

Szakmai anyagok, tudományos cikkek és összefoglalók a pulzáló elektromágneses mezők alkalmazása a gyógyításban témakörben

1. Spine fusion for discogenic low back pain: outcome in patients treated with or without pulsed electromagnetic field stimulation. - Marks RA. Richardson Orthopaedic Surgery, Texas, USA.
2. The Effect of Pulsed Electromagnetic Fields in the Treatment of Osteoarthritis of the Knee and Cervical Spine. Report of Randomized, Double-Blind, Placebo Controlled Trials - Trock D. et.al. Department of Medicine, Danbury Hospital, CT. J. of Rheumatology
3. Low-amplitude, extremely low frequency magnetic fields for the treatment of osteoarthritic knees: a double-blind clinical study. V - Jacobson J. et.al. Inst. for Biophysical Research, Jupiter, FL, USA
4. Pulsed Electromagnetic Field Therapy, PEMT. How does it work? - Lecture abstract Dr. D. Laycock, Ph.D. Med. Eng. MBES, MIPEM, B.Ed.
5. Magnetic pulse treatment for knee osteoarthritis: a randomised, double-blind, placebo-controlled study. - Pipitone N. et.al. Rheumatology Department, King's College Hospital (Dulwich), London, UK.
6. Electrochemical therapy of pelvic pain: effects of pulsed electromagnetic fields (PEMF) on tissue trauma. - Jorgensen W. et.al. International Pain Research Institute, Los Angeles, California
7. Evaluation of electromagnetic fields in the treatment of pain in patients with lumbar radiculopathy or whiplash syndrome. - Thuile Ch. et.al. International Society of Energy Medicine, Vienna, Austria.
8. We assessed the efficacy and tolerability of low-frequency pulsed electromagnetic fields (PEMF) therapy in patients with clinically symptomatic knee osteoarthritis (OA) in a randomised, placebo-controlled, double-blind study of six weeks' duration. - Nicolò Pipitone, David L. Scott
9. Pulsed magnetic field therapy and the physiotherapist - Dr. D. C. Laycock, Ph.D. Med. Eng. Westville Consultants
10. Treatment of migraine with pulsing electromagnetic fields: a double-blind, placebo-controlled study. - Sherman R. et.al. Orthopedic Surgery Service, Madigan Army Medical Center, Tacoma, WA, USA.
11. Beneficial effects of electromagnetic fields - Bassett C. Bioelectric Research Center, Columbia University New York

12. Therapeutic effects of pulsed magnetic fields on joint diseases
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14. Prevention of osteoporosis by pulsed electromagnetic fields.
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The Effect of Pulsed Electromagnetic Fields in the Treatment of Osteoarthritis of the Knee and Cervical Spine. Report of Randomized, Double-Blind, Placebo Controlled Trials

OBJECTIVE. We conducted a randomized, double blind clinical trial to determine the effectiveness of pulsed electromagnetic fields (PEMF) in the treatment of osteoarthritis (OA) of the knee and cervical spine. **METHODS.** A controlled trial of 18 half-hour active or placebo treatments was conducted in 86 patients with OA of the knee and 81 patients with OA of the cervical spine, in which pain was evaluated using a 10 cm visual analog scale, activities of daily living using a series of questions (answered by the patient as never, sometimes, most of the time, or always), pain on passive motion (recorded as none, slight, moderate, or severe), and joint tenderness (recorded using a modified Ritchie scale). Global evaluations of improvement were made by the patient and examining physician. Evaluations were made at baseline, midway, end of treatment, and one month after completion of treatment.

RESULTS. Matched pair t tests showed extremely significant changes from baseline for the treated patients in both knee and cervical spine studies at the end of treatment and the one month follow-up observations, whereas the changes in the placebo patients showed lesser degrees of significance at the end of treatment, and had lost significance for most variables at the one month follow-up. Means of the treated group of patients with OA of the knee showed greater improvement from baseline values than the placebo group by the end of treatment and at the one month follow-up observation. Using the 2-tailed t test, at the end of treatment the differences in the means of the 2 groups reached statistical significance for pain, pain on motion, and both the patient overall assessment and the physician global assessment. The means of the treated patients with OA of the cervical spine showed greater improvement from baseline than the placebo group for most variables at the end of treatment and one month follow-up observations; these differences reached statistical significance at one or more observation points for pain, pain on motion, and tenderness.

CONCLUSION. PEMF has therapeutic benefit in painful OA of the knee or cervical spine.

Trock D. et.al. Department of Medicine, Danbury Hospital, CT. J. of Rheumatology

Low-amplitude, extremely low frequency magnetic fields for the treatment of osteoarthritic knees: a double-blind clinical study.

CONTEXT: Non-invasive magneto-therapeutic approaches to bone healing have been successful in past clinical studies. **OBJECTIVE:** To determine the effectiveness of low-amplitude, extremely low frequency magnetic fields on patients with knee pain due to osteoarthritis. **DESIGN:** Placebo-controlled, randomized, double-blind clinical study.

SETTING: 4 outpatient clinics. **PARTICIPANTS:** 176 patients were randomly assigned to 1 of 2 groups, the placebo group (magnet off) or the active group (magnet on).

INTERVENTION: 6-minute exposure to each magnetic field signal using 8 exposure sessions for each treatment session, the number of treatment sessions totalling 8 during a 2-week period, yielded patients being exposed to uniform magnetic fields for 48 minutes per treatment session 8 times in 2 weeks. The magnetic fields used in this study were generated by a resonator, which consists of two 18-inch diameter (46-cm diameter) coils connected in

series, in turn connected to a function generator via an attenuator to obtain the specific amplitude and frequency. The range of magnetic field amplitudes used was from 2.74×10^{-7} to 3.4×10^{-8} G, with corresponding frequencies of 7.7 to 0.976 Hz. OUTCOME

MEASURES: Each subject rated his or her pain level from 1 (minimal) to 10 (maximal) before and after each treatment and 2 weeks after treatment. Subjects also recorded their pain intensity in a diary while outside the treatment environment for 2 weeks after the last treatment session (session 8) twice daily: upon awakening (within 15 minutes) and upon retiring (just before going to bed at night). RESULTS: Reduction in pain after a treatment session was significantly ($P < .001$) greater in the magnet-on group (46%) compared to the magnet-off group (8%). CONCLUSION: Low-amplitude, extremely low frequency magnetic fields are safe and effective for treating patients with chronic knee pain due to osteoarthritis.

Jacobson J. et.al. Inst. for Biophysical Research, Jupiter, FL, USA

Pulsed Electromagnetic Field Therapy, PEMT. How does it work?

All living cells within the body possess potentials between the inner and outer membrane of the cell, which, under normal healthy circumstances, are fixed. Different cells, e.g. Muscle cells and Nerve cells, have different potentials of about -70 mV respectively. When cells are damaged, these potentials change such that the balance across the membrane changes, causing the attraction of positive sodium ions into the cell and negative trace elements and proteins out of the cell. The net result is that liquid is attracted into the interstitial area and swelling or oedema ensues. The application of pulsed magnetic fields has, through research findings, been shown to help the body to restore normal potentials at an accelerated rate, thus aiding the healing of most wounds and reducing swelling faster. The most effective frequencies found by researchers so far, are very low frequency pulses of a 50Hz base. These, if gradually increased to 25 pulses per second for time periods of 600 seconds (10 minutes), condition the damaged tissue to aid the natural healing process.

Pain reduction is another area in which pulsed electromagnetic therapy has been shown to be very effective. Pain signals are transmitted along nerve cells to pre-synaptic terminals. At these terminals, channels in the cell alter due to a movement of ions. The membrane potential changes, causing the release of a chemical transmitter from a synaptic vesicle contained within the membrane. The pain signal is chemically transferred across the synaptic gap to chemical receptors on the post-synaptic nerve cell. This all happens in about 1/2000th of a second, as the synaptic gap is only 20 to 50 nm wide. As the pain signal, in chemical form, approaches the post-synaptic cell, the membrane changes and the signal is transferred. If we look at the voltages across the synaptic membrane then, under no pain conditions, the level is about -70 mV. When the pain signal approaches, the membrane potential increases to approximately +30 mV, allowing a sodium flow. This in turn triggers the synaptic vesicle to release the chemical transmitter and so transfer the pain signal across the synaptic gap or cleft. After the transmission, the voltage reduces back to its normal quiescent level until the next pain signal arrives.

The application of pulsed magnetism to painful sites causes the membrane to be lowered to a hyper-polarization level of about -90 mV. When a pain signal is detected, the voltage must now be raised to a relatively higher level in order to fire the synaptic vesicles. Since the average change of potential required to reach the trigger voltage of nearly +30 mV is +100 mV, the required change is too great and only +10 mV is attained. This voltage is generally too low to cause the synaptic vesicle to release the chemical transmitter and hence the pain

signal is blocked. The most effective frequencies that have been observed from research in order to cause the above changes to membrane potentials, are a base frequency of around 100Hz and pulse rate settings of between 5 and 25Hz.

Lecture abstract Dr. D. Laycock, Ph.D. Med. Eng. MBES, MIPEM, B.Ed.

Magnetic pulse treatment for knee osteoarthritis: a randomised, double-blind, placebo-controlled study.

We assessed the efficacy and tolerability of low-frequency pulsed electromagnetic fields (PEMF) therapy in patients with clinically symptomatic knee osteoarthritis (OA) in a randomised, placebo-controlled, double-blind study of six weeks' duration. While the treated group demonstrated improvement over different indices to the contrary, the control group demonstrated none. There were no clinically relevant adverse effects attributable to active treatment. These results suggest that the unipolar magnetic devices are beneficial in reducing pain and disability in patients with knee OA resistant to conventional treatment in the absence of significant side effects.

Pipitone N. et.al. Rheumatology Department, King's College Hospital (Dulwich), London, UK.

Electrochemical therapy of pelvic pain: effects of pulsed electromagnetic fields (PEMF) on tissue trauma.

Unusually effective and long-lasting relief of pelvic pain of gynaecological origin has been obtained consistently by short exposures of affected areas to the application of a magnetic induction device. Treatments are short, fast-acting, economical and in many instances have obviated surgery. This report describes typical cases such as dysmenorrhoea, endometriosis, ruptured ovarian cyst, acute lower urinary tract infection, post-operative haematoma, and persistent dyspareunia in which pulsed magnetic field treatment has not, in most cases, been supplemented by analgesic medication. Of 17 female patients presenting with a total of 20 episodes of pelvic pain, 16 patients representing 18 episodes (90%) experienced marked, even dramatic relief, while two patients representing two episodes reported less than complete pain.

Jorgensen W. et.al. International Pain Research Institute, Los Angeles, California.

Evaluation of electromagnetic fields in the treatment of pain in patients with lumbar radiculopathy or whiplash syndrome.

Back pain and whiplash syndrome are very common diseases involving tremendous costs and extensive medical effort. A quick and effective reduction of symptoms, especially pain, is required. In two prospective randomized studies, patients with either lumbar radiculopathy in the segments L5/S1 or whiplash syndrome were investigated. Electromagnetic devices are pulsed field (PEMF) and constant wave (CW) types. These studies indicate both are effective, PEMF usually more quickly than CW. Pulsed magnetic fields appear to have a considerable and statistically significant potential for reducing pain in cases of lumbar radiculopathy and whiplash syndrome.

Thuile Ch. et.al. International Society of Energy Medicine, Vienna, Austria.

We assessed the efficacy and tolerability of low-frequency pulsed electromagnetic fields (PEMF) therapy in patients with clinically symptomatic knee osteoarthritis (OA) in a randomised, placebo-controlled, double-blind study of six weeks' duration.

Patients with radiographic evidence and symptoms of OA (incompletely relieved by conventional treatments), according to the criteria of the American College of Rheumatology, were recruited from a single tertiary referral centre. 75 Patients fulfilling the above criteria were randomised to receive active PEMF treatment by unipolar magnetic devices or placebo. Six patients failed to attend after the screening and were excluded from analysis. The primary outcome measure was reduction in overall pain assessed on a four-point Likert scale ranging from nil to severe. Secondary outcome measures included the WOMAC Osteoarthritis Index (Likert scale) and the EuroQol (Euro-Quality of Life, EQ-5D). Baseline assessments showed that the treatment groups were equally matched. Although there were no significant differences between active and sham treatment groups in respect of any outcome measure after treatment, paired analysis of the follow-up observations on each patient showed significant improvements in the actively treated group in the WOMAC global score ($p = 0.018$), WOMAC pain score ($p = 0.065$), WOMAC disability score ($p = 0.019$) and EuroQol score ($p = 0.001$) at study end compared to baseline. In contrast, there were no improvements in any variable in the placebo-treated group. There were no clinically relevant adverse effects attributable to active treatment. These results suggest that PEMF magnetic devices are beneficial in reducing pain and disability in patients with knee OA resistant to conventional treatment in the absence of significant side-effects. Further studies using different types of magnetic devices, treatment protocols and patient populations are warranted to confirm the general efficacy of PEMF therapy in OA and other conditions.

Nicolò Pipitone, David L. Scott

Pulsed magnetic field therapy and the physiotherapist

The therapeutic effect of the application of pulsed magnetic field therapy (PMFT) has at last received world-wide recognition, although for a long time many practitioners saw it only as an aid to fracture union. Research has now shown that it has the potential to improve a wide range of conditions, although few understood just how it achieved its effectiveness. Extensive research has since been carried out to determine the mechanism by which this occurs. For the physiotherapist, presented with a wide range of clinical problems, PMFT is an invaluable aid to the clinic.

Resolution of soft tissue injuries:

Over the past few years, research has shown that its effectiveness is not through heat production - as is the case with some modern treatments - but is at the cellular level. One significant outcome of this is the effect it has on soft tissue injuries. As early as 1940 it was suggested that magnetic fields might influence membrane permeability. It has since been established that magnetic fields can influence ATP (Adenosine Tri-phosphate) production; increase the supply of oxygen and nutrients via the vascular system; improve the removal of waste via the lymphatic system; and help to re-balance the distribution of ions across the cell membrane. Healthy cells in tissue have a membrane potential difference between the inner

and outer membrane. This causes a steady flow of ions through its pores. In a damaged cell the potential is raised and an increased and an increased sodium inflow occurs. As a result, interstitial fluid is attracted to the area, resulting in swelling and oedema.

The application of PMFT to damaged cells accelerates the re-establishment of normal potentials (Sansaverino) increasing the rate of healing and reducing swelling. This can help to disperse bruising also. A magnetic field pulsed at 5Hz with a base frequency of 50Hz can have the same effect as an ice pack in that in that it causes vasoconstriction.

Effects on fracture repair:

Acceptance of magnetic fields in medicine came about foremost in the field of orthopedics. Low frequency and low intensity fields have been used extensively for the treatment of non-union fractures. By 1979 this method was approved in the USA as a safe and effective treatment for non-union fractures; for failed arthroses; and for congenital pseudo-arthroses. According to Bassett this method has been used by more than 6,000 surgeons. The success rate was over 80% for tibial lesions. No patient suffered complications and biological side-effects included improved healing and increased neural function. In-depth research carried out to investigate this, shows that magnetic fields influence the process of bone formation in the intercellular medium. Madronero showed that bone healing was promoted by means of the influence of the magnetic field on the crystal formation of calcium salts.

Pain reduction:

Pulsed magnetic field therapy has been shown to bring about a reduction of pain, which again is due to action at the cellular level. Pain is transmitted as an electric signal, which encounters gaps at intervals along its path. The signal is transferred in the form of a chemical signal across the synaptic gap and this is detected by receptors on the post-synaptic membrane. A charge of about -70mV exists across the inner and outer membranes, but when a pain signal arrives it raises this to +30mV. This action causes channels to open in the membrane, triggering the release of a chemical transmitter and allowing ions to flow into the synaptic gap. The cell then re-polarizes to its previous resting level. Research by Warneke suggests that PMFT affects the quiescent potential of the membrane, lowering it to a hyper-polarized level of -90mV. Transmission is effectively blocked since the pain signal is unable to raise the potential to the level required to trigger the release of the chemical transmitter. Again, the frequency of the applied magnetic field is important, as the most effective frequency to produce this effect was found to be a base frequency of 100Hz pulsed at between 5 and 25 pulses per second.

Clinical applications:

The value of pulsed magnetic field therapy has been shown to cover a wide range of conditions, with well documented trials carried out by hospitals, rheumatologists and physiotherapists. For example, the department of rheumatology at Addenbrookes Hospital carried out investigations into the use of PMFT for the treatment of persistent rotator cuff tendinitis. The treatment was applied to patients who had symptoms refractory to steroid injection and other conventional treatments. At the end of the trial, 65% of these were symptom free, with 18% of the remainder being greatly improved.

Lau (School of Medicine, Loma University, USA) reported on the application of PMFT to the problems of diabetic retinopathy. Patients were treated over a 6-week period, 76% of the patients had a reduction in the level of numbness and tingling. All patients had a reduction of pain, with 66% reporting that they were totally pain-free. Many research studies, including Lau, reported on the application of PMFT for conditions such as sports injuries and for patients with joint and spinal problems. Although these are too numerous to mention individually, in almost every instance there was a reduction, if not complete resolution of symptoms. Soft tissue injuries and joint pains tended to be resolved within 5 days of treatment. Patients with cervical problems and low back pain were also successfully treated,

whereas previous treatment with ice, traction and other therapies had been unsuccessful. In yet another trial, the effect of applying PMFT to sufferers of Multiple Sclerosis was investigated (Geseo) 70% of sufferers had a reduction of weakness, pain and spasticity, with 50% reporting improvement of their bladder incontinence. Through the evaluation of hundreds of research papers, a number of points have been established regarding PMFT: The field must be pulsed, with low frequency to achieve the best effect.

Different conditions require different frequencies. For example, 5Hz causes vasoconstriction whilst 10Hz and above causes vasodilatation. Biological effectiveness is achieved in just 10 minutes for most injuries, so that long treatment sessions are not required. When used at the correct level there are no recorded side effects. Although PMFT is not yet recommended for use during pregnancy or in the presence of tumors, there are papers to suggest that magnetic fields can inhibit the growth of tumors.

Dr. D. C. Laycock, Ph.D. Med. Eng. Westville Consultants

Treatment of migraine with pulsing electromagnetic fields: a double-blind, placebo-controlled study.

The effect of exposure to pulsing electromagnetic fields on migraine activity was evaluated by having 42 subjects (34 women and 8 men), who met the International Headache Society's criteria for migraine, participate in a double-blind, placebo-controlled study. During the first month of follow-up, 73% of those receiving actual exposure, reported decreased headaches (45% substantial decrease, 14% excellent decrease) compared to half of those receiving the placebo (15% worse, 20% good, 0% excellent). Ten of the 22 subjects who had actual exposure received 2 additional weeks of actual exposure, after their initial 1-month follow-up. All showed decreased headache activity (50% substantial, 38% excellent). Eight of the subjects in the placebo group elected to receive 2 weeks of actual exposure after the initial 1-month follow-up with 75% showing decreased headache activity (38% substantial, 38% excellent). In conclusion, exposure to pulsing electromagnetic fields for at least 3 weeks is an effective, short-term intervention for migraine.

Sherman R. et.al. Orthopedic Surgery Service, Madigan Army Medical Center, Tacoma, WA, USA.

pine fusion for discogenic low back pain: outcome in patients treated with or without pulsed electromagnetic field stimulation.

Sixty-one randomly selected patients who underwent lumbar fusion surgeries for discogenic low back pain between 1987 and 1994 were retrospectively studied. All patients had failed to respond to preoperative conservative treatments. Forty-two patients received adjunctive therapy with pulsed electromagnetic field (PEMF) stimulation, and 19 patients received no electrical stimulation of any kind. Average follow-up time was 15.6 months postoperatively. Fusion succeeded in 97.6% of the PEMF group and in 52.6% of the unstimulated group ($P < .001$)

Marks RA. Richardson Orthopaedic Surgery, Texas, USA.

Beneficial effects of electromagnetic fields.

Selective control of cell function by applying specifically configured, weak, time-varying magnetic fields has added a new, exciting dimension to biology and medicine. Field parameters for therapeutic, pulsed electromagnetic field (PEMFs) were designed to induce voltages similar to those produced, normally, during dynamic mechanical deformation of connective tissues. As a result, a wide variety of challenging musculoskeletal disorders have been treated successfully over the past two decades. More than a quarter million patients with chronically ununited fractures have benefitted, worldwide, from this surgically non-invasive method, without risk, discomfort, or the high costs of operative repair. Many of the athermal bioresponses, at the cellular and subcellular levels, have been identified and found appropriate to correct or modify the pathologic processes for which PEMFs have been used. Not only is efficacy supported by these basic studies but by a number of double-blind trials. As understanding of mechanisms expands, specific requirements for field energetics are being defined and the range of treatable ills broadened. These include nerve regeneration, wound healing, graft behavior, diabetes, and myocardial and cerebral ischemia (heart attack and stroke), among other conditions. Preliminary data even suggest possible benefits in controlling malignancy.

Bassett C. Bioelectric Research Center, Columbia University New York

Therapeutic effects of pulsed magnetic fields on joint diseases.

The present paper describes the effects of pulsed magnetic fields (PMF) on diseases of different joints, in chronic as well as acute conditions where the presence of a phlogistic process is the rule. Optimal parameters for PMF applications were sought at the beginning of the study and then applied for 11 years; a technical modification in the PMF generator was introduced 5 years ago to satisfy the requirement of a hypothesis advanced to understand the mechanism of PMF treatment.

3,014 patients were treated by means of MF at extremely low frequencies and intensities. Patient follow-up was pursued as constantly as possible. Pain removal, recovery of joint mobility and maintenance of the improved conditions represented the parameters for judging the results as good or poor. The chi-square test was applied in order to evaluate the probability that the results are not casual. A general average value of 78.8% of good results and 21.2% of poor results was obtained. Higher (82%) percentages of good results were observed when single joint diseases were considered with respect to multiple joint diseases (polyarthrosis); in the latter, the percentage of good results was definitely lower (66%). The high percentage of good results obtained and the absolute absence of both negative results and undesired side-effects, together with the therapeutic advantage due to a technical modification in the PMF generator, led to the conclusion that magnetic field treatment is an excellent physical therapy in cases of joint diseases. A hypothesis is advanced that external magnetic fields influence trans-membrane ionic activity.

Riva Sanseverino, E. et.al. Università di Bologna, Italy.

Modification of biological behavior of cells by Pulsing Electromagnetic fields, (PMFT)

On the major part of the calcified mass of adult bone there are no changes in bone mass, however there is a part on which bone is being formed and a part on which bone is being resorbed. Decalcification occurs when bone resorption is greater than boneformation. Bone formation comprises two steps, the laying down of the extra-cellular matrix and the deposition therein of bone salts. The dynamic processes of formation and destruction of bone are under cellular control. Bone formation is controlled by single nuclear cells called Osteoblasts, and bone resorption by multinuclear giant cells are called Osteoclasts. Bone is a specialized connective tissue, in which a matrix consisting of collagen fibers and a large variety of other proteins and ground substance are impregnated with a solid mineral. The bone matrix is responsible for the resistance of bone to tractional and torsional forces. The collagen forms more than 25 % of the bones and is synthesized by osteoblasts. On the bone surface collagen fibers are normally arranged in concentric rings of hard calcified matrix.

The bone minerals provide to the bone compressive strength and rigidity. It contains the mineral salts hydroxyapatite and calcium. In addition there are small amounts of magnesium hydroxide, fluoride and sulphate. As these salts are deposited in the framework formed by the collagen fibers of the matrix, crystallization occurs and the tissue hardens. This process is called calcification or mineralisation. Both the concentrations of ions of calcium and phosphate in the extracellular fluid maintain crystallization. If the concentration is not adequate the tissue will not be hard enough resulting in increased bone fracture risk.

There are two types of bone structure. Cortical (compact) bone and trabecular (spongy) bone. Cortical bone is more dense and constitutes of 80 % of the skeletal mass and forms the external layer of all bones in the human body. Trabecular bone consists of lamellae arranged in an irregular latticework of thin plates of bone and helps long bones to resist the stress of weight placed on them.

The process by which bone forms is called ossification. Bone forms either by the mineralisation of cartilage or directly by osteoblasts in a collagenous matrix. During the first two decades of life bone grows, followed by consolidation and reaching its peak value around thirty five years. After this peak, bone loss starts. Nutritional factors, especially calcium intake, the level of physical activity and generic factors are important in determining the peak bone mass.

When a bone is fractured, it heals with bone. Bone is the only solid tissue in the body that can replace itself. Bone healing is simple when it occurs smoothly, complicated when it does not. The process is being initiated by stimuli from the bone itself. Fractures through bone with a good blood supply, surrounded by muscle and without soft tissue trauma, have an excellent chance of healing, but fractures at the middle of long bones, particularly with extensive soft tissue damage, have a high incidence of non-union.

Selected low-energy time-varying electromagnetic fields have been used during the past 15 years to treat un-united fractures (non-unions). More than 100,000 patients, mainly in the USA, have been treated. Retrospective studies have substantiated their biological effectiveness in large numbers. Bone is responsive to the mechanical demands placed on it. When loading diminishes, as it does during bed rest, immobilization and weightlessness, bone mass is lost. On the other hand when loading is increased correctly, bone mass increases.

Results of bio-mechanical and histologic investigations prove that electromagnetic fields not only prevent bone loss, but also restores bone mass, once lost. A program was set up at McGill University of Montreal, where was found that electromagnetic fields damp boneresorption activity. Furthermore prove was found that selected electromagnetic fields increase bone formation.

The resorption of bone is lowest and formation of new bone greatest, when energy of the imposed fields is concentrated in the lower frequency components. These results are consistent with other studies showing, that cells respond to a broad spectrum of frequencies.

They appear to be most sensitive to frequencies in the range of those produced endogenously, that is in the range of 100 Hz or less.

Tissue dosimetry studies show that the frequency response of cortical bone over a range of 100 Hz to 20 kHz show a steep roll off between 100 and 200 Hz.

Electromagnetic fields at specific frequencies have shown to produce osteogenic effects in a turkey ulna model. Furthermore low-amplitude signals decrease bone resorption in a canine fibular model. Lifestyle factors like malnutrition, smoking, excessive use of alcohol and a sedentary lifestyle contribute to, and worsen, osteoporosis. It is not known whether this response derives from decreased osteoblastic activity, increased osteoclastic resorption, or both. Elderly persons can heal fractures in normal intervals, showing that osteoblasts can be activated by appropriate stimuli.

A study at the University of Hawaii School of Medicine was designed to provide concrete data on the restoration of bone mass in post-menopausal females. A total of 20 subjects between 57 and 75 years, all with decreased bone mineral density as defined by a bone densitometer, were treated during a period of 12 weeks. After a period of 6 weeks the bone density rose in those patients with an average of 5.6%.

Electromagnetic fields do modify biological behavior by inducing electrical changes around and within the cell. The key to rational use of electromagnetic fields lies in the ability to define the specific treatment parameters (amplitude, frequency, orientation and timing). Properly applied pulsed electromagnetic fields, if scaled for whole body use, has clear clinical benefits in the treatment of bone diseases and related pain, often caused by micro-fractures in vertebrae. In addition, joint pain caused by worn out cartilage layers can be treated successfully, through electromagnetic stimulation, increasing the partial oxygen pressure and resulting in increased calcium transport. Repair and growth of cartilage is thus stimulated, preventing grinding of the bones.

Ben Philipson, Curatronic Ltd.

How can pulsed electromagnetic field therapy assist in the healing of bones and ligaments?

Bone is essentially calcium structure which contains trace elements. One particular element recently identified is Alpha Quartz. This is the same type of material used in computers and digital or electronic watches. When this material is compressed, it develops a voltage across its two compressive faces, a phenomenon known as the piezoelectric effect. The old crystal pickups on record players used this effect to generate electrical sound signals. Gas appliances and some cigar lighters also utilize the same effect to generate a spark for ignition.

In bone, areas of stress generate small electric charges which are greater than those of less stressed areas, so that polarized bone-laying cells (osteoblasts) are believed to be attracted to these areas and begin to build up extra bone material to counter the stress.

With bone injuries, bleeding occurs to form a haematoma in which capillaries quickly form, transporting enriched blood to the injury site. Pulsed Magnetic Field therapy of a base frequency of 50Hz, pulsed at above 12Hz, causes vasodilatation and capillary dilatation, so helping to speed up the process of callus formation. Within the bone itself, pulsed electromagnetism causes the induction of small eddy currents in the trace elements, which in turn purify and strengthen the crystal structures. These have the same effect as the stress-induced voltages caused by the alpha quartz and as such, attract bone cells to the area under treatment. This can, therefore, accelerate the bone healing process to allow earlier mobilization and eventual full union. Ligaments and tendons are affected in similar ways to

solid bone by pulsed electromagnetic therapy, since they are uncalcified bone structures in themselves.

Dr. D. C. Laycock, Ph.D. Med. Eng. Westville Consultants.

Prevention of osteoporosis by pulsed electromagnetic fields.

Using an animal model, we examined the use of pulsed electromagnetic fields, induced at a physiological frequency and intensity, to prevent the osteoporosis that is concomitant with disuse. By protecting the left ulnae of turkeys from functional loading, we noted a loss of bone of 13.0 per cent compared with the intact contralateral control ulnae over an eight-week experimental period. Using a treatment regimen of one hour per day of pulsed electromagnetic fields, we observed an osteogenic dose-response to induced electrical power, with a maximum osteogenic effect between 0.01 and 0.04 tesla per second. Pulse power levels of more or less than these levels were less effective. The maximum osteogenic response was obtained by a decrease in the level of intracortical remodeling, inhibition of endosteal resorption, and stimulation of both periosteal and endosteal new-bone formation. These data suggest that short daily periods of exposure to appropriate electromagnetic fields can beneficially influence the behavior of the cell populations that are responsible for bone-remodeling and that there is an effective window of induced electrical power in which bone mass can be controlled in the absence of mechanical loading.

Rubin C. et.al. Dep. of Orthopaedics, State University of New York J Bone Joint Surg Am

A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures.

A total of 45 tibial shaft fractures, all conservatively treated and with union delayed for more than 16 but less than 32 weeks were entered in a double-blind multi-centre trial. The fractures were selected for their liability to delayed union by the presence of moderate or severe displacement, angulation or comminution or a compound lesion with moderate or severe injury to skin and soft tissues. Treatment was by plaster immobilisation in all, with active electromagnetic stimulation units in 20 patients and dummy control units in 25 patients for 12 weeks. Radiographs were assessed blindly and independently by a radiologist and an orthopaedic surgeon. Statistical analysis showed the treatment groups to be comparable except in their age distribution, but age was not found to affect the outcome and the effect of treatment was consistent for each age group. The radiologist's assessment of the active group showed radiological union in five fractures, progress to union in five but no progress to union in 10. In the control group there was union in one fracture and progress towards union in one but no progress in 23. Using Fisher's exact test, the results were very significantly in favour of the active group ($p = 0.002$). The orthopaedic surgeon's assessment showed union in nine fractures and absence of union in 11 fractures in the active group. There was union in three fractures and absence of union in 22 fractures in the control group. These results were also significantly in favour of the active group ($p = 0.02$). It was concluded that pulsed electromagnetic fields significantly influence healing in tibial fractures with delayed union.

Sharrard WJ Royal Hallamshire Hospital, Sheffield, England. J Bone Joint Surg

A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions.

A randomized double-blind prospective study of pulsed electromagnetic fields for lumbar interbody fusions was performed on 195 subjects. There were 98 subjects in the active group and 97 subjects in the placebo group. A brace containing equipment to induce an electromagnetic field was applied to patients undergoing interbody fusion in the active group, and a sham brace was used in the control group. In the active group there was a 92% success rate, while the control group had a 65% success rate (P greater than 0.005). The effectiveness of bone graft stimulation with the device is thus established.

Mooney V. Orthopaedic Surgery, University of California Spine

Fundamental and practical aspects of therapeutic uses of pulsed electromagnetic fields (PEMFs).

The beneficial therapeutic effects of selected low-energy, time-varying magnetic fields, called PEMFs, have been documented with increasing frequency since 1973. Initially, this form of athermal energy was used mainly as a salvage for patients with long-standing juvenile and adult nonunions. Many of these individuals were candidates for amputation. Their clearly documented resistance to the usual forms of surgical treatment, including bone grafting, served as a reasonable control in judging the efficacy of this new therapeutic method, particularly when PEMFs were the sole change in patient management. More recently, the biological effectiveness of this approach in augmenting bone healing has been confirmed by several highly significant double-blind and controlled prospective studies in less challenging clinical circumstances. Furthermore, double-blind evidence of therapeutic effects in other clinical disorders has emerged. These data, coupled with well-controlled laboratory findings on pertinent mechanisms of action, have begun to place PEMFs on a therapeutic par with surgically invasive methods but at considerably less risk and cost. As a result of these clinical observations and concerns about electromagnetic "pollution", interactions of nonionizing electromagnetic fields with biological processes have been the subject of increasing investigational activity. Over the past decade, the number of publications on these topics has risen exponentially. They now include textbooks, speciality journals, regular reviews by government agencies, in addition to individual articles, appearing in the wide spectrum of peer-reviewed, scientific sources. In a recent editorial in *Current Contents*, the editor reviews the frontiers of biomedical engineering focusing on Science Citation Index methods for identifying core research endeavors. Dr. Garfield chose PEMFs from among other biomedical engineering efforts as an example of a rapidly emerging discipline. Three new societies in the bioelectromagnetics, bioelectrochemistry, and bioelectrical growth and repair have been organized during this time, along with a number of national and international committees and conferences. These activities augment a continuing interest by the IEEE in the U.S. and the IEE in the U.K. This review focuses on the principles and practice behind the therapeutic use of "PEMFs". This term is restricted to time-varying magnetic field characteristics that induce voltage waveform patterns in bone similar to those resulting from mechanical deformation. These asymmetric, broad-band pulses affect a number of biologic processes athermally. Many of these processes appear to have the ability to modify selected pathologic states in the musculoskeletal and other systems.

Bassett C. Dep. Orthopedic Surgery, Columbia University, New York. Crit Rev Biomed Eng

Pulsed electromagnetic fields promote collagen production in bone marrow fibroblasts via athermal mechanisms.

Primary and passaged cultures of fibroblasts (RBMFs) raised from the bone marrow stroma of young rabbits were treated with pulsed electromagnetic fields (PEMFs) from the start of each culture until 1 week after they became confluent. The PEMF treatment had no effect on cell proliferation, estimated by phase contrast microscopy, by ³H-thymidine incorporation into DNA, or by total DNA assay. Collagen production, estimated by conversion of ³H-proline to ³H-hydroxyproline in nondialyzable material was markedly elevated in postconfluent cultures, but not in cultures that had only just reached confluence. About 65% of ³H-hydroxyproline was in low molecular weight form, and a correlation between collagen breakdown and cyclic AMP (cAMP) levels in RBMFs was demonstrated by adding dibutyryl cAMP or prostaglandin E3 (PGE2) to the culture medium concurrently with ³H-proline. The PEMF apparatus caused an insufficient temperature rise (less than 0.1 degree C) to account for these results. We propose that the rise in collagen production is consistent with the hypothesis that PEMFs act by reducing cAMP levels in RBMFs, and that thermal effects are insignificant.

Farndale R. et.al Calcif Tissue Int

Modulation of collagen production in cultured fibroblasts by a low-frequency pulsed magnetic field.

Primary cultures of chicken tendon fibroblasts have been exposed for various periods to a low-frequency, pulsed magnetic field, and the effects on protein and collagen synthesis have been examined by radioisotopic incorporation. Total protein synthesis was increased in confluent cells treated with a pulsed magnetic field for the last 24 h of culture as well as in cells treated for a total of 6 days. However, in 6 day-treated cultures, collagen accumulation was specifically enhanced as compared to total protein, whereas after short-term exposure, collagen production was increased only to the same extent as total protein. Levels of cyclic AMP were significantly decreased after 6-day pulsed magnetic field treatment, probably as a consequence of diminished adenylate cyclase activity. Exposure to pulsed magnetic field had no effect on cell proliferation or collagen phenotype. These results indicate that a pulsed magnetic field can specifically increase production of collagen, the major differentiated function of fibroblasts, possibly by altering cyclic-AMP metabolism.

Murray J. et.al. Biochim Biophys Acta

Results of pulsed electromagnetic fields (PEMFs) in ununited fractures after external skeletal fixation.

Of 147 patients with fractures of the tibia, femur and humerus, in whom an average of 3.3 operations had failed to produce union, all were treated with external skeletal fixation in situ and pulsed electromagnetic fields (PEMFs). Of the 147, 107 patients united for an overall success rate of 73%. Union of the femur occurred in 81% and the tibia in 75%. Only five of

13 humeri united. Failure to achieve union with PEMFs was most closely associated with very wide fracture gaps and insecure skeletal fixation devices.

Marcer M. et.al. Clin Orthop

Osteonecrosis of the femoral head treated by pulsed electromagnetic fields (PEMFs): a preliminary report.

This has been a preliminary report with a short-term follow-up of a small number of observations (28 hips of 24 patients). The follow-ups ranged from 6 to 36 months, with an average of 17.8 months. Only eleven hips (in eleven patients) were followed an average of 8 months after cessation of the treatment. It should be emphasized that this was a "pilot" study, in which no control series was used to determine the natural course of the disease in a comparable clinical setting. Of note was the pain relief, in 19 of 23 patients with moderate to severe pretreatment pain. Also there was an improved function, which suggests that at least in approximately two thirds of the patients there was some clinical benefit from this mode of treatment. In eight hips, clinical conditions did not change; and in two they worsened, requiring further treatment. Eighteen remaining hips were thought to have benefited by the treatment. Six femoral heads that had already developed varying degrees of collapse (Ficat Type III) collapsed further (1 to 2 mm), and two round heads (Ficat II) progressed to off-round (Ficat III). This preliminary study suggests that further exploration of pulsed electromagnetic fields (PEMFs) is warranted in the treatment of osteonecrosis of the femoral head.

Eftekhar N. et.al. Hip

Treatment of therapeutically resistant non-unions with bone grafts and pulsing electromagnetic fields.

This study reviews the cases of eighty-three adults with ununited fractures who were treated concomitantly with bone-grafting and pulsed electromagnetic fields. An average of 1.5 years had elapsed since fracture and the use of this combined approach. Nearly one-third of the patients had a history of infection, and an average of 2.4 prior operations had failed to produce bone union. Thirty-eight patients who were initially treated with grafts and pulsed electromagnetic fields for ununited fractures with wide gaps, synovial pseudarthrosis, and malalignment achieved a rate of successful healing of 87 per cent. Forty-five patients who had initially been treated unsuccessfully with pulsing electromagnetic fields alone had bone-grafting and were re-treated with pulsing electromagnetic fields. Ninety-three per cent of these fractures healed. The residual failure rate after two therapeutic attempts, one of which was operative, was 1.5 per cent. The median time to union for both groups of patients was four months.

Bassett C. Et.al. J Bone Joint Surg Am

Effects of a pulsed electromagnetic field on a mixed chondroblastic tissue culture.

A mixed tissue culture predominantly composed of chondroblastic tissue was perturbed by a pulsed electromagnetic field (PEMF). Some cultures were nonconfluent, and purposely retarded in growth to resemble an atrophic nonunion, while others were grown to confluence in about one-half the time as a model for a hypertrophic nonunion. These two groups tested the effect of growth rate upon the products of cell proliferation and differentiation. The slowly growing cultures were stimulated to synthesize hydroxyproline. The rapidly growing cultures showed a large increase in lysozyme activity, and increase in hyaluronate and DNA, and a decrease in glycosaminoglycan. Exogenous lysozyme further decreased the glycosaminoglycan synthesis in the presence of PEMF. Chitotriose, a specific lysozyme inhibitor abolished this effect. Cycloheximide, a protein synthesis inhibitor, did not abolish the activation of lysozyme found in the matrix. Thus lysozyme appears to be activated by PEMF. These observations of the rapidly growing confluent cultures are consistent with events described in the normal healing of a bone fracture or endochondral growth. Thus, PEMF appears to promote normal healing, probably by altering cartilaginous lysozyme activity in the matrix, and possibly the sequence of events leading to calcification.

Norton LA Clin Orthop

Biological effects of magnetic fields: studies with microorganisms.

Five bacteria and one yeast were grown in magnetic fields of 50-900 gauss with frequencies of 0-0.3 HZ and square, triangular, or sine waveform. Growth of these microorganisms could be stimulated or inhibited depending upon the field strength and frequency of the pulsed magnetic field. Spore germination and mutation frequency were unaffected by the magnetic fields used in this study.

Moore R. Can J Microbiol

Influence of magnetic fields on calcium salts crystal formation: an explanation of the 'pulsed electromagnetic field' technique for bone healing.

In the search for a mechanism by means of which a magnetic field deparalyses non-unions and enhances bone tissue formation, the influence of continuous magnetic fields on the formation of calcium phosphate crystal seeds has been investigated. From this perspective, an explanation is given of a working mode in conventional equipment for pulsed electromagnetic field treatment; this is compared with multifunction equipment.

Madronero A J Biomed Eng

Treatment of nonunion using pulsed electromagnetic fields: a retrospective follow-up study.

Pulsed electromagnetic fields (PEMF) are a useful means of treating cases of fracture nonunion. In 67.7% of nonunions with a disability time of at least 24 months, complete consolidation was obtained. This success rate is increased to 76.6% if we exclude nonunion, that presented contraindications for treatment with PEMF. The disability time had no effect

on the success rate. Lesions of the humerus and atrophic nonunion had an unfavorable prognosis.

Meskens M. et.al. Dep. Orthopedic Surgery, University Hospital, Pellenberg, Belgium. Acta Orthop Belg

Effects of pulsed electromagnetic fields on Steinberg ratings of femoral head osteonecrosis.

95 Patients with femoral head osteonecrosis met the protocol for treatment of 118 hips with selected pulsed electromagnetic fields (PEMFs). Etiologies included trauma (17), alcohol (9), steroid use (46), sickle cell disease (2), and idiopathy (44). The average age was 38 years, and the average follow-up period since the onset of symptoms was 5.3 years. PEMF treatment had been instituted an average of 4.1 years earlier. By the Steinberg quantitative staging method of roentgenographic analysis, none of the 15 hips in Stages 0-III showed progression, and grading improved in nine of 15. Eighteen of 79 hips (23%) with Stage IV lesions progressed and none improved. In the Stage V category, one of 21 hips (5%) worsened and none improved. Three Stage VI lesions were unchanged. The overall rate of quantified progression for the 118 hips, 87% of which had collapse present when entering the program, was 16%. This value represents a reversal of the percentage of progression reported recently by other investigators using conservative and selected surgical methods. PEMF patients also have experienced long-term improvements in symptoms and signs, together with a reduction in the need for early joint arthroplasty.

Bassett C. et.al. Orthopaedic Hospital, Riverdale, NY Clin Orthop

Stimulation of experimental endochondral ossification by low-energy pulsing electromagnetic fields.

Pulsed electromagnetic fields (PEMFs) of certain configuration have been shown to be effective clinically in promoting the healing of fracture nonunions and are believed to enhance calcification of extracellular matrix. In vitro studies have suggested that PEMFs may also have the effect of modifying the extracellular matrix by promoting the synthesis of matrix molecules. This study examines the effect of one PEMF upon the extracellular matrix and calcification of endochondral ossification in vivo. The synthesis of cartilage molecules is enhanced by PEMF, and subsequent endochondral calcification is stimulated. Histomorphometric studies indicate that the maturation of bone trabeculae is also promoted by PEMF stimulation. These results indicate that a specific PEMF can change the composition of cartilage extracellular matrix in vivo and raises the possibility that the effects on other processes of endochondral ossification (e.g., fracture healing and growth plates) may occur through a similar mechanism.

Aaron R. et.al. Dep. Biochemistry and Biophysics, University of Rhode Island J Bone Miner Res

Role of pulsed electromagnetic fields in recalcitrant non-unions.

Twenty-nine patients of recalcitrant nonunion of long bones were treated by pulsed electromagnetic fields in an attempt to bring about osteogenesis. The pulse used was rectangular, equal mark space wave in the astable, continuous mode operating at a frequency of 40 Hertz. The success rate was 82.5%. The result was not dependent on the age, sex, time of nonunion or the presence of infection. However, the results were uniformly poor when infection and fracture instability were coexistent in the same patient.

Delima DF, Tanna DD J Postgrad Med

In vitro low frequency electromagnetic field effect on fast axonal transport.

The objective of this study was to evaluate the effects of a low frequency electromagnetic field on fast axonal transport for future neuroprosthetic applications. Changes in speeds and densities of retrograde fast organelle transport in rat sciatic nerve preparations were measured in vitro upon exposure to 15 and 50 Hz pulsed magnetic fields with peak intensities of 4.4 and 8.8 mT. Maximum current density of the induced eddy current was calculated to be about 40 microA/cm². Video enhanced differential interference contrast microscopy was used to record axons supporting active organelle transport. Strong effects were observed in myelinated axons (cessation of transport in up to 10 min). Such effects may eventually be used as part of a neuroprosthesis to noninvasively modify or couple to various parts of the nervous system.

Zborowski M. et.al. Dep. Artificial Organs, Cleveland Clinic Found. ASAIO Trans

Effects of pulsed extremely-low-frequency magnetic fields on skin wounds in the rat.

Rats with skin-wounds surgically created on their backs were exposed immediately after surgery and every 12 h thereafter to pulsed, extremely-low-frequency magnetic fields. The shape of the pulse was a positive triangle (50 Hz, 8 mT peak). The rate of healing of skin wounds was evaluated macroscopically and by light and electron microscopy at 6, 12, 21, and 42 days after the operation. A significant increase in the rate of wound contraction was found in rats treated with magnetic fields. Forty-two days after surgery all treated animals show fully closed wounds, while control rats at the same time intervals still lacked a final 6% of the wound surface to be covered. Treated rats showed earlier cellular organization, collagen formation and maturation, and a very early appearance of newly formed vascular network.

Ottani V. et.al. Istituto di Anatomia, Bologna, Italy. Bioelectromagnetics

Treatment of delayed union and nonunion of the tibia by pulsed electromagnetic fields. A retrospective follow-up.

The results of a clinical follow-up of 57 tibial lesions treated with pulsed electromagnetic fields at least six months after the primary lesion occurred proved that this noninvasive method can be a valuable alternative to other commonly accepted modes of therapy. The overall success rate was 75% but could be improved to 81% when the proper indications were met.

Meskens M. et.al. Dep. Orthopaedics, University Hospital, Pellenberg Bull Hosp Jt Dis Orthop Inst

Enhanced responsiveness to parathyroid hormone and induction of functional differentiation of cultured rabbit costal chondrocytes by a pulsed electromagnetic field.

Pulsed electromagnetic fields promote healing of delayed united and ununited fractures by triggering a series of events in fibrocartilage. We examined the effects of a pulsed electromagnetic field (recurrent bursts, 15.4 Hz, of shorter pulses of an average of 2 gauss) on rabbit costal chondrocytes in culture. A pulsed electromagnetic field slightly reduced the intracellular cyclic adenosine 3',5'-monophosphate (cAMP) level in the culture. However, it significantly enhanced cAMP accumulation in response to parathyroid hormone (PTH) to 140% of that induced by PTH in its absence, while it did not affect cAMP accumulation in response to prostaglandin E1 or prostaglandin I2. The effect on cAMP accumulation in response to PTH became evident after exposure of the cultures to the pulsed electromagnetic field for 48 h, and was dependent upon the field strength. cAMP accumulation in response to PTH is followed by induction of ornithine decarboxylase, a good marker of differentiated chondrocytes, after PTH treatment for 4 h. Consistent with the enhanced cAMP accumulation, ornithine decarboxylase activity induced by PTH was also increased by the pulsed electromagnetic field to 170% of that in cells not exposed to a pulsed electromagnetic field. Furthermore, stimulation of glycosaminoglycan synthesis, a differentiated phenotype, in response to PTH was significantly enhanced by a pulsed electromagnetic field. Thus, a pulsed electromagnetic field enhanced a series of events in rabbit costal chondrocytes in response to PTH. These findings show that exposure of chondrocytes to a pulsed electromagnetic field resulted in functional differentiation of the cells.

Hiraki Y. et.al. Dep. Biochemistry and Calcified-Tissue Metabolism, Faculty of Dentistry, Osaka University, Japan. Biochim Biophys Acta

Impulse magnetic-field therapy for erectile dysfunction: a double-blind, placebo-controlled study.

This double-blind, placebo-controlled study assessed the efficacy of 3 weeks of pulsing magnetic-field therapy for erectile dysfunction (ED). In the active-treatment group, all efficacy endpoints were significantly improved at study end ($P < \text{or} = .01$), with 80% reporting increases in intensity and duration of erection, frequency of genital warmth, and general well-being. Only 30% of the placebo group noted some improvement in their sexual activity; 70% had no change. No side effects were reported.

Pelka R. Et.al. Universitat der Bundeswehr Munchen, Neubiberg/Munich, Germany.

Comparison of electromagnetic field stimulation on the healing of small and large intestinal anastomoses.

Magnetic fields have been shown to affect biologic processes. Accordingly, an experimental study was designed to investigate the effect of electromagnetic field therapy on intestinal healing and to compare small and large intestinal anastomoses. Conclusions: Electromagnetic

field stimulation provided a significant gain in anastomotic healing in both small and large intestine. The study demonstrated a significant increase in both biochemical and mechanical parameters.

Nayci A. et.al. Cakmak M, Aksoyek S, Renda N, Yucesan S. Department of Pediatric Surgery, Mersin University Medical Faculty, Turkey.

The efficacy of un-united tibial fracture treatment using pulsing electromagnetic fields: relation to biological activity on non-union bone ends.

Thirty un-united tibial fractures with a median time since injury of 18+/-9 months were treated by electrical stimulation using pulsing electromagnetic field therapy. Union was achieved in 25 cases (83.3%) in a median interval of 8.6+/-3.2 months. Patient age, gender, the presence of surgical hardware, length of disability, and the number of surgical procedures did not affect the outcome. Un-united fractures that appeared to be hypertrophic or sclerotic, indicating a good blood supply to the bone ends, all healed.. Pulsing electromagnetic field therapy is an effective treatment for un-united tibial fractures with good blood supply to the bone ends.

Ito H. et.al. Department of Orthopaedic Surgery, Nippon Medical School, Tokyo, Japan.

Ultrastructural study of hyaluronic acid before and after the use of a pulsed electromagnetic field, electrolysis, in the treatment of wrinkles.

BACKGROUND. Treatment of wrinkles has become an increasing problem for dermatologists. Hyaluronic acid is a component of the family of glycosaminoglycans (GAGS, substances known for their property of retaining water), that significantly decreases with aging and in wrinkles. A new technique that uses a specific pulsed electromagnetic field, electrolysis, has been introduced in the treatment of wrinkles associated with aging. The treatment is based on the reported in vitro effects of specific electromagnetic fields on fibroblast cultures (e.g., an increase in DNA synthesis and in the production of collagen and presumably also of GAGS). **METHODS.** The in vivo effects of the electromagnetic field on aged skin (3 subjects aged 50, 56 and 60 years), with particular focus on the ultrastructural modifications and GAGS amount before and after the treatment, were evaluated by electron microscope. **RESULTS.** The ultrastructural study (tissue stained with alcian blue) showed after treatment a significant increase ($p < 0.005$) of the electron-dense granules (corresponding to hyaluronic acid), located in collagen elastic fibers, and in the soluble matrix. This presumably leads to subsequent edema that was clinically evident after the treatment. **CONCLUSIONS.** These data suggest that the increased levels of GAGS and the subsequent edema of the dermis could explain at least in part the clinical changes observed after electrolysis treatment (e.g., swelling and "disappearance" of the wrinkle).

Ghersetich I. Et.al. De. of Dermatology, University of Florence, Italy. Int J Dermatol

Optimization of electric field parameters for the control of bone remodeling: exploitation of an indigenous mechanism for the prevention of osteopenia.

The discovery of piezoelectric potentials in loaded bone was instrumental in developing a plausible mechanism by which functional activity could intrinsically influence the tissue's cellular environment and thus affect skeletal mass and morphology. Using an in vivo model of osteopenia, we have demonstrated that the bone resorption that normally parallels disuse can be prevented or even reversed by the exogenous induction of electric fields. Importantly, the manner of the response (i.e., formation, turnover, resorption) is exceedingly sensitive to subtle changes in electric field parameters. Fields below 10 microV/cm, when induced at frequencies between 50 and 150 Hz for 1 h/day, were sufficient to maintain bone mass even in the absence of function. Reducing the frequency to 15 Hz made the field extremely osteogenic. Indeed, this frequency-specific sinusoidal field initiated more new bone formation than a more complex pulsed electromagnetic field (PEMF), though inducing only 0.1% of the electrical energy of the PEMF. The frequencies and field intensities most effective in the exogenous stimulation of bone formation are similar to those produced by normal functional activity. This lends strong support to the hypothesis that endogenous electric fields serve as a critical regulatory factor in both bone modeling and remodeling processes. Delineation of the field parameters most effective in retaining or promoting bone mass will accelerate the development of electricity as a unique and site-specific prophylaxis for osteopenia. Because fields of these frequencies and intensities are indigenous to bone tissue, it further suggests that such exogenous treatment can promote bone quantity and quality with minimal risk or consequence.

Rubin C. Et.al. Dep. Orthopaedics, State University of New York J Bone Miner Res

Pulsed magnetic fields improve osteoblast activity during the repair of an experimental osseous defect.

The influence of pulsed low-frequency electromagnetic fields (PEMFs) on bone formation was investigated in studies of the healing process of transcortical holes, bored at the diaphyseal region of metacarpal bones of six adult horses, exposed for 30 days to PEMFs (28 G peak amplitude, 1.3 ms rise time, and 75 Hz repetition rate). A pair of Helmholtz coils, continuously powered by a pulse generator, was applied for 30 days to the left metacarpal bone, through which two holes, of equal diameter and depth, had been bored at the diaphyseal region. Two equal holes, bored at the same level in the right metacarpal and surrounded by an inactive pair of Helmholtz coils, were used as controls. All horses were given an intravenous injection of 25-30 mg/kg of tetracycline chloride on the 15th and again on the 25th day after the operation and were killed 5 days later. The histomorphometric analysis indicated that both the amount of bone formed during 30 days and the mineral apposition rate during 10 days (deduced from the interval between the two tetracycline labels) were significantly greater ($p < 0.01$ and $p < 0.0001$, respectively) in the PEMF-treated holes than in the controls. As did a previous investigation, these preliminary findings indicate that PEMFs at low frequency not only stimulate bone repair but also seem to improve the osteogenic phase of the healing process, at least in our experimental conditions.

Cane V. et.al. Institute of Human Anatomy, University of Modena, Italy. : J Orthop Res

Use of pulsed electromagnetic fields in treatment of loosened cemented hip prostheses. A double-blind trial.

A double-blind trial of pulsed electromagnetic fields (PEMFs) for loosened cemented hip prostheses was conducted at two centers. Of the 40 patients who enrolled, 37 met entry criteria and were available for analysis. All patients completed six months of treatment (either active or control units). Success was determined clinically by a Harris hip score greater than or equal to 80 points (or an increase of ten points if initially greater than or equal to 70 points). Ten of the 19 active units were successes (53%), whereas two of the 18 controls (11%) exhibited a placebo effect, a statistically significant and clinically relevant result. A 60% relapse rate among the active successes was seen at 14 months poststimulation, and despite maintenance therapy of one hour per day, the relapse rate increased to 90% at three years. These data suggest that for loosened cemented hip prostheses, use of PEMFs is a treatment option to delay revision hip surgery.

Kennedy W. et.al. Theda Clark Regional Medical Center, Wisconsin. Clin Orthop

The effect of low-frequency electrical fields on osteogenesis.

An in vivo animal model of disuse osteopenia was used to determine the osteogenic potential of specific components of electrical fields. The ability of a complex pulsed electrical field to inhibit loss of bone was compared with the remodeling response generated by extremely low-power, low-frequency (fifteen, seventy-five, and 150-hertz) sinusoidal electrical fields. The left ulnae of thirty adult male turkeys were functionally isolated by creation of distal and proximal epiphyseal osteotomies and then were exposed, for one hour each day, to an electrical field that had been induced exogenously by means of magnetic induction. After a fifty-six-day protocol, the remodeling response was quantified by a comparison of the cross-sectional area of the mid-part of the diaphysis of the functionally isolated ulna with that of the intact contralateral ulna. Disuse resulted in a 13 per cent mean loss of osseous tissue, which was not significantly different than the 10 per cent loss that was caused by disuse treated with inactive coils. Exposure to the pulsed electrical fields prevented this osteopenia and stimulated a 10 per cent mean increase in the bone area. The osteogenic influence of the sinusoidal electrical fields was strongly dependent on the frequency; the 150, seventy-five, and fifteen-hertz sinusoidal fields, respectively, generated a -3 per cent, + 5 per cent, and + 20 per cent mean change in the bone area. These results suggest a tissue sensitivity that is specific to very low-frequency sinusoidal electrical fields and they imply that the induced electrical fields need not have complex waveforms to be osteogenic. Since the frequency and intensity range of the sinusoidal fields producing the greatest osteogenic response are similar to the levels produced intrinsically by normal functional activity, these results support the hypothesis that electricity plays a role in the retention of the normal remodeling balance within mature bone.

McLeod K. et.al. Dep. Orthopaedics, School of Medicine, State University of New York, : J Bone Joint Surg Am

Treatment of ununited tibial fractures: a comparison of surgery and pulsed electromagnetic fields (PEMF).

The use of pulsed electromagnetic fields (PEMF) is gaining acceptance for the treatment of ununited fractures. The results of 44 articles published in the English language literature have been compiled to assess the effectiveness of PEMF vs surgical therapy. For ununited tibial

fractures, 81% of reported cases healed with PEMF vs 82% with surgery. After multiple failed surgeries, the success rate of PEMF is reported to be greater than with surgery; this discrepancy increases with additional numbers of prior surgeries. In infected nonunions, the results of surgical treatment decreased by 21% and were less than the results utilizing PEMF (69% vs 81%). In open fractures, surgical healing exceeded PEMF (89% vs 78%), whereas in closed injuries PEMF cases healed more frequently (85% vs 79%). In general, PEMF treatment of ununited fractures has proved to be more successful than noninvasive traditional management and at least as effective as surgical therapies. Given the costs and potential dangers of surgery, PEMF should be considered an effective alternative. Experience supports its role as a successful method of treatment for ununited fractures of the tibia.

Gossling H. Et.al. Dep. Orthopedic Surgery, University of Connecticut Orthopedics

Long-term pulsed electromagnetic field (PEMF) results in congenital pseudarthrosis.

Ninety-one patients with congenital pseudarthrosis of the tibia have been treated with pulsed electromagnetic fields (PEMFs) since 1973 and all except 4 followed to puberty. Lesions were stratified by roentgenographic appearance. Type I and type II had gaps less than 5 mm in width. Type III were atrophic, spindled, and had gaps in excess of 5 mm. Overall success in type I and II lesions was 43 of 60 (72%). Of those 28 patients seen before operative repair had been attempted, 7 of 8 type I lesions healed (88%), whereas 16 of 20 type II lesions healed (80%) on PEMFs and immobilization alone. Only 19% (6 of 31) type III lesions united, only one of which did not require surgery. Sixteen of 91 limbs (18%) were ultimately amputated, most before treatment principles were fully defined in 1980. Fourteen of these 16 patients (88%) had type III lesions. Refracture occurred in 22 patients, most as the result of significant trauma, in the absence of external brace support. Twelve of the 19 refractures, retreated with PEMFs and casts, healed on this regime. Episodic use of PEMFs proved effective in controlling stress fractures in several patients until they reached puberty. PEMFs, which are associated with no known risk, appear to be an effective, conservative adjunct in the management of this therapeutically challenging, congenital lesions.

Bassett C. et.al. Bioelectric Research Center, Riverdale, New York Calcif Tissue Int

Protection against focal cerebral ischemia following exposure to a pulsed electromagnetic field.

There is evidence that electromagnetic stimulation may accelerate the healing of tissue damage following ischemia.. Exposure to pulsed electromagnetic field attenuated cortical ischemia edema on MRI at the most anterior coronal level by 65% ($P < 0.001$). On histologic examination, PEMF exposure reduced ischemic neuronal damage in this same cortical area by 69% ($P < 0.01$) and by 43% ($P < 0.05$) in the striatum. Preliminary data suggest that exposure to a PEMF of short duration may have implications for the treatment of acute stroke.

Grant G. et.al. Department of Neurosurgery, Stanford University, California

Modulation of bone loss during disuse by pulsed electromagnetic fields.

The effect of pulsed electromagnetic fields (PEMFs) on bone loss associated with disuse was investigated by applying 1.5 Hz repetitions of 30 ms bursts of asymmetric pulses, varying from +2.5 to -135 mV, to bones deprived of their normal functional loading. The proximal portion of one fibula in each of a group of ovariectomised adult female beagle dogs was isolated from functional loading *in vivo* by proximal and distal osteotomies. Comparison of these prepared bones with their intact contralateral controls after 12 weeks, showed a 23% reduction in cross-sectional area. In similarly prepared bones exposed to PEMFs for 1 h per day, 5 days per week, this bone loss was substantially and significantly reduced to 9% ($p = 0.029$). There was no evidence of any new bone formation on the periosteal surface of prepared fibulae in treated or untreated situations. PEMF treatment was not associated with any significant change in number of osteons per mm² formed within the cortex of the bones, their radial closure rate, or their degree of closure. The modulation in loss of bone area associated with exposure to PEMFs can, therefore, be inferred to be due to a reduction in resorption on the bone surface.

Skerry T. et.al. Dep. of Anatomy, University of Bristol, U.K. J Orthop Res

Treatment of chronic varicose ulcers with pulsed electromagnetic fields: a controlled pilot study.

To evaluate the efficacy of pulsed electromagnetic fields (PEMF) in healing of chronic varicose ulcers, 19 patients with this condition were included in a double-blind controlled clinical trial. All patients received standard ulcer therapy throughout the duration of the study and were randomly divided into two groups to receive either active or inactive PEMF therapy. Active therapy was provided by the use of a pair of Helmholtz coils on a twice weekly basis over a five week period and inactive therapy was provided on an identical regimen with identical coils wound so that no magnetic field was produced when an electric current was passed through them. The clinician and patients were unable to distinguish the active or inactive coils. No statistically relevant difference was noted between the two groups in the healing rates of the ulcer, change in the lower leg girth, pain or infection rates. However there was a trend in favour of a decrease in ulcer size and lower leg girth in the group treated with active PEMF. As PEMF is a novel treatment for chronic varicose ulcers, more work needs to be done to establish treatment parameters and its usefulness in the treatment of this condition.

Todd D. et.al. Dep. Dermatology, Belfast City Hospital. Ir Med J

Low energy high frequency pulsed electromagnetic therapy for acute whiplash injuries. A double blind randomized controlled study.

The standard treatment of acute whiplash injuries (soft collar and analgesia) is frequently unsuccessful. Pulsed electromagnetic therapy PEMT has been shown to have pro-healing and anti-inflammatory effects. This study examines the effect of PEMT on the acute whiplash syndrome. PEMT as described is safe for domiciliary use and this study suggests that PEMT has a beneficial effect in the management of the acute whiplash injury.

Foley-Nolan D. et.al. Mater Hospital, Dublin, Ireland.

Bone density changes in osteoporosis-prone women exposed to pulsed electromagnetic fields (PEMF).

To determine the effect of a 72 Hz pulsating electromagnetic field (PEMF). Bone mineral densities of the treated radii measured by single-photon densitometry increased significantly in the immediate area of the field during the exposure period and decreased during the following 36 weeks. The data suggest that properly applied PEMF, if scaled for whole-body use, may have clinical application in the prevention and treatment of osteoporosis.

Tabrah F. et.al. University of Hawaii School of Medicine, Honolulu.

Effect of pulsed magnetic fields on human umbilical endothelial vein cells

The long-term goal of this program was to examine the efficacy of electromagnetic fields as an adjunct therapy to facilitate wound repair. The experiments reported here were directed to the question of whether pulsed electromagnetic fields (PEMF) could facilitate endothelial cell migration following induction of a wound. These studies were based on a report that weak PEMF facilitated cell migration in a wounded confluent monolayer culture of human umbilical vein cells. Experiments reported in this paper were an attempt to reproduce and extend these observations. Our data support the original observations. Further, we examined several hypotheses in an attempt to clarify the mechanism of interaction between the applied electromagnetic fields and cells. The data do not support the hypothesis that PEMF is acting in a manner similar to endothelial cell-growth factor, a normal component of the growth medium, or that PEMF applied at the time of cell transfer enhance DNA replication. We have found that PEMF is more effective in accelerating migration if they induce an electric field that is perpendicular rather than parallel to the sides of the wound.

Goodman, E. et.al J. Biomedical Res. Inst., Univ. Wisconsin, WI, USA

Effects of pulsed magnetic fields in the therapy of osteoporosis induced by ovariectomy in the rat.

This paper presents preliminary results on the effects of pulsed electromagnetic fields (EMF) in the therapy of post menopausal osteoporosis induced by ovariectomy in female rats aged ten months. In particular, the effects of the intensity of pulsed EMF applied at constant frequency has been studied. Magnetic fields pulsed at 50 Hz were used having a positive sinusoidal wave form with a maximum intensity of 30 and 70 Gauss. Treatment lasting one hour per day for 4 months showed that the pulsed EMF with 30 Gauss of maximum intensity are able to slow down the bone mass loss, keeping it within some 10%; with pulsed EMF with 70Gauss of maximum intensity, instead, no significant bone mass loss was observed.

Zati, A.et.al. Institute Orthopaedic Rizzoli, University of Bologna.

Possible therapeutic applications of pulsed magnetic fields

Magnetotherapy is a relatively new, nowadays however, relatively widespread method in several medical disciplines. The mechanism proper of the favorable action of the pulsed

magnetic field on the living organism is not quite clear so far, clinical investigations revealed, however, a favorable anti-inflammatory, angioedematous and analgesic therapeutic effect. The authors sought an optimal frequency of the pulsed magnetic field with regard to the character of the disease. They focused attention above all on treatment of acute and chronic inflammatory conditions of the locomotor apparatus, ischaemia of the blood vessels of the lower extremities, dyspeptic syndrome, lactation mastitis and other diseases. One therapeutic cycle lasted 20 minutes, the mean number of cycles varied between 5.8 and 7.7. A regression of complaints was recorded as a rule after 2-3 sessions. The optimal frequency of the pulsed magnetic field seems to be a value between 10.0 and 25.0 Hz. It is useful in particular in severe conditions to repeat the therapeutic cycle after 2-3 months. The advantage of this therapeutic method is the minimal number of contraindications.

Navratil, L. et.al. Czech Republic

The Canadian experience with pulsed magnetic fields in the treatment of un-united tibial fractures

A clinical survey of 56 patients was conducted at four different centers in Canada to evaluate the effect of extremely low frequency pulsed magnetic fields (PMF) on un-united fractures of the tibia. All ten patients with delayed union and 84% of the 44 patients with non-union healed. One case with a traumatic pseudarthrosis and one with a congenital pseudarthrosis failed to respond to treatment. These results compare favorably to those reported by others using a system with different pulse characteristics. Prolonged immobilization is necessary and poses problems of rehabilitation. Non-unions with a gap between the tibial fragments and pseudarthroses are better treated with bone grafting and internal fixation prior to electrical stimulation.

Haas, W. et.al. J. of Clin. Orthop.

Pulsed magnetic field therapy for tibial non-union. Interim results of a double-blind trial.

English patients with tibial fractures which had remained un-united for at least 52 weeks were randomly allocated to either active or dummy pulsed magnetic field stimulators and treated in full leg plasters for 24 weeks with a non-weight bearing conservative regimen, as is usual with such techniques. Fractures in 5 of the 9 patients with working machines united and fractures in 5 of the 7 patients with dummy machines also united. These early results of this double-blind trial are compatible with a difference in success rate at 24 weeks on active treatment of + 33% to -61% (95% confidence limits) compared with the success rate on the dummy stimulators. The high proportion 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.

Barker, A. et.al Lancet

Pulsed Magnetic Field Therapy For Insomnia: A Double-Blind, Placebo-Controlled Study

This 4-week double-blind, placebo-controlled study assessed the efficacy of impulse magnetic-field therapy for insomnia. One hundred one patients were randomly assigned to either active treatment (n = 50) or placebo (n = 51) and allocated to one of three diagnostic groups: (1) sleep latency; (2) interrupted sleep; or (3) nightmares. Efficacy endpoints were intensity of sleep latency, frequency of interruptions, sleepiness after rising, daytime sleepiness, difficulty with concentration, and daytime headaches. In the active-treatment group, the values of all criteria were significantly lower at study end ($P < .00001$). The placebo group also showed significant symptomatic improvement ($P < .05$), but the differences between groups were highly significant ($P < .00001$). Seventy percent (n = 34) of the patients given active treatment experienced substantial or even complete relief of their complaints; 24% (n = 12) reported clear improvement; 6% (n = 3) noted a slight improvement. Only one placebo patient (2%) had very clear relief; 49% (n = 23) reported slight or clear improvement; and 49% (n = 23) saw no change in their symptoms. No adverse effects of treatment were reported.

Uni der Bundeswehr Munich, Germany.

Pulsed electromagnetic fields increase growth factor release by nonunion cells.

The mechanisms involved in pulsed electromagnetic field stimulation of nonunions are not known. Animal and cell culture models suggest endochondral ossification is stimulated by increasing cartilage mass and production of transforming growth factor-beta 1. For the current study, the effect of pulsed electromagnetic field stimulation on cells from human hypertrophic (n = 3) and atrophic (n = 4) nonunion tissues was examined. Cultures were placed between Helmholtz coils, and an electromagnetic field (4.5-ms bursts of 20 pulses repeating at 15 Hz) was applied to 1/2 of them 8 hours per day for 1, 2, or 4 days. There was a time-dependent increase in transforming growth factor-beta 1 in the conditioned media of treated hypertrophic nonunion cells by Day 2 and of atrophic nonunion cells by Day 4. There was no effect on cell number, [3H]-thymidine incorporation, alkaline phosphatase activity, collagen synthesis, or prostaglandin E2 and osteocalcin production. This indicates that human nonunion cells respond to pulsed electromagnetic fields in culture and that transforming growth factor-beta 1 production is an early event. The delayed response of hypertrophic and atrophic nonunion cells (> 24 hours) suggests that a cascade of regulatory events is stimulated, culminating in growth factor synthesis and release.

Guerkov H. et.al. Dep. of Orthopaedics, Univ. of Texas Health Science Center. Clin Orthop

Comparative study of bone growth by pulsed electromagnetic fields.

Pulsed electromagnetic fields have been widely used for treatment of non-united fractures and congenital pseudarthrosis. Several electrical stimulation systems such as air-cored and iron-cored coils and solenoids have been used the world over and claimed to be effective. Electrical parameters such as pulse shape, magnitude and frequency differ widely, and the exact bone-healing mechanism is still not clearly understood. The study attempts to analytically investigate the effectiveness of various parameters and suggests an optimal stimulation waveform. Mathematical analysis of electric fields inside the bone together with Fourier analysis of induced voltage waveforms produced by commonly used electrical

stimulation wave-forms has been performed. A hypothesis based on assigning different weightings to different frequencies for osteogenic response has been proposed. Using this hypothesis astonishingly similar effective values of electric fields have been found in different systems. It is shown that effective electric field rather than peak electric field is the main parameter responsible for osteogenesis. The results are in agreement with experimental findings made on human beings by different investigators.

Gupta T. et.al. Dep. Electrical Engineering, Harcourt Butler Technological Institute, Kanpur, India. Med Biol Eng Comput

Long-term follow-up of fracture non-unions treated with PEMF.

One hundred thirty-nine established fracture non-unions were treated using a pulsed electromagnetic field (PEMF) device that also recorded patient usage. Patients who used the device less than an average of three hours a day had a success rate of 35.7% (5/14), while those who used the device in excess of three hours daily had an 80% success rate (108/135). The difference in the success rate was statistically significant at p less than .05. Treatment success was unaffected by long versus short bone, open versus closed fractures, nonunion of nine to 12 months duration compared to one to ten years, age of patient (whether less than or greater than age 60), gender, recalcitrant versus first time treatment, infected versus non-infected non-unions, fracture gaps up to 1cm, or weight bearing versus non-weight bearing. Ninety-seven fractures in 90 patients (90% follow-up) who averaged more than three hours of PEMF treatment daily and were originally classified as healed were reevaluated clinically and radiographically at four years following treatment (range: 3.6-5.4 years; mean: 4.1 years). Eighty-nine (92%) maintained a solid union. The success rate of PEMF treatment for nonunion repair demonstrated no statistically significant change over long-term follow-up.

Garland D. Et.al. University of Southern California School of Medicine, Los Angeles, California. Contemp Orthop

Augmentation of bone repair by pulsed elf magnetic fields.

Tibial osteotomies in rats were exposed for 2, 3, 5 and 8 weeks to a pulsed extremely low frequency magnetic field. The shape of the pulse was a double halfwave (50 Hz, 70 G). The rate of bone healing was evaluated by light and electron microscopy. An increase of bone healing was found in rats treated with magnetic fields persisting throughout the tested time. The accelerated healing process produced a sequence of morphological appearances identical to those of a normal fracture callus being the enhancement of osteogenesis produced by an acceleration of preliminary ossification.

Ottani V. et.al. Istituto di Anatomia Umana Normale, Bologna, Italy. Anat Anz

The development and application of pulsed electromagnetic fields (PEMFs) for ununited fractures and arthrodeses.

This article deals with the rational and practical use of surgically noninvasive pulsed electromagnetic fields (PEMFs) in treating ununited fractures, failed arthrodeses, and congenital pseudarthroses (infantile nonunions). The method is highly effective (more than 90 per cent success) in adult patients when used in conjunction with good management techniques that are founded on biomechanical principles. When union fails to occur with PEMFs alone after approximately four months, their proper use in conjunction with fresh bone grafts insures a maximum failure rate of 1 to 1.5 per cent. Union occurs because the weak electric currents induced in tissues by the time-varying fields effect calcification of the fibrocartilage in the fracture gap, thereby setting the stage for the final phases of fracture healing by endochondral ossification. The efficacy, safety, and simplicity of the method has prompted its use by the majority of orthopedic surgeons in this country. In patients with delayed union three to four months postfracture, PEMFs appear to be more successful and healing, generally, is more rapid than in patients managed by other conservative methods. For more challenging problems such as actively infected nonunions, multiple surgical failures, long-standing (for example, more than two years postfracture) atrophic lesions, failed knee arthrodeses after removal of infected prostheses, and congenital pseudarthroses, success can be expected in a large majority of patients in whom PEMFs are used. Finally, as laboratory studies have expanded knowledge of the mechanisms of PEMF action, it is clear that different pulses affect different biologic processes in different ways. Selection of the proper pulse for a given pathologic entity has begun to be governed by rational processes similar, in certain respects, to those applied to pharmacologic agents.

Bassett CA Clin Plast Surg & Orthop Clin North Am

Pulsed electromagnetic field stimulation of MG63 osteoblast-like cells affects differentiation and local factor production.

Pulsed electromagnetic field stimulation has been used to promote the healing of chronic non-unions and fractures with delayed healing, but relatively little is known about its effects on osteogenic cells or the mechanisms involved. The purpose of this study was to examine the response of osteoblast-like cells to a pulsed electromagnetic field signal used clinically and to determine if the signal modulates the production of autocrine factors associated with differentiation. Confluent cultures of MG63 human osteoblast-like cells were placed between Helmholtz coils and exposed to a pulsed electromagnetic signal consisting of a burst of 20 pulses repeating at 15 Hz for 8 hours per day for 1, 2, or 4 days. Controls were cultured under identical conditions, but no signal was applied. Treated and control cultures were alternated between two comparable incubators and, therefore, between active coils; measurement of the temperature of the incubators and the culture medium indicated that application of the signal did not generate heat above the level found in the control incubator or culture medium. The pulsed electromagnetic signal caused a reduction in cell proliferation on the basis of cell number and [³H]thymidine incorporation. Cellular alkaline phosphatase-specific activity increased in the cultures exposed to the signal, with maximum effects at day 1. In contrast, enzyme activity in the cell-layer lysates, which included alkaline phosphatase-enriched extracellular matrix vesicles, continued to increase with the time of exposure to the signal. After 1 and 2 days of exposure, collagen synthesis and osteocalcin production were greater than in the control cultures. Prostaglandin E₂ in the treated cultures was significantly reduced at 1 and 2 days, whereas transforming growth factor-beta₁ was increased; at 4 days of treatment, however, the levels of both local factors were similar to those in the controls. The results indicate enhanced differentiation as the net effect of pulsed electromagnetic fields on

osteoblasts, as evidenced by decreased proliferation and increased alkaline phosphatase-specific activity, osteocalcin synthesis, and collagen production. Pulsed electromagnetic field stimulation appears to promote the production of matrix vesicles on the basis of higher levels of alkaline phosphatase at 4 days in the cell layers than in the isolated cells, commensurate with osteogenic differentiation in response to transforming growth factor-beta1. The results indicate that osteoblasts are sensitive to pulsed electromagnetic field stimulation, which alters cell activity through changes in local factor production.

Lohmann C. et.al. Dep. Orthopaedics, University Texas Health Science Center, San Antonio J Orthop Res

Pulsed electromagnetic fields affect the intracellular calcium concentrations in human astrocytoma cells.

Experiments assessed whether long term exposure to 50 Hz pulsed electromagnetic fields with a peak magnetic field of 3 mT can alter the dynamics of intracellular calcium in human astrocytoma U-373 MG cells. Pretreatment of cells with 1.2 μ M substance P significantly increased the $[Ca^{2+}]_i$. The same effect was also observed when $[Ca^{2+}]_i$ was evaluated in the presence of 20 mM caffeine. After exposure to electromagnetic fields the basal $[Ca^{2+}]_i$ levels increased significantly from 143 \pm 46 nM to 278 \pm 125 nM. The increase was also evident after caffeine addition, but in cells treated with substance P and substance P + caffeine we observed a $[Ca^{2+}]_i$ decrease after exposure. When we substituted calcium-free medium for normal medium immediately before the $[Ca^{2+}]_i$ measurements, the $[Ca^{2+}]_i$ was similar to that measured in the presence of Ca^{2+} . In this case, after EMFs exposure of cells treated with substance P, the $[Ca^{2+}]_i$, measured without and with addition of caffeine, declined from 824 \pm 425 to 38 \pm 13 nM and from 1369 \pm 700 to 11 \pm 4 nM, respectively, indicating that electromagnetic fields act either on intracellular Ca^{2+} stores or on the plasma membrane. Moreover the electromagnetic fields that affected $[Ca^{2+}]_i$ did not cause cell proliferation or cell death and the proliferation indexes remained unchanged after exposure.

Pessina G. et.al. Inst. of General Physiology and Nutritional Science, University of Siena, Italy. Bioelectromagnetics

Pulsed electromagnetic fields promote bone formation around dental implants inserted into the femur of rabbits.

The present study examined the effect of applying a pulsed electromagnetic field (PEMF) on bone formation around a rough-surfaced dental implant. A dental implant was inserted into the femur of Japanese white rabbits bilaterally. A PEMF with a pulse width of 25 microseconds and a pulse frequency of 100 Hz was applied. PEMF stimulation was applied for 4 h or 8 h per day, at a magnetic intensity of 0.2 mT, 0.3 mT or 0.8 mT. The animals were sacrificed 1, 2 or 4 weeks after implantation. After staining the resin sections with 2% basic fuchsin and 0.1% methylene blue, newly formed bone around the implant on tissue sections was evaluated by computer image analysis. The bone contact ratios of the PEMF-treated femurs were significantly larger than those of the control groups. Both the bone contact ratio and bone area ratio of the 0.2 mT- and 0.3 mT-treated femurs were significantly larger than the respective value of the 0.8 mT-treated femurs ($P < 0.001$). No significant difference in

bone contact ratio or bone area ratio was observed whether PEMF was applied for 4 h/day or 8 h/day. Although a significantly greater amount of bone had formed around the implant of the 2-week treated femurs than the 1-week treated femurs, no significant difference was observed between the 2-week and 4-week treated femurs. These results suggest that PEMF stimulation may be useful for promoting bone formation around rough-surfaced dental implants. It is important to select the proper magnetic intensity, duration per day, and length of treatment.

Matsumoto H. et.al. Dep. of Fixed Prosthodontics, School of Dentistry, University of Hokkaido, Ishikari-Tobetsu, Japan. J. of Clin Oral Implants

PEMF data collection and analysis.

Eighty-five patient records were reviewed retrospectively to determine the status of lumbar spinal fusion in patients who had undergone surgery of posterior lumbar interbody fusion (PLIF) and/or by a posterolateral (PL) approach, and received postoperative therapy with a noninvasive device that generated pulsed electromagnetic fields (PEMF). Sixty-six patients (77.6%) had risk factors associated with a poor prognosis for healing, including smoking, prior back surgery, multiple spinal levels fused, diabetes mellitus, and obesity. Roentgenographic and clinical evidence indicated that all but two patients achieved successful fusion. The characteristics of these two patients were age 40-55 years, 1 male and 1 female, both were smokers, 1 primary fusion and 1 revision fusion, and both patients underwent single-level PLIF using autogenous graft. After the treatment, seven (8%) patients reported no change in level of pain, but the remainder (92%) reported that pain decreased by one to three levels. Of the 83 patients with successful spinal fusion, 29 (34.9%) were assessed as "excellent," 45 (54.2%) as "good," 3 (3.6%) as "fair," and 6 (7.2%) as "poor." Adjunctive treatment with PEMF appeared effective in promoting spinal fusion following PLIF or PL procedures across all patient subgroups.

Richard A. Silver, M.D. Tucson Orthopaedic & Fracture Surgery Associates, Ltd., Tucson, AZ.

Therapeutic effects of alternating current pulsed electromagnetic fields in multiple sclerosis.

Multiple sclerosis is the third most common cause of severe disability in patients between the ages of 15 and 50 years. The cause of the disease and its pathogenesis remain unknown. The last 20 years have seen only meager advances in the development of effective treatments for the disease. No specific treatment modality can cure the disease or alter its long-term course and eventual outcome. Moreover, there are no agents or treatments that will restore premorbid neuronal function. A host of biological phenomena associated with the disease involving interactions among genetic, environmental, immunologic, and hormonal factors, cannot be explained on the basis of demyelination alone and therefore require refocusing attention on alternative explanations, one of which implicates the pineal gland as pivotal. The pineal gland functions as a magnetoreceptor organ. This biological property of the gland provided the impetus for the development of a novel and highly effective therapeutic modality, which involves transcranial applications of alternating current (AC) pulsed electromagnetic fields flux density. This review summarizes recent clinical work on the effects of transcranially

applied pulsed electromagnetic fields for the symptomatic treatment of the disease. Sandyk R. Dep. of Neuroscience, Institute for Biomedical Engineering and Rehab Services of

Touro College, Dix Hills, New York.

Double-blind study of pulsing magnetic field effects on multiple sclerosis

We performed a double-blind study to measure the clinical and sub-clinical effects of an alternative medicine electromagnetic device on disease activity in multiple sclerosis (MS). The MS patients were exposed to a magnetic pulsing device where the frequency of the magnetic pulse was in the 4-13 Hz range. A total of 30 MS patients wore the device on pre-selected sites between 10 and 24 hours a day for 2 months. Half of the patients (15) randomly received a device that was magnetically inactive and the other half received an active device. Each MS patient received a set of tests to evaluate MS disease status before and after wearing the device. The tests included (1) a clinical rating (Kurtzke, EDSS), (2) patient-reported performance scales, and (3) quantitative electro-encephalography (QEEG) during a language task. Although there was no significant change between pretreatment and post-treatment in the EDSS scale, there was a significant improvement in the performance scale (PS) combined rating for bladder control, cognitive function, fatigue level, mobility, spasticity, and vision (active group -3.83 ± 1.08 , $p < 0.005$; placebo group -0.17 ± 1.07 , change in PS scale). There was also a significant change between pre-treatment and post-treatment in alpha EEG magnitude during the language task recorded at various electrode sites on the left side. In this double-blind, placebo-controlled study, we have demonstrated a statistically significant effect of the magnetic pulsing device on patient performance scales and on alpha EEG magnitude during a language task.

Richards T. et.al. Dep. Radiology, University of Washington

Pulsing magnetic field effects on brain electrical activity in multiple sclerosis

Multiple sclerosis (MS) is a disease of the central nervous system. Clinical symptoms include central fatigue, impaired bladder control, muscle weakness, sensory deficits, impaired cognition, and others. The cause of MS is unknown, but from histologic, immunologic, and radiologic studies, we know that there are demyelinated brain lesions (visible on magnetic resonance images) that contain immune cells such as macrophages and T-cells (visible on microscopic analysis of brain sections). Recently, a histologic study has also shown that widespread axonal damage occurs in MS along with demyelination. What is the possible connection between MS and bio-electromagnetic fields? We recently published a review entitled "Bio-electromagnetic applications for multiple sclerosis," which examined several scientific studies that demonstrated the effects of electromagnetic fields on nerve regeneration, brain electrical activity (electro-encephalography), neurochemistry, and immune system components. All of these effects are important for disease pathology and clinical symptoms in multiple sclerosis (MS). EEG was measured in this study in order to test our hypothesis that the pulsing magnetic device affects the brain electrical activity, and that this may be a mechanism for the effect we have observed on patient-reported symptoms. The EEG data reported previously were measured only during resting and language conditions. The purpose of the current study was to measure the effect of the electromagnetic device on EEG activity during and after photic stimulation with flashing lights. After photic stimulation, there

was a statistically significant increase in alpha EEG magnitude that was greater in the active group compared to the placebo group in electrode positions P3, T5, and O1 (analysis of variance $p < .001$, $F=14$, $DF = 1,16$). In the comparison between active versus placebo, changes measured from three electrode positions were statistically significantly even after multiple comparison correction.

Richards TL, Acosta-Urquidi, J In Biologic Effects of Light 1998 Symposium

Treatment with weak electromagnetic fields improves fatigue associated with multiple sclerosis.

It is estimated that 75-90% of patients with multiple sclerosis (MS) experience fatigue at some point during the course of the disease and that in about half of these patients, subjective fatigue is a primary complaint. In the majority of patients fatigue is present throughout the course of the day being most prominent in the mid to late afternoon. Sleepiness is not prominent, but patients report that rest may attenuate fatigability. The pathophysiology of the fatigue of MS remains unknown. Delayed impulse conduction in demyelinated zones may render transmission in the brainstem reticular formation less effective. In addition, the observation that rest may restore energy and that administration of pemoline and amantadine, which increase the synthesis and release of monoamines, often improve the fatigue of MS suggest that depletion of neurotransmitter stores in damaged neurons may contribute significantly to the development of fatigue in these patients. The present report concerns three MS patients who experienced over several years continuous and debilitating fatigue throughout the course of the day. Fatigue was exacerbated by increased physical activity and was not improved by rest. After receiving a course of treatments with picotesla flux electromagnetic fields (EMFs), which were applied extracranially, all patients experienced improvement in fatigue. Remarkably, patients noted that several months after initiation of treatment with EMFs they were able to recover, after a short period of rest, from fatigue which followed increased physical activity. These observations suggest that replenishment of monoamine stores in neurons damaged by demyelination in the brainstem reticular formation by periodic applications of picotesla flux intensity EMFs may lead to more effective impulse conduction and thus to improvement in fatigue including rapid recovery of fatigue after rest.

Sandyk R. NeuroCommunication Research Laboratories, Danbury, CT, USA.

Effects of pulsed electromagnetic fields on rat skin metabolism.

In an attempt to approach the mechanism of action of pulsed electromagnetic fields (PEMF) on biological systems, the effects on protein synthesizing activity and on membrane transport have been examined in rat skin. PEMF characterized by specific physical parameters stimulate the incorporation of L-[U-14C] isoleucine into the proteins of rat skin as well as the alpha-amino [1-14C] isobutyric acid uptake during incubation in buffer medium with extracellular electrolyte composition. Analogous incubation experiments carried out in an intracellular medium results in an inhibitory effect of PEMF on both biological functions. Addition of 10^{-3} M ouabain to the incubation medium, partially blocking the Na^+/K^+ -ATPase pump mechanism, apart from reducing amino acid transport, results in an overall disappearance of any stimulatory effects by PEMF. PEMF applied to the skin in the presence of 10^{-3} M 2,4-dinitrophenol uncoupling the oxidative phosphorylation in the mitochondria

and seriously restricting protein synthesis, still provides a limited stimulatory effect on protein synthesizing activity and on membrane transport. The effects of PEMF may well be understood by an increased availability of precursor elements controlled at the cell membrane level. Indeed the observed effects may even be simulated outside electromagnetic fields by modifications in the electrolyte composition of the incubation medium.

De Loecker W. Et.al. Biochemal dep. Universiteit Leuven, Belgium. Biochim Biophys Acta

<http://www.curatronic.com/scientific2.html> :



Augmented bone-matrix formation and osteogenesis under magnetic field stimulation in vivo XRD, TEM and SEM investigations.

Singh P, YashRoy RC, Hoque M. Biophysics and Electron Microscopy Section, Indian Veterinary Research Institute, Izatnagar-243122, UP, India. psingh67@yahoo.com

Bone is a composite biomaterial, which is formed, when proteins constituting collagen fibers attract calcium, phosphate and hydroxide ions in solution to nucleate atop the fibers. It grows into a hard structure of tiny crystallites of hydroxyapatite, aligned along the long axis of collagen fibers. The present work reports the stimulating effect of static magnetic field on microstructure and mineralization process of bone repair. A unilateral transverse fracture of mid-shaft of metacarpal was surgically created in healthy goats under thiopental sedation and xylocaine analgesia. Two bar magnets (approximately 800 gauss/cm² field strength) were placed across the fracture line at opposite pole alignment immobilized in Plaster of Paris (POP) splint bandage for static magnetic field stimulation. Radiographs were taken at weekly intervals up to 45 days. Results show that formation of extra-cellular matrix and its microstructure can be influenced by non-invasive physical stimulus (magnetic field) for achieving an enhanced osteogenesis, leading to quicker regeneration of bone tissue in goats. X-ray diffraction (XRD) patterns of treated (magnetic field-exposed) and control samples revealed the presence and orientation of crystalline structures. Intensity of diffraction peaks corresponding to 310 and 222 planes were enhanced with respect to 211 families of reflections, indicating preferential alignment of the crystals. Also, the percent crystallinity and crystal size were increased in treated samples. The study provides a biophysical basis for augmented fracture healing under the influence of semi-aligned static magnetic field applied across the fracture line.

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Fundamental and practical aspects of therapeutic uses of pulsed electromagnetic fields (PEMFs).

Bassett CA. Department of Orthopedic Surgery, Columbia University, New York, New York.

The beneficial therapeutic effects of selected low-energy, time-varying magnetic fields, called PEMFs, have been documented with increasing frequency since 1973. Initially, this form of athermal energy was used mainly as a salvage for patients with long-standing juvenile and adult nonunions. Many of these individuals were candidates for amputation. Their clearly documented resistance to the usual forms of surgical treatment, including bone grafting, served as a reasonable control in judging the efficacy of this new therapeutic method, particularly when PEMFs were the sole change in patient management. More recently, the biological effectiveness of this approach in augmenting bone healing has been confirmed by several highly significant double-blind and controlled prospective studies in less challenging clinical circumstances. Furthermore, double-blind evidence of therapeutic effects in other clinical disorders has emerged. These data, coupled with well-controlled laboratory findings on pertinent mechanisms of action, have begun to place PEMFs on a therapeutic par with surgically invasive methods but at considerably less risk and cost. As a result of these clinical observations and concerns about electromagnetic "pollution", interactions of nonionizing electromagnetic fields with biological processes have been the subject of increasing investigational activity. Over the past decade, the number of publications on these topics has risen exponentially. They now include textbooks, speciality journals, regular reviews by government agencies, in addition to individual articles, appearing in the wide spectrum of

peer-reviewed, scientific sources. In a recent editorial in *Current Contents*, the editor reviews the frontiers of biomedical engineering focusing on Science Citation Index methods for identifying core research endeavors. Dr. Garfield chose PEMFs from among other biomedical engineering efforts as an example of a rapidly emerging discipline. Three new societies in the bioelectromagnetics, bioelectrochemistry, and bioelectrical growth and repair have been organized during this time, along with a number of national and international committees and conferences. These activities augment a continuing interest by the IEEE in the U.S. and the IEE in the U.K. This review focuses on the principles and practice behind the therapeutic use of "PEMFs". This term is restricted to time-varying magnetic field characteristics that induce voltage waveform patterns in bone similar to those resulting from mechanical deformation. These asymmetric, broad-band pulses affect a number of biologic processes athermally. Many of these processes appear to have the ability to modify selected pathologic states in the musculoskeletal and other systems.

Crit Rev Biomed Eng. 1989;17(5):451-529.

Effects of static magnetic and pulsed electromagnetic fields on bone healing.

Darendeliler, M., Darendeliler, A., & Sinclair, P.

The effect of static magnetic fields and pulsed electromagnetic fields on bone healing in guinea pigs was investigated. The static magnetic fields were produced using neodymium magnets, and the magnetic field strengths that the guinea pigs were exposed to averaged about 500 gauss. The study concluded that "both static and pulsed electromagnetic fields seemed to accelerate the rate of bone repair when compared to the control group."

International Journal of Adult Orthodontic and Orthognathic Surgery, 1997;12, 43-53.

Strong static magnetic field stimulates bone formation to a definite orientation in vitro and in vivo.

Kotani H, Kawaguchi H, Shimoaka T, Iwasaka M, Ueno S, Ozawa H, Nakamura K, Hoshi K. Department of Biomedical Engineering, Graduate School of Medicine, University of Tokyo, Japan.

The induction of bone formation to an intentional orientation is a potentially viable clinical treatment for bone disorders. Among the many chemical and physical factors, a static magnetic field (SMF) of tesla order can regulate the shapes of blood cells and matrix fibers. This study investigated the effects of a strong SMF (8 T) on bone formation in both in vivo and in vitro systems. After 60 h of exposure to the SMF, cultured mouse osteoblastic MC3T3-E1 cells were transformed to rodlike shapes and were orientated in the direction parallel to the magnetic field. Although this strong SMF exposure did not affect cell proliferation, it up-regulated cell differentiation and matrix synthesis as determined by ALP and alizarin red stainings, respectively. The SMF also stimulated ectopic bone formation in and around subcutaneously implanted bone morphogenetic protein (BMP) 2-containing pellets in mice, in which the orientation of bone formation was parallel to the magnetic field. It is concluded that a strong SMF has the potency not only to stimulate bone formation, but also to regulate its orientation in both in vitro and in vivo models. This is the first study to show the regulation of the orientation of adherent cells by a magnetic field. We propose that the combination of a

strong SMF and a potent osteogenic agent such as BMP possibly may lead to an effective treatment of bone fractures and defects.

J Bone Miner Res. 2002 Oct;17(10):1814-21.

Use of physical forces in bone healing.

Nelson FR, Brighton CT, Ryaby J, Simon BJ, Nielson JH, Lorch DG, Bolander M, Seelig J. Henry Ford Hospital, Detroit, MI, USA.

During the past two decades, a number of physical modalities have been approved for the management of nonunions and delayed unions. Implantable direct current stimulation is effective in managing established nonunions of the extremities and as an adjuvant in achieving spinal fusion. Pulsed electromagnetic fields and capacitive coupling induce fields through the soft tissue, resulting in low-magnitude voltage and currents at the fracture site. Pulsed electromagnetic fields may be as effective as surgery in managing extremity nonunions. Capacitive coupling appears to be effective both in extremity nonunions and lumbar fusions. Low-intensity ultrasound has been used to speed normal fracture healing and manage delayed unions. It has recently been approved for the management of nonunions. Despite the different mechanisms for stimulating bone healing, all signals result in increased intracellular calcium, thereby leading to bone formation.

J Am Acad Orthop Surg. 2003 Sep-Oct;11(5):344-54.

Effect of some electric signals transmitted by an induction coil on weight increase, incorporation of marker, and histological and ultrastructural appearance of the skeleton in a chick embryo.

Duriez R, Bassett A.

Embryo Chicks were exposed to various types of electrical impulses transmitted by induction coils between the 6th and 13th day of incubation. Compared with controls, the Chick tibias showed a highly significant increase in weight and length as well as increased incorporation of tritiated thymidine. In addition, the total weight of the treated embryos was significantly greater than that of the controls. The results suggest that the effects of these electro-magnetic fields, particularly their skeletal effects, act principally on cellular multiplication and/or enhanced cellular activity following an increase in protein synthesis.

C R Seances Acad Sci D. 1980 Jun 23;290(23):1483-6.

Effects of static magnetic field on bone formation of rat femurs.

Yan QC, Tomita N, Ikada Y.

Institute for Frontier Medical Sciences, Kyoto University, Japan.

Effects of static magnetic fields (SMF) on bone formation of rat femurs, were evaluated using tapered rods made of magnetized and unmagnetized samarium cobalt of the same size. They were implanted transcortically into the middle diaphysis of rat femurs under press-fit loading. The bone mineral density (BMD) and bone calcium content were measured 12 weeks after implantation by dual-energy X-ray absorptiometry and chemical analysis with o-

cresolphthalein complexon, respectively. The result revealed that the femurs adjacent to magnetized specimens had significantly higher BMD and calcium content than those adjacent to the unmagnetized specimen ($p < 0.01$). However, the value of BMD and calcium content of rats with magnetized specimens was similar to that of non-operated rats. No specific change was found in the body weight, serum Ca, activity of alkaline phosphatase, hemogram, and BMD of the tibia and humerus among the magnetized and unmagnetized. These results suggest that the long-term local SMF stimulation on the bone has a local effect to prevent the decrease in BMD caused by surgical invasion or implantation.

Med Eng Phys. 1998 Sep;20(6):397-402.

Static magnetic field effects on bone formation of rats with an ischemic bone model.

Xu S, Tomita N, Ohata R, Yan Q, Ikada Y.

Institute for Frontier Medical Sciences, Kyoto University, Kyoto, Japan.

Effects of a static magnetic field were studied on bone formation using an ischemic rat femur model. Metal rods were prepared from magnetized and unmagnetized samarium cobalt to have tapered structure, both with the same geometrical dimension, and were implanted transcortically into the middle diaphysis of 88 rat femurs. Both sides of the rat femoral artery were ligated to create an ischemic bone model, followed by implantation of the tapered rod to the femur. The bone mineral density (BMD) and weight of the femurs were measured at 1st and 3rd week after implantation. The result at the 3rd week post-implantation revealed that the BMD and weight of the ischemic bone model rats were significantly reduced, compared with that of non-operated femur. It was also found that the magnetized group had significantly higher bone weights than the unmagnetized ($p < 0.05$). The BMD of the rats implanted with the magnetized rods were similar to those of the non-operated ($p > 0.05$). This enhancement of the femoral bone formation of the ischemic rat model by the static magnetic field seems to be due to the improved blood circulation of the femur.

Biomed Mater Eng. 2001;11(3):257-63.

Effects of pulsed electromagnetic field stimulation on distraction osteogenesis in the rabbit tibial leg lengthening model.

Fredericks DC, Piehl DJ, Baker JT, Abbott J, Nepola JV.

Bone Healing Research Laboratory, Department of Orthopaedic Surgery, University of Iowa College of Medicine, Iowa City, Iowa 52242, USA. douglas-fredericks@uiowa.edu

The purpose of this study was to determine whether exposure to pulsed electromagnetic field (PEMF) would shorten the healing time of regenerate bone in a rabbit tibial distraction model. Beginning 1 day after surgery, mid-shaft tibial osteotomies, stabilized with external fixators, were distracted 0.25 mm twice daily for 21 days and received either no exposure (sham control) or 1 hour per day exposure to low-amplitude, low-frequency PEMF. Tibiae were tested for torsional strength after 9, 16, and 23 days post-distraction. PEMF-treated tibiae were significantly stronger than shams at all three time points. By 16 days post-distraction, the PEMF group had achieved biomechanical strength essentially equivalent to intact bone. Shams did not achieve normal biomechanical strength even after 23 days post-distraction. In this tibial distraction model, short daily PEMF exposures accelerated consolidation of regenerate bone. Clinical usefulness awaits testing.

J Pediatr Orthop. 2003 Jul-Aug;23(4):478-83.

Effects of static magnetic fields on bone formation in rat osteoblast cultures.

Yamamoto Y, Ohsaki Y, Goto T, Nakasima A, Iijima T.

Departments of Orthodontics.

Although the promotional effects on osteoblasts of pulsed electromagnetic fields have been well-demonstrated, the effects of static magnetic fields (SMF) remain unclear; nevertheless, magnets have been clinically used as a 'force source' in various orthodontic treatments. We undertook the present investigation to study the effects of SMF on osteoblastic differentiation, proliferation, and bone nodule formation using a rat calvaria cell culture. During a 20-day culture, the values of the total area and the number and average size of bone nodules showed high levels in the presence of SMF. In the matrix development and mineralization stages, the calcium content in the matrix and two markers of osteoblastic phenotype (alkaline phosphatase and osteocalcin) also showed a significant increase. Accordingly, these findings suggest that SMF stimulates bone formation by promoting osteoblastic differentiation and/or activation.

J Dent Res. 2003 Dec;82(12):962-6.

Treatment of wrist and hand fractures with natural magnets: preliminary report

Costantino C, Pogliacomì F, Passera F, Concari G.

The Authors, after having defined the phenomenon and the biological characteristics of natural magnets, evaluate their ability in accelerating the formation of bone callus in hand and wrist fractures compared to treatment with immobilization in a plaster cast. Forty patients (4 females and 37 males) between 20 and 86 years of age were treated. A small natural magnet was inserted in each of the plaster casts (diameter: 2cm, height: 0.5cm) made of 4 blocks in Neodymium-Iron-Boron, capable of generating 4 magnetic poles (2 positive and 2 negative) of diagonal alternate polarity that produced a symmetric, quadruple static magnetic field. The created magnetic flow was wavelike, concentrated in one direction, and developed a force up to 12,500 gauss. From this study it has emerged that inserting a quadruple magnet in a plaster cast in hand and wrist fractures results in the formation of bone callus in an average time that is 35% inferior [shorter] to the standard time. Accelerating the healing of the fracture is important since it reduces immobilization time for the joints involved, avoiding subsequent weakness and stiffness and allowing the patient to begin rehabilitative physiotherapy sooner, which permits a faster functional recovery.

Acta bio-medica: Atenei Parmensis 2007 Dec;78(3):198-203. PMID: 18330079

Modification of fracture repair with selected pulsing electromagnetic fields.

Bassett CA, Valdes MG, Hernandez E.

We assayed different pulsing electromagnetic fields for their effects on the mechanical and histological repair properties of an osteotomy of the radius of the rat fourteen days postoperatively. Highly significant differences were found in the control and experimental initial load values and their decay as a function of time. These results correlate well with the

histological pattern in the bridging callus. A pulse that produces an increase (above the control level) in initial load by a factor of 2.4 and a slower decay was characterized by more extensive calcification of fibrocartilage and its replacement by fibrous bone at this early, but important, stage in fracture-healing.

J Bone Joint Surg Am. 1982 Jul;64(6):888-95.

Effect of a static magnetic field on fracture healing in a rabbit radius. Preliminary results.

Bruce GK, Howlett CR, Huckstep RL.

To ascertain what effect a static magnetic force has on a healing fracture, samarium cobalt magnets were implanted adjacent to induced radial fractures in adult rabbits. A magnetic field of 220-260 G was generated at the fracture site. The radii were allowed to heal for four weeks and the contralateral fractured bones acted as controls. Healing bone units were assessed microscopically and mechanically. Significantly greater forces (p less than 0.01) were required to break those bone units exposed to magnetic fields. However, no significant difference was found when comparing the longitudinal midcallus areas from magnetized and nonmagnetized limbs.

Clin Orthop 1987 Sep;(222):300-6.

Effects of electromagnetic fields in experimental fracture repair.

Otter MW, McLeod KJ, Rubin CT.

Program in Biomedical Engineering, State University of New York at Stony Brook 11794-8181, USA.

The clinical benefits of electromagnetic fields have been claimed for 20 centuries, yet it still is not clear how they work or in what circumstances they should be used. There is a large body of evidence that steady direct current and time varying electric fields are generated in living bone by metabolic activity and mechanical deformation, respectively. Externally supplied direct currents have been used to treat nonunions, appearing to trigger mitosis and recruitment of osteogenic cells, possibly via electrochemical reactions at the electrode-tissue interface. Time varying electromagnetic fields also have been used to heal nonunions and to stabilize hip implants, fuse spines, and treat osteonecrosis and osteoarthritis. Recent research into the mechanism(s) of action of these time varying fields has concentrated on small, extremely low frequency sinusoidal electric fields. The osteogenic capacity of these fields does not appear to involve changes in the transmembrane electric potential, but instead requires coupling to the cell interior via transmembrane receptors or by mechanical coupling to the membrane itself.

Clin Orthop. 1998 Oct;(355 Suppl):S90-104.

Pulsed electromagnetic fields for the treatment of bone fractures.

Satter Syed A, Islam MS, Rabbani KS, Talukder MS.

Industrial Physics Division, BCSIR Laboratories, Dhaka.

The effectiveness of electrical stimulation and Pulsed Electro Magnetic Field (PEMF) stimulation for enhancement of bone healing has been reported by many workers. The mechanism of osteogenesis is not clear, therefore, studies look for empirical evidence. The present study involved a clinical trial using low amplitude PEMF on 19 patients with non-union or delayed union of the long bones. The pulse system used was similar in shape to Bassett's single pulse system where the electric voltage pulse was 0.3 mSec wide repeating every 12 mSec making a frequency of about 80 Hz. The peak magnetic fields were of the order of 0.01 to 0.1 m Tesla, hundred to thousand times smaller than that of Bassett. Among the 13 who completed this treatment schedule the history of non-union was an average of 41.3 weeks. Within an average treatment period of 14 weeks, 11 of the 13 patients had successful bone healing. The two unsuccessful cases had bone gaps greater than 1 cm following removal of dead bone after infection. However, use of such a low field negates Bassett's claim for a narrow window for shape and amplitude of wave form, and justifies further experimental study and an attempt to understand the underlying mechanism.

Bangladesh Med Res Counc Bull. 1999 Apr;25(1):6-10.

Non-operative salvage of surgically-resistant pseudarthroses and non-unions by pulsing electromagnetic fields. A preliminary report.

Bassett CA, Pilla AA, Pawluk RJ.

This report documents, for the first time, to the authors' knowledge, the therapeutic use in humans of low energy, electromagnetic fields pulsing in the extremely low frequency (E.L.F.) range. These fields, established outside the body, were used to treat congenital and acquired pseudarthroses and non-unions. Energy of this type appears to affect biological processes, not through heat production, but through electrically-induced changes in the environment of cells within the organism. Of the 29 patients included in the study, 17 had experienced at least one failure of surgical repair and, in each of these, amputation had been recommended. The overall success rate, including those patients treated with inadequate pulse characteristics and those who failed to follow the protocol, was in excess of 70 per cent. Improvements in the specificity of pulse characteristics hold promise for increasing the rate of success. The simple, clinical methodology, which is conducted on an out-patient basis, appears to be both safe and effective. It can be applied with or without surgery. This approach requires additional controlled investigations before it is ready for general use in the orthopaedic community. The indications for amputation of surgically-resistant pseudarthroses, however, should be reassessed. The principles and technology, which have been established during this endeavor, may have physiologic and practical significance for processes other than pseudarthrosis and non-union.

Clin Orthop. 1977 May;(124):128-43.

Acceleration of repair of non-unions by electromagnetic fields.

Sedel L, Christel P, Duriez J, Duriez R, Evrard J, Ficat C, Cauchoix J, Witvoet J.

This work deals with the results obtained by four French orthopaedic departments using the electromagnetic field stimulation for non union treatment. This is the method established by A. Bassett. 37 cases are studied, the results are known for 35 of them with 6 failures and 29

successes. The failures can be explained for four of them by a bad application of the device. Concerning the 29 successful cases, the role of the stimulation is discussed. Discarding those who have been treated a short time after a surgical procedure, those who have been immobilized more than 6 months and those where the non union could have been a delayed union, it remains 14 successful cases apparently undisputable. For them the role of the electromagnetic field stimulation seems real.

Rev Chir Orthop Reparatrice Appar Mot. 1981;67(1):11-23.

Treatment of ununited tibial diaphyseal fractures with pulsing electromagnetic fields.

Bassett CA, Mitchell SN, Gaston SR.

One hundred and twenty-five patients with one hundred and twenty-seven ununited fractures of the tibial diaphysis were treated exclusively with pulsing electromagnetic fields. The overall success rate in healing of the fracture with this surgically non-invasive out-patient method was 87 per cent. The success rate was not materially affected by the age or sex of the patient, the length of prior disability, the number of previous failed operations, or the presence of infection or metal fixation.

J Bone Joint Surg Am. 1981 Apr;63(4):511-23.

Treatment of therapeutically resistant non-unions with bone grafts and pulsing electromagnetic fields.

Bassett CA, Mitchell SN, Schink MM.

This study reviews the cases of eighty-three adults with ununited fractures who were treated concomitantly with bone-grafting and pulsed electromagnetic fields. An average of 1.5 years had elapsed since fracture and the use of this combined approach. Nearly one-third of the patients had a history of infection, and an average of 2.4 prior operations had failed to produce bone union. Thirty-eight patients who were initially treated with grafts and pulsed electromagnetic fields for ununited fractures with wide gaps, synovial pseudarthrosis, and malalignment achieved a rate of successful healing of 87 per cent. Forty-five patients who had initially been treated unsuccessfully with pulsing electromagnetic fields alone had bone-grafting and were re-treated with pulsing electromagnetic fields. Ninety-three per cent of these fractures healed. The residual failure rate after two therapeutic attempts, one of which was operative, was 1.5 per cent. The median time to union for both groups of patients was four months.

J Bone Joint Surg Am. 1982 Oct;64(8):1214-20.

The development and application of pulsed electromagnetic fields (PEMFs) for ununited fractures and arthrodeses.

Bassett CA.

This article deals with the rational and practical use of surgically noninvasive pulsed electromagnetic fields (PEMFs) in treating ununited fractures, failed arthrodeses, and congenital pseudarthroses (infantile nonunions). The method is highly effective (more than 90

per cent success) in adult patients when used in conjunction with good management techniques that are founded on biomechanical principles. When union fails to occur with PEMFs alone after approximately four months, their proper use in conjunction with fresh bone grafts insures a maximum failure rate of 1 to 1.5 per cent. Union occurs because the weak electric currents induced in tissues by the time-varying fields effect calcification of the fibrocartilage in the fracture gap, thereby setting the stage for the final phases of fracture healing by endochondral ossification. The efficacy, safety, and simplicity of the method has prompted its use by the majority of orthopedic surgeons in this country. In patients with delayed union three to four months postfracture, PEMFs appear to be more successful and healing, generally, is more rapid than in patients managed by other conservative methods. For more challenging problems such as actively infected nonunions, multiple surgical failures, long-standing (for example, more than two years postfracture) atrophic lesions, failed knee arthrodeses after removal of infected prostheses, and congenital pseudarthroses, success can be expected in a large majority of patients in whom PEMFs are used. Finally, as laboratory studies have expanded knowledge of the mechanisms of PEMF action, it is clear that different pulses affect different biologic processes in different ways. Selection of the proper pulse for a given pathologic entity has begun to be governed by rational processes similar, in certain respects, to those applied to pharmacologic agents.

Orthop Clin North Am. 1984 Jan;15(1):61-87.

Results of pulsed electromagnetic fields (PEMFs) in ununited fractures after external skeletal fixation.

Marcer M, Musatti G, Bassett CA.

Of 147 patients with fractures of the tibia, femur and humerus, in whom an average of 3.3 operations had failed to produce union, all were treated with external skeletal fixation in situ and pulsed electromagnetic fields (PEMFs). Of the 147, 107 patients united for an overall success rate of 73%. Union of the femur occurred in 81% and the tibia in 75%. Only five of 13 humeri united. Failure to achieve union with PEMFs was most closely associated with very wide fracture gaps and insecure skeletal fixation devices.

Clin Orthop. 1984 Nov;(190):260-5.

Healing of nonunion of a fractured lateral condyle of the humerus by pulsing electromagnetic induction.

Das Sarkar S, Bassett CA.

Department of Orthopaedic Surgery, Sandwell District General Hospital, Lyndon, West Midlands, United Kingdom.

Nonoperative salvage of a surgically resistant case of established nonunion of a fracture of the lateral condyle of the humerus in a child is described. Solid union was achieved by treatment with pulsed electromagnetic fields. A review of the literature indicates that this is the first published report of such a case.

Contemp Orthop. 1991 Jan;22(1):47-51.

Pulsing electromagnetic field treatment in ununited fractures and failed arthrodeses.

Bassett CA, Mitchell SN, Gaston SR.

Pulsing electromagnetic fields (PEMFs) induce weak electric currents in bone by external coils on casts or skin. This surgically noninvasive, outpatient method, approved by the Food and Drug Administration in November 1979, produced confirmed end results in 1,007 ununited fractures and 71 failed arthrodeses, worldwide. Overall success at Columbia-Presbyterian Medical Center was 81%; internationally, 79%; and in other patients in the United States, 76%. Treatment with PEMFs was effective in 75% of 332 patients (a subset) with an average 4.7-year disability duration, an average of 3.4 previous operative failures to produce union, and a 35% rate of infection. Eighty-four percent of carpal naviculars and 82% of femoral neck-trochanteric nonunions were united. After attempted arthrodeses could not salvage a failed total-knee prosthesis, PEMFs promoted healing in 85% of patients. When coils were unsuccessful alone, combining them with surgical repair was effective.

JAMA. 1982 Feb 5;247(5):623-8.

Congenital "pseudarthroses" of the tibia: treatment with pulsing electromagnetic fields.

Bassett CA, Caulo N, Kort J.

During the past seven years, 34 patients with infantile nonunions associated with congenital "pseudarthroses" completed treatment with pulsing electromagnetic fields (PEMFs). An analysis of results reveals that 17/34 (50%) have achieved complete healing with biomechanically sound union and radiographic demonstration of remodularization. Union with function, i.e., healing with continued need for protection, was achieved in 7/34 (21%). Failure was the outcome in 10/34 patients (29%). Most of these occurred in males with a history of early fracture (less than 1 year) and with spindled, hypermobile lesions (Type III). During the early period of the study, PEMFs were the sole means of treatment. After a "coil effect" had been demonstrated, surgical realignment, immobilization and grafting were combined with PEMF treatment. Fundamentals of orthopedic management developed by the larger experience with adult nonunions were found to apply equally to infantile nonunions treated with PEMFs. These include effective immobilization of the fracture site and controlled "stress working" during recovery to facilitate gradual remodeling. PEMFs have been demonstrated to be a potentially useful adjunct in the orthopedic surgeon's armamentarium for treating infantile nonunions (congenital "pseudarthroses").

Clin Orthop. 1981 Jan-Feb;(154):136-48.

Congenital pseudoarthrosis of the tibia: treatment with pulsing electromagnetic fields.

Kort JS, Schink MM, Mitchell SN, Bassett CA.

Ninety-two patients with congenital pseudoarthrosis (infantile nonunion) were treated with pulsing electromagnetic fields (PEMF) in the United States and Europe in the past eight years. This represents the largest group of patients with infantile nonunions in which a common treatment modality has been used. Excluding the ten lesions (11%) which healed with refracture 48 lesions (59%) healed whereas 34 (41%) failed to heal. The success rate in 23 type I and 34 Type II lesions was 77% and 76%, respectively. Surgery in association with PEMF treatment did not improve the results of treatment. The most important variable was

the radiographic morphology of the nonunion gap. Patients with spindled bone ends, a large gap and a grossly mobile lesion had a very poor prognosis relative to patients with a cystic or sclerotic transverse fracture line with a gap of less than 5 mm. The key to success in the treatment of infantile nonunions has been the combination of PEMF treatment with good orthopedic management, consisting of rigid immobilization, a nonweight-bearing status and rehabilitation with impact loading exercise. Infantile nonunion remains a major challenge to the orthopedic surgeon, but PEMFs appear to offer some important advantages for overcoming this pernicious condition. Dr. Harold Boyd's discussion of this paper follows. It was his final address to the AAOS.

Clin Orthop. 1982 May;(165):124-37.

Pulsing electromagnetic fields to achieve arthrodesis of the knee following failed total knee arthroplasty. A preliminary report.

Bigliani LU, Rosenwasser MP, Caulo N, Schink MM, Bassett CA.

Treatment with pulsing electromagnetic fields was used as an adjunct in twenty patients who had had a knee arthrodesis after failure of a total joint arthroplasty. Eighteen had had an infected arthroplasty; one, mechanical loosening; and one, recurrent dislocation. Arthrodesis had been attempted twenty-five times in these twenty patients prior to application of the coils. These procedures included the use of twenty-two external fixation frames, one compression plate, one intramedullary rod, and one cylinder cast. Two groups of patients were identified: those with non-union and those with delayed union. Fourteen patients began treatment six months or more after arthrodesis and were considered to have a non-union. The other six patients started treatment less than six months after attempted arthrodesis because there was no evidence of progression toward union. They were considered to have delayed union. In seventeen (85 per cent) of the twenty patients a clinically solid arthrodesis with roentgenographic evidence of bone-bridging was achieved. The average time to union after coil therapy was started was 5.8 months, with a range of three to twelve months. The patients who started coil treatment earlier after arthrodesis showed a tendency to heal faster. The three patients who had failures were the only ones who did not adhere to the protocol, and all three were in the non-union group. All patients with a solid arthrodesis were free of pain and able to walk at the time of follow-up, nine to thirty-one months after the completion of treatment. The use of pulsing electromagnetic fields appears to be a valuable non-invasive adjunct when performing arthrodesis of the knee after failed total joint arthroplasty.

J Bone Joint Surg Am. 1983 Apr;65(4):480-5.

Long-term pulsed electromagnetic field (PEMF) results in congenital pseudarthrosis.

Bassett CA, Schink-Ascani M.

Bioelectric Research Center, Riverdale, New York 10463.

Ninety-one patients with congenital pseudarthrosis of the tibia have been treated with pulsed electromagnetic fields (PEMFs) since 1973 and all except 4 followed to puberty. Lesions were stratified by roentgenographic appearance. Type I and type II had gaps less than 5 mm in width. Type III were atrophic, spindled, and had gaps in excess of 5 mm. Overall success in type I and II lesions was 43 of 60 (72%). Of those 28 patients seen before operative repair had been attempted, 7 of 8 type I lesions healed (88%), whereas 16 of 20 type II lesions healed

(80%) on PEMFs and immobilization alone. Only 19% (6 of 31) type III lesions united, only one of which did not require surgery. Sixteen of 91 limbs (18%) were ultimately amputated, most before treatment principles were fully defined in 1980. Fourteen of these 16 patients (88%) had type III lesions. Refracture occurred in 22 patients, most as the result of significant trauma, in the absence of external brace support. Twelve of the 19 refractures, retreated with PEMFs and casts, healed on this regime. Episodic use of PEMFs proved effective in controlling stress fractures in several patients until they reached puberty. PEMFs, which are associated with no known risk, appear to be an effective, conservative adjunct in the management of this therapeutically challenging, congenital lesions.

Calcif Tissue Int. 1991 Sep;49(3):216-20.

The effect of postoperative electromagnetic pulsing on canine posterior spinal fusions.

Kahanovitz N, Arnoczky SP, Hulse D, Shires PK.

An experimental canine study was devised to evaluate the efficacy of a noninvasive adjunct to improve the rate and quality of the posterior fusion mass over the standard surgical technique. Ten large adult mongrel dogs underwent a three-level lumbar spinal fusion. Bone excised from the spinous processes was packed in removed facet joints and over the decorticated laminae. To insure rigid internal fixation, custom-made distraction instrumentation was placed bilaterally under the laminae of the vertebrae above and below the three fused vertebrae. Five dogs underwent electromagnetic pulsing, and five dogs acted as controls. Two dogs were sacrificed at 4, 6, 9, 12, and 15 weeks to assess the radiographic and histologic status of the fusion mass. Preoperative and preautopsy hematologic studies as well as gross and histologic autopsy specimens revealed no abnormalities attributable to the electromagnetic pulsing. High-resolution radiography and histologic studies showed earlier incorporation of the graft, improved new bone formation, and better organization of the fusion mass in the 4-, 6-, and 9-week stimulated specimens. However, by 12 and 15 weeks there did not appear to be any histologic or radiographic differences between the stimulated and control dogs. Although electromagnetic pulsing appears to produce an early accelerated osteogenic response, it does not appear to improve the overall results of primary canine spinal fusions.

Spine. 1984 Apr;9(3):273-9.

Treatment of failed posterior lumbar interbody fusion (PLIF) of the spine with pulsing electromagnetic fields.

Simmons JW.

This paper presents a technique and discusses the results of treating failed posterior lumbar interbody fusions (PLIFs) of the spine with pulsing electromagnetic fields (PEMFs). Thirteen male patients suffering from failed PLIFs, with an average time of 40 months since the last surgical fusion attempt, were the subjects of this study. PEMFs were applied by the patient according to strict criteria but in the comfort of their home. Initial and subsequent medical evaluations closely monitored the patient's condition and progress. PEMFs promoted a significant increase in bone formation in 85% (11 of 13) of the patient pool and achieved body-to-body fusion throughout the intervertebral disc space in 77% (ten of 13) over the treatment period. The treatment required no hospitalization, reduced morbidity, and avoided

the risks associated with surgical intervention. The results suggest that this surgically noninvasive outpatient therapy may become a successful alternative treatment of failed PLIF.

Clin Orthop. 1985 Mar;(193):127-32.

Effects of pulsing electromagnetic fields (PEMF) on the course of vertebral fusion callus. A histological study.

Guizzardi S, Di Silvestre M, Govoni P, Strocchi R, Scandroglia R.

Istituto di Istologia ed Embriologia Generale, Università degli Studi di Parma.

In this paper the findings concerning the effectiveness of PEMF on the evolution of the vertebral fusion callus are reported. The study has been carried on by preparing postero-lateral arthrodesis in the lumbar spinal tract in rats. In this tract the laminae have been decorticated, the articular processes prepared by decortication and removal of the articular cartilage, and the spinal processes removed and employed as osteoinductive material. The rats sacrificed after 4 and 8 weeks, show how the decorticated areas are clearly influenced from PEMF, an early appearance of the bony fusion callus is already evident in the treated group just after 4 weeks. Also the articular areas are influenced from PEMF but less markedly than the decorticated one; in these areas after 8 weeks the fusion callus is prevalently cartilaginous even if areas of calcification are detectable inside. This different behaviour can be explained with the absence of any form of spinal fusion by means of surgical tools.

Acta Biomed Ateneo Parmense. 1990;61(5-6):227-35.

A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions.

Mooney V. - Division of Orthopaedic Surgery, University of California, Irvine.

A randomized double-blind prospective study of pulsed electromagnetic fields for lumbar interbody fusions was performed on 195 subjects. There were 98 subjects in the active group and 97 subjects in the placebo group. A brace containing equipment to induce an electromagnetic field was applied to patients undergoing interbody fusion in the active group, and a sham brace was used in the control group. In the active group there was a 92% success rate, while the control group had a 65% success rate (P greater than 0.005). The effectiveness of bone graft stimulation with the device is thus established.

Spine. 1990 Jul;15(7):708-12.

Effects of smoking and maturation on long-term maintenance of lumbar spinal fusion success.

Mooney V, McDermott KL, Song J.

Department of Orthopaedics, University of California San Diego, USA.

This is a follow-up study of a multicenter, randomized, placebo-controlled clinical trial conducted in accordance with the condition for Food and Drug Administration approval for pulsed electromagnetic fields. The purpose of this study was to evaluate the long-term efficacy and safety of pulsed electromagnetic fields for spinal fusion. An earlier clinical trial

study was conducted to evaluate the efficacy of Pulsed Electromagnetic Fields to enhance fusion success at one year follow-up. In the original study, 195 patients undergoing interbody fusion were enrolled. Of the 195 patients, 98 were in the active group and 97 were in the placebo group. Study results showed a 92% successful fusion rate in the active group compared to 68% in the placebo group. For this long-term follow-up study, all patients who had healed in the original study were recalled for a follow-up radiograph. Radiographs were assessed by the attending surgeon for fusion assessment, when possible. The results of this long-term follow-up study showed that there was a reduction in maintenance of the fusion over time by 25%, but that the reduction was unrelated to treatment group and correlated statistically with whether the patient was a smoker.

J Spinal Disord. 1999 Oct;12(5):380-5.

Pulsing electromagnetic fields (PEMFs) in spinal fusion: preliminary clinical results.

Di Silvestre M, Savini R.

Istituto Ortopedico Rizzoli, Bologna.

Pulsing electromagnetic fields (PEMFs) were used during the postoperative management of 31 patients submitted to lumbosacral posterolateral fusion (PLF). The fusions were stimulated with PEMFs during the first 2 of the 4 months of postoperative immobilization. Consolidation of PLF was obtained in 20 of the 31 patients after 2 months of stimulation, thus, healing time was cut in half. After 4 months, fusion was observed in 30 out of the 31 cases submitted to stimulation (96%).

Chir Organi Mov. 1992 Jul-Sep;77(3):289-94.

Pulsed electromagnetic field stimulation on posterior spinal fusions: a histological study in rats.

Guizzardi S, Di Silvestre M, Govoni P, Scandroglio R.

Institute of Histology and Embryology, University of Parma, Italy.

This study reports the histological data relative to the effect of pulsed electromagnetic fields (PEMFs) on the evolution of posterior arthrodesis induced in the lumbar vertebrae of 12 adult male Sprague-Dawley rats. After the operation, one group of six rats was stimulated with PEMFs for 18 h per day, by means of a pair of coils fixed to the outside of the cage. A control group of six rats was given no stimulation after surgery. In the groups stimulated with PEMFs an acceleration of the process of bone callus organization was already observed after 4 weeks, and even more so after 8: An early replacement was in fact observed of the newly formed cartilage tissue with primary bone (at 4 weeks) and subsequently with secondary bone (after 8 weeks).

J Spinal Disord. 1994 Feb;7(1):36-40.

The effect of pulsed electromagnetic fields on instrumented posterolateral spinal fusion and device-related stress shielding.

Ito M, Fay LA, Ito Y, Yuan MR, Edwards WT, Yuan HA.

Department of Orthopaedics, Hokkaido University School of Medicine, Sapporo, Japan.

STUDY DESIGN: This study was designed to examine stress-shielding effects on the spine caused by rigid implants and to investigate the effects of pulsed electromagnetic fields on the instrumented spine.

OBJECTIVES: To investigate the effects of pulsed electromagnetic fields on posterolateral spinal fusion, and to determine if osteopenia induced by rigid instrumentation can be diminished by pulsed electromagnetic fields.

SUMMARY OF BACKGROUND DATA: Although device-related osteopenia on vertebral bodies is of a great clinical importance, no method for preventing bone mineral loss in vertebrae by stiff spinal implants has been effective.

METHODS: Twenty-eight adult beagles underwent L5-L6 destabilization followed by posterolateral spinal fusion. The study was divided into four groups: 1) Group CNTL: without instrumentation, without pulsed electromagnetic fields, 2) Group PEMF: without Steffee, with pulsed electromagnetic fields, 3) Group INST: with Steffee, without pulsed electromagnetic fields, 4) Group PEMF + INST: with Steffee, with pulsed electromagnetic fields. At the end of 24 weeks, the dogs were killed, and L4-L7 segments were tested biomechanically without instrumentation. Radiographs and quantitative computed tomography assessed the condition of the fusion mass.

RESULTS: Stress shielding was induced in the anterior vertebral bodies of L6 with the Steffee plates; bone mineral density was increased with the addition of pulsed electromagnetic fields, regardless of the presence or absence of fixation. A decrease in flexion and bending stiffness was observed in the Group INST; pulsed electromagnetic fields did increase the flexion stiffness regardless of the presence or absence of fixation, although this was not statistically significant.

CONCLUSIONS: Use of pulsed electromagnetic fields has the potential to minimize device-related vertebral-bone mineral loss.

Spine. 1997 Feb 15;22(4):382-8.

Use of electromagnetic fields in a spinal fusion. A rabbit model.

Glazer PA, Heilmann MR, Lotz JC, Bradford DS.

Department of Orthopaedic Surgery, University of California, San Francisco, USA.

STUDY DESIGN: The biomechanical and histologic characteristics of posterolateral spinal fusion in a rabbit model with and without the application of a pulsed electromagnetic field were analyzed in a prospective, randomized trial. In addition, fusion rate with and without a pulsed electromagnetic field in this model was assessed by biomechanical testing, radiographs, and manual palpation.

OBJECTIVES: To evaluate the influence of a pulsed electromagnetic field on the spinal fusion rate and biomechanical characteristics in a rabbit model.

SUMMARY OF BACKGROUND DATA: Previous studies performed to assess the benefits of a pulsed electromagnetic field in spinal fusion have been complicated by the use of

instrumentation, and the animal models used do not have a pseudarthrosis rate comparable to that seen in humans. In contrast, the posterolateral intertransverse process fusion in the rabbit is uncomplicated by the use of instrumentation and has been shown to have a pseudarthrosis rate similar to that found in humans (5-35%). METHODS: Ten New Zealand white rabbits each were randomly assigned to undergo spinal fusion using either 1) autologous bone with electromagnetic fields, or 2) autologous bone without electromagnetic fields. A specially designed plastic constraint was used to focus the pulsed electromagnetic field over the rabbits' lumbar spine 4 hours per day. Animals were killed at 6 weeks for biomechanical and histologic testing.

RESULTS: The rate of pseudarthrosis, as evaluated radiographically and manually in a blinded fashion, decreased from 40% to 20% with the pulsed electromagnetic field, but this decrease in the nonunion rate was not statistically significant given the number of animals per group. Biomechanical analysis of the fusion mass showed that a pulsed electromagnetic field resulted in statistically significant increases in stiffness (35%), area under the load-displacement curve (37%), and load to failure of the fusion mass (42%). Qualitative histologic assessment showed increased bone formation in those fusions exposed to a pulsed electromagnetic field.

CONCLUSIONS: This study demonstrates the reproducibility of a rabbit fusion model, and the ability of a pulsed electromagnetic field to induce a statistically significant increase in stiffness, area under the load-displacement curve, and load to failure of the fusion mass. This investigation provides a basis for continued evaluation of biologic enhancement of spinal arthrodesis with the use of a pulsed electromagnetic field.

Spine. 1997 Oct 15;22(20):2351-6.

Outcomes after posterolateral lumbar fusion with instrumentation in patients treated with adjunctive pulsed electromagnetic field stimulation.

Bose B.

Medical Center of Delaware, Newark, USA.

Fusion success and clinical outcome were determined in 48 high-risk patients who underwent posterolateral lumbar fusions with internal fixation and were treated with adjunctive pulsed electromagnetic field (PEMF) stimulation postoperatively. An independent radiographic assessment demonstrated a success rate of 97.9%. Following treatment, 59% of the working patients returned to their employment. Overall clinical assessment was excellent in 4.2% of patients, good in 79.2%, and fair in 16.7%; no patient had a poor clinical assessment.

Adv Ther. 2001 Jan-Feb;18(1):12-20.

Electrical stimulation of spinal fusion: a scientific and clinical update

Kahanovitz N.

*Hospital for Joint Diseases, 301 E. 17th Street, New York, NY 10003, USA.
nkspinemd@aol.com*

BACKGROUND CONTEXT: For over two decades, a number of electrical stimulation devices have achieved increasing acceptance as adjuncts to lumbar spinal fusion. Direct

current electrical stimulation, pulsed electromagnetic fields and more recently capacitive coupling have been shown to have varying effectiveness when used to increase the success of lumbar spinal fusion.

PURPOSE: The various electrical stimulation devices will be reviewed with respect to the available basic science evidence validating their use as spinal fusion adjuncts, as well as a review of the current clinical data available to allow not only a discussion of their overall clinical applicability, but more specifically their use in specific spinal disorders and spinal fusion techniques.

METHODS: The existing peer-reviewed scientific literature will be used to ascertain the scientific and clinical efficacy of electrical stimulation to enhance lumbar spinal fusion.

CONCLUSION: Electrical stimulation devices have emerged as valid adjuncts to attaining a solid lumbar spinal fusion. However, not all stimulators are equally scientifically effective nor are they equally effective clinically in achieving increased fusion success.

Spine J. 2002 Mar-Apr;2(2):145-50.

Combined magnetic fields accelerate and increase spine fusion: a double-blind, randomized, placebo controlled study.

Linovitz RJ, Pathria M, Bernhardt M, Green D, Law MD, McGuire RA, Montesano PX, Rehtine G, Salib RM, Ryaby JT, Faden JS, Ponder R, Muenz LR, Magee FP, Garfin SA. San Dieguito Orthopaedics, Encinitas, California 92024, USA. rjlmd@pacbell.net

STUDY DESIGN: The clinical study conducted was a prospective, randomized, double-blind, placebo-controlled trial.

OBJECTIVES: The purpose of this study was to evaluate the effect of combined magnetic fields on the healing of primary noninstrumented posterolateral lumbar spine fusion.

SUMMARY OF BACKGROUND DATA: Combined magnetic fields, a new type of biophysical stimulus, have been shown to act by stimulating endogenous production of growth factors that regulate the healing process. This is the first placebo-controlled study to assess the effect of an electromagnetic stimulus on primary noninstrumented posterolateral lumbar spine fusion surgery as well as the first evaluation of combined magnetic fields as an adjunctive stimulus to lumbar spine fusion.

METHODS: This multicenter investigational study was conducted at 10 clinical sites under an Investigational Device Exemption from the United States Food and Drug Administration. Eligible patients had one-level or two-level fusions (between L3 and S1) without instrumentation, either with autograft alone or in combination with allograft. The combined magnetic field device used a single posterior coil, centered over the fusion site, with one 30-minute treatment per day for 9 months. Randomization was stratified by site and number of levels fused. Evaluation was performed 3, 6, and 9 months after surgery and 3 months after the end of treatment. The primary endpoint was assessment of fusion at 9 months, based on radiographic evaluation by a blinded panel consisting of the treating physician, a musculoskeletal radiologist, and a spine surgeon.

RESULTS: Of 243 enrolled patients, 201 were available for evaluation. Among all patients with active devices, 64% healed at 9 months compared with 43% of patients with placebo devices: a significant difference ($P = 0.003$ by Fisher's exact test). Stratification by gender showed fusion in 67% of women with active devices, compared with 35% of those with placebo devices ($P = 0.001$ by Fisher's exact test). By contrast, there was not a statistically significant effect of the active device in this male study population. In the overall population of 201 patients, repeated measures analyses of fusion outcomes (by generalized estimating equations) showed a main effect of treatment, favoring the active treatment ($P = 0.030$). In a model with main effect and a time by treatment interaction, the latter was significant ($P = 0.024$), indicating acceleration of healing. Performed in the full sample of 243 patients, results of the intent-to-treat analysis were qualitatively the same as in the evaluable sample of 201 patients.

DISCUSSION: This investigational study demonstrates that combined magnetic field treatment of 30 min/d increases the probability of successful spine fusion, and statistical analysis using the generalized estimating equations model suggests an acceleration of the healing process. This is the first randomized clinical trial of noninstrumented primary posterolateral lumbar spine fusion, with evaluation by a blinded, unbiased panel. This is the first double-blind study performed to date assessing noninstrumented fusion outcome with extremely critical radiographic criteria. The lower overall fusion rates in this study are attributed to the high-risk patient group with an average age of 57 years, the use of noninstrumented technique with posterolateral fusion only, and the reliance on extremely critical radiographic and clinical criteria and blinded panel for fusion assessment without surgical confirmation.

CONCLUSIONS: In conclusion, the adjunctive use of the combined magnetic field device was statistically beneficial in the overall patient population, as has been shown in previous studies of adjunctive bone growth stimulation for spine fusion. For the first time, stratification of fusion success data by gender demonstrated that the female study population responded positively to the adjunctive combined magnetic field treatment, with no statistically significant effect observed in the male study population. Adjunctive use of the combined magnetic field device significantly increased the 9-month success of radiographic spinal fusion and showed an acceleration of the healing process.

Spine. 2002 Jul 1;27(13):1383-9; discussion 1389.

Osteonecrosis of the femoral head treated by pulsed electromagnetic fields (PEMFs): a preliminary report.

Eftekhar NS, Schink-Ascani MM, Mitchell SN, Bassett CA.

This has been a preliminary report with a short-term follow-up of a small number of observations (28 hips of 24 patients). The follow-ups ranged from 6 to 36 months, with an average of 17.8 months. Only eleven hips (in eleven patients) were followed an average of 8 months after cessation of the treatment. It should be emphasized that this was a "pilot" study, in which no control series was used to determine the natural course of the disease in a comparable clinical setting. Of note was the pain relief, in 19 of 23 patients with moderate to severe pretreatment pain. Also there was an improved function, which suggests that at least in approximately two thirds of the patients there was some clinical benefit from this mode of treatment. In eight hips, clinical conditions did not change; and in two they worsened,

requiring further treatment. Eighteen remaining hips were thought to have been benefited by the treatment. Six femoral heads that had already developed varying degrees of collapse (Ficat Type III) collapsed further (1 to 2 mm), and two round heads (Ficat II) progressed to off-round (Ficat III). This preliminary study suggests that further exploration of pulsed electromagnetic fields (PEMFs) is warranted in the treatment of osteonecrosis of the femoral head.

Hip. 1983;:306-30.

Effects of pulsed electromagnetic fields on Steinberg ratings of femoral head osteonecrosis.

Bassett CA, Schink-Ascani M, Lewis SM.

New York Orthopaedic Hospital, Columbia Presbyterian Medical Center, Riverdale, NY 10463.

Between 1979 and 1985, 95 patients with femoral head osteonecrosis met the protocol for treatment of 118 hips with selected pulsed electromagnetic fields (PEMFs). Etiologies included trauma (17), alcohol (9), steroid use (46), sickle cell disease (2), and idiopathy (44). The average age was 38 years, and the average follow-up period since the onset of symptoms was 5.3 years. PEMF treatment had been instituted an average of 4.1 years earlier. By the Steinberg quantitative staging method of roentgenographic analysis, none of the 15 hips in Stages 0-III showed progression, and grading improved in nine of 15. Eighteen of 79 hips (23%) with Stage IV lesions progressed and none improved. In the Stage V category, one of 21 hips (5%) worsened and none improved. Three Stage VI lesions were unchanged. The overall rate of quantified progression for the 118 hips, 87% of which had collapse present when entering the program, was 16%. This value represents a reversal of the percentage of progression reported recently by other investigators using conservative and selected surgical methods. PEMF patients also have experienced long-term improvements in symptoms and signs, together with a reduction in the need for early joint arthroplasty.

Clin Orthop. 1989 Sep;(246):172-85.

Use of pulsed electromagnetic fields in Perthes disease: report of a pilot study.

Harrison MH, Bassett CA.

A pilot study of pulsed electromagnetic fields (PEMFs) in the treatment of 10 older children with unilateral Perthes disease of the hip is reported. Patients were allowed to walk using crutches, with the affected hip splinted by the Birmingham containment orthosis during the day. For 10 h during the night the affected hip was exposed to PEMFs delivered via a pair of coils, mounted anterior and posterior to the hip joint on a plastic abduction orthosis. Splintage time of this group was compared with that of 72 patients selected at random from a historical control group of 200 patients. The 72 patients and the 10 children were assigned to early or late groups depending on the radiologic evolution of the disease when treatment commenced. The group of 10 children showed an overall reduction of time in all splintage of 32% in early cases (to 12.8 months) and 18% in late cases (to 13.5 months). No untoward effects were detected during the 2 years that these children have been under observation. In view of the apparent safety of PEMFs and their effects in this limited population of older patients with

advanced Perthes disease, a double-blind study in younger patients with earlier lesions seems to be justified.

J Pediatr Orthop. 1984 Sep;4(5):579-84.

<http://www.therionmagnetics.com/magnetic-therapy-research-fracture-healing.html#>

