with an acute diaphyseal fracture of the tibia
- Exclusion criteria were fractures with intra-articular extension, pathological fractures, pregnancy, or having an implanted pacemaker or defibrillator

Interventions:

- Initial management of the fracture was individualized to the patient by the treating surgeon
 - o Open fractures were 28% of the total
 - o 72% of the fractures were treated with intramedullary nailing; 15% with plating, 10% with closed reduction, and 2% with external fixation
- Randomization was to either PEMF (n=106) or sham PEMF (n=112)
 - o Identical-appearing devices were furnished by the manufacturer of the device, and a representative of the company instructed each patient in its use and fitted the device to the patient within two weeks of the fracture
 - o Patients were instructed to wear the device over the fracture site for ten hours per day for 12 weeks
 - o Each device had an internal recording system to measure compliance with the instructions for its use
 - o Patients were contacted within two weeks of device placement to increase compliance
 - o Compliance was defined as an average daily use over six hours

Outcomes:

- The primary outcome was the rate of secondary surgery (intramedullary nail dynamization, revision fixation, and/or bone grafting) within the first 12 months after the fracture
 - o The decision to do secondary surgery was at the discretion of the primary surgeon, who was blinded to device assignment
 - o Ancillary comparisons of the primary outcome were done at 3 and 6 months

- Secondary outcomes included radiographic union within 6 months, defined as union of three of four cortices on AP and lateral films, read by blinded trauma surgeons
- Functional outcomes at 12 months were assessed with an 80-point Lower Extremity Functional Scale, and the physical component score of the SF-36 was taken at 12 months as a measure of health status
- Average compliance was 6.2 hours per day, which was lower than anticipated, but was comparable between groups
 - Smokers and patients with open fractures were less likely to be compliant, but patients with cast treatment were more likely to be compliant
- 16 patients in the PEMF and 15 patients in the sham group had the primary outcome of secondary surgery for delayed union or nonunion; there was no difference between the two groups at 12 months, or in the ancillary comparisons at 3 and 6 months
- Some subgroup analyses were done on the primary outcome
 - For open and closed fractures analyzed separately, there was no difference between PEMF and sham PEMF
 - For compliant and noncompliant patients, there was no difference between the groups
- For radiographic union at 3 and 6 months, there was no difference in rates of fracture union, but only 43% of the patients had x-rays at 3 months and 36% had them at 6 months
- The SF-36 and lower extremity functional scores also did not significantly differ between the two groups

Authors' conclusions:

- PEMF, used as an adjunct to standard care for acute tibial fractures, does not decrease the rate of secondary surgical procedures in the first twelve months after the fracture
- The subgroup analyses, which included a per-protocol analysis which would be expected to present PEMF in the best light, did not change the estimates of the lack of effect of PEMF
- Although slow recruitment meant that the initial target of 340 patients was not achieved, the study was powered to detect a clinically meaningful benefit of PEMF
 - There was a small measured benefit of the sham PEMF over the true PEMF, and the addition of 81 randomized patients would not likely have reversed the results enough to show that PEMF provided a benefit in terms of secondary surgery
- Secondary surgery, unlike radiographic union, is a patient-important outcome
- We do not recommend PEMF to treat acute tibial shaft fractures
- For established nonunions, the effect of PEMF may differ from that of fresh fractures, which are too dissimilar to be directly comparable to nonunions

Comments:

- The study has numerous strengths, including a sample size large enough to test the effectiveness of PEMF in the setting of acute diaphyseal fractures of the tibia, and supports an evidence statement that PEMF does not improve the rate of secondary surgical procedures in that setting
- No inferences about PEMF in the setting of delayed fracture unions can be made from this study
- The fact that the devices had electronic monitoring systems to measure actual device use, was useful in ruling out device failure due to noncompliance

Assessment: high quality study which supports good evidence that in the setting of acute tibial shaft fractures, pulsed electromagnetic field devices provide no benefits in terms of reducing the rate of secondary surgical procedures in the first twelve months following the acute fracture