Clinical prospective study of Pulsed Signal Therapy effectiveness

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Introduction: Physical background

Pulsed Signal Therapy (PST) is a procedure developed as far back as the early '70s by the German-American medical practitioner and physicist Dr R Markoll, being based on the earlier Magnetic Field Therapy. Its aim is the treatment of non-specific articular conditions. During several observational studies between 1973 and 1988 he optimised the magnetic field energy's delivery system, which consists of a magnetic field generator, an electronic interface and an air coil. The joint to be treated is placed in this coil and exposed to pulsed signals for one hour at a time over nine consecutive weekdays, interrupted only by a weekend. The PST apparatus carries a pure magnetic field output signal, and employs direct current with unidirectional biological frequencies below 30 Hz. The "waveform" is quasi-rectangular, with the measured field strength being mostly below 2 mT (equivalent to 20 Gauss). The system is controlled through a pulsed unidirectional magnetic DC field with a load cycle of over 50%. The pulse train is modulated and has several dominant frequencies with many output frequencies, implemented via a free-running diode; the result is optimisation of the inductance characteristics.
Various frequency/amplitude combinations are used during the one-hour treatment. These combinations are switched over automatically, and transmitted under continuous control. Induction of treatment takes place first, during the initial 10 minutes; this is followed by the actual treatment through a combination of pulsed signals during the remaining 50 minutes.

Hypotheses concerning the effective mechanism

Several *in vitro* studies found stimulation of important components of the extracellular cartilage matrix, proteoglycanes and collagens, under the effect of PST on cartilage explants, i.e. through an increasing stimulation of chondrocytes (1, 2, 3). Corresponding positive stimulation mechanisms probably also apply to the bone tissue (osteocyte stimulation with microfracture mending) and the soft and connective tissue surrounding the joint (tendon attachments to musculature, ligament structures, articular capsule, synovia) since the majority of patients already display, during the course of treatment, a distinct reduction in pain and increased mobility of the affected joint.
The likely mechanisms involved are:

- Osseous mending of subchondral microfractures
- Increased production of proteoglycanes and collagen
- Formation of a cartilaginous protective layer via periosteal nociceptors through the repair of cartilage defects
- Reduced secretion of cartilage-eroding metalloprotein enzymes
- Regeneration of cartilage structures which functionally and morphologically participate in cartilage-bone transition
- Muscle relaxation and ligament flexibilisation, with cessation of pathological proprioreceptor activity in the articular region, also in the joint capsule.

Several open questions still remain with regard to the effective mechanism of PST and the induced processes, answers to which should be possible at least in part through further investigations and *in vitro* studies during the course of the next few years.

Experience from previous studies

Extensive controlled clinical studies were carried out in the USA between 1989 and 1994, at a total of three research centres. Almost 10,000 patients were treated as part of these investigations, and several randomised, placebo-controlled, double-blind clinical control studies carried out (4).

Verification study in gonarthrosis

To supplement the currently-available American PST studies, we carried out an investigation into the results of PST treatment of gonarthrosis (additional study groups consist of patients with coxarthrosis and degenerative spinal complaints, however these will only be concluded in autumn 1998).

Patients

80 patients altogether were inducted into the gonarthrosis group from January to July 1997. The first follow-up examination 2 months after completion of therapy is available for 78 patients; the second follow-up, 6 months post-therapy, has already been carried out for 69 patients. 5 patients have been removed from the study so far.
In order to form the most homogeneous patient groups possible, appropriate inclusion and exclusion criteria have been set.

Inclusion criteria: Age > 40
Symptomatic complaints over at least the past 3 months
Radiological stage II and III after Kellgren
Independent processing of the VAS part

Exclusion criteria: Cardiac pacemaker
Well-defined adiposity
Malignant underlying condition
Homolateral coxarthrosis
Intra-articular injection 1 month before PST

Surgical intervention 3 months before PST

Methodology

Treatment of the 80 gonarthrosis study patients was carried out lege artis (for 1 hour at a time on 9 consecutive weekdays, interrupted only by one weekend). The relevant knee joint was positioned in the knee coil, with the region of main complaint lying at the coil's edge. The course of treatment was monitored through a multipart status-data record for each patient, captured on four occasions (before the start of treatment, after completion of the nine one-hour therapy sessions and at two follow-up examinations, 2 and 6 months after completion of treatment). This record consists of:

- The routine PST treatment-record card. This card scores pain intensity, pain frequency, restriction of mobility, any swelling, overheating, reddening and paresthesia in the relevant knee joint on a scale of 0 to 4;
- An objective standardised examination protocol adapted from Potter. Genicular pain, active and passive mobility, deformities and instabilities, restricted extension and quadriceps force are assessed on a scale of 0 to 7;
- A VAS (visual analogue scale) record of everyday activities in the form of self-assessment, with a total of 30 questions;
- Aa VAS statement of pain intensity and mobility restriction.

Evaluation at 2 months after therapy

Follow-up examination at 2 months post-therapy was carried out in 78 of the 80 patients treated. X-ray tests assigned 33 patients to gonarthrosis stage II, 45 to stage III after Kellgren. 2 patients had been removed from the on-going study up to that time. 18 patients were on auxiliary analgesic medication, mainly with Diclofenac Sodium. This initial medication was not altered at first. 14 patients discontinued the pain-relief medication, 2 reduced their intake and another 2 maintained their initial dosage.

Table 1: Patient characteristics

Patients total	Already injection series	Already arthroscopy	Mean height	Mean weight
n = 78	n = 43	n = 29	167.9 cm	76.3 kg

Comparison of the individual investigatory parameters at the various times provided the following results:

Table 2: Results at 2 months post-therapy

RESULTS at 2 months post-therapy

	Before therapy 78 patients	After therapy 78 patients	2 months post-therapy 78 patients
PST protocol	12.0 points	9.0 points	5.9 points
Reduction, %	**max. 28**	**25.1%**	**50.9%**
Standard, Potter	14.2 points	10.5 points	7.7 points
Reduction, %	**max. 50**	**25.9%**	**46.1%**
VAS questions	138.3 cm	93.2 cm	67.8 cm
Reduction, %	**max. 300**	**32.6%**	**51.0%**
VAS statement	6.5	3.9 cm	2.9 cm
Reduction, %	**max. 10**	**39.5%**	**54.7%**

Slight reduction in knee-joint complaints was observed even during the therapy period, with the initial worsening, typical of PST at the start of treatment, occurring in nearly all patients. The best first evaluation was provided by the patients themselves, with a reduction in original genicular pain intensity of almost 40% as per VAS statement. Both PST protocol and standardised examination protocol exhibited a 25% score-reduction. As far as the VAS questions on various daily activities are concerned, the patients' self-assessment with a mean reduction of 32% was slightly worse than the assessment purely of genicular pain. This early therapeutic success and onset of effectiveness relies partly on a certain placebo effect, which of course plays some role in every treatment. However, this may also be regarded as another indication that PST, via complex mechanisms, intervenes in pain modulation very early on thereby providing the patient with relief.

At the time of first follow-up examination, 2 months after PST treatment, a mean reduction by around 50% of the initial complaints was observed in the 78 patients then examined, with only minor discrepancies between the individual investigation protocols. If one sets the threshold of successful treatment at a reduction in original complaints > 20% with regard to all 4 investigation parameters, then a response to PST was achieved in 57 out of 78 patients = 73.1%.
It is established that the achieved therapeutic success during the follow-up examination 2 months after completion of treatment, compared to the values immediately on its completion, had distinctly increased (nearly doubled). This was to be expected on the basis of the theoretical approach and models developed to explain PST's effective mechanism (5, 6). These assume cartilage regeneration and a corresponding improvement of articular mechanics within a period of 6-8 weeks. Naturally, for the patient this would mean a reduction in pain, improved mobility and load-bearing capability of the PST-treated knee joint.

Evaluation at 6 months post-therapy

Follow-up examination at 6 months post therapy was completed in 69 of the 80 treated patients. X-ray tests allocated 29 patients to gonarthrosis stage II, 40 to stage III after Kellgren. 5 patients had been removed from the current study up till then.

Table 1 [sic]: Patient characteristics

Patients total	Already injection series	Already arthroscopy	Mean height	Mean weight
n = 69	n = 39	n = 27	167.7 cm	75.4 kg

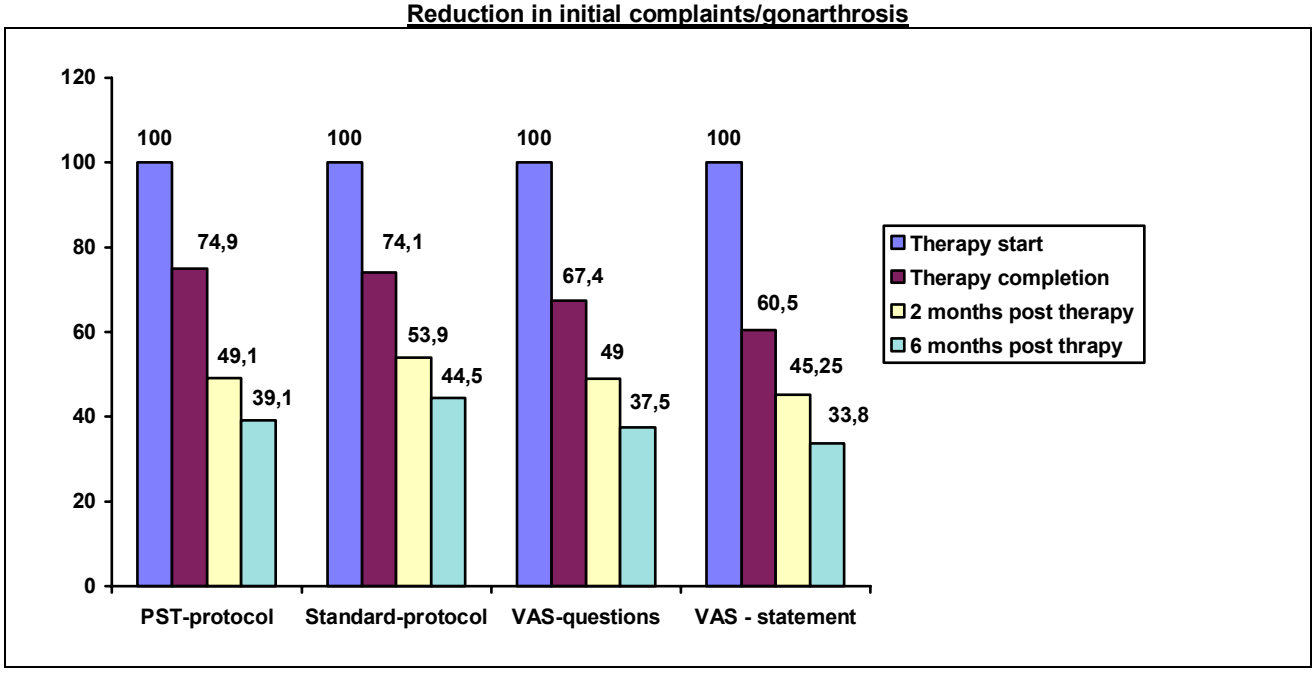
Table 2 [sic]: Results at 6 months post therapy

RESULTS at 6 months post-therapy

Time	Before therapy	After therapy	2 months post	6 months post
Number	69 patients	69 patients	69 patients	69 patients
PST protocol	11.9 points	8.9 points	5.7 points	4.7 points
Reduction, %	**max. 28**	**24.8%**	**51.9%**	**60.9%**
Standard, Potter	14.3 points	10.5 points	7.5 points	6.4 points
Reduction, %	**max. 50**	**26.3%**	**48.5%**	**55.5%**
VAS questions	141.4 cm	93.8 cm	65.4 cm	53 cm
Reduction, %	**max. 300**	**33.6%**	**53.7%**	**62.5%**
VAS statement	6.5 cm	3.9 cm	2.7 cm	2.2 cm
Reduction, %	**max. 10**	**40.3%**	**58.5%**	**66.2%**

Interpreted graphically, the results can be displayed in the following diagram:

Reduction in initial complaints/gonarthrosis



Considered overall, a reduction of ca. 60% from the original findings or statements was observed in the individual investigation parameters, with only minor variations. This applies to patient mean. A reduction in the original complaint > 20% with regard to all 4 investigation parameters was achieved in 51 out of 69 patients = 73.9%. The result found as early as 2 months after PST showed yet another slight improvement, with the patients' self-assessment once again being the highest. Comparison of the 2 follow-up examination results exhibits not only constancy of the achieved articular status, but in quite a few cases a more extensive improvement with regard to the parameters investigated, first and foremost in the successfully treated patients. A further important result consists in the documentation using the PST protocol, with the recording and evaluation of complaints and a 61.2% reduction, providing slightly better values that the standard protocol after Potter (55.3%) and slightly worse ones than the patients' own scoring through the VAS statement (66.2%). Thus the PST protocol appears to be very practicable, since its values lie between a purely objective assessment by the investigator and a purely subjective one by the patient.
These figures confirm the results of the USA studies currently available as well as the therapeutic successes of PST users in Germany, which by now have reached well into four figures and are documented via the VITAL database. VITAL is a software program which utilises the PST protocol as a standard for documenting and assessing the results of PST treatment, and allows centralised evaluation of the overall PST treatment courses.

Discussion

The results of the verification study are highly promising, and strongly point to the conclusion that PST should at least be considered as a regenerative cartilage treatment. Research into the effective mechanism needs to be consolidated and tested through further studies, principally in the biochemical field. This applies, of course, to all connective tissue cells, since it has already been established experimentally, using various electromagnetic potentials, that electric potentials (current) affect the synthesis output of connective tissue cells (7, 8, 9, 10).
The final results of the other study groups will be available in autumn 1998. It will then be demonstrated whether PST exhibits similarly impressive success in the case of other indications, which clearly is theoretically to be expected.

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