



Appendix A

Summary Critique of Studies Cited by RS Medical

| Reference | Indication | Treatment/ Stim. | Waveform Accurately Identified | Sample Size | Previous Treatments | Treatment | Follow-up | Success Measurement |
|------------------------|---|---------------------|--------------------------------------|--|--|---|---------------------|---|
| Abeed et al., 1998 | Non-union fracture long bones | CC | No | 16 | Surgical treatment or casting alone | Device to be used each day until low battery signal, approximately 7-8 hours | 12 weeks | Radiographic healing defined as the presence of bone trabeculae across the full width of the fracture on all 4 views |
| Adams et al., 1992 | Non-union scaphoid | PEMF | No | 54 | No operation during or just before PEMF treatment | Not specified | 3 months minimum | Standard radiographic evaluation |
| Basset et al., 1982 | <ul style="list-style-type: none"> ▪ Non-union long bone ▪ Failed arthrodeses | PEMF | No | <p>> 6000 enrolled</p> <p>1078 evaluabe (case series)</p> | Not specified | <ul style="list-style-type: none"> ▪ 10-12 hours/day ▪ Plaster cast ▪ No weight bearing during early stages for unstable lesions in lower extremity ▪ Graded, protected rehabilitation | Not specified | <ul style="list-style-type: none"> ▪ Roentgenographic evidence of "cortical bridging, trabecular bridging, or both with major modifications of the radiolucent gap ▪ Clinical evidence of no motion at old fracture site on stress, no local tenderness, no pain on ambulation, and no further plaster immobilization |
| Basset et al., 1982 | <ul style="list-style-type: none"> ▪ Non-union long bone ▪ Non-union other bones | PEMF | No | 83 | <ul style="list-style-type: none"> ▪ Surgery ▪ Bone graft ▪ PEMF alone in 45 patients | <ul style="list-style-type: none"> ▪ 10 hours/day ▪ No weight bearing for unstable lower extremity non-unions ▪ Graded, protected rehabilitation | Not specified | <ul style="list-style-type: none"> ▪ No detectable motion or tenderness on physical exam ▪ No pain on weight-bearing ▪ No further requirement for external support ▪ Osseous bridging of gap defect on radiograph |
| Basset et al., 1977 | <ul style="list-style-type: none"> ▪ Non-union long bones ▪ Non-union other bones ▪ Pseudoarthroses ▪ Pathological acquired lesions | PEMF | No | 29 | One or more unsuccessful surgeries | <ul style="list-style-type: none"> ▪ 12-16 hours/day ▪ Casting ▪ No weight bearing for non-unions of lower extremity unless patient was ambulatory on "mechanically stable" lesion prior to PEMF therapy | Not specified | Unspecified radiographic and/or clinical evidence |

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| Basset et al., 1978 | Non-union long bones | PEMF | No | 220 | Modified during course of study to include unoperated non-unions and delayed non-unions | <ul style="list-style-type: none"> ▪ 12-16 hours/day ▪ Cast ▪ No weight bearing in lower extremity fractures ▪ Compression exercises at 3 months ▪ External support in lower extremity fractures | 3 month - initial 3 years complete | <ul style="list-style-type: none"> ▪ Radiographic obliteration of radiolucent lines ▪ Mechanical stability on clinical testing ▪ No local tenderness ▪ Function with or without external protective splint |
| Bassett et al., 1981 | Non-union long bones (tibia) | PEMF | No | 125 | Not specified | <ul style="list-style-type: none"> ▪ 10 hours/day with no segment less than 1 hour ▪ No weight bearing ▪ Plaster cast | 4-6 week intervals | Evidence of healing based on changes in fracture gap and dense bone flanking as assessed by radiograph |
| Benazzo et al., 1995 | Stress Fractures | CC | No | 25 fractures; 21 patients | Not specified | <ul style="list-style-type: none"> ▪ Continuous treatment starting at the time of diagnosis ▪ Some patients immobilized in plaster cast | Biweekly until fracture healed or improved or until no additional progress was noted at 3 evaluations | Healed or not healed per radiograph |
| Bose, 2001 | Spinal lumbar fusion | PEMF | No | 48 | <ul style="list-style-type: none"> ▪ Posterolateral lumbar fusion ▪ Internal fixation ▪ Augmented iliac crest bone graft in some patients | 4 hours/day | 24 months | <ul style="list-style-type: none"> ▪ Radiographic evidence of at least 2-point bridging ▪ No radiolucency ▪ Intact hardware |
| Brighton and Pollack, 1985 | <ul style="list-style-type: none"> ▪ Non-union long bones ▪ Non-union of clavicle carponavic | CC | No | 22 fractures; 20 patients | <ul style="list-style-type: none"> ▪ Bone graft and electrical stimulation ▪ Bone graft alone ▪ Electrical therapy | Continuous electrical treatment with immobilized plaster cast | 12 weeks | <ul style="list-style-type: none"> ▪ Healed - bone trabeculae crossing the full width of fracture line on all 4 roentgenograms ▪ Failure - bone trabeculae did not cross width of fracture on all 4 views and showed no progress |

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| Brighton et al., 1995 | Non-union long bone (tibia) | CC | No | 271 (case series) | Not specified | 24 hours/day | 12-24 weeks | <ul style="list-style-type: none"> ▪ Healed - bony trabeculae spanning the full width of gap ▪ Failed - all 4 radiographic views taken serially during a 3 month period showed no progressive changes yet bony continuity restored |
| Caullay and Mann, 1982 | Non-union long bones (tibia) | PEMF | No | 4 | Not specified | <ul style="list-style-type: none"> ▪ 12-16 hours/day or total of approx 1600 hours ▪ No weight bearing | Not specified | Unspecified radiographic and clinical evidence |
| Cheng et al., 1985 | <ul style="list-style-type: none"> ▪ Non-union long bones ▪ Congenital pseudoarthroses ▪ Benign cystic lesions | PEMF | No | 63 | Not specified | 14 hours/day | Not specified | Unspecified clinical and radiological evidence of union |
| Colsen et al., 1988 | Non-union long bones | PEMF | No | 32 | Not specified | <ul style="list-style-type: none"> ▪ 12-15 hours/day ▪ Non-weight bearing | 1 year (max) | Unspecified radiographic and clinical evidence |
| Delima and Tanna, 1989 | Non-union or delayed union long bones | PEMF | No | 29 | various | <ul style="list-style-type: none"> ▪ 16-18 hours/day ▪ No weight bearing ▪ Axial compression exercises after calcification and haziness of fracture gap ▪ Partial weight bearing after mature lamellar bone bridging gap | 3 months | Unspecified radiographic evidence |
| Dhawan et al., 2004 | Elective hindfoot arthrodesis | PEMF | No | 64 | Elective triple arthrodesis or subtalar arthrodesis | <ul style="list-style-type: none"> ▪ 10 days post surgery ▪ 12 hours/day ▪ No weight bearing in short leg cast | 27 weeks (max) | Radiographic evidence of fusion |
| DiSilvestre and Savini, 1992 | Spinal lumbar fusion | PEMF | No | 31 | <ul style="list-style-type: none"> ▪ Posterolateral lumbar fusion ▪ Iliac crest grafts ▪ Unilateral laminectomy to at least 3 levels in some patients (received instrumentation) | <ul style="list-style-type: none"> ▪ 10-12 hours/day for days 5-60 ▪ Plaster cast for 4 months ▪ Weight bearing at day 5 (earlier for instrumented patients) ▪ Immobilization day 60-120 | 4 months | Evaluation of radiographic parameters defined by Dawson |

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| Fontenesi et al., 1983 | <ul style="list-style-type: none"> ▪ Non-union long bones ▪ Non-union other bones ▪ Established pseudoarthrosis | PEMF | No | 33 | Not specified | <ul style="list-style-type: none"> ▪ 12 hours/day for at least 60 days ▪ Conventional cast, functional cast, external fixation, or internal fixation ▪ Weight bearing allowed in some cases | Seen every 60 days | Unspecified radiographic and clinical union |
| Frykman et al., 1986 | Non-union scaphoid | PEMF | No | 44 | Not specified | Not specified | Not specified | Unspecified radiographic criteria |
| Garland et al., 1991 | <ul style="list-style-type: none"> ▪ Non-union long bone ▪ Non-union other bones ▪ Failed joint fusion procedures | PEMF | No | 181 patients (139 completed study) | <ul style="list-style-type: none"> ▪ Bone grafting ▪ Internal fixation | 8 hours/day for 6 months or until union | 6 months Some patients evaluated at 4 years | <ul style="list-style-type: none"> ▪ Radiographic evidence of cortical bridging and/or trabecular bridging with major modification of the radiolucent gap on any view ▪ Overall callus showed progression ▪ Clinical evidence of no cast, no motion at fracture site, no or minimal pain at non-union site |
| Goodwin et al., 1999 | Lumbar spinal fusion | CC | No | 337 | <ul style="list-style-type: none"> ▪ Posterior or anterior lumbar interbody fusion ▪ Posterolateral fusion ▪ Autograft, allograft, or graft mixture ▪ Internal fixation device except interbody fusion cage | <ul style="list-style-type: none"> ▪ 24 hours/day until healing occurred ▪ Treatment stopped at 9 months if no healing | 12 months | <ul style="list-style-type: none"> ▪ Radiographic: documentation of solid fusion by both investigator and independent radiologist. ▪ Clinical: rated excellent or good |
| Gossling et al., 1992 | Non-union long bones | PEMF | No | N/A literature review of articles on tibial fracture | <ul style="list-style-type: none"> ▪ 14 articles on primary surgical treatment ▪ 28 articles on PEMF | Not specified | Varied per paper | Varied per paper |

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| Heckman et al., 1981 | <ul style="list-style-type: none"> ▪ Non-union long bones ▪ Non-union other bones | PEMF | No | 174 | <ul style="list-style-type: none"> ▪ yes, not specified ▪ internal fixation | <ul style="list-style-type: none"> ▪ 12 hours/day ▪ Immobilization ▪ No weight bearing for lower extremity fractures | 3 months | <ul style="list-style-type: none"> ▪ Radiographic criteria - fuzziness and clouding at fracture site and decreased density or softening of the sclerotic bone ends at fracture site ▪ Trabecular bridging of gap ▪ Remedullarization of bone ▪ Clinical criteria - decreased pain and mobility at fracture site with manipulative stress |
| Hinsenkamp et al., 1985 | <ul style="list-style-type: none"> ▪ Non-union long bones ▪ Non-union other bones | PEMF | No | 308 | Surgical procedure (80.6%) | 12 hours/day in one or more sequences | 3 years (max) | Not specified |
| Holmes, 1994 | Non-union metatarsal | PEMF | No | 9 | Not specified | <ul style="list-style-type: none"> ▪ 8-10 hours/day ▪ Weight bearing short leg cast ▪ Non-weight bearing short leg cast, or weight bearing shoe | 4 months | <ul style="list-style-type: none"> ▪ Radiographic evidence of trabecular bridging across fracture line ▪ Pain free gait ▪ Ambulation without cast or walking boot or post-op wooden shoe |
| Ito and Shirai, 2001 | Non-union long bone (tibia) | PEMF | No | 30 | Not specified | <ul style="list-style-type: none"> ▪ 8 hours/day ▪ No weight bearing ▪ PTB cast and brace if clinically needed | Every 6 weeks | <ul style="list-style-type: none"> ▪ Radiographic confirmation in 2 planes showing bony trabecular crossing at least ½ the width of fracture |
| Jenis et al., 2000 | Lumbar spinal fusion | PEMF | No | 61 | Instrumentation and autogenous iliac crest bone graft | At least 2 hours on 90% of the first 150 days of treatment | 12 months | <ul style="list-style-type: none"> ▪ Radiographic evaluation - 3 point scale ▪ Clinical evaluation rated poor - excellent |
| Linovitz et al., 2002 | Lumbar spinal fusion | CMF | No | 243 (enrolled) 201 (evaluated) | <ul style="list-style-type: none"> ▪ Primary non-instrumented intertransverse fusion ▪ Some autograft bone, with or without allograft material | Controlled by internal timer and microprocessor | 9 months | 3 point scale based on continuity in fusion mass and whether there is motion within the mass |

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| Madronero et al., 1988 | Non-union and delayed union long bones (radius) | PEMF | No | 10 | Implanted metallic plates allowed | Not specified | Not specified | <ul style="list-style-type: none"> ▪ Radiological evidence of presence of bone callus, pseudoarthrotic resolution ▪ Absence of spontaneous pain or pain under pressure ▪ No movement at fracture site |
| Marcer et al., 1984 | Non-union long bones | PEMF | No | 147 | External skeletal fixation and PEMF | 10 hours/day (recommended) | Not specified | <ul style="list-style-type: none"> ▪ No detectable motion or tenderness, no pain on weight-bearing, no need for external support ▪ Radiographic evidence of bone bridging gap |
| Meskens et al., 1990 | Non-union long bones | PEMF | No | 34 | Not specified | <ul style="list-style-type: none"> ▪ 1-3 months: 14 hours/day ▪ 4-6 months: 10 hours/day ▪ 6 months on: at night only ▪ Axial compression exercises on x-ray evidence of bone growth ▪ Mobilization and partial weight bearing when patient could support half body weight | Not specified | <ul style="list-style-type: none"> ▪ X-ray evidence of bridging and disappearance of gap ▪ No movement at fracture site ▪ No pain or pain on percussion of fracture |
| Meskens et al., 1990 | Non-union long bones | PEMF | No | 57 | Not specified | <ul style="list-style-type: none"> ▪ 1-3 months: 14 hours/day ▪ 4-6 months: 10 hours/day ▪ 6 months on: at night only ▪ Cast ▪ No weight bearing until signs of healing ▪ Progressive rehabilitation | Every 6-8 weeks | <ul style="list-style-type: none"> ▪ Mechanical stability on clinical testing ▪ Absence of local tenderness; and ▪ Obliteration of fracture gap on radiographs |
| Mooney, 1990 | Lumbar spinal fusion | PEMF | No | 206 (195 completed study) | <ul style="list-style-type: none"> ▪ Surgical interbody spinal fusion ▪ Various graft material ▪ Internal fixation for some patients | 8 hours/day | Not specified | Radiographic analysis indicated 50% assimilation of fusion |

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| O'Connor, 1985 | Non-union long bones | PEMF | No | 54 | Multiple - not specified | <ul style="list-style-type: none"> ▪ 12 hours/day ▪ Cast ▪ Internal or external fixation ▪ No weight bearing ▪ Axial compression exercises upon clinical stability of non-union | 12 months (max) | Unspecified radiographic evidence |
| Scott and King, 1994 | Non-union long bones | CC | No | 23 | Cast or brace support | <ul style="list-style-type: none"> ▪ Electrical stimulation not specified ▪ Cast or brace support continued ▪ Weight bearing allowed | 6 months | <ul style="list-style-type: none"> ▪ Clinical assessment of pain and motion ▪ Radiographic assessment of callus |
| Sedel et al. | <ul style="list-style-type: none"> ▪ Non-union long bone ▪ Non-union clavicle | PEMF | No | 39 | Not specified | <ul style="list-style-type: none"> ▪ Not specified ▪ Cast | Not specified | Not specified |
| Sharrard, 1982 | <ul style="list-style-type: none"> ▪ Non-union long bones (mostly tibia) ▪ Non-union other bones (ankle, knee, capitellum) | PEMF | No | 52 patients; 53 fractures | Surgery (at least 6 months previous) | <ul style="list-style-type: none"> ▪ 12-16 hours/day ▪ Axial compression exercises when evidence of increased density in gap ▪ Gradual weight bearing | 12 months | <ul style="list-style-type: none"> ▪ No clinical movement at fracture ▪ No pain or tenderness ▪ Radiographic evidence of bony tissue crossing at least ½ width of gap |
| Sharrard, 1990 | Non-union long bones (tibial shaft) | PEMF | No | 48 | Cast (not more than 32 weeks) | <ul style="list-style-type: none"> ▪ 12 hours/day no segment less than 1 hour ▪ No weight bearing ▪ Antibiotics and analgesics allowed | 3 months | Concurrence of orthopedic surgeon and radiologist on degree of healing |
| Simmons et al., 2004 | Lumbar spinal fusion | PEMF | No | 100 (with consistent device use) | Not specified | 2 hours/day for at least 90 days | Not specified | <ul style="list-style-type: none"> ▪ Radiologic criteria: 50% assimilation of graft ▪ Clinical: criteria from previously published paper |
| Simmons, 1985 | Lumbar spinal fusion | PEMF | No | 13 | Previous posterior lumbar interbody fusion | 8-10 hours/day with each session at least one hour | 12 months | Radiographic evidence of extent of bony fusion throughout nonunion site |
| Simonis et al., 1984 | <ul style="list-style-type: none"> ▪ Non-union long bones (tibia, ulna, radius) ▪ Non-union knee | PEMF | No | 15 | Not specified | <ul style="list-style-type: none"> ▪ Electrical treatment not specified ▪ Denham External Fixator ▪ Progressive weight bearing | Monthly evaluations | Not specified |