

PAIN MANAGEMENT

A Practical Guide for Clinicians

SIXTH EDITION

Editor **Richard S. Weiner**



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Pulsed Signal Therapy: A Practical Guide for Clinicians*

Richard Markoll, M.D., Ph.D.

Before the next century is out of its infancy, physics will be as important in the treatment of disease as pharmacology and biotechnology are today. ... The future holds exciting and rewarding prospects for those ... who use their diverse knowledge and skills as teams to forge the principles for a new era of medical therapeutics. Without interdisciplinary effort, however, success will be elusive. ... Herein lies our challenge.

C. Andrew L. Bassett

A DESCRIPTION OF THE SERVICE

The development of Pulsed Signal Therapy (PST™) was initiated 3 decades ago following proof that pulsed electromagnetic fields (PEMF) could promote the healing of bone fractures and reports that they could also relieve pain due to osteoarthritis and traumatic joint damage. Because most of these latter claims were based on anecdotal observations and different PEMF devices had varied characteristics, an effort was made to determine whether a pulsed electromagnetic field with specific parameters might provide superior and more consistent results. The normal stimulus for cartilage production and bone formation results from piezoelectric signals that generate a “streaming potential” in the extracellular matrix when skeletal structures are subjected to physical pressure. Bones that are immobilized in a cast for long periods of time become

demineralized, and conversely, it has been shown that regular exercise helps build stronger bones. Because this restorative electrical signal is impaired in osteoarthritic joints, it seemed logical to attempt to define and accurately reproduce this natural physiologic stimulus so that similar benefits could be achieved in affected tissues not subjected to any load. Basic science research that focused on physical chemistry as well as clinical trials conducted between 1973 and 1988 confirmed the validity of this approach. Since then, the ability of PST to relieve osteoarthritic pain and improve mobility has been unequivocally verified in double-blind and open label clinical trials of over 100,000 patients with osteoarthritis of the knee and other joints. This noninvasive treatment is not associated with any pain or discomfort and long-term follow-up confirms sustained efficacy as well as an absence of any adverse side effects.

More recently, PST has been found to be effective in temporomandibular joint syndrome (TMJ), tinnitus, which is difficult to cure, and periodontal disease, an established risk factor for heart attack and stroke. PST is currently administered at over 500 sites in 16 countries, where it is reimbursed by fiscal intermediaries and governmental agencies because of its proven cost effectiveness and safety record. Many facilities are located in clinics associated with academic medical institutions or respected hospitals, such as The American Hospital in Paris. PST presently is approved only for veterinary use in the United States.

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The PST device consists of a control box connected to a ring-shaped coil that emits a proprietary pulsed electromagnetic field. Different coil sizes have been developed to treat peripheral joints (knees, shoulders, and wrists), the spine (cervical, thoracic, and lumbar vertebral bodies), tinnitus and dental disorders, and for veterinary applications as illustrated in Figures 57.1 through 57.4.

The joint to be treated is placed inside the coil and exposed to PST, usually for 1 hour on 9 consecutive days, interrupted only by a weekend. It is important to emphasize that PST is a patented procedure that should not be confused with PEMF devices that make similar claims but have scant supportive scientific clinical or basic research data.

THE HISTORY OF THE SCIENCE

The Yellow Emperor's Canon of Internal Medicine, which dates back 4000 years, describes how lodestones applied to acupuncture points could be used to relieve pain. Cleopatra allegedly wore one on her forehead while sleeping to prevent aging. In the Middle Ages, lodestones were also ground up to make powders to be applied as a magnetic salve to promote wound healing. Paracelsus believed they could be ingested to treat everything from diarrhea and epilepsy to various types of hemorrhage. By the middle of the 18th century, more powerful carbon-steel magnets that could be made in different shapes corresponding to any organ or structure in the body that required treatment became available. Magnet mania swept through Europe and France due to Mesmer, who used various magnetic paraphernalia in his salon to increase the flow of "animal magnetism," which could cure anything. Although Mesmer was discredited, the popularity of magnets steadily increased in the United States. By the beginning of the 20th century, magnetic insoles, rings, belts, girdles, caps, and other apparel were sold to cure everything from athletes' feet and baldness to menstrual cramps and impotency. The use of magnets to relieve pain declined with the advent of drugs and surgical procedures that could provide proven benefits. Over the past decade, they have become popular again because of stronger and smaller neodymium products that are easier to apply, and aggressive marketing by manufacturers eager to capture part of the estimated billion dollar worldwide market. While some studies do suggest that permanent magnets may relieve the pain of diabetic neuropathy, post-polio syndrome, and carpal tunnel syndrome, the action mechanism is obscure and there is little evidence of sustained benefits.

It is not clear when electricity was initially used to treat illness, but the electric catfish, which is indigenous to the Nile, is portrayed in Egyptian mural paintings that date back to 4000 B.C. The first recorded medical application was in 46 A.D. by Scribonius Largus, a Roman physician who used



FIGURE 57.1 Osteoarthritis of the knee.



FIGURE 57.2 Tinnitus.

a live torpedo fish to treat a patient with gout, and who also wrote that headaches and other pains could be cured by standing in shallow water near these electric fish. The powerful South American electric eel was introduced in Europe in 1750 and people flocked to be treated with its "natural" electricity. The invention of the Leyden jar around the same time dramatically demonstrated the ability of stored electricity to produce muscle contractions, and as batteries were progressively improved during the 19th and early 20th centuries, numerous types of "medical coils" increasingly appeared. Electromagnetic therapy was viewed as a legitimate subspecialty, much like the rapidly growing fields of



FIGURE 57.3 TMJ and periodontal disease.



FIGURE 57.4 Veterinary applications.

radiology and radium therapy and was used by over 10,000 physicians and countless others to treat almost every type of pain or functional complaint. There were numerous instruments with names like "The Dynamiser" and "Oscilloclast," based on theories that each organ and person were "tuned" to a specific wavelength that could rejuvenate them. Claims were frequently made by charlatans to promote the sale of worthless devices. The 1910 Flexner report, which stated that there was no scientific basis for any of these outlandish and fraudulent claims, and the introduction of X-ray and electrocautery instrumentation that provided proven benefits, led to their gradual demise. However, as with permanent magnets, there also has been a recent resurgence of various types of "electromedical" devices that continue to make unsupported claims.

Pulsed electromagnetic fields have been used to treat nonunion bone fractures for several decades, with a relatively consistent success rate of 70 to 80% in several

countries. (Bassett, Pilla, & Pawluk, 1977; Brighton & Pollack, 1985). In 1979, the FDA approved certain PEMF devices for the treatment of fractures that failed to unite satisfactorily within 9 months. This approach has benefited hundreds of thousands of patients including some where nonunion had persisted for 15 or more years despite surgical and other interventions. In 1990, approval was granted for failed spinal fusions of any age.

PST is based on the application of a very specific type of pulsed electromagnetic field to bone and adjacent tissues. The PST device generates a pure magnetic field output signal that employs direct current with unidirectional biological frequencies below 30 Hz. The "waveform" is quasi-rectangular with measured field strengths generally below 2 mT or 20 Gauss. The system is controlled through a pulsed unidirectional magnetic DC field with multiple output frequencies implemented via a free-wheeling diode to optimize the inductance characteristics. Various frequency/amplitude combinations are switched over automatically and transmitted under continuous control during the treatment period. Induction of treatment takes place during the first 10 minutes, followed by a combination of pulsed signals that delivers the therapy over the remaining 50 minutes. PST differs from conventional alternating-current magnetic field therapies such as the Krause-Lechner type system as illustrated in Figure 57.5.

This system coil delivers an alternating-current magnetic field that generates a sinusoidal waveform. This signal does not conform with what normally takes place in the body, because electrical activities in all living organisms follow only direct-current-oriented processes. PST also differs from other pulsed electromagnetic field (PEMF) approaches that utilize a direct-current-oriented signal transmitted at a specific intensity and a particular frequency that remains constant during treatment, as illustrated in Figure 57.6.

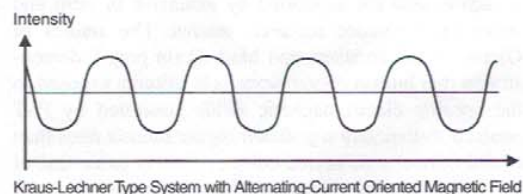


FIGURE 57.5 Krause-Lechner type system.

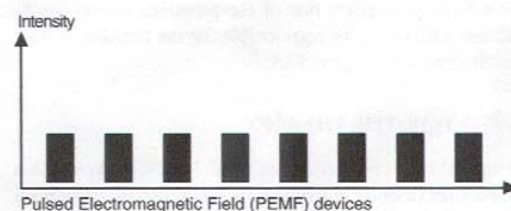


FIGURE 57.6 Conventional PEMF.

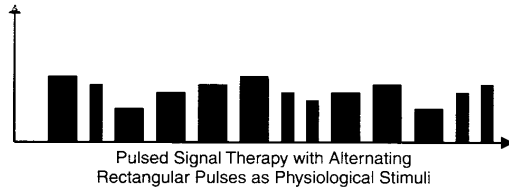


FIGURE 57.7 Pulsed signal therapy (PST).

While standard pulsed electromagnetic field devices do deliver a direct current signal, it never varies in either amplitude or frequency, which is also inconsistent with electrical signaling in living organisms. In contrast, pulsed signal therapy delivers changing pulsed electromagnetic signals in an alternating fashion that mimics signals generated in the body that are known to stimulate chondrocyte activity. The intensity of these rectangular pulses lies predominantly in the range of 0.5 to 1.5 milliTesla with relatively low frequencies that range from 10 to 20 Hz, as shown in Figure 57.7. The low biological frequencies and energy field strength at which PST operates is in a physiologic range, which helps explain why treatment is both effective and safe.

The most important distinction between patented PST and other electromagnetic therapies that are often in the public domain lies in proprietary specific amplitude, frequency, and repetition parameters. These have been designed to simulate physiological electrical signals in order to reproduce their biological benefits. PST's patented signal (pulsed DC magnetic field: 0.28 W., max. 20 gauss; 5–24 Hz; quasi-rectangular waveform) is the only electromagnetic stimulus with proof of efficacy in rigorously controlled clinical trials, as well as safety based on long-term follow-up. In sharp contrast to other devices making similar claims, the proposed mechanisms of action also are supported by extensive *in vitro* and other basic science research studies. The studies of Gierse, Breul, Faensen, and Markoll (in prep.) demonstrated that human chondrocyte cell cultures exposed to the specific electromagnetic fields generated by PST attained statistically significant higher mitosis rates than chondrocytes in untreated cultures (nearly twice that of the control group). Nerucci, Marcolongo, and Markoll (2000) demonstrated that PST enhances proteoglycan concentration in human chondrocyte cultures. These *in vitro* findings support one of the proposed action mechanisms believed to be responsible for the benefits of PST as illustrated in Figure 57.8.

NEED FOR THE THERAPY

Osteoarthritis currently affects 20.7 million Americans and its prevalence is expected to increase to 40 million within the next 20 years. It is responsible for 7 million physician visits and 3 million hospitalizations per year,

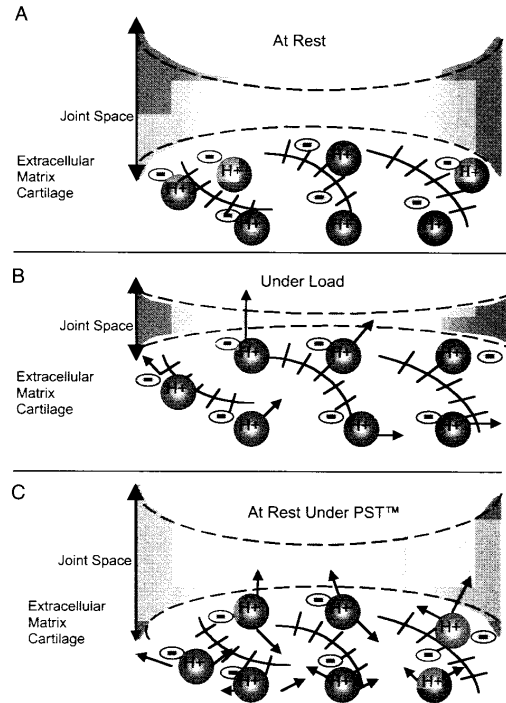


FIGURE 57.8 Action mechanism of PST. (A) Extracellular matrix at rest. An equilibrium exists between hydrogen and negative charges in the extracellular matrix, and there is no streaming potential of ionic flux as in (B) and (C). (B) Extracellular matrix under pressure. When the joint space is compressed as a result of physical pressure, a streaming potential is created as fixed negative charges in fluid are forced out of hydrogen protons to move into the joint space. (C) Extracellular matrix, as in (A), with PST. A similar streaming potential can be generated in the resting state by PST. This is from the forced movement of hydrogen protons, which results in alternating energies stimulating chondrocytes in matrix connective tissue. PST stimulates physiological streaming potentials as in (B).

with annual medical costs averaging \$2655.00 (Gabriel, Crowson, Campion, & O'Fallon, 1997). Sales of products to treat osteoarthritis in the world's seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom, and Japan) totaled approximately \$1.6 billion in 1998, and according to one recent report, are forecast to leap to more than \$4 billion in 2008 (The Marketletter, 1999). Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most commonly prescribed medications in the United States, accounting for more than 70 million prescriptions per year. Approximately 14 to 20 million patients take an NSAID on a daily basis (Statistical Bulletin, 1992). This figure is not inclusive of over-the-counter use of nonste-

roidal anti-inflammatory drugs, estimated to be greater than 26 billion tablets per year. This number has grown steadily since NSAIDs first became available without a prescription in 1983, and as the use of aspirin as a cardioprotective agent has increased.

According to the Food and Drug Administration, NSAIDs cause more adverse drug reactions than any other class of drugs. Harmful kidney, central nervous system, and hematologic effects can occur, but gastrointestinal (GI) complications are far and away the most common and serious. The prevalence of endoscopic evidence of gastric ulceration is estimated at 10 to 20% and most of these patients have no prodromal symptoms or warnings that there is any problem (Hochberg, et al., 1995; Henrietta, 1999). There are approximately 200,000 hospitalizations a year due to NSAID-related GI bleeding and ulcer complaints. Up to one in ten patients taking NSAIDs will suffer some serious gastrointestinal complication causing 70,000 hospitalizations and 10,000 to 20,000 deaths each year (Fries, 1991). The economic impact of these complications has been estimated at approximately \$1.5 to 4 billion annually (Smalley & Griffin, 1996; Smalley, et al., 1996). The significance of this is underscored by the advent of COX-2 inhibitor NSAIDs, which have fewer GI complications but are not significantly more effective in relieving pain and are much more expensive. Both Celebrex® and Vioxx®, the only two currently approved in the United States, easily surpassed Viagra® as the best-selling medication within the first 12 months of their introduction.

Numerous nonprescription drugs and nutritional supplements for the treatment of osteoarthritis are popular and a variety of medical and surgical approaches are also available. Some of these are summarized and compared to PST in Table 57.1.

This is not intended to be a comprehensive list of therapies for osteoarthritis but rather an indication of the diverse treatments available. For example, as this chapter was being completed, there was a report that Cat's Claw, a popular herbal treatment, had been shown to be equally or more effective than a prescription NSAID for osteoarthritis in a European double-blind study. However, the drug is not available in the United States and there are other questions about the validity of the study. Similarly, permanent magnets are widely used to treat pain but I am not aware of any studies showing them to be effective in osteoarthritis. It is important to emphasize that unlike PST, most of these and other popular remedies provide inconsistent benefits and must be used on an ongoing basis.

Joint and adjacent soft tissue damage due to trauma is also a huge and growing problem that responds to PST. According to the Institute for Preventive Medicine in Ann Arbor, Michigan, "Sports injury is the most under-recognized major public health problem facing the world

community. In addition to being an enormous public health issue, injuries continue to usurp our limited healthcare financial resources" (Nicholl, Coleman, & Williams, 1995). Numerous reports confirm that joint pain resulting from some sport injury affects millions of people of all ages all over the world. In England and Wales alone, there are 29 million sports incidents per year that require new or ongoing treatment (Bijur, 1995). An Albert Einstein College of Medicine study estimates that every year there are close to 4.5 million sports and recreation injuries to American children and adolescents alone (Madhok, 1993).

INDICATIONS AND CONTRAINDICATIONS

While the vast majority of clinical trials have been devoted to osteoarthritis, PST also has been found to be effective in relieving pain and disability due to trauma, temporomandibular joint disease, tinnitus, periodontal disease, carpal tunnel syndrome, osteoporosis, tendonitis and convalescence following surgical repair of ligaments, fresh bone fractures, aseptic necrosis, fibromyalgia, sciatica, post-polio syndrome, migraine, metatarsalgia, acute burns, immune deficiency disorders, drug resistant epilepsy, diabetic neuropathy, herniated disc and Dupuytren's Contracture, as are discussed in the following section. There are no known contraindications to pulsed signal therapy, and it has been used successfully in hemophiliacs with joint problems. Although there are no reported adverse effects in patients who are pregnant or have implanted pacemakers, treatment is avoided because of potential medical-legal problems.

RESULTS TO DATE

Double-blind clinical trials and other open label randomized studies conducted in the United States, Canada, France, Italy, and Germany over the past decade are summarized in Table 57.2. The protocol initially used 30-minute treatment periods for 18 days, but it was subsequently found that a 1-hour treatment for 9 days was more effective. Administering therapy for 1-hour twice a day for 5 successive days because of time constraints also has had good results, but there are insufficient data to determine whether this might be a satisfactory option.

The initial double-blind studies in the United States were conducted in three treatment centers and reported in the *Journal of Rheumatology* (Trock, et al., 1993; Trock, Bollet, & Markoll, 1994). Pain was evaluated using WOMAC and later OMERACT III validated instruments of outcome measures. Functionality was measured using WOMAC and modified Ritchie scales, as well as global evaluations of improvement by the patient and examining

TABLE 57.1
Osteoarthritis Treatment Modalities Compared with PST

Treatment Common Home Remedies	Duration of Relief	Adverse Side Effects
	External Application	
Heat	Several hours	None
Heat and cold	Several hours	None
Paraffin baths	Several hours	None
Rest and exercise	Several hours	None
Capsaicin (hot pepper)	Variable duration when effective	Burning sensation at site of application
Dimethyl sulfoxide (DMSO)	A few hours	Garlic odor to breath
	Oral Administration	
Glucosamine; chondroitin sulfate preparations	Effective for several hours in some double-blind studies but not others; must be taken continuously	Concerns about possible development of insulin resistance and/or diabetes
Methyl sulfonyl methane (MSM) and various herbal products	Variable and no good double-blind studies; must be taken continuously	None
Homeopathic preparations	Unknown; no good double-blind studies	None
Nonprescription NSAIDs and analgesics	2–8 hours; requires chronic administration	Gastrointestinal ulcerations, bleeding, kidney, and liver complications
	Prescription Medications	
NSAIDs	3–12 hours; requires chronic administration	Gastrointestinal ulceration, bleeding not uncommon (see text); may also affect the rate at which damaged cartilage regenerates
Glucocorticoid steroids	4–8 hours depending on dose; requires chronic administration	Fluid retention, gastric ulceration, diabetes
Codeine and its congeners	4–6 hours; requires chronic administration	Dependency and addiction
Viscosupplementation-hyaluronic acid (HA) injection	Up to 6 months	Long-term effects not known and benefits are controversial
Chondrocyte culture implantation	Variable and still experimental	Very expensive and long-term benefits or complications not known
	Surgical Procedures	
Arthroscopy	Variable depending on condition	Soft tissue, bone, and articular complications, as well as unexplained pain occur; in one study of 71 patients, there were 82 complications in 50 wrists
Osteotomy	Variable depending on condition	Negative side effects often outweigh benefits Decrease in muscle mass
Resection	Variable depending on condition	Negative side effects often outweigh benefits; rehabilitation required
Arthrodesis	Variable depending on condition	Negative side effects often outweigh benefits; loss of flexibility
Total joint replacement (Arthroplasty)	Approximately 10 years, but may be risky if done more than once	Long rehabilitation, not long lasting enough for younger people
	Electrical Stimulation	
Transcutaneous electric nerve stimulation (TENS) and cranioelectricalstimulation (CES)	Variable and requires multiple treatments if effective	None; does not affect cartilage loss which will cause pain to recur
High voltage pulsed galvanic stimulation (HVPGS), interferential electrical stimulation, MENS (minimal electrical noninvasive stimulation)	Variable but not long lasting and requires repeated treatment	None; does not affect cartilage loss which will cause pain to recur
Pulsed signal therapy	Sustained pain relief and cartilage growth continues after treatment	None

TABLE 57.2
Documented PST Clinical Studies

Study Design	Facility	Study Director(s)	Publication	Results/Notes
A double-blind trial of the clinical effects of pulsed electromagnetic fields in osteoarthritis	Yale University School of Medicine Teaching Hospital, Waterbury, CT	Thomas P. Greco Richard Markoll	<i>Journal of Rheumatology</i> , 20 (3), 1993	Pilot study
A double-blind trial of the clinical effects of pulsed electro-magnetic fields in osteoarthritis	Yale University School of Medicine Teaching Hospital, Waterbury, CT	David H. Trock Alfred Jay Bollet Richard H. Dyer L. Peter Fielding W. Kenneth Miner Richard Markoll	<i>Journal of Rheumatology</i> , 20 (3), 1993	Good to very good results, with high statistical significance
The effect of pulsed electromagnetic fields in the treatment of osteoarthritis of knee and cervical spine	Yale University School of Medicine Teaching Hospital, Melville, NY	David H. Trock Alfred Jay Bollet Richard Markoll	<i>Journal of Rheumatology</i> , 21 (3), 1994	Good to very good results, with high statistical significance
Treatment of painful osteoarthritis with pulsed electro-magnetic fields	Yale University School of Medicine Teaching Hospital, Danbury, CT	David H. Trock Alfred Jay Bollet Susan H. DeWitt Richard Roseff Michel Spiegel Richard Markoll	<i>Yale Danbury Clinical Journal</i>	Good to very good results, with high statistical significance
Comprehensive report of all patients treated with magnetic therapy	Yale University School of Medicine Teaching Hospital, Waterbury, CT	Alfred Jay Bollet David H. Trock	<i>Yale Clinical Presentations</i>	Good to very good results, with high statistical significance
Diagnostic profile of pulsed signal therapy patient population treatment of degenerative joint disease, muscle/ligament/tendon injuries, disc degeneration-herniation	McGill University, Vancouver, Canada	Cecil Hershler	<i>Canadian Presentation</i> , Vancouver, Montreal	High statistical significance
Completed Clinical Studies/Europe				
Étude de vérification de l'efficacité analgésique des champs électromagnétiques pulsés (PST) dans la gonarthrose	Cochin Hospital, Paris, France	C.-J. Menkés Serge Perrot	American College of Rheumatology (Presentation) Nov. 1998. Submitted to <i>Journal of Rheumatology</i>	Good to very good results, with high statistical significance
Prospective clinical study of osteoarthritis of the knee	Niguarda Hospital, Milano, Italy	M. Cossu N. Portale	<i>La Riabilitazione - Rivista di Medicina Fisica e Riabilitazione</i> April-June 31, 1998.	High statistical significance
Prospective, clinical verification study of PST in osteoarthritis of the knee and hip and degenerative LWS changes	PST Treatment Center, Munich, Germany Technische Universität, Munich, Germany	Stephan Frhr. Von Gumpfenberg Knut Pfeiffer Harald Martin	The British Institute of Musculoskeletal Medicine (in press)	High statistical significance
Multicenter study of the clinical effect of PST in osteoarthritis of the knee (Grade II and III, Kellgren)	Ludwig-Maximilian University, Munich, Germany	Rainer Breul Stephan Frhr. Von Gumpfenberg Michael Faensen Horst Cotta	<i>Journal of Orthopaedic Medicine</i> (in press)	Further documentation and analysis of patient data

(continued)

TABLE 57.2 (CONTINUED)
Documented PST Clinical Studies

Study Design	Facility	Study Director(s)	Publication	Results/Notes
Perpetual prospective study (VITAL: Visual Therapy Log, see below)	Ludwig-Maximilian University, Munich, Germany	Rainer Breul Friedrich Hahn Dieter Rost	The Society of Orthopaedic Medicine (in press)	High statistical significance. Further documentation and analysis of patient data
Procedural proposal for patients suffering with osteoarthritis of the knee by means of PST vs. placebo	University of Siena, Siena, Italy	Roberto Marcolongo	<i>Journal of Rheumatology</i> (in press)	High statistical significance

physician. It should be emphasized that only qualified physicians and health professionals are licensed to administer PST and only after they have satisfactorily completed training in our treatment protocol with each specific device. This includes detailed instructions on how to conduct a double-blind trial, as well as obtain an accurate history, and perform a thorough physical examination before and after treatment. For the past decade, all therapists also have been required to use our specially developed computer software program called "VITAL" (Visual Therapy Log) which captures all relevant follow-up details using a form of WOMAC evaluation criteria. A recent analysis of data obtained from monitoring 70,000 patients through our VITAL program confirms sustained benefits and no evidence of long-term adverse effects. Ongoing clinical studies are outlined in Table 57.3.

It should be noted that Tables 57.2 and 57.3 refer only to clinical trials dealing with osteoarthritis. Numerous studies have been performed or are in progress for a variety of the disorders.

Because PST was designed to repair and restore any type of connective tissue damage, we have explored its use in a variety of disorders including.

TRAUMA

In May 1990, we initiated a 4-year study of 1000 patients under the auspices of a Yale University teaching hospital in Connecticut. Several hundred patients with various sport injuries resulting from swimming, bowling, bicycling, jogging, tennis, basketball, baseball, golf, skiing, ice skating, boxing, gymnastics, handball, hockey, karate, mountain climbing, soccer, track and field, wrestling, as well as others sustained by fire and police personnel were included. Because most of the patients were relatively young and healthy, they responded very rapidly to PST compared to our experience with elderly patients with chronic diseases. Since 1996, we have developed a large number of sports-type injury clinics in Europe and Asia. Currently, PST is available to most European soccer players within their clubs' medical facilities. Following a

request, PST also was made available for German Field and Track athletes at the Sydney 2000 Olympic Games.

TINNITUS

Tinnitus is a common disorder characterized by a ringing, buzzing, or other persistent sound described as everything from a teakettle's whistle to the test tone for the Emergency Broadcast System. It can have many causes, is sometimes associated with dizziness or other neurological complaints, and it is estimated that more than 50 million Americans are affected. While there is no cure, one authority believes that tinnitus patients should be treated as if they had chronic pain. In a study of 160 adults with severe tinnitus reported at a recent meeting of the American Academy of Otolaryngology, it was emphasized that subjects additionally complained of stress, anxiety, fatigue, and depression, symptoms also common in patients suffering from chronic pain, and our experience has been similar. We conducted three prospective clinical trials in Berlin, Nuremberg, and Munich, Germany using untreated patients (population at large) as a control. A total of 199 patients were treated, 128 females and 71 males ranging in age from 17 to 78 years (mean age 57 years). Patients suffering from long-standing chronic tinnitus (Grades II, III, or IV) who had failed to respond to various types of therapies were randomly selected. Treatment consisted of 12 1-hour PST sessions conducted over a 2-week period. Using validated measurement instruments based on the accepted Goebel-Hiller Protocol developed at the University of Tübingen, all patients were evaluated before and at the end of treatment, and 6 and 12 weeks after the treatment. Data on hearing loss and other relevant parameters were also obtained. A gratifying and progressive trend of improvement was reported at the end of treatment and 6 weeks later. Final evaluation 12 weeks following treatment revealed that 26% were unchanged, 52% were very significantly improved, and 22% were now completely symptom free. No adverse side effects were reported or noted. Almost three out of

TABLE 57.3
Clinical Studies Currently in Progress

Study Design	Facility	Study Director(s)	Size	Publication	Results/Notes
Study of the clinical effect of PST in trials of the synovial liquid in osteoarthritis of the knee	Auguste-Victoria-Hospital Berlin, University of Erlangen	Detlef Schuppan Michael Faensen Richard Markoll	40	Study in progress, to be submitted for publication	Study began: December 1998 End date: December 2001
Trial of the medium-term effect of PST therapy vs. placebo in osteoarthritis of the knee	Prof. Kahan, Hospital Ranguel, Toulouse E. Vignon, Hospital E. Herriot Lyon	André Kahan	230	Study in progress, to be submitted for publication	Study began: September 2001 End date: Spring 2002

four stated that they were very satisfied and would definitely recommend PST, including some in the group who reported no change. Many in the significantly improved cohort reported a loss or diminution of high-frequency pitch ringing or replacement by a low-frequency hum that was much less disturbing.

Much larger European studies are in progress and a pilot study of 100 patients has been agreed upon in the United States. Presently, an extended multiphase clinical study, under the auspices of the Medical Director of the German Tinnitus League, is in progress. The first phase of the study was completed and evaluated at the end of 2000 and demonstrated significant results in the same etiology domain as previously observed

TEMPOROMANDIBULAR JOINT DISORDER (TMJ)

During follow-up evaluation of patients who were treated for osteoarthritis of the cervical spine, it was noted that a significant number of patients indicated that their temporomandibular joint disorder (TMJ) complaint also improved. Based on these observations, we completed a pilot study of 30 patients who reported an 80% improvement in their TMJ symptoms. Based on these encouraging results, a randomized prospective, double-blind study of 120 patients was undertaken in patients with varied TMJ complaints at five European centers. Statistically significant improvement in pain and mandibular mobility was confirmed. Another double-blind study of 102 patients at the University Dental Clinic in Greifswald, Germany, and a third study at the Freie Universität in Berlin reported similar improvement. As a result of the above studies, PST was recently approved for the treatment of tinnitus and TMJ disorders by appropriate European regulatory bodies in accordance with the International Medical Device Directive and the International Organization for Standardization (ISO) 9000. I should add that following a detailed audit of our Munich facility, PST received ISO 9001 and EN 46002 certifications for standards for quality. The company also received the CE mark in 1998 after demonstrating compliance with the

Medical Device Directive. The ISO 9000 is a required certification for medical devices that corresponds to FDA approval in the United States.

PERIODONTAL DISEASE

An open label clinical study was undertaken in 1999 at the Rothlauf Dental Clinic in Munich, Germany. Sixty patients with chronic periodontal gum disease were enrolled. Significant improvement was documented clinically and objectively with X-ray studies in all patients. Gingival pockets were not as deep and periodontal tissue became thicker. A subgroup of patients who had a routine scraping and cleaning procedure within 2 years of receiving PST showed the greatest improvement. The objective video and/or X-ray has been described as "remarkable." A clinical study of human patients at the University of Milan is now in progress and will be completed toward the end of 2001. Ongoing studies at the University of Modena have confirmed efficacy in an animal model of periodontal disease.

CARPAL TUNNEL SYNDROME

A pilot study involving 45 patients with intractable symptoms demonstrated relief of pain and a full return to all normal activities within 3 weeks of completing a series of treatments, thus avoiding surgery. A clinical study in the United States of patients with intractable pain is currently underway to document improvement and explore possible mechanisms of action.

TENDINITIS AND LIGAMENTOUS DAMAGE

Our experience has consistently been that tendinitis due to rotator cuff injury or golfer's elbow responds dramatically within 3 weeks. A surgical procedure is the treatment of choice for repairing a torn anterior cruciate ligament in the knee, and full recovery generally requires 6 to 8 months of rehabilitation. In more than two dozen patients who received PST immediately after

such surgery, full recovery was obtained within 3 months. Meniscal tears also respond well.

OSTEOPOROSIS

In one controlled study of 100 women aged 55 to 75 with X-ray evidence of moderate to advanced osteoporosis, the mean increase in bone density was greater than 25% following PST treatment.

FRESH BONE FRACTURES

While most bone fractures heal within a few weeks, spiral and various compound fractures may require casting and extensive rehabilitation for more than 3 months. We have treated a wide variety of fresh fractures, and our experience has been that the time required for casting is reduced by more than half

ASEPTIC NECROSIS

Aseptic necrosis of bone is a painful problem that does not respond to medication. Surgery is costly, usually only partially effective, and entails a long period of convalescence. We have treated aseptic necrosis since 1990, and in one study of 17 patients, 15 showed marked improvement, particularly with respect to relief of pain.

FIBROMYALGIA

Fibromyalgia is characterized by the constant presence of widespread pain so severe that it often is incapacitating. Signs and symptoms include muscle pain, aches, stiffness, disturbed sleep, depression, and fatigue. In the United States, 5 million people may be afflicted with its symptoms. It has been estimated that 15 to 20% of patients seen by U.S. rheumatologists may have fibromyalgia. The disorder shares many of the symptoms of myofascial and chronic fatigue syndrome and primarily affects women aged 25 to 50 years. Our experience has been that PST treatment relieves the signs and symptoms of fibromyalgia in over 80% of severe cases.

POST-POLIOMYELITIS SYNDROME

Post-poliomyelitis syndrome is manifested by complaints of joint pain and difficulty walking that may surface decades after an attack of poliomyelitis. In a study of five such patients who received a course of 18 PST treatments, all had relief of pain and ambulation was significantly improved. In one patient who had not been able to bend her ankle or walk without a marked limp for 62 years, range-of-ankle-motion returned to 60% of normal, her limp disappeared, and she was able to discard her cane and return to an active social life, including dancing

SCIATICA

Sciatica is a term used to describe severe referred pain in the leg and often due to pressure on the sciatic nerve from pathology in the lumbar region. Our experience has been that PST treatment can provide significant improvement within 2 or 3 weeks.

METATARSALGIA

Metatarsalgia is a general term used to describe pain in the ball of the foot due to a variety of disorders such as Morton's neuroma, or atrophy of the plantar fat pad. In more than 50 patients with metatarsalgia who had received 15 to 18 PST treatments, over 80% were pain free or only "had a slight twinge once in a while."

PLANTAR FASCIITIS

This problem is due to soft tissue inflammation in the foot which also causes severe pain when attempting to walk. Our experience in over 40 patients with nonspecific fasciitis shows dramatic improvement with complete recovery and an absence of pain following a standard course of PST treatment.

ACUTE BURNS

A European study of 23 acute burn patients demonstrated that reepithelialization occurred in less than 50% of the anticipated time following a course of PST treatment

IMMUNE DEFICIENCY DISORDERS

An open-label European study of 25 patients with neutropenia or pancytopenia due to immune system dysfunction showed significant improvement that persisted for up to 1 year in some instances. While anecdotal, treating hematologists were impressed with these results.

DRUG-RESISTANT EPILEPSY

Three patients with drug-resistant epilepsy were treated in an uncontrolled study. Complete neurological evaluation was obtained prior to and 1 and 3 months following PST treatment. All the neurologists concluded that their patients had experienced such significant improvement that a large pilot study is planned with a more specific protocol and parameters.

DIABETIC NEUROPATHY

Diabetic Neuropathy is a serious complication of diabetes mellitus manifested by pain and tingling and a loss of sensation. There is no treatment for this disorder, which

often leads to severe foot infections and amputation of various portions of the lower extremities. In one study of 17 patients with well-documented diabetic neuropathy, 16 reported marked improvement and an increase in quality of life following PST treatment because they had regained the ability to engage in many daily activities that were previously difficult or impossible.

MIGRAINE

In a pilot study of seven patients with a long history of migraine headaches, 15 PST treatments were administered over a 3-week period. A 9-month follow-up of five patients revealed a mean average of less than one attack per month per patient over this time period. These results were so impressive that a larger double-blind study is planned.

AVASCULAR NECROSIS AND ANKYLOSING SPONDYLITIS

This disorder also respond well to PST. We have treated 100 patients with bilateral avascular necrosis of the neck of the femur in the past 2 years, with remarkable relief of symptoms as well as objective evidence of radiological improvement. Ankylosing spondylitis is another indication for PST and treatment is targeted to the source of the referred pain rather than its location.

BACK AND NECK PAIN

Due to herniated disk, spondylolisthesis, and other lumbosacral problems can improve significantly following PST treatment. A double-blind study of 176 patients, 81 with cervical spine and 86 with knee complaints reported in the *Journal of Rheumatology* (Trock, Bollet, & Markoll, 1994) reported marked improvement following nine PST sessions with an absence of pain and a return to normal activities 4 to 6 weeks following treatment.

DUPUYTREN'S CONTRACTURE

In its early stages Dupuytren's Contracture responds to PST and can significantly shorten the recovery period following surgical procedures.

In addition to the above, a variety of other disorders have responded to PST. In 1996, we treated a 15-year-old girl with a tentative diagnosis of osteochondritis dissecans who was unable to walk without assistance or crutches. She received the standard program of nine consecutive sessions over a 10-day period. On the 14th day, she was able to walk for short periods without crutches and progressively improved so that 3 weeks later, she was able to join a walking tour in Greece. Although advised not to participate in any strenuous hiking activities, she was able to keep up with the group

climbing hills and tough terrain with no difficulty. She has not received any additional treatment, and she was able to enter a course in karate training later in 1996, and subsequently achieved Black Belt status. At present, she continues to pursue an unusually active life with no orthopedic complaints.

PREDICTIONS

This chapter began with C. Andrew L. Bassett's emphasis on the "vast interdisciplinary gap between biophysics and medicine" and the need for physicians to have more basic science education. The importance of this component has now been recognized, as relevant courses in physics are increasingly being integrated and introduced into the medical curriculum. This is vividly illustrated by the clinical benefits of PST, which is based entirely on solid physical chemistry research.

In a 1993 article, Bassett also made the following prediction:

Against this background, it is clear that the physical control of certain pathologic states with selected time-varying magnetic fields can be highly effective, safe and economic in comparison to present treatment methods. As *in vitro* (tissue culture) and *in vivo* (animal) studies progress, substantial biomechanistic data support a rational expansion for clinical investigation to include PEMF use for speeding nerve repair for benefiting cardiac ischaemia (i.e. heart attacks), and for controlling loss of function following a cerebral vascular accident (stroke). Experimental results, also, suggest that conditions as diverse as adult onset diabetes and cancer deserve the concerted research attention of the bioelectromagnetics community.

C. Andrew L. Bassett, 1993

Andy Bassett, a good friend who was very supportive of our research, unfortunately did not live long enough to see his prophecy fulfilled well ahead of schedule. Along with Bob Becker and others, he pioneered the use of electromagnetic fields for the treatment of fractures that failed to unite, and stimulated many others to explore the use of electromagnetic fields for diverse clinical disorders. Pasche (1999) has proven the efficacy and safety of low energy emission fields (LEET) for the treatment of insomnia and anxiety disorders in rigidly controlled double-blind polysomnography studies at major sleep centers. Other forms of cranioelectrical stimulation can markedly improve depression and repetitive transcranial magnetic stimulation (rTMS) has been particularly effective in patients resistant to medication. Sodi Pallares (2000) has demonstrated remarkable reversal of metastatic malignancies and

terminal cardiomyopathy with a combined magnetotherapy–metabolic regimen.

These and other observations, such as Liboff's (1985) ion cyclotron resonance studies, are difficult to explain in terms of Newtonian physics. They appear to defy the laws of thermodynamics because these feeble forces produce nonthermal effects that do not appear to involve caloric exchange. However, as Rosch and Adey (1999) have proposed, they do become comprehensible from a quantum physics perspective, and are consistent with an emerging paradigm of energy medicine that views communication in the body at a physical/atomic level rather than the current chemical/molecular model.

Life on earth evolved under constant geomagnetic influences, so it should not be surprising that all living cells, tissues, and organs are sensitive "electromagnetic systems" with specific electrical or magnetic resonance characteristics. Becker (1990) has shown that our bodies exhibit a positive polarity along the central axis, and a negative polarity in peripheral structures. He also has demonstrated that this polarity is reversed in hypnosis and anesthesia, as well as following an injury that creates a positive potential at the trauma site. He believes that this reversal of polarity generates a microcurrent of injury that is conducted through Schwann and glial cell sheaths surrounding neurons, which act to initiate repair and regenerative processes. Nordenström (2000) has proposed that there is a local build-up of positively charged ions following injury that creates an electrical voltage potential between opposite ions that are separated. Much as occurs in a battery, this energy can be tapped once the circuit is closed to permit the flow of electricity between these charged areas. The speed, versatility, and integration of these activities suggest the existence of the biologic equivalent of electrical systems composed of electrodes, switches, amplifiers, resistors, and capacitors that can store and regulate energy flow, which he refers to as "Biologically Closed Electrical Circuits" (BCEC). Based on this, he has developed a very effective treatment program for metastatic lung tumors that has now been replicated by others in tens of thousands of patients all over the world.

As enthusiasm for "electroceuticals" grows, there will undoubtedly be claims of other therapeutic triumphs. There are already reports of benefits for patients with everything from Alzheimer's and Parkinson's disease to multiple sclerosis, migraine, and epilepsy. Unfortunately, it may be difficult to distinguish between approaches that are authentic and promising and are supported by a scientific rationale, and others based on anecdotal reports and speculation by well-meaning but misinformed zealots. In addition, entrepreneurs and charlatans eager to cash in on the growing popularity of bioelectromagnetic medicine who may take advantage of desperate patients for whom conventional medicine has little to offer. As their efforts

TABLE 57.4
Questions to Ask When Evaluating
Electromagnetic Devices Claiming to
Relieve Pain or Provide Other Benefits

1. Have rigidly supervised double-blind studies been conducted in a clearly defined and properly selected patient cohort under the auspices of a university medical center or affiliated teaching facility?
YES___
2. Are the individuals conducting the study and the supervising Scientific Director of the organization offering the therapy qualified scientists with appropriate academic or other medical credentials, as opposed to salespeople or engineers?
YES___
3. Have follow-up studies been performed that demonstrate long-term sustained benefits, safety, and absence of adverse side effects?
YES___
4. Have any supportive basic science studies been performed at university-affiliated or recognized research centers by appropriately qualified scientists?
YES___
5. Have the results of clinical trials and supportive basic science studies been published in established peer reviewed medical and scientific journals as opposed to popular lay publications, other media presentations, or self-serving press releases?
YES___
6. In addition to Institutional Review Board approval, has an academic or other appropriate teaching facility reviewed and signed off on the study protocol and the results that were obtained?
YES___
7. Has the device or procedure been patented, and if so, are these merely simple design patents as opposed to process patents that cover the technology?
YES___
8. Is there a definitive database that can be made available to provide background information that explains the biological effects of the therapy being offered?
YES___

are shown to be worthless, there is apt to be a rising tide of resentment from the public as well as the scientific community, with the danger that the baby will be thrown out with the bathwater.

One way to prevent this when evaluating various claims is to ask the questions in Table 57.4 and compare the responses with PST.

PST can answer a resounding YES to all of these. Our experience has been that others can respond satisfactorily to only one or two, and in some cases none. There is little doubt in my mind that bioelectromagnetic therapies will be increasingly incorporated into mainstream medicine in the millennium, *if we can separate the wheat from the chaff*. As Andy Bassett predicted, this has already started to occur and some current standard treatments are likely to be supplanted.

This "energy medicine" paradigm also may provide important insights into how acupuncture, homeopathy, the laying on of hands, faith healing, placebos, as well as prayer can relieve pain and provide other rewards. Pfeiffer (2000) has already demonstrated with Kirlian photography that there are marked differences in energy levels before and after treatment with PST. Similar approaches may lead to a greater understanding of how we can communicate with other living systems to improve health and harmony in nature. As Jules Henri Poincaré noted this should be the goal of the true scientist:

The scientist does not study nature because it is useful; he studies it because he delights in it, and he delights in it because it is beautiful. If it were not beautiful, it would not be worth knowing, and if nature were not worth knowing, life would not be worth living.

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