L45 PULSED SIGNAL THERAPY FOR THE TREATMENT OF OSTEOARTHRITIS: DOUBLE-BLIND & CLINICAL STUDY […]

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PULSED SIGNAL THERAPY FOR THE TREATMENT OF OSTEOARTHRITIS: DOUBLE-BLIND AND CLINICAL STUDY RESULTS IN 70,000 PATIENTS

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Introduction. Double-blind clinical trials and other open label randomized studies were conducted in the USA, Canada, France, Italy and Germany, to determine the effectiveness of a specific pulsed electromagnetic field called Pulsed Signal Therapy (PST) which consists of a pulsed DC magnetic field: 0.28 W., max. 20 gauss; 5-24 Hz; quasi-rectangular wave-form, for the treatment of osteoarthritis of the knee, hip, lower back and cervical spine. Previous studies had shown that changes in placebo groups had less statistical significance at the end of treatment, and had lost statistical significance for most variables at the one-month follow-up. In contrast, treatment groups consistently demonstrated statistical significant and sustained benefits.

Material, Methods. Controlled double-blind and observational open label studies were undertaken byDrs. David

H. Trock and Alfred J. Bollet at Danbury Hospital, Conn. USA (Teaching Affiliate of Yale University School of Medicine); Cecil Herschler, University of Vancouver, Canada; Prof. Menkes, Cochin Hospital, Paris, France; Prof. E. Radaelli, Ospedale Niguarda – Ca Granda, Milan, Italy; Prof. Fhr. Von Gumppenberg, University School of Medicine , Munich, Germany; Prof. Rainer Breul, Ludwigs Maximillian University School of Medicine, Munich, Germany; Prof. D. Schuppan, University of Erlangen, Germany; Prof. M. Faensen, Auguste-Victoria Teaching Hospital, Berlin, Germany; Prof. M. Sittinger, Humboldt University, Berlin, Germany; Drs. F. Nerucci, A. Fioravanti, C. Tofi, K. Riegeschi and Prof. R. Marcolongo, Institute of Rheumatology, University of Siena, Siena, Italy. The LMU, Munich, Germany two year multi-center clinical study produced data from >30,000 patients.

Results. Initially, 18 half-hour treatments and then a 9 one-hour treatment program, (active or placebo in the double-blind and active in the open label studies) were conducted in seventy thousand patients over a ten year period in the USA, Canada and Europe. 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 physician.

Matched pair tests and other statistical analysis showed extremely significant changes from baseline for the treated patients irrespective of the joint treated. The changes in the placebo patients showed lesser degrees of statistical significance at the end of treatment, and had lost significance for most variables at the one month follow up. The open label analysis and results were consistent with the double-blind results.

Conclusion. Pulsed Signal Therapy treatment provides significant improvement in pain and limitation of motion, the two major complaints of patients suffering from osteoarthritis of the knee, hip, lower back and cervical spine. It is not associated with any discomfort or side effects and long-term follow-up evaluation has confirmed its safety and sustained improvement. PST is a patented, non-invasive treatment that should not be confused with other approaches or devices frequently described or referred to as Pulsed Electromagnetic

Field Therapy.