PULSED SIGNAL THERAPY FOR THE TREATMENT OF OSTEOARTHRITIS: DOUBLE BLIND AND PROSPECTIVE STUDY RESULTS IN MORE THAN 35,000 PATIENTS

Richard Markoll
Bio-Magnetic Therapy Systems, Florida (USA) an Munich (Germany)

Introduction

Pulsed Signal Therapy (PST) is based on the application of pulsed electromagnetic fields to the tissues of the motor-skeleton system.
It has been reported in several studies that the rate of synthesis of proteoglycans and collagen in cartilaginous tissue increases when the tissue is stimulated by pulsed electromagnetic fields. Especially the treatment with PST forces streaming potentials in the extracellular matrix of the cartilage which stimulates the chondrocytes to synthesize components of the matrix. Double-blind clinical trials and other open label prospective studies have now been conducted over a ten year period in the USA, Canada, France, Italy and Germany, to determine the effectiveness of the proprietary pulsed electromagnetic for the treatment of osteoarthritis of the knee, hip, lower back and cervical spine.

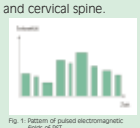
Fig. 1: Pattern of pulsed electromagnetic fields of PST


Fig. 2: The basic scientific aspects of PST


Fig. 3: Chondrozyt


Fig. 4: Knee Coil

Material and methods

Controlled double-blind and prospective open label studies were undertaken by D. H. Trock and A. J. Bollet at Danbury Hospital, Conn. USA, (Teaching Affiliate of Yale University School of Medicine) (1, 2); C. Hershler, University of Vancover, Canada (*) ; C. J. Menkes, Cochin Hospital, Paris, France (3), E. Radaelli, Ospedale Niguarda – Ca Granda, Milano, Italy (*); and Fhr. S. von Gumppenberg, TU University School of Medicine, Munich, Germany (*).
Initially, 18 half-hour treatments and later 9 one-hour treatments, (active or placebo in the double-blind and active in the prospective open label studies) were conducted 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. Over 35,000 patients have been studied to date.
The results of the present paper are based on the standard PST protocols which use five point visual scales (VAS) for pain intensity and frequency and pain on motion

0 = none/never,
1 = slight/seldom,
2 = moderate /sometimes,
3 = severe/often,
4 = extreme/always

at the following times: before PST treatment, after PST treatment, 6 weeks after PST treatment, 6 month after PST treatment and 1 year after PST treatment.

Results

The following tables and graphs show the results of the statistical analyses. Table 1 contains the size of the analyzed patients groups:

Table1: Numbers of 4 analyzed patients groups at 4 observation points.

	Baseline	After PST	6 Week Follow-up	6 Month Follow-up	1 Year Follow-up
Hip-Joint	3405	2983	2009	649	187
Knee-Joint	9123	8097	5199	1673	414
Cervical Spine	966	848	505	166	58
Lumbal Spine	2832	2432	1549	505	174

Table 2 contains the matched pair tests of the analyzed patients groups:

Table 2: p Values for matched pair t tests of data for 4 analyzed patients groups, comparing baseline values to later observation points

	Hip Joint	Knee Joint	Cervical Spine	Lumbal Spine
	P-Value	P-Value	P-Value	P-Value
Intensity of Pain				
Before/after therapy	<,0001	<,0001	<,0001	<,0001
Before/after 6 weeks	<,0001	<,0001	<,0001	<,0001
Before/after 6 Month	<,0001	<,0001	<,0001	<,0001
Before/after 1 Year	<,0001	<,0001	<,0001	<,0001
Frequency of Pain				
Before/after therapy	<,0001	<,0001	<,0001	<,0001
Before/after 6 weeks	<,0001	<,0001	<,0001	<,0001
Before/after 6 Month	<,0001	<,0001	<,0001	<,0001
Before/after 1 Year	<,0001	<,0001	<,0001	<,0001
Pain on Motion				
Before/after therapy	<,0001	<,0001	<,0001	<,0001
Before/after 6 weeks	<,0001	<,0001	<,0001	<,0001
Before/after 6 Month	<,0001	<,0001	<,0001	<,0001
Before/after 1 Year	<,0001	<,0001	<,0001	<,0001

For all analyzed groups (hip joint, knee joint, cervical spine, lumbal spine) the matched pair tests show significant improvement with $p < 0,0001$ between the data before treatment and the follow-ups after treatments.

In the following graphs the improvement of pain (intensity, frequency, in motion) after PST treatment is expressed in percentages to the baseline.

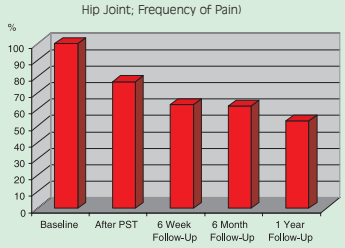

Fig. 5: Intensity of pain of Hip Joint in percentage to the baseline at 4 different observation points.

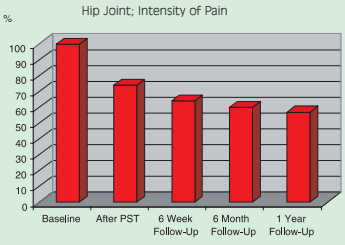

Fig. 6: Frequency of pain of Hip Joint in percentage to the baseline at 4 different observation points.

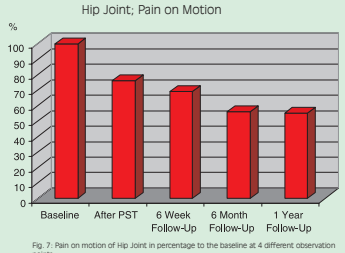

Fig. 7: Pain on motion of Hip Joint in percentage to the baseline at 4 different observation points.

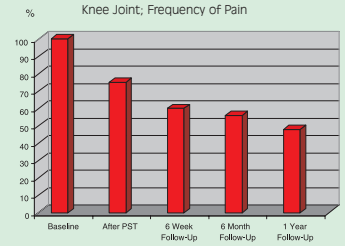

Fig.8 : Frequency of pain of Knee Joint in percentage to the baseline at 4 different observation points.

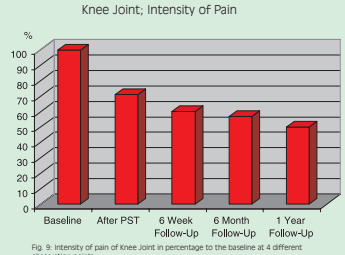

Fig. 9: Intensity of pain of Knee Joint in percentage to the baseline at 4 different observation points.

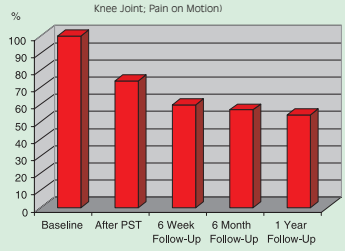

Fig. 10: Pain on motion of Knee Joint in percentage to the baseline at 4 different observation points.

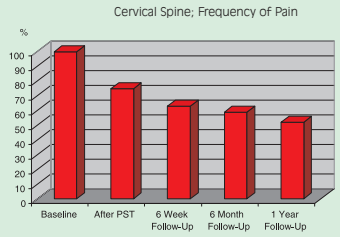

Fig.11: Frequency of pain of Cervical Spine in percentage to the baseline at 4 different observation points.

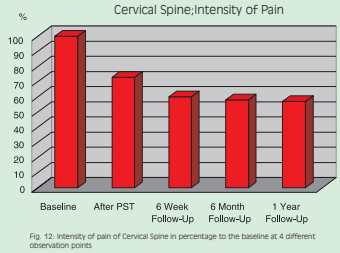

Fig. 12: Intensity of pain of Cervical Spine in percentage to the baseline at 4 different observation points

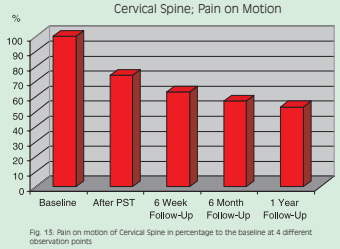

Fig. 13: Pain on motion of Cervical Spine in percentage to the baseline at 4 different observation points

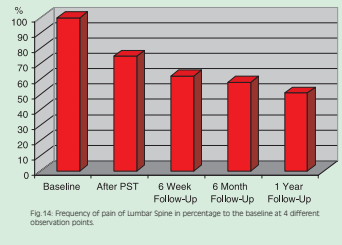

Fig.14: Frequency of pain of Lumbar Spine in percentage to the baseline at 4 different observation points.

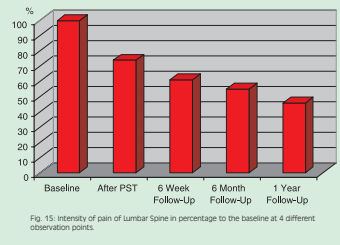

Fig. 15: Intensity of pain of Lumbar Spine in percentage to the baseline at 4 different observation points.

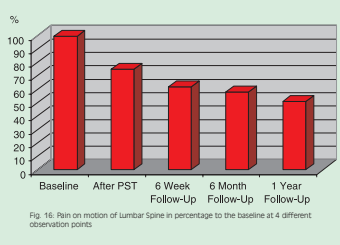

Fig. 16: Pain on motion of Lumbar Spine in percentage to the baseline at 4 different observation points

In all investigated groups the improvement in pain (intensity, frequency, in motion) is significant to the baseline with $p < 0.0001$ and leads to a pain reduction between 40 and 50% after 1 year follow–up.

Discussion

In previous studies it has been shown that the changes in the placebo patients had less significance at the end of treatment, and had lost significance for most variables at the one month follow up. The open label analysis and these data were consistent with the double-blind results.

Conclusion

These studies provide continuing evidence for the use of PST in obtaining improved functionality along with effective and safe relief from chronic pain associated with Osteoarthritis.

Literature

(1) A double-blind trial of the clinical effects of Pulsed Fields in Osteoarthritis, D. H. Trock et al., The Journal of Rheumatology (1993) 20:456.
(2) The effect of Pulsed Electromagnetic Fields in the Treatment of Osteoarthritis of the Knee and Cervical Spine, D.H. Trock, A.J. Bollet, R. Markoll, The Journal of Rheumatology (1994) 21:1903.
(3) Etude de vérification de l' efficacité antalgique des champs électromagnétiques pulsés (PST) dans la gonarthrose, C.-J. Menkes, S. Perrot, Arthritis Rheumatology (1998) 9:357.
* in Preparation/chronic pain associated with Osteoarthritis.