Article Review

Author	Journal or Book	Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Barker AT, Dixon RA, Sharrard WJ, Sutcliffe ML	*Lancet*	1984	Randomized Double-Blind Clinical Trial	Static radiographs and clinical examinations were performed at 12 week intervals. At week 24, the full leg cast was removed and a full clinical exam was performed.	16 patients with ununited tibial fractures for a minimum of 52 weeks randomly assigned to either active or dummy pulsed magnetic field stimulators and treated in full leg casts for 24 weeks with a non-weightbearing regimen.	At week 24, 5/9 patients (56%) in the active treatment group had clinically united compared to 5/7 (71%) of the control group. These results are compatible with a difference in success rate at 24 weeks on active treatment of +33% to -61% (95% CI) compared with the success rate on the dummy stimulators.	This is the first interim analysis of a double-blind study that had difficulty accruing patients and therefore the data is based on a patient sample of only 16 patients. Authors conclude that "the high proportions of fractures uniting in the control group suggests that conservative management of non-union is effective and this may explain much of the success attributed to pulsed magnetic field therapy."

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Bassett CA, Mitchell SN, Gaston CR	*Journal of the American Medical Association*	1982	Case Series	For inclusion in this study, a definable endpoint of healed or failed was required. Radiographically: Patients were considered healed if cortical and/or trabecular bridging with major modification of the radiolucent gap occurred. Clinically: No motion at the old fracture site on stress, no local tenderness, no pain on ambulation, and no further immobilization noted.	1,007 patients with ununited fractures and 71 cases of failed fusion Three major geographic locations: 1) ColumbiaPresbyterian Med Center (220 pts) 2) Other US treatment centers (625 pts) 3) International treatment centers (233pts) Disability time before treatment divided into three categories: 1) <9 months 2) 9-24 months 3) >2 years	Overall success rate of 77% (834 healed and 244 failed) Location specific success: Columbia-Presbyterian: 81% International: 79% Other US: 76% Success rate for failed arthrodeses alone was 82%. Of the 1,007 ununited fractures, 65% involved the tibia. Success rate for these fractures was 82% in all three geographic regions. Authors conclude that "PEMF stimulation increased callus formation and trabecular bridging at the osteotomy level."	Patients in the 2 groups where PEMFs were applied < 24 months after fracture might not constitute a valid test because of the possibility of spontaneous union; however, subset of 332 patients in the >2 year group had an average heal rate of 75%. Only 1,078 patients of a total of 6,000 were used in the analysis. Patients who discontinued use of the device in less than one month were excluded from the analysis. No control group or matching utilized; patients were selected by "referral from the responsible local orthopaedic surgeon or by private consultation at Columbia." Long Bones represented 97% of the total ununited fractures treated.

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Bassett CA, Mitchell SN, Gaston SR	*The Journal of Bone and Joint Surgery (American Volume)*	1982	Case Series	Changes in the fracture gap and dense bone flanking it during the various stages of healing.	125 patients with 127 tibial lesions. -- M/F ratio of 2.7:1 -- Average age of 36 yrs -- average of 2.4 failed surgeries -- average pre-treatment disability of 28 months In all patients, the clinical and radiographic features of the nonunion had not changed for a minimum of 4 months prior to starting treatment. Patients were classified as having a delayed union or a nonunion. Delayed union -- No clinical or radiographic evidence of union at 4-9 months after fracture. Nonunion -- a fracture that had not united by nine months after fracture.	The overall success rate for union was 87%. Failure rate of 13% includes all fractures in which healing did not occur, regardless of the cause. For duration of disability, healed rate (%) by months: <9 months = 86% (n = 28) 9-24 mo = 87% (n = 56) 24-48 mo = 94% (n = 19) >48 mo = 82% (n = 22) 5 refractures occurred after union -- These were attributed to external causes such as specific reinjury, failure to use proper external support during rehab, etc.	Author notes that of particular interest is the heal rate (82%) in a group of 22 patients who had an average disability time of 7.6 yrs and numerous surgical interventions. This study uses a subset of patients reported on earlier and focuses solely on patients seen at the university hospital at which the author is affiliated. Author gives specific information about the management and treatment of patients who have bone growth stimulators applied where the distinct pattern of radiographic progress is not seen. Although it is reported that electromagnetic stimulation compares favorable with surgical repair and is not affected by age , the duration of disability, the presence of infection, and the number of previously failed operations, little statistical analysis is provided.

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Beckenbaugh, RD	*Orthopaedic Transactions*	1985	Case Series	Patients were evaluated with tri-spiral tomography to assess the the degree of angulation and/or deformity, as well as the status of the nonunion.	24 patients with 24 established nonunions of the scaphoid varying in age from 4-48 months treated between 1981 and 1984. 10 patients were treated in a short arm cast for a stimulation period of 2 to 9 months. 14 patients were treated for a stimulation period of 4.5 to 6 months with a long arm cast.	In the short arm cast patients, an initial heal rate of less than 50% led to a protocol change to a long arm cast for the remainder of treatment. The eventual heal rate was 87% for the combined treatment groups (19/24). Author concludes that "the length of the nonunion did not appear to be a factor as three patients with nonunions of greater than 3 years healed with electrical stimulation and casting."	Author states that because "routine radiographs are often misleading and inaccurate with regard to the status of union or nonunion" all patients were evaluated by tri-spiral tomography. This is an interesting observation because most studies use radiographic healing as an important parameter in determining nonunion. This was a short report without significant descriptions of factors that may have affected the results such as patient characteristics, age, co-morbidities, etc. Aditionally, there was no statistical analysis provided.

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Borsalino G, Bagnacani M, Bettati E, et al.	*Clinical Orthopaedics and Related Research*	1988	Randomized Double-Blind Clinical Trial	X-rays at 40 and 90 days post-surgery were taken (AP view) and evaluated for the presence of periosteal bone callus rated 0-3 (0 = No osteogenic image to 3 = osteotomy fragments linked by tissue analagous to femoral bone tissue). The presence of trabecular bridging at the osteotomy site was also checked and evaluated on a similar 0-3 scale. Callus relative density compared to the density of iliac bone was also measured to quantify calcification and maturity of the callus.	32 patients aged <70 with degenerative osteoarthritis surgically treated for intertrochantic osteotomy were randomized on the third day after surgery to receive either an active or control electromagnetic stimulator (16 active, 16 control). Patients were instructed to use stimulators for 8 hrs per day for 3 months. Active Control Female 69% 75% Mean age 56 55 Mean weight (kg) 72.6 66.5	1 patient in the treatment group stopped stimulation and was excluded from the analysis. At 40 days post surgery, x-ray analysis showed that bone callous presence was more pronounced in the stimulated group than the control group ($p < .02$). No significant statistical difference was observed between groups for bone callus relative density. At 90 days post surgery, periosteal bone callus presence, relative density, and presence of trabecular bridging were all statistically significantly different between groups.	Although randomization into active or control groups occurred, the entire group of patients receiving surgery were all serially drawn from the patient population of the senior author who performed all of the surgeries. While he acknowledges that this "homogenous" population offerred an excellent opportunity to study electrical stimulation, selection bias may be an issue. While this study involved electrical stimulation, it is not entirely relevant to nonunions and electrical stimulation and therefore its utility for examining this issue is limited.

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Brighton CT, Shaman P, Heppenstall RB, et al.	*Clinical Orthopaedics and Related Research*	1995	Retrospective Case Series	Dependent variable either "healed" or "failed." Diagnosis of nonunion was made radiographically when no progressive signs of healing of the callus were seen during a 3 month period. Each nonunion had to be at least 9 months in duration.	Two continuous independent variables were 1) patient age (in years), and 2) duration of nonunion (in months). Categorical independent variable were treatment type, gender, osteomyelitis, prior electrical treatment, prior bone graft, fracture condition, nonunion type, fracture type, presence or absence of metal, and fracture location. 271 total patients -- 167 patients treated with direct current, 56 patients with capacitative coupling, and 48 patients with bone graft surgery. Average age was 35.4 years, average duration of nonunion was 23.5 months, and males outnumbrered females by 3 to 1.	When no risk factors were present, there were no significant differences in the heal rate among the three treatment methods at 10 month duration of nonunions. As progresively more risk factors were present, the heal rate decreased significantly regardless of the method of treament. Duration of nonunion tended to decrease the heal rate in the treatment of tibial nonunion.	Authors point out that because double-blind studies are often difficult to do when surgery vs another experimental technique is compared, logistic regresion comparing these three methods of treatment mitigated certain issues of experimenter bias. They also state that "the results in this article should be assessed and interpreted with caution, because the present study was retrospective, did not incorporate randomization, and did not involve a double-blind protocol." This study utilized patient data from 1971 to 1993. It is difficult to determine how the record review was done for this study. All patients had to have had a a nonunion that was "at least 9 months in duration" and therefore no data is available for patients who had a nonunion for a shorter duration.

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Bronk JT, Ilstrup D, Blander ME	*Proceedings of the Orthopaedic Research Society*	1997	Retrospective Case Series	Humeral shaft fractures at the Mayo Clinic between 1983-1992. Patients with open fractures and metastatic disease were excluded. Fractures considered healed when: 1) Immobilization was discontinued and the patient returned to unrestricted activity, or 2) The treating physician indicated in the chart that the fracture was healed.	115 patients -- 58 male/57 female	104 Patients healed, 11 developed nonunion. The nonunion rate did not vary with fracture location, comminution, or fracture pattern, but was affected by gender (14% female/5% male). Females had a significantly greater time to union and a significantly greater probability of developing nonunion ($p=0.0006$). Age had a significant effect on the time to healing in all analyses (ANOVA, $p<0.0001$). Authors propose "that age and gender effect the biological process central to fracture repair, implying that fractures in locations other than the humeral shaft are similarily affected by age and gender."	Outcomes were either determined by the physician or self-reported by the patient and no parameters were provided as to how these outcomes were defined. No information was provided by the authors regarding the age distribution of the patients. Although the authors determined that age effects the biological processes central to fracture repair, specific ages or age ranges were not reported. Patient population was composed exclusively of patients at the Mayo Clinic - generalizability to the US population may be limited.

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Calandra JJ, Goldner RD, Hardaker WT	*Orthopedics*	1992	Review Article	NA	NA	Authors report: "Wrist fractures occupying the middle third of the scaphoid have a nonunion rate of 30%, even with appropriate immobilization. Proximal one-third fractures have the poorest blood supply. These fractures are characterized by protracted healing times and a nonunion rate that may approach 90%." "If the fracture is less than five years old and the patient is asymptomatic or has minimal osteoarthritic changes on radiograph, the nonunion may effectively be treated with pulsed electromagnetic stimulation combined with cast immobilization.	This article provides a review of scaphoid fractures but has little review or comment about PEMFs.

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Chiacchierini RP, C.L. McIntosh and Associates		1999	Unpublished Statistical Analysis	"Success" was defined as a dichotomous variable with the values 1 (success) and 0 (failure).	260 patients who used the EBI, Inc. Bone Healing System. The data set contained four variables: (1) Age (in yrs -- values between 8 and 82), (2) GL_NGL (met treatment guidelines or did not meet treatment guidelines -- values 1 and 0), (3) DISAB (number of months the patient had the fracture -- values between O days and 300 months), (4) Result (success or no success -- values 1 and 0).	P values for age , guideline, and month are not significant in the logistic regression (p = .39, .91, and .17 respectively) indicating that there is no evidence of a relationship between result and any of the three variables. Age and disability time were then considered as a categorical variable and broken down into 4 age and disability groups. Another logistic regression was performed and the resulting p values were found not to be statistically significant, indicating that age and disability time had no effect on result.	Author used a logistic regression model for purposes of this analysis. Only 45 of the 260 patients used in this analysis were aged 55 and older (17%) and the difference in healing rates does appear to be different between those patients under 55 and those 55 and older, although the author reports that by conducting Blackwelder's test adjusting for a region of indifference of 6.5% there is no statistically significant difference the two groups. No explanation was provided as to how the variable "success" (ie healed) was measured.

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Covance Health Economics and Outcomes Services, Inc.			Unpublished Statistical Analysis	This analysis examined a 5% random sample of all Medicare beneficiaries' claims between 1995-1997 to determine the period between initial diagnosis of nonunion and an operative bone graft repair with any subsequent hospitalizations that included an orthopedic procedure. Additional analyses also provided the distribution of nonunion bone graft procedures by anatomic site.	Projected to the entire Medicare population, there were 8,220 unique nonunion fracture patients from 1995-1997. Of these patients, there were 13,200 invasive bone graft procedures.	Humerus, Femur and Tibia/Fibula accounted for 57% of these procedures. 4,480 patients had a second hospitalization after the initial diagnosis of nonunion and surgical intervention. 10% of the total patient population had a follow-up bone graft procedure; 24% had a follow-up orthopedic procedure. 40% of fracture claims linked to the same anatomic site as the initial diagnosis of nonunion and bone graft procedure were identified. Humerus, Femur, and Tib/Fib accounted for 93% of these claims. Median time from fracture to nonunion bone graft procedure (months); Scapula (5.39); Humerus (6.02); Radius/Ulna (3.02); Femur (8.26); Patella (1.94); Tibia/Fibula (5.06).	Authors report that "no fracture claims linked across setting to the initial nonunion bone graft procedure for carpals and metacarpals, tarsals and metatarsals, or other anatomic sites." Limitations of the Medicare Standard Analytic Files (SAF) and the posibilities of miscoding must be considered when examining this analysis. These limitations in the data were not fully explored in this analysis. No ranges were reported and there was no statistical analysis comparing bone grafting and electrical stimulation. There was limited data available for patients who had fractures other than in long bones.

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De Haas WG, Watson J, Morrison DM	*Journal of Bone and Joint Surgery (American Volume)*	1980	Case Series	Union -- parameters not defined	17 patients with established nonunion of the tibia. The period from the time of injury ranged from 9 months to five years. Average age of the patients was 34 years.	15 of the 17 fractures (88%) united both clinically and radiographically.	This article was essentially a series of case studies and was an early investigation into electrical stimulation for fracture healing. At that point in time, author concluded that the treatment "is simple and it appears to be safe" and furthermore, that "in the absence of a control series, and particularly with so few patients, the effectiveness of the treatment may be questioned."

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Dunn WA, Rush GA	*Southern Medical Journal*	1984	Case Series	X-rays at 6 week intervals to evaluate healing. If the fracture had not united after 12 months, treatment was considered to have failed.	35 patients (32 fractures, 3 osteotomies) with nonunion, where nonunion was defined as " a fracture that had not united by nine months after fracture." Average age of these patients was 33.2 years. 18 of the nonunions were tibial (51%), 8 were femoral (23%), and 3 were humeral (9%).	Overall success rate for this group was 81%.	Although a sucesss rate of 81% was reported, in three instances bone grafting was required with PEMF. Some comparison of this group of patients were made with an earlier group of patients who had had implanted bone growth stimulators, but this data is not relevant for this analysis. Authors point out that PEMF with surgery appears to offer an extremely high successs rate as well improving drainage in infected patients. Besides tibial and femoral nonunions, other fractures were only minimally represented in this study.

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EBI, Inc.		1999	Unpublished Patient Registry	Outcomes included "success rates," "improved quality of life," and "degree of improvement."	814 patients who were 65 and older, who started treatment with the EBI Bone Healing system not less than 3 months nor greater than 5 months from the original fracture, and were treated with the device between 1994 and 1999. Data collection forms were sent to each of the patient's physicians. 158 responses were received (19.4% response rate). The sample consisted of 112 females and 42 males with a mean age of 74 and a mean disability time of 4 months. There were 146 cases of nonunion. 46% had no surgical procedures, 37% had internal fixation. Humerus, femur, tibia, and tibia/fibula accounted for 68% of fractures.	In the outcome assessment, a "success" rate of 88.5% was achieved. An intent to treat analysis, counting all patients lost to follow up as unsuccessful, revealed a 69% "success rate." 87% of physicians indicated that there was an improvement in the patient's quality of life after treatment. 94% of the responses indicated that the degree of improvement was somewhat significant, significant, or very significant. 84% of the patients returned to normal activity.	This unpublished analysis of a physician survey regarding patients who used the EBI Bone Healing System had a low response rate and therefore could suffer from bias. The authors did not identify whether the instrument used was valid and reliable. The outcome parameters of "success" were not identified.

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Frykman GK, Taleisnik J, Peters G. et al.	*The Journal of Hand Surgery*	1986	Retrospective Case Series	Review of all cases treated with a PEMF system from 1979-1984.	All cases of nonunited scaphoid fractures treated with PEMFs from 1979-1984. To be included in the study, fracture had to be nonunited and at least 6 months old, with no surgical procedures performed during or just before treatment. 50 patients were initially treated, and 44 were included in the analysis (41 males) with a mean age of 25. Length of time from injury to PEMF treatment averaged 40 months (range 6-241 months).	Fractures healed in 80% of patients. At follow-up, wrist extension had a mean of 83.5%; flexion, 93.1%; radial deviation, 85%; and ulnar deviation, 91.1% of the opposite normal wrist. Grip strength at follow-up averaged 83% of the opposite hand. A statistically significant difference in healing resulted between the group of patients whose fractures were more than 60 months old and those less than 60 months old ($p < .001$).	This study did include follow up to 33 months (longer than other studies cited) and used return to work as an additional outcome. The analysis of the nine patients whose fractures failed to heal was detailed and provided good information. Authors point out that "although there is some controversy in the literature regarding the need to treat asymptomatic nonunions of the scaphoid, recent reports indicate that the longer the duration of the nonunion, the greater the degenerative process."

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Garland DE, Moses B, Salyer W	*Contemporary Orthopaedics*	1991	Prospective Non-Randomized Clinical Trial	Patients were considered healed when -- Radiographically: 2 out of 3 independent orthopaedists indicated that cortical and/or trabecular bridging with major modification of the radiolucent gap on any view was shown as well as progression of the overall callus from baseline. Clinically: When patients were non-casted, had no motion at the fracture site, and had absent or minimal pain at the nonunion site.	181 patients with 193 nonunion fractures enrolled by 131 investigators at 74 institutions. 118 males (avg age 38) 63 females (avg age 49) Injuries treated included: * Long Bone (67.4%) * Short Bone (18.1%) * Failed Fusion (14.4%) Nonunion was defined as "a fracture or an arthrodeses that failed to demonstrate both clinical and radiographic union at least nine months after the original insult."	139 patients completed the 12 week minimum PEMF trial (77%). 13 patients who averaged <3 hrs of daily PEMF use were excluded from the study. Their success rate was determined to be statistically significantly different than the 126 patients with >3 hrs per day of PEMF treatment (80% vs 38%, $p<0.05$) Success rate of 83% in long bones vs 81% in short bones was achieved. 90% follow up rate after 4 yrs confirmed healing in 92% of patients with no statistically significant difference between the 4 yr success rate and the original rate.	Open vs closed fractures, nonunion of 9 to 12 month duration compared to one to ten years, age of patient, gender, recalcitrant vs first time treatment, infected vs noninfected, fracture gaps up to 1 cm, long vs short bone, or weightbearing vs non-weightbearing showed no statistical difference in this study. Note that these findings contradict many previous studies. No mention of particular device used and no discussion of the possibility that different devices may have different properties which affect the PEMF dosage. No intent to treat analysis was performed on the patients who did not complete the 12 week trial. Statistical analysis was not fully explained.

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Gossling HR, Bernstein RA, Abbot J	*Orthopedics*	1992	Literature Analysis	Search of Medline English literature citations from 1977 to 1987 using key descriptor terms related to electrical stimulation for fracture healing. A subset of papers with data were selected for analysis.	NA	14 articles reported on primary surgical treatment of tibial ununited fractures, 28 articles on PEMF treatment of tibial ununited fractures. Overall success rate for surgical treatment of 569 ununited tibial fractures was 82%. Overall success rate for PEMF treatment of 1718 ununited tibial fractures was 81%.	Authors state that because no consensus exists about what constitutes nonunion, "the use of ununited fracture refers both to delayed and nonunion fracture" which depends on the judgement of the physician reporting the study. Most patients had more than one failed surgical procedure prior to PEMF treatment. Authors point out that the success rate of primary surgery and PEMF treatment are essentially equivalent, and that these findings are "even more significant when one considers that in the past PEMF was most often used to treat highly recalcitrant nonunions after multiple failed surgeries."

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Hayda RA, Brighton CT, Esterhai JL	*Clinical Orthopaedics and Related research*	1998	Review article	NA	NA	NA	This article reviews the pathophysiology of delayed union by examining the different variables that may affect the process, including local limb status before injury, host response to injury, nature of the injury, iatrogenic impact on healing, and pharmacologic interractions. Authors do not address electrical stimulation for fracture healing in this article.

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Holmes, GB	*Foot and Ankle International*	1994	Case Series	Anteropsterior and lateral radiographs were evaluated for confirmation and classification of the fracture. Completion of healing was determined by trabecular bridging across the fracture line, pain-free gait, and the achievement of ambulation without a cast.	Nine Jones fractures with clinical and radiographic signs of delayed union and nonunion (Torg classification II-III) selected from a multicenter pool between 1987-1990. 5 males/4 females, mean age of 36 years (range 21-59). 1 patient had prior bone graft surgery. 3 patients had nonweightbearing casts applied, 6 patients were treated in a short leg weightbearing cast or postop shoe. 5 patients had delayed union, 4 patients had nonunion. Mean duration of treatment prior to the use of PEMF was 2.8 months.	All fractures healed with a mean time to healing of 4 months (range 2-8 months). Follow-up ranged from 24-60 months. Nonweightbearing patients had a mean heal time of three months. Weightbearing patients had a mean heal time of 4.5 months. There were no reported recurrences of symptoms or refractures. All patients returned to their pre-injury activities.	Although strict criteria were determined for inclusion in this study, there was no mention made of how many patients were selected from the larger pool of patients who had diagnoses of Jones Fractures at the different centers. This study had a very small sample size, with no control group or matching utilized. No detailed statistical analysis was provided. Authors point out that the unsatisfactory length of time for healing and inherent drawbacks to surgical intervention led to this examination of PEMFs for these fractures. A good analysis comparing this study to others involving surgical intervention was provided.

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Orthologic, Inc.		1998	Unpublished Patient Registry	Determination of healed or not healed made by physician with no specific criteria given.	All physician diagnosed nonunions from December 1994-December 1998. Excluded: * Vertebrae and flat bones * Nonunion diagnosis earlier than 2 months * Nonunion diagnosis where the date of injury, fracture site, or outcome was unknown * Multiple bone related diagnosis in addition to nonunion All patients were treated for 30 minutes per day and the device was provided for up to 270 days of treatment. Information was obtained about 2370/5300 patients (45% response rate)	Overall "success" (heal) rates averaged 75.1% -- ranged from 57.2% (humerus) to 87.5% (phalanx, finger) Data presented in tabular form by months applied from injury, (success rate): * 2 months -- 82.6% * 3 months -- 79.5% * 4 months -- 80.8% * 5 months -- 76.2% * 6 months -- 74.5% * 7 months -- 77.2% * 8 months -- 75.8% * 9 months -- 68.7% Of patients 65 and over (438/2370, 18.5%), heal rate at: * 2 and 3 months -- 81.2% * 4 and 5 months -- 76.5% * 6 and 7 months -- 70.4% * > 8 months -- 61.1%	This patient registry data was evaluated by the FDA and approved for updating the premarket approval application originally submitted by Orthologic. Data was collected on less than 50% of the patients for whom the device was prescribed. Additionally, success (measured by healing) was an outcome determined by each individual physician with no pre-established parameters. Patients aged 65 and over accounted for only 18.5% of the registry. Compliance with treatment was self-reported and no additional patient information regarding co-morbidities were examined. Because of the nature of patient registries, it is difficult to make any statements about causality from these results.

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Orthologic, Inc.	*NA*	1997	Case Series	Healed criteria included: * Clinically no pain or motion at the fracture site * 3 or more cortices bridged o radiograph * Final outcome verified by an independent panel Inclusion criteria included: * No evidence of union 9 months after injury * No surgery 3 months prior to enrollment * No radiographic evidence of healing within at least 3 months prior to enrollment	112 patients (116 fractures) enrolled by investigators at 17 sites between 1989 and 1991 who used the Orthologic 1000 for 30 minutes per day. Patient population was 73% male, median age of 38 yrs. Nonunions treated included: * Tibia (45%) * Femur (16%) * Scaphoid (15%) * Humerus (8%) * Ulna (6%) * Fibula (5%) * Other (5%)	80 patients (84 fractures) completed the treatment (71%). Success rate of 60.7% for all fractures -- 75.6% for all tibial fractures.	This study was presented in brochure format and had no statistical analysis associated with it. Limited information was provided on the methodology of the study, selection biases, etc. Because of this limited information, it is difficult to make statements about causality from these results.

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Otter MW, McLeod KJ, Rubin CT	*Clinical Orthopaedics and Related research*	1998	Review Article	NA	NA	Authors report: "Nevertheless, even in the absence of a mechanistic description of field cell interractions, advances have been made that are critical to the expansion of electromagnetic field treatment from the realm of nonunion fracture healing to the treatment of prosthetic loosening, prevention of osteoporosis, and treatment of nonskeletal tissues such as skin, nerve, and vascular tissues."	This review article provides a thorough overview of the history and application of electromagnetic field therapy. The authors also provide a desciption of the proposed action mechanisms of pulsed electromagnetic fields as well as describe the cellular responses to extremely low intensity electric fields.
Parnell EJ, Simonis RB	*Journal of Bone and Joint Surgery (British Volume)*	1991	Randomized Double-Blind Clinical Trial	United/Not United	18 patients in the active group, 16 in the control group, all with tibial nonunions. According to the authors "the two groups were well matched with respect to age, sex, interval since injury, incidence of infection, and mal-alignment of the non-union."	In the active group, 16 united (89%). In the control group, 8 united (50%, p = .033)	This study was presented in a one page format and does not discuss in any detail methods, results, patient characteristics, parameters for defining union, etc. Moreover, length of time since fracture or elapsed time of nonunion is not discussed.

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Ryaby, JT	*Clinical Orthopaedics*	1998	Review Article	This article reviews the history of electric and electromagnetic field use in fracture repair. The author also summarizes the results of several double blind clinical trials involving electrical stimulation for fracture healing, particularly in nonunions.	NA	Author states: "Electric and electromagnetic devices have been shown to affect the healing process positively in delayed union, nonunions, and osteotomies. These outcomes have been validated by statistically significant double blind clinical trials." "On the basis of these recent double blind clinical trials, electric and electromagnetic fields are a viable alternative for the clinical orthopaedic surgeon to have as part of his armamentarium in the treatment of complex problem fractures."	Author points out that there are several open questions concerning PEMF use and nonunions including: "at what time after injury should electric stimulation be applied?" He also notes that studies evaluating conventional surgical treatments for nonunion have not been criticized for lacking double blind prospective features as have studies evaluating PEMFs. Patient registry data which provides information on fracture type, anatomic location, time since injury, etc. is emphasized as possibly useful for investigators to use to study additional indications for electrical stimulator devices.

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Sharrard WJ		1993	Unpublished Letter	Positive final outcome was defined in this follow-up letter as "healing with no further surgery" an average of 2 years (median 15 months) after treatment was initiated.	[Data from 1990 Sharrard study] 51 patients enrolled between 1981 and 1987 at 16 clinical centers. 45 patients completed trial (20 active, 25 control). Patients were included if they had ununited fractures of the tibia after at least 16 weeks and not more than 32 weeks after treatment by immobilisation in a long-leg plaster cast and no surgical procedures. Nonunion was determined by the presence of movement at the fracture site and radiologically by the presence of a fracture line.	In the active group, 17 patients healed with no further surgery (85%), and 3 patients required surgery (15%). In the control group, 8 patients healed with no further surgery (32%), 8 patients required surgery (32%), 6 required PEMF therapy after 12 weeks (24%) and 3 patients were lost to follow-up.	This unpublished letter, provided by EBI, Inc. follows up on Sharrard's earlier study and provides data on what the author considers "positive final outcome," (healing with no further surgery). Author concludes that "one can be relatively confident that positive radiographic assessment after 12 weeks, an intermediate outcome, is an accurate predictor of positive final outcome." This is a difficult statement to assess given the paucity of data supplied in this short letter.

Author	Journal or Book	Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Sharrard WJ	*The Journal of Bone and Joint Surgery (British Volume)*	1990	Prospective, Randomized Sham Controlled Double Blind Study	Mobility of the fracture, the presence of pain on stressing it, and local tenderness were assessed by independent orthopaedic surgeons before and after treatment. They defined 3 groups: 1) No Progress 2) Improved but not united 3) United Anteroposterior and lateral radiographs were taken as well, with the parameters of radiographic exposure and the x-ray machine the same before and after treatment. Radologists defined 4 groups: 1) No progress 2) Progress to union 3) Probable Union 4) Full Union	51 patients enrolled between 1981 and 1987 at 16 clinical centers. 45 patients completed trial (20 active, 25 control). Mean age of the control group was 45.4 yrs, active group 34.7 yrs. The control group was 72% male, the active group was 70% male. Patients were included if they had ununited fractures of the tibia after at least 16 weeks and not more than 32 weeks after treatment by immobilisation in a long-leg plaster cast and no surgical procedures. Nonunion was determined by the presence of movement at the fracture site and radiologically by the presence of a fracture line.	Results after the 12 week trial: Active Control Union 3 0 Probable union 2 1 Progress to union 5 1 No Progress 10 23 * Fisher's exact test p = .002 for full union vs rest Orthopaedic surgeon's assessment: Active Control United 9 3 Improved 2 5 No Progress 9 17 * Fisher's exact test p = .02 for united vs rest Analysis of age and treatment effect between patients 35 or less vs 35 or greater between groups by Fisher's exact test p = .07 for both active and control.	Author emphasizes that it is difficult to perform valid double blind studies of fracture treatment because of the "wide spectrum" of injury type and varieties of treatment. For this reason, this trial was limited to fractures of the tibia that had received only limited conservative treatment. The asumption that simple displaced tibial fractures are likely to be united or to be approaching union by 16 weeks led to a study design which selected moderately or severely displaced fractures with a tendency to delayed union or nonunion. Author attributes the low rate of union as an indication that the patients selected had a "very poor prospect for union." Only 51 patients were recruited over a six year time span, 6 of whome were excluded from the study for reasons provided by the author. Moreover, age was only stratified into 35 and less and those over 35; no detailed analysis of age was provided.