Pulsed Signal Therapy:
Powerful Pain Relief and Promising Potential

Richard Markoll, M.D., Ph.D. responds to questions posed by Dr. Stanley Kornhauser about Pulsed Signal Therapy.

RICHARD MARKOLL M.D., Ph.D. and DR. STANLEY H. KORNHAUSER, Ph.D.

Dr. Kornhauser: ***In my recent interview with Dr. Paul J. Rosch, "Magnetotherapy and 21st Century Medicine," he quoted Andrew L. Bassett from a 1992 article, "In the decade to come, bioelectromagnetics will assume a therapeutic importance equal to, or greater than, that of pharmacology or surgery today." Dr. Rosch was confident that his Tenth International Montreux Congress on Stress in March, 1999 would prove that this prophecy had already been fulfilled. In a recent conversation, Dr. Rosch told me he was particularly impressed with Pulsed Signal Therapy (PST) and after listening to him and reading your abstract, I understand why. How did you come to develop this impressive modality for pain relief?***

Dr. Markoll: I'll begin by emphasizing that at the 1993 annual American Congress of Surgery meeting, Bassett also said, "There is a vast interdisciplinary gap between biophysics and medicine. We should endeavor to bridge this gap." Andy Bassett was a good friend, and it is regrettable that he did not live to see both of these predictions come true. What some have referred to as "electroceuticals" have started to replace drugs, and a year of physics is now required for entry into medical school, and two would be preferred. When we began our bioelectromagnetic therapy research about thirty years ago, it was based on the very approach that Basset, Becker, Liboff, and other pioneers in the field had championed. We started out with in vitro biophysics and biochemical investigations that we believed would provide a solid foundation for future clinical applications. In the mid-seventies, we completed a four-year pilot study of 1,000 patients with various types of musculoskeletal disorders characterized by persistent pain. Each received eighteen one-half hour treatments using a specific energy signal that had been formulated from our basic science research. Statistical analysis of the results revealed that about four out of five patients experienced not only significant pain relief, but also substantial increases in previously limited ranges of motion, as well as other indices of improved function. The FDA reviewed these findings, and we received our initial device registration certificate on October 10, 1980. Since then, we have continued to fine-tune our treatment protocol, which now provides safe and effective pain relief in about ninety percent of patients.

Dr. Kornhauser: ***Where can one receive PST?***

Dr. Markoll: We presently operate over two hundred and fifty clinics located in thirteen countries, where PST has satisfied strict regulatory requirements for proof of efficacy and safety. The majority of these are in Europe, with our headquarters being in Munich. In 1993, we submitted a twenty-four-volume document to the FDA to obtain Pre-Market Approval. Since then, we have provided a number of amendments to further our goal of being able to provide this treatment here. Our U.S. headquarters are located in Boca Raton, where we also have a separate 5000 square foot research and development facility.

Dr. Kornhauser: ***Following the initial pilot study, what other research or clinical trials have you performed?***

Dr. Markoll: We subsequently treated over 5000 patients in clinical trials supervised by senior physicians with particular expertise in arthritis. These were conducted at Yale University School of Medicine teaching hos-

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Mechanism of Action of Pulsed Signal Therapy

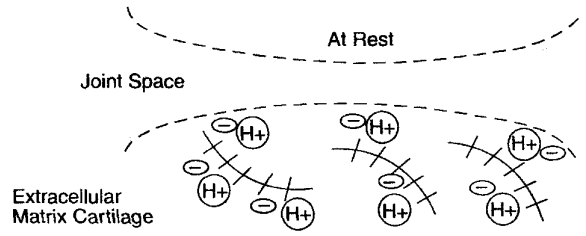

FIGURE 1. At rest, an equilibrium exists between hydrogen protons and negative charges in the extracellular cartilage matrix, and there is no streaming potential.

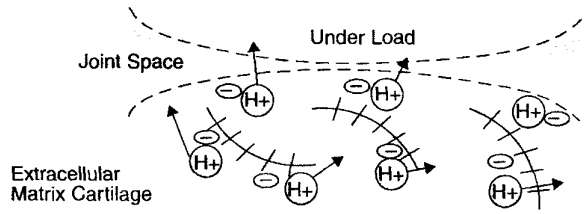

FIGURE 2. When the joint space is compressed as a result of physical pressure, a streaming potential is created as fixed negative charges in fluid forced out of cartilage cause hydrogen protons to move into the joint space.

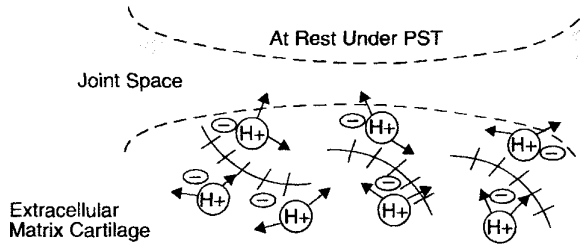

FIGURE 3. A similar streaming potential can be generated in the resting state by PST. This is due to the forced movement of hydrogen protons which results in alternating energies stimulating chondrocytes in matrix connective tissue.

pitals, and the results, which were published in the *Journal of Rheumatology*, confirmed statistically significant improvements in pain and disability. Pain and inability to function adequately in one or more activities of daily living are the two main complaints that bring arthritis patients to physicians' offices. Equally encouraging was the very high safety profile, and improved overall quality of life that resulted from better sleep patterns and increased mobility.

Dr. Kornhauser: ***Can you explain the mechanism of action of PST?***

Dr. Markoll: Although bone appears to be a solid and stable structure, like all living tissues, it is constantly being built up and broken down by anabolic and catabolic activities that influence its formation. Every joint in the body is surrounded by an electrical field that promotes this process of bone regeneration in healthy, active individuals. Activity is important, since it produces physical pressure on cartilage that initiates these bioelectric reparative processes. When deprived of this stimulus due to immobility and lack of use, bone begins to atrophy. Traumatic injury, osteoarthritis, and other diseases also cause a disruption of this energizing field that hinders its regenerative properties. PST utilizes a very specific biological frequency signal directed at the affected joint, adjacent cartilage, and connective tissue, that corrects this by producing the same streaming potential produced by pressure (Figures 1-3). As this healing electrical field is restored, there is a progressive reduction in the pain and swelling that result when cartilage and bone wear away due to disease or trauma.

It would be impossible in a brief interview to describe and explain all the biophysical, biochemical, and piezoelectric reactions that we have studied. However, we have assembled a database of over 2500 scientific reports

few other countries, charges are picked up by National Health Insurance. The physician workup and ancillary services should be reimbursable in the U.S, and would probably provide reimbursement for half the charges.

If fiscal intermediaries do a long term cost analysis comparing PST with standard treatments, as has been done elsewhere, the economic advantages should be impressive. For instance, few are aware of the side effects of medicines traditionally used to ease pain. This is especially true for NSAID's (non-steroidal anti-inflammatory drugs) that can cause ulcers and gastrointestinal bleeding, but mask the usual early warning signs. Close to 100 million prescriptions are filled for these every year, and non-prescription sales are probably much higher.

Erosions in the lining of the stomach or ulcerations occur in 40 percent of patients taking NSAID's for extended periods, and well over 100,000 are hospitalized annually for NSAID complications, at an average cost of $10,000 for each admission. This is not trivial, since ten percent of patients admitted to the hospital for stomach bleeding never get out alive. The new "super aspirin" selective cox-2 inhibitors have been found to cause bleeding. They are no more effective than regular aspirin, cost about $100 a month, and not much is known about their long term side effects. There can also be significant kidney complications, and a Mayo Clinic study of patients admitted for nephropathy concluded that over ten percent could be traced to these drugs. Even one or two ibuprofen capsules taken a few days a week can result in kidney damage, and in those with existing disease, can cause tubular necrosis and renal shutdown that necessitates dialysis.

Many older individuals with painful osteoarthritis often take blood thinners and other medications that don't mix well with NSAID's, aspirin, and combination products that contain these. Acetaminophen in combination with alcohol can cause liver damage that may be irreversible and fatal, and the FDA recently mandated label changes to include this warning. Cortisone and related drugs reduce inflammation and pain, but in addition to ulcers, can cause osteoporosis, mental disturbances, and increased susceptibility to infections because of suppression of immune system resistance. Antidepressants, which are increasingly being prescribed as an adjunctive pain relief therapy, can also have very disturbing side effects. The addiction potential for opiates and drugs containing codeine is well known, and long term use is similarly not advised. In contrast, PST is not associated with any of these dangerous and costly complications. If you look at the long-term picture, there are significant savings, and PST would be a bargain at any price for individuals at risk for some of these problems.

FIGURE 4. Patients being treated with PST for knee pain.

Dr. Kornhauser: ***Why isn't PST approved in the United States?***

Dr. Markoll: Actually, I have been impressed with the FDA's willingness to work with us to provide PST here, so that patients don't have to go to Mexico or Canada for treatment. But their job is not easy. On the one hand, pharmaceutical companies and medical device manufacturers complain about the tremendous cost and years it can take to receive approval. On the other, consumer advocate groups protest that many products are brought to market prematurely, without adequate safeguards against long term consequences. The FDA is underfunded and understaffed. It cannot possibly do everything that is required of it with respect to food safety, monitoring adverse reactions, deciding which herbal supplements to regulate, and numerous other protective duties to protect our health, one of which is insuring long term safety to avoid another thalidomide tragedy.

The FDA is extremely thorough, and their diligence in insisting on rigorous proof of safety has saved countless lives. But even if they do approve a drug as being safe, it is impossible to predict what will happen if it is taken along with other medications, or in patients with certain disorders, as we are witnessing

(a) For tinnitus and otosclerosis. (b) For TMJ and periodontal disease. (c) For animals.

FIGURE 5. Research is underway to find new applications for PST.

with Viagra. Posicor, a highly touted antihypertensive drug, was banned only ten months after it had been introduced, but it took twelve years to recall the popular antihistamine Seldane. The 1997 FDA Modernization Act is designed to streamline the approval process without sacrificing present safety standards.

We had several excellent presentations dealing with U.S. and European approval mechanisms for medical devices at the recent Montreux Congress including a detailed explanation of this new legislation by an FDA official who is actively involved in its implementation. The FDA also recognizes that other countries have strict requirements, and in some instances, as in the case of the German Commission E regulation of herbal supplements, are ahead of us in evaluating and setting standards. As a result, there is a growing tendency towards global harmonization in this area that may spill over to others.

Dr. Kornhauser: ***Have you tried PST for complaints other than pain, and can it be used in conjunction with other treatments?***

Dr. Markoll: The answer is yes to both. Osteoporosis investigations are underway in Italy, and it seems likely that synergistic effects might be obtained from combining PST with conventional treatments for this disorder.

We are also looking into whether benefits could be improved or accelerated by concomitant nutritional interventions with glucosamine, chondroitin sulfate, MSM (methylsulfonylmethane), and other natural and safe glyco- and phytonutritional compounds that have been demonstrated to relieve osteoarthritic pain. We are very excited about the results of pilot studies in patients with tinnitus, otosclerosis, carpal tunnel, and TMJ complaints, as well as periodontal disease, which has now been linked to an increased incidence of heart attacks and accelerated atherosclerosis. There are also important implications for veterinary medicine, and as we continue to expand our R&D efforts here and abroad, I suspect we will find more applications. These all require designing different devices to insure accurate delivery of the proper signal (Figure 5).

Dr. Kornhauser: ***There were several other magnetotherapy presentations at the Congress. How do they compare with PST with respect to efficacy?***

Dr. Markoll: There were many fine papers covering different bioelectromagnetic approaches to the treatment of Parkinson's disease, multiple sclerosis, epilepsy, migraine, addictive disorders, cancer, heart disease, insomnia, anxiety, depression, and other stress related disorders that support Dr. Rosch's contention that Basset's prediction has already come true. There were also several others dealing with pain, and there is little doubt that many of these approaches, as well as permanent magnets, can provide pain relief for certain patients. I would not want to give the impression that PST is the only magnetotherapy modality that can be effective, but I suspect that few can approach our close to 90 percent success rate. In addition, I am not aware

of any approach or device that has been as thoroughly researched and verified in carefully controlled double blind studies.

Dr. Kornhauser: ***As word of the efficacy of PST and other proven magnetotherapies spreads, spurious copycat devices claiming to be just as good and less expensive will undoubtedly flood the market. How can one discriminate between these and legitimate products?***

Dr. Markoll: That's another excellent question. One has only to look at the confusing and conflicting claims of various brands of herbal and nutritional supplements, or from magnet manufacturers, each competing to convince consumers that they are superior. This is a growing problem that must concern the FDA and other regulatory agencies mandated to protect the public. Consumers should ask themselves the following questions when evaluating unapproved alternative therapies:

- Were adequate and well-controlled double-blind studies performed at academia affiliated facilities?
- Have the results been published in recognized peer reviewed journals rather than magazines and self-serving publications?
- What basic science research has been completed to support various claims, and to explain possible mechanisms of action?
- What are the qualifications of the Scientific Director of the organization offering the product and of the individuals who conducted the basic research and clinical trials?
- Are there patents for the treatment or device, and if so, are they process patents covering the technology or merely simple design patents?
- Is there a definitive database of the biological effects of the treatment or device, and long term safety records similar to those we insist on for PST?

I suspect that very few providers of alternative products will be able to respond satisfactorily to the majority of these queries.

Dr. Kornhauser: ***Has the FDA approved any magnetotherapy approaches, instruments, or devices?***

Dr. Markoll: Yes. I think that just as MRI (magnetic resonance imaging) has proven to be superior over previous diagnostic procedures, there will be similar breakthroughs in the clinical use of electromagnetic therapies. The only currently approved indication for magnetotherapy is for the treatment of fractures that have failed to unite after a year. This has proven effective in hundreds of thousands of patients over the past two decades, even in bone fragments that have been separated for 15 or more years. We are hopeful that other magnetotherapy approaches will soon be approved in view of the new FDA streamlined procedures that were explained at the Congress. There appears to be some light at the end of the tunnel. □

THE AUTHORS

Dr. Richard Markoll *received his Ph.D. in physical chemistry from the University of Cologne, and did postgraduate research at Ludwig Maximilians University and Max Planck Institute in Munich. He received his M.D. from Grace University School of Medicine, an affiliate of Cambridge University, and did his internship and subsequent medical training at Johns Hopkins and Yale University School of Medicine. His early research involved developing the first practical synthetic lubricants for the steel industry and multipurpose products for military applications. He subsequently pioneered and developed Pulsed Signal Therapy for the treatment of arthritis, and is the sole author of the process patent for its use in this as well as athletic and other traumatic bone injuries. He has been interviewed by all the major national TV networks here and abroad, and written up in The New York Times. Dr. Markoll can be reached in the U.S. at BMTS, Inc., One South Ocean Blvd. Suite 204, Boca Raton, FL 33432, 561/394-4994, FAX 561/394-2150, and in Europe at BMTS, GmbH, Implerstr. 71 RG, 81371 Munich, Germany, 49 89 747-3050, FAX 49 89 747-305-20, e-mail: BMTS@Mindspring.com*

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