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Low-Intensity Pulsed Ultrasound and Pulsed Electromagnetic Field in the Treatment of Tibial Fractures: A Systematic Review

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Objective: To compare the effects of low-intensity pulsed ultrasound (LIPUS) or pulsed electromagnetic fields (PEMF) on fracture healing through a systematic review of original, English-language clinical research reports.

Data Sources: A search of MEDLINE, Physiotherapy Evidence Database (PEDro), and ProQuest to identify clinical trials of LIPUS or PEMF with fractures in humans, written in English, published from 1966 through 2004. Key words were *ultrasound, fracture, tibial, electric current*, and *healing.*

Study Selection: After search limits were applied, 17 papers were assessed independently by 2 reviewers. Papers were excluded from consideration if they lacked (1) random allocation of treatments, (2) inclusion of skeletally mature patients of either sex with a current fracture, (3) blinding of both the patient and the assessors as to treatment group, (4) administration of either LIPUS or PEMF treatments to one of the treatment groups, or (5) assessment of time to fracture healing or proportion of fractures healed, as determined radiographically, clinically, or both.

Data Extraction: Eight trials met the inclusion criteria. Methodologic quality of all trials was assessed using the PEDro criteria. Outcome measures were tabulated.

Data Synthesis: Heterogeneity among studies precluded direct comparison of the efficacy of LIPUS to that of PEMF.

Conclusions: The studies we included in our review were of generally high methodologic quality. The evidence suggests that LIPUS may speed healing of acute tibial fractures. Comparison studies of these modalities are needed to guide treatment of fractures sustained by athletic individuals.

Key Words: nonunion, modalities, radiographic healing, clinical healing

Low-intensity pulsed ultrasound (LIPUS) and pulsed electromagnetic fields (PEMF) are used in fracture care. What is the effect of such interventions on the acceleration of acute fracture healing and the healing of nonunions? Do treatment responses to these devices differ?

We have observed an increase in the number of athletes receiving LIPUS or PEMF treatments to promote fracture healing. Numerous authors[1–16] have reported that LIPUS or PEMF with specific energy delivery settings have positive effects in bone healing. The bones most frequently mentioned in the research are the vertebrae and long bones.

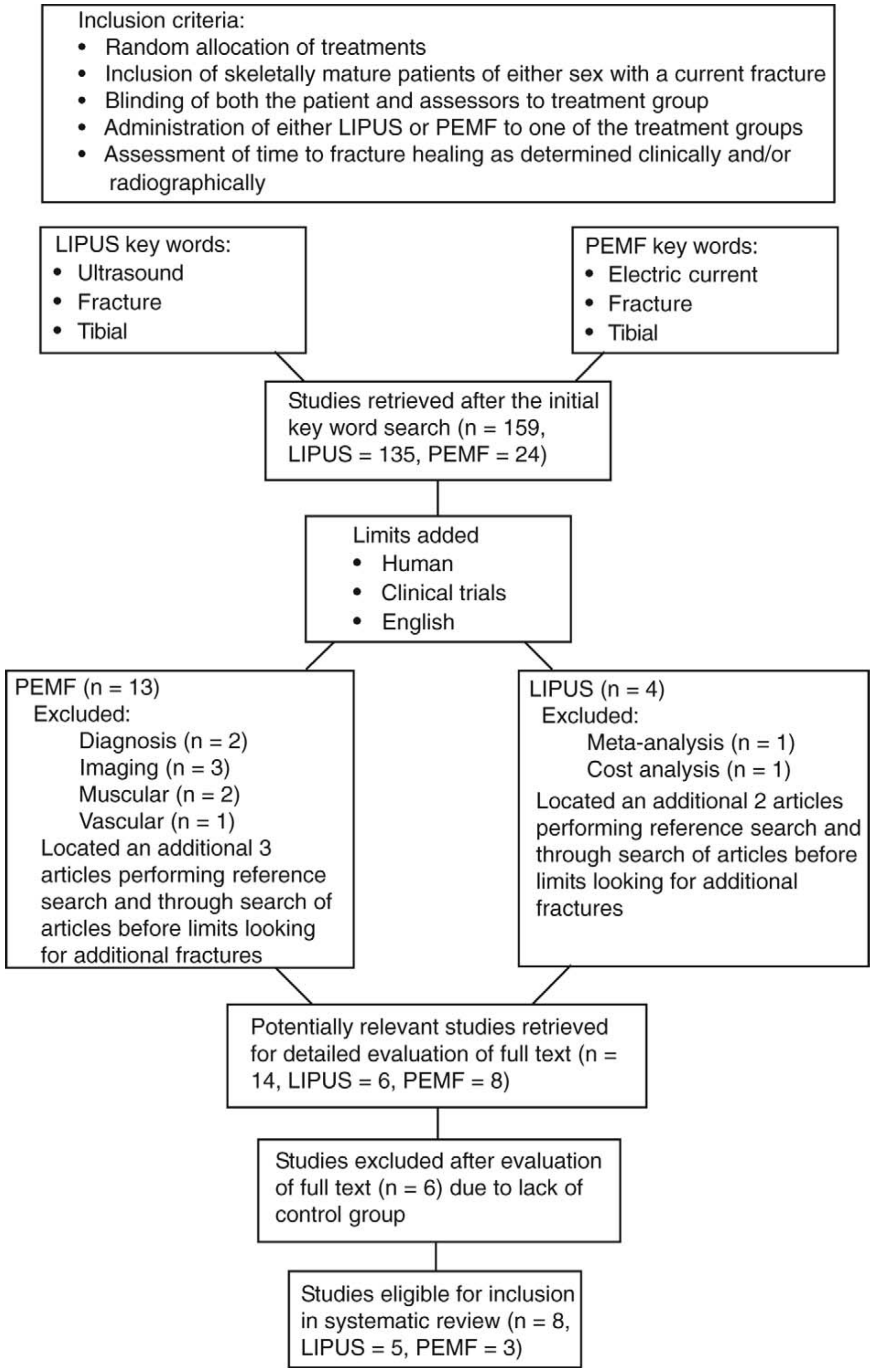
We also have encountered questions from students and athletes as to which of the devices is more effective. In response, we searched for comparison studies. Finding none, we conducted a systematic review of clinical trials concerning the treatment of fractures with LIPUS and PEMF bone stimulators in order to assess and compare the effects on fracture healing time. We believe that all providers involved in the care of injured athletic patients should have an understanding of each aspect of the plan of care and should be able to address or appropriately direct questions from the athlete-patient. Our report provides current responses to these questions and provides direction for future investigations that will offer more definitive answers.

METHODS

Two authors (N.A.W. and J.P.) independently identified relevant randomized clinical trials through a systematic search of several electronic databases: MEDLINE (1966 through 2004), Physiotherapy Evidence Database (PEDro) (1929 through 2004), and ProQuest (1987 through 2004) (Figure). The key words we used were *ultrasound, fracture*, and *tibial* with limits of *human, clinical trials*, and *written in English.* We initially focused on the tibia because a cursory review of the literature suggested that this bone would allow for the best opportunity to compare responses to the devices. However, this search yielded only 4 papers. Therefore, we removed the limits from the search criteria and found 5 additional studies. The authors of 4 of the studies used ultrasound for imaging; authors of the fifth provided a cost analysis.

To find additional studies of LIPUS, we performed a hand search of the references within the clinical reports and added 2 papers. We conducted a similar search using the key words *electric current, fracture*, and *tibial* in addition to the previously mentioned limits. This search yielded 2 papers. In an attempt to locate additional research, we dropped the limits and found 13 studies, but of these, 2 were diagnostic in nature, 3 related to imaging, 2 involved muscular healing, and 1 addressed vascular response. Thus, a total of 5 clinical trials of PEMF for fracture healing remained for further investigation.

Due to the small number of trials relating to tibial fracture healing that were identified, we expanded our search to include treatment of fractures in all bones with LIPUS or PEMF. First, we searched using the aforementioned limits with *ultrasound, fracture*, and *bone.* This yielded 58 papers. The key word *healing* was added to the list, resulting in 7 studies. Four in-



Identification of Relevant Studies for Systematic Review. LIPUS indicates low-intensity pulsed ultrasound; PEMF, pulsed electromagnetic fields.

volved only treatment of tibial fractures, 1 was an imaging study, another was specific to diagnostics, and 1 reported on healing of the femur, radius, ulna, humerus, metatarsal, and clavicle with LIPUS.[8] A similar search was then done for *electric current*, in place of *ultrasound* in the previous search. This yielded 3 papers, 2 of which concentrated on the tibia only, and 1 related to the femur, tibia, radius, and humerus.[14] These additional studies were retained for this review.

We independently applied previously established inclusion criteria to assess the methods of each potentially eligible study. The following criteria had to be met: random allocation of treatments, inclusion of skeletally mature patients of either sex with a current fracture, blinding of both the patient and the assessors as to treatment group, administration of either LIPUS or PEMF treatments to one of the treatment groups, and assessment of time to fracture healing or proportion of fractures healed as determined radiographically, clinically, or both.

We assessed the quality of the selected studies and independently abstracted the data. For a checklist, we adopted the PEDro 10-point scale.[17] The PEDro scale is based on 2 prem-

Table 1. Characteristics of Included Studies

Treatment	Authors	Year of Publication	n	Tibia Only?	PEDro* Score	Study Accepted	Study Rejected	Reason Study Rejected
Low-intensity pulsed ultrasound	Cook et al[3]	1997	67	X	8	X		
	Emami et al[4]	1999	32	X	9	X		
	Emami et al[5]	1999	30	X	10	X		
	Heckman et al[6]	1994	67	X	9	X		
	Leung et al[7]	2004	30	X	8	X		
	Nolte et al[8]	2001	29		5		X	Lacked control group
Pulsed electromagnetic fields	Barker et al[9]	1984	16	X	8	X		
	Bassett et al[10]	1982	83		6		X	Lacked control group
	Bassett et al[11]	1981	127	X	6		X	Lacked control group
	Benazzo et al[12]	1995	25		4		X	Lacked control group; treatment: capacitive coupling
	Brighton et al[13]	1995	271	X	5		X	Lacked control group; treatment: capacitive coupling and direct current
	Satter Syed et al[14]	1999	13		3		X	Lacked control group
	Sharrard[15]	1990	45	X	10	X		
	Simonis et al[16]	2003	34	X	9	X		

*PEDro indicates Physiotherapy Evidence Database.

ises, internal validity and adequate statistical information to allow for interpretation.[17] In a subsequent consensus meeting, we discussed each criterion. Because the articles already were rated in PEDro, the ratings were used as a third voice in the assessment process. When we disagreed about assessments, we discussed our concerns until we attained a consensus.

RESULTS

We identified 159 studies related to LIPUS (135) and PEMF (24), of which 14 were human clinical trials published in English (Figure). Of the 14 studies, 2 were excluded from the final analysis because another form of electric stimulation was studied.[12,13] Four were excluded[8,10,11,14] due to lack of a control group for comparison (Table 1). The PEDro scores for the 8 retained and 6 excluded studies are found in Table 1.

Study Characteristics

We extracted and tabulated the study population, intervention, outcomes, and follow-ups; we reported results of the assessed trials. The 8 trials that were retained for analysis involved 321 patients, although Emami et al[4,5] reported on the same patients in both of their papers; thus, 291 different patients were included. The sample sizes ranged from 16 to 67, and the mean number of patients studied per investigation was 40.1. The most frequent mechanism of injury for a fracture of the tibia was a motor vehicle accident. Authors of 4 studies[8,10,12,14] included assessment of fracture healing of the femur, humerus, radius/ulna, fibula, fifth metatarsal, talus, scaphoid, and clavicle; however, none of these trials included a control group.

On assessing the other characteristics of the included studies, we noted considerable heterogeneity. The clinical trials were heterogeneous with regard to subject demographics, management of fractures in terms of casting and fixation, measurements of healing, timing of assessments, and the specific outcomes measured.

Outcome Measures

Radiographic healing of 3 of the 4 cortices was the most common outcome measure[3–6,15,16] and is considered the gold standard. Some investigators, however, reported the number of days to healing,[3–7,17,18] whereas others reported the proportion of healed fractures at specific time points.[9,15,16] Clinical analyses of healing provided another research measure. Included in the clinical analyses were pain via visual analog scale,[9,15] tenderness via palpation and weight-bearing status,[7,10] and degrees of motion at the fracture site upon physical stress.[10,15] Most of the authors recorded a final healing time and lacked continuous measures over time.

Effectiveness of Treatment

The 8 reports[3–7,9,15,16] included in our final assessment are summarized in Tables 2 and 3. Five of the LIPUS studies[3–7] provided sufficient data for calculation of individual effect sizes for at least 1 of the key outcome measures. These effect sizes were calculated by subtracting the treatment mean from the control mean and then dividing that value by the SD of the control group.[19] Risk ratios were calculated for the PEMF studies[9,15,16] because these investigators evaluated the proportion of fractures healing across time (12, 15, or 24 weeks); therefore, an average number of days to healing was not provided. Authors[15,16] of 2 studies of PEMF suggested that active treatment leads to more rapid healing. In a smaller study, one group[9] reported a high rate of healing in treated and untreated patients, with no additional benefit from PEMF. Significant differences between groups are reported based on the P values ($P = .05$) provided by the researchers.

Summary of Clinical Reports: Low-Intensity Pulsed Ultrasound Versus Placebo Low-Intensity Pulsed Ultrasound

Five sets of authors[3–7] compared the healing rates of acute tibia fractures treated with active LIPUS or placebo LIPUS. Fracture management differed between the studies; details and

Table 2. Effect Size Estimates for Individual Studies of Low-Intensity Pulsed Ultrasound (LIPUS) in Tibia Fracture Healing*

Intervention	Authors	n	Clinical Healing†	Radiographic Healing‡
LIPUS + internal fixator versus placebo LIPUS + internal fixator	Emami et al[4]	32	Effect size = −0.27	Effect size = −2.7
	Emami et al[5]	30	Not reported	Effect size = −2.2
LIPUS versus placebo LIPUS	Cook et al[3]	67	Nonsmokers Effect size = 1.1111 Smokers Effect size = 0.87	Nonsmokers Effect size = 2.5862 Smokers Effect size = 3.0
LIPUS + cast versus placebo LIPUS + cast	Heckman et al[6]	67	Effect size = 2.70	Effect size = 4.2
LIPUS + internal or external fixator versus placebo LIPUS + internal or external fixator plus cast	Leung et al[7]	30	Weight bearing Effect size = 2.0	Not reported

*Effect size indicates the effectiveness of the treatment. A positive ratio represents an effect in favor of the treatment group.
†*Clinical healing* was defined as no motion at the fracture site, no pain or tenderness with palpation, and no pain or tenderness with full weight bearing.
‡*Radiographic healing* was defined as bridging of 3 of the 4 bony cortices.

Table 3. Effect Size Estimates for Individual Studies of Pulsed Electromagnetic Fields (PEMF) in Tibia Fracture Healing*

Intervention	Authors	n	Radiographic Healing†
PEMF + full-leg plaster cast + non–weight bearing versus placebo PEMF + full-leg plaster cast + non–weight bearing	Barker et al[9]	16	24 weeks: 57% relative risk increase 48 weeks: 50% relative risk increase
	Sharrard[15]	45	12 weeks: risk ratio = 6.25
PEMF + external fixator versus placebo PEMF + external fixator	Simonis et al[16]	34	15 weeks (all): risk ratio = 78% Nonsmokers: absolute risk reduction = 33% Smokers: risk ratio = 53%

*Effect size indicates the effectiveness of the treatment. A positive ratio represents an effect in favor of the treatment group.
†Number of unions achieved by indicated time.

sample sizes for each are reported in Table 4. The treatment values for these 5 studies[3–7] were a burst width of 200 microseconds containing 1.5-MHz sine waves, with a repetition rate of 1 KHz and a spatial average temporal intensity of 30 mV/cm^2. In each study, LIPUS was applied 20 minutes daily. The total duration of treatment differed, however, and ranged from 75 days[4,5] to 140 days,[3,6] with Leung et al[7] treating for 120 days. The inclusion and exclusion criteria of the 5 studies[3–7] were similar. Emami et al[4,5] treated fractures with a statically locked intramedullary rod, whereas Cook et al[3] and Heckman et al[6] treated fractures with closed reduction and cast immobilization. Patients in the Leung et al[7] trial experienced complex fractures requiring internal or external fixation. It is unclear if differences in fracture management influenced the healing response to LIPUS.

Emami et al[4,5] reported nonsignificant differences in radiographic union rate (125 days for placebo, 155 days for active treatment), orthopaedic clinical assessment of fracture healing (125 days for placebo, 129 days for active treatment), and the average time from fracture until radiographic evidence of the first callus formation (37 days for placebo, 40 days for active treatment).

Cook et al,[3] Heckman et al,[6] and Leung et al[7] reported faster radiographic and clinical healing in those patients treated with active LIPUS. Cook et al[3] specifically focused on the effects of the active versus placebo LIPUS treatments on smokers and nonsmokers. Cook et al[3] showed reductions in time to clinical and radiographic healing in nonsmokers treated with LIPUS (84 and 96 days, respectively) versus the placebo control (96 and 129 days, respectively). They also found differences in the time to clinical and radiographic healing in smokers treated with LIPUS (103 and 96 days, respectively) versus the placebo control (175 and 125 days, respectively). The differences in time to healing reported in each of the studies[3,6,7] were statistically significant.

Summary of Clinical Reports: Pulsed Electromagnetic Field Versus Placebo Pulsed Electromagnetic Field

Three groups[9,15,16] compared active treatments of PEMF with placebo treatments of PEMF; however, treatment settings in each study were different. Barker et al[9] used active machines producing a 1- to 5-mT peak, 5-millisecond burst waveform repeated at 15 Hz for 12 to 16 hours a day. Sharrard's[15] signal consisted of bursts of 20 individual pulses of a quasi-rectangular form followed by a sharper reverse form, with the bursts repeated at 15 Hz for 12 hours a day. Finally, Simonis et al[16] used a peak current of 6 A at 150 V with the duration of the generated pulse set at 3 milliseconds in intervals of 40 milliseconds for 14 hours a day. Variations in treatment settings and the energy delivered to the tissues may have led to differences in outcomes. We were unable to locate studies comparing PEMF settings.

Sharrard[15] and Simonis et al[16] reported that a greater proportion of patients demonstrated radiographic healing when treated with PEMF than with placebo at 12 and 15 weeks, respectively. Patients in the Simonis et al[16] study were treated after an oblique fibular osteotomy and application of a unilateral fixator. Those in the Sharrard[15] study were treated with a full-leg plaster cast and restricted from weight bearing. Barker et al[9] defined a healed fracture when 2 independent observers

Table 4. Summary of Included Articles With Specific Fracture Treatments*

Authors	Treatment	Type of Treatment	n
Cook et al[3]	LIPUS	Closed reduction and cast immobilization	67 (including 3 grade I open fractures[23])
Emami et al[4]	LIPUS	Closed reduction and intramedullary nail	32 (including 6 grade I open fractures[23])
Emami et al[5]	LIPUS	Closed reduction and intramedullary nail	30 (including 4 grade I open fractures[23])
Heckman et al[6]	LIPUS	Closed reduction and cast immobilization	67 (including 3 grade I open fractures[23])
Leung et al[7]	LIPUS	Complex fractures: internal or external fixation	30 (including 17 open grade I–IIIA fractures[23])
Barker et al[9]	PEMF	Nonunion at 52 wk	16
Sharrard[15]	PEMF	Nonunion at 16 to 32 wk	45
Simonis et al[16]	PEMF	Nonunion at 52+ wk	34

*LIPUS indicates low-intensity pulsed ultrasound; PEMF, pulsed electromagnetic fields.

were unable to detect movement at the fracture site with stress and with lack of a gap on radiograph. Barker et al[9] found little difference in the rate of nonunion at 24 weeks in patients treated with and without PEMF who also received immobilization with a full-leg plaster cast and were restricted from weight bearing. Sharrard[15] found that less tenderness was experienced by patients treated with PEMF (1.6) than with placebo (2.7) when assessed on a visual analog scale rating at 12 weeks posttreatment ($P = .18$).

DISCUSSION

Low-intensity pulsed ultrasound and PEMF are used to treat fractures of all types. However, a relatively limited number of randomized, controlled clinical trials have been used to investigate the efficacy of these treatments. Focusing on tibial fractures, we found 6 studies suggesting a benefit to using LIPUS and PEMF for fracture union.[3,6,7,9,15,16] Others, however, have failed to show a beneficial effect.[4,5] The studies we included in our review were of generally high methodologic quality (rating 8 or higher on the PEDro scale). To our knowledge, ours is the first systematic review attempting to compare the efficacy of LIPUS with that of PEMF. Unfortunately, such a comparison is not possible due to the heterogeneity in the outcomes measured and the timing of assessments. Moreover, the PEMF studies involved treatment of nonunions (Table 4), whereas the studies of LIPUS involved treatment of acute fractures.

The difference in the findings of Emami et al[4,5] and the other LIPUS investigators[3,6,7] could be the result of other factors, including management. The descriptions of the natures of the fractures were similar across studies (Table 4), however, except that those in the Leung et al[7] report sustained more complex fractures. The patients included in the reports by Emami et al[4,5] were all treated with intramedullary nails. The effect of intramedullary nailing on responses to LIPUS has not, to our knowledge, been reported.

Other than the reports by Emami et al,[4,5] the papers[3,6,7] we included in our review are in agreement with a previous meta-analysis by Heckman et al.[1] The authors[1] concluded that LIPUS may reduce the time to fracture healing for fractures treated nonoperatively. Effect sizes were calculated to estimate the magnitude of the treatment effect.[20] Cohen[19] proposed that effect sizes of 0.2 represent small differences; 0.5, moderate differences; and 0.8+, large differences. Effect sizes for radiographic and clinical healing ranged from 1.9 magnitude[7] to 4.2 magnitude,[6] whereas reports of clinical healing alone ranged from 0.5 magnitude[7] to 2.7 magnitude.[6]

The meta-analysis by Heckman et al[1] and the studies we included investigated healing of tibial fractures. Kristiansen et al[21] reported accelerated healing (38% less time to union than in controls) of dorsally angulated radial fractures in a multicenter, prospective, controlled clinical trial. We found no randomized, controlled clinical trials involving LIPUS in the treatment of fracture nonunions.

We limited our search to clinical trials that included a control group and were written in English. In 2002, LIPUS was approved by the Food and Drug Administration for the treatment of established nonunions.[22] The use of patients as their own controls in studies investigating the treatment of nonunion fractures is now accepted research practice. Nolte et al[8] reported that 80% of the femur, radius, and scaphoid fractures treated with LIPUS healed in an average of 155 days and 75% of ‘‘other’’ bones healed in approximately 167 days, despite a long period of nonunion.

Authors of each of the randomized, controlled trials related to healing of nonunion fractures with PEMF, however, reported cases of healing with placebo stimulation. The lack of control groups precludes conclusions that no healing would have occurred without intervention. Yet the high success rates reported by Nolte et al[8] certainly suggests that LIPUS is effective in the treatment of delayed healing and nonunion fractures.

Few high-quality controlled clinical trials of PEMF exist. We found 2 reports of PEMF fracture treatments that did not involve a control group, in addition to those we included. Each group reported high rates of long-bone union between 14 weeks and 5.2 months. Regarding long-bone fractures, Satter Syed et al[14] found that 84.6% (11 of 13) experienced successful bone healing within an average treatment period of 14 weeks. Similarly, when Bassett et al[10] studied the effects of PEMF on the tibia and the femur, the healing rate was 93% (65 of 70) or greater in an average of 4 months. Bassett et al[10] performed additional work with the tibia and once again found that, in an average of 5.2 months, 87% (110 of 127) of all nonunions had healed with non–weight-bearing treatment. In addition to the results of the randomized clinical trials, the findings of Satter Syed et al[14] and Bassett et al[10] suggest that PEMF speeds healing of tibial and other long-bone fractures.

CONCLUSIONS

Because the authors of the controlled LIPUS trials reported days to healing and those studying PEMF provided proportions of the groups with united fractures, it is not possible to compare the effects of these interventions. We recommend that investigators in future PEMF studies record time to healing in days, similar to what is done in LIPUS research.

Low-intensity pulsed ultrasound speeds acute fracture healing and promotes healing in nonunion fractures. At present, the efficacy of this treatment is best supported by the randomized, controlled clinical trials of acute tibial fractures[3,14,15] available. Controlled clinical trials assessing the management of other acute fractures are needed. Evidence suggests that PEMF also increases the proportion of nonunion fractures that heal without additional intervention.

Comparison studies of these 2 modalities may prove useful in helping clinicians to select the most effective treatments for various fractures across a spectrum of patients. We also recommend that investigators stratify patients based on fracture status (acute versus nonunion), fixation (internal versus external), and smoking. Smoking tobacco slows down the regeneration of bone tissue,[7] and a disproportionate number of smokers in either a treatment or a control group may bias the results in favor or disfavor of fracture treatments.

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