PULSED SIGNAL THERAPY

TREATMENT OF CHRONIC PAIN DUE TO TRAUMATIC SOFT TISSUE INJURY

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ABSTRACT

Introduction: Pulsed Signal Therapy (PST) is a form of therapy that involves directing a series of magnetic pulses through injured tissue. Each magnetic pulse induces a tiny electrical signal that stimulates cellular repair. PST has been used in the treatment of chronic pain associated with connective (bone, cartilage, tendon) tissue injury. A review of the current literature indicates that PST has a positive effect on bone and cartilage repair and leads to a decrease in chronic pain in patients with osteoarthritis. We examined the effect of PST in the treatment of joint associated soft tissue injury (traumatic, including motor vehicle accident).

Objective: We conducted a retrospective study to establish the effectiveness of pulsed electromagnetic fields (PST) in the treatment of chronic pain. We divided the PST patients into two groups:

1) Osteoarthritis (OA) Group N=45
This was a group of patients who were complaining of pain either in the spine or in a specific joint (knee, hip, ankle, shoulder). There was clearly documented evidence of OA with minimal soft tissue involvement.
2) Soft Tissue Injury (STI) Group N=35
This was a group of patients who were complaining of pain either in the spine or in a specific joint (knee/hip/shoulder) where no documented evidence of OA or bony change existed, but there was clinical evidence of soft tissue injury.

Data was extracted from standard PST evaluation forms which included the medical histories and diagnoses of all PST patients. This data was used as criteria for inclusion or exclusion of the subjects in the above two groups. The basis for the PST treatment's effectiveness was self reported symptom evaluations involving a five point visual analog scale (for pain intensity and frequency). This information was routinely obtained prior to the initial treatment, at the time of the final PST treatment (approximately 9 days later) and at a 6 week follow-up.

Results: Using a matched pair t-test, significant changes from base-line scores were found *within* both groups. By change we mean a decline in the intensity and/or frequency of pain. The differences between pre- and post-treatment scores were highly significant at the 6 week follow-up (in both groups $p<0.001$ for both clinical variables). The extent of the improvement was also compared *between* the groups. A modified X^2 (median) test showed no statistically significant difference between the means of these improvements in the two groups at the 6 week follow-up ($p>0.1$).

Conclusions:

1) The extent of improvement (after PST) at the six week follow-up for patients with joint-associated soft tissue injury is in the same range as improvement experienced by patients with OA.
2) Both groups of patients experience a statistically significant improvement (compared to their pre-treatment state) at six week post PST treatment.

This was not a controlled study and was based on data collected by the nurse/therapist on PST patients passing through the PST treatment protocol. All of the patients treated were complaining of chronic pain that had not responded to conventional therapy. The etiology of the pain was different in the two groups: the OA group included predominantly non-traumatic bony OA, while the cause of the pain in the soft tissue injury group was presumably trauma.

Introduction

Pulsed electromagnetic fields have been used in the treatment of non-union and related problems in bone healing since the 1970's with a relatively consistent success rate of 70-80% in several countries (1,2). Pulsed Signal Therapy (PST) is based on the application of pulsed electromagnetic fields to bone and associated soft tissue.

The physical effect of PST on various types of connective tissue was investigated in several studies (3,4,5) although the best documented was the effect on cartilaginous tissue (6,7,8) where an increased rate of synthesis of proteoglycans and collagen was reported. The stimulation of chondrocytes is thought to occur due to the release of "streaming" potentials when the joint is subjected to stress (7). These "streaming" potentials serve the purpose of converting the mechanical force of cartilage compression into an electrical phenomenon (hydrogen ions follow the flow of fluid out of the cartilage leaving the negatively charged extracellular matrix behind) that is capable of stimulating chondrocytes to synthesize more matrix components. In the cases of joint damage (where there is a reduction in proteoglycan content due to a breakdown or change in chondrocyte metabolism), these potential flows are reduced. As a result, the electric field around the joint is disturbed - the continuous stimulation of the chondrocytes to regenerate the matrix is compromised. In addition, cartilage compressibility changes with degeneration.

This is where PST exerts its effect. When the damaged joint is positioned in the PST air-coil, electrical signals are induced via a pulsed magnetic field in chondrocytes

that, due to pathological changes in the extracellular matrix, no longer receive physiological signals. The electric currents generated in the matrix, by induction, stimulate the chondrocytes and, subsequently, cartilage repair. Randomized, placebo controlled, double-blind studies (9, 10) showed that between 70 and 80% of osteoarthritis patients who received PST experienced a significant reduction in chronic pain.

Ligaments and tendons have, in this respect, properties similar to cartilage. Water content in these tissues is in the 60-80% range and fluid displacement analogous to that in joint cartilage would follow mechanical stress. A logical extension is that ligaments and tendons, possessing these properties, react to PST in the same manner as cartilage and bone. The experimental data largely supports this proposition: Nishimura (13) found that "results suggest that PEMFs enhanced the blood flow and increased the fibroblasts at the defect. At the same time, pulsed electromagnetic fields directly stimulated the collagen production from the fibroblasts, thus accelerate[ing] the healing process of the ligament", however another study (12) documented "no significant effect [was] observed on either the healed strength of the tendon repair or the adhesion formation between the repair and the surrounding tissues". Clinical results (11), although relatively sparse, suggest positive effects of pulsed electromagnetic fields in patients suffering from tendinitis.

The Vancouver PST clinic recorded a substantial improvement in symptoms of chronic pain in patients with injured ligaments and tendons (in the area of a particular joint). Furthermore, the extent of improvement seemed to approximate that experienced by the patients suffering from osteoarthritic joint changes. We wished examine the results attained in the PST treatment of joint associated soft tissue injury (usually due to trauma such as motor vehicle accidents). For the purpose of this preliminary report, we used information from the existing records in the Vancouver PST clinic, routinely gathered by the physician and nurse therapists.

Materials and Methods

Study design

The basis for the PST treatment's effectiveness was self reported symptom evaluations (pain intensity and frequency) involving a five point visual analog scale. Given the nature of the records available, a retrospective study was performed to establish whether the improvement in patients with soft tissue injury was of the same degree as that experienced by OA patients.

Since the records were provided only by the Vancouver PST clinic, all patients included in this study have been treated on the same equipment at the same site according to standard PST protocol. The patients underwent a series of nine one-hour treatments under identical conditions: Positioning, duration, frequency settings were the same for all patients.

Inclusion/Exclusion Criteria

Records of all patients that had been treated to the same date at the Vancouver location were carefully reviewed and data was extracted from standard PST evaluation forms which included the medical histories (incl. diagnostic imaging reports) and diagnoses of all PST patients. Next, two groups were extracted for further analysis:

1) Osteoarthritis (OA) Group N=45

This was a group of patients complaining of pain either in the spine or in a specific joint (knee, hip, ankle, shoulder). There was clearly documented evidence of OA with minimal soft tissue involvement. All of the patients in this group came to the clinic with the diagnosis of OA.

2) Soft Tissue Injury (STI) Group N=35

This was a group of patients complaining of pain either in the spine or in a specific joint (knee/hip/shoulder) where no documented evidence of OA or bony change existed on diagnostic imaging, but there was clinical evidence of soft tissue injury in the form of localized palpable tenderness in the region of the joint.

None of the patients discontinued the treatment or dropped-out.

All patients, in accordance with the PST protocol, were asked to continue their maintenance medications and to avoid introducing any new treatments for six weeks following completion of the PST series.

As a part of the initial admission procedure, all patients signed a release that their records would be used for the purpose of research (under condition of strict confidentiality).

Effectiveness Measurements

The basis for PST treatment's effectiveness were self reported symptom evaluations involving a five point visual analog scale (pain intensity and frequency). This information was routinely obtained prior to the initial treatment, at the time of the final PST treatment (approximately 9 days later) and at a six week follow-up.

The visual analogue scale is a recommended standard in the evaluation of chronic pain (14). The patients were asked to choose a rating for each symptom describing its severity and timing:

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

Each of the three nurse therapists involved in obtaining the evaluations from patients adhered to the same ground rules:

- the patient should rate the pain according to its worst manifestation,
- follow-up ratings were always relative to initial assessment,
- evaluation focused only on the treated area, not other possible areas as sources of pain,
- patients were encouraged to give "intermediate" responses (e.g. 2.5 for a rating between 2 and 3) when indecisive - this resulted in an essentially continuous scale.

Safety

Pulsed Signal Therapy (PST) with its low-intensity magnetic field has been proven safe and does not need any major precautions. Patients with active malignant neoplasm and pregnant women are routinely not accepted for PST treatment. Patient comfort is regularly checked during each one hour treatment as required by PST treatment protocol.

Equipment

Standard Pulsed Signal Therapy equipment was used. All equipment was delivered in good working order and operated only by certified staff members.

Field frequency	<30 Hz
Magnetic field strength	10-20 G
Coil current	<2 A
Power Source voltage	120 V
Pulse phase duration	67ms

Table 1: *Electromagnetic field parameters for standard PST equipment.*

Study

The subjects were treated between July 1, 1997 and July 25, 1998. The patients were seen by the same physician before commencement and completion of the treatment series. Areas of treatment and treatment positions were determined by the physician and treatment was conducted by certified nurse therapists (three nurses were involved) in accordance with PST protocol. This ensured consistency in treatment of all patients.

Patient Demographics

Referred to the PST clinic were patients who had not responded to other conventional forms of therapy (medication, physiotherapy, chiropractic treatment, massage therapy). The duration of their symptoms varied widely (1.5-30 years in the OA group and 0.5-10 years in the STI group).

The data was processed in Microsoft Excel 7.0.

	N	Sex	Duration of Symptoms (years)
OA Group	**45**	30F/15M	7.73+/-6.75
STI Group	**35**	20F/15M	3.50+/-2.20

Table 2: *Patient Demographics*

	Baseline Score	***Score After 9 sessions***		***Score at 6 Week Follow-up***	
	mean+/- SD	mean+/- SD	p value	mean+/- SD	p value
OA Group (N=45)	3.31+/-0.50	2.38+/-1.11	$3x10^{-6}$	1.91+/-1.16	$8x10^{-8}$
STI Group (N=35)	3.12+/-0.77	2.76+/-0.90	0.0108	2.19+/-0.95	$9x10^{-6}$

Table 3-1: *Intensity of Pain following the PST treatment (mean absolute scores on the 5 point visual analogue scale).*

Results

Data describing intensity and frequency of pain was collected prior to commencement of PST treatment, at the end of the treatment series, and at six week follow-up.

Degree of improvement was expressed as a percentage value of improvement relative to an initial baseline.

Matched pair t-test analysis of pre- and post-treatment data revealed statistically significant improvement in both groups. In the STI group, however, the level of significance dramatically increased between the two post-

	Baseline Score	***Score After 9 sessions***		***Score at 6 Week Follow-up***	
	mean+/- SD	mean+/- SD	p value	mean+/- SD	p value
OA Group (N=45)	3.231+/-0.79	2.32+/-1.13	$9x10^{-7}$	1.89+/-1.11	$7x10^{-8}$
STI Group (N=35)	3.34+/-0.65	2.76+/-0.90	$7x10^{-4}$	2.19+/-0.95	$2x10^{-5}$

Table 3-2: *Frequency of Pain following the PST treatment (mean absolute scores on the 5 point visual analogue scale).*

treatment sets of scores .

In the STI group, the mean % improvement in intensity of pain relative to baseline scores was 13.3% at the end of the treatment series which increased to 28.6% when measured at six week follow-up (Table 4-1 and 4-2). The mean % improvement in frequency of pain was somewhat higher (18.7% and 30.2%) in the same group. An identical analysis of the scores in the OA group indicated that a 26.9% (mean) intensity of pain improvement rate was reached by the end of the treatment series and it continued to rise to 39.9% (mean) at six week follow-up. Of all patients, only two in each group had greater improvement immediately after the treatment series than at six week follow-up. Other patients demonstrated the following scenarios (number of patients in each group):

1) no improvement at all (14 in OA, 8 in STI),
2) no improvement immediately after 9 sessions but improved by the six week follow-up (6 in OA, 16 in STI),
3) same level of improvement after the series of treatments and at six week follow-up (14 in OA, 4 in STI),
4) continuous improvement reported on each occasion (11 in OA, 7 in STI).

	Intensity of Pain (mean+/-SD)	Frequency of Pain (mean+/-SD)
OA Group (N=45)	26.9+/-31.5	28.6+/-30.5
STI Group (N=35)	13.3+/-20.2	18.7+/-27.8

p>0.1

Table 4-1: *Pain intensity and frequency % improvement from baseline assessed <u>after 9 sessions</u> of PST*

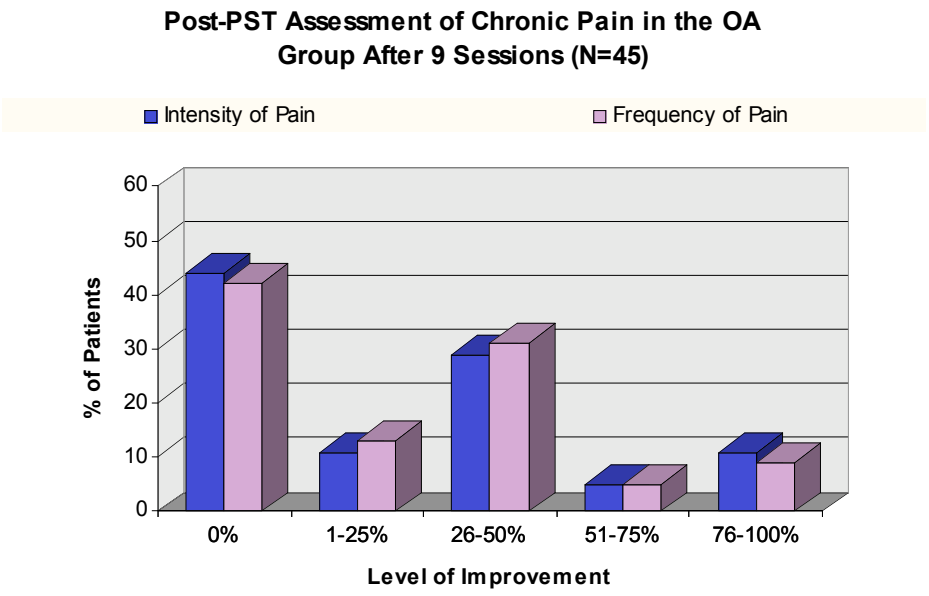
A comparative analysis of the two patient groups (median test) showed no significant difference between the groups (p>0.1). At the 6 week follow-up, in the STI group, 15 out of 35 (42.8%) patients had scores higher than the common median, while in the OA group, 29 out of 45 (64.4%) patients experienced above average results.

No side effects or symptoms were reported by patients or noted by physician/nurse in any of the patients that were treated.

The goal of this study was not to test for a possible placebo effect in treated patients, hence the absence of a control group. Other studies have already reported significant improvement as compared to a control placebo group (9,10). In addition, the improvement in both groups described in this study showed a trend that persisted beyond the period of the therapy. Patients continued to improve during the six week period that followed the delivery of PST. Preliminary analysis of data at the six month point continues to show ongoing improvement (not included in this paper).

	Intensity of Pain (mean+/-SD)	Frequency of Pain (mean+/-SD)
OA Group (N=45)	39.9+/-34.2	39.1+/-34.0
STI Group (N=35)	28.6+/-27.7	30.2+/-30.3

p>0.1



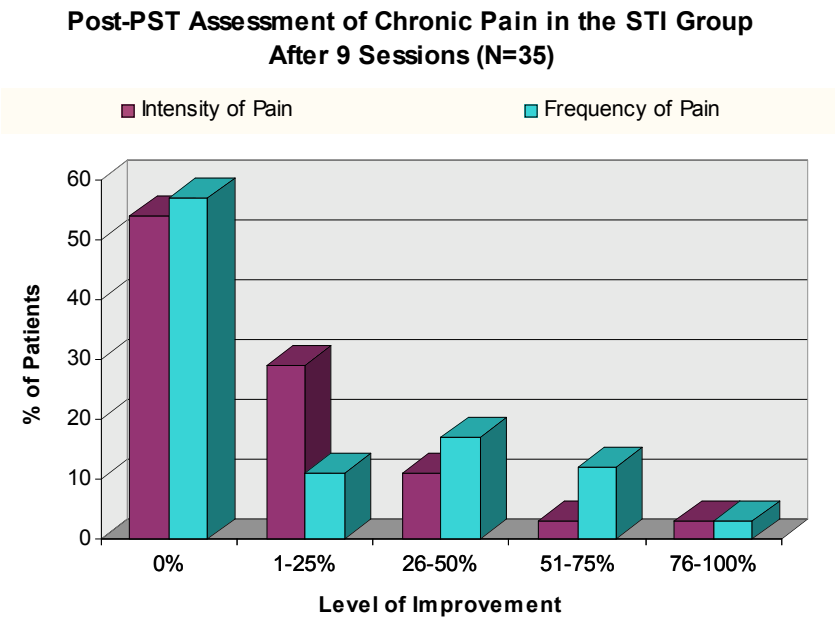


Table 4-2: *Pain intensity and frequency % improvement from baseline assessed at the 6 week follow-up of PST*

Discussion

Previous studies have shown that pulsed electromagnetic fields heal fractures and are effective in the treatment of symptomatic osteoarthritis. A double blind, randomized, placebo study of therapeutic effects of pulsed electromagnetic fields (9) reported that patients with knee osteorthritis averaged between 29 and 36% improvement in each of the chosen variables (pain, activities of daily living, pain on motion, tenderness) at the end of the one month follow-up period. Our study shows that these fields are as effective in the treatment of STI (i.e. clinical tenderness in soft tissue structures around the joint, complaints of pain and limitation in function but no diagnostic image positive for bony involvement). This raises intriguing hypotheses as to the nature of soft tissue injury in the studied group:

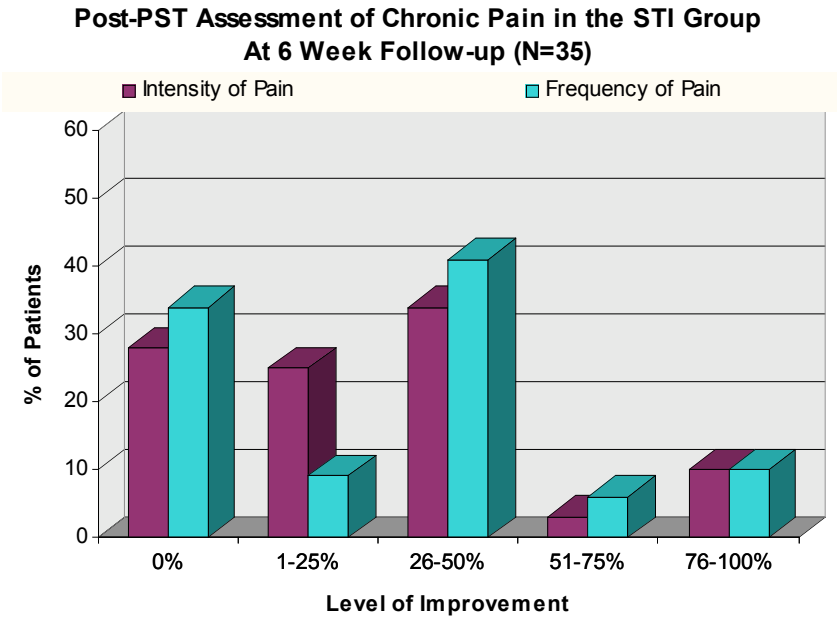
(i) the injury is purely in tendon, ligament, etc. - hence, the action of streaming potentials in soft tissue is identical to that in bone,

(ii) soft tissue injury is really traumatic aggravation of bone or the junction of bone and soft tissue (enthesis),

(iii) soft tissue injury is really traumatic early osteoarthritis.

The only real difference between STI and OA responses to PST noted in this study seems to be timing. The OA patients tend to respond quicker. However, by six weeks, responses in both groups are of equal extent.

Despite the results of clinical and in vitro studies that suggest a positive effect of PST on deposition of new connective tissue (bone or cartilage) and subsequent diminishment of symptoms (pain, restriction of movement) in osteoarthritic patients, these changes do not seem to be detectable by diagnostic imaging. A study of the relationship of radiographic and clinical changes in knee OA (15) found that there is no correlation between the two, suggesting that the radiographic findings may not be a significant indication of clinical improvement in post-PST patients.



Diagnostic blocks of zygoapophysial joints in the cervical spines of patients with chronic post-traumatic neck pain positively localized the lesion to the joint (16), whereas X-rays, CT scans or MR imaging of the same joints were negative for any objective injury. This revealed the inadequacy of diagnostic imaging in detection of an anatomical basis for the painful irritation in the small joints of the cervical spine, since the prevalence of zygoapophysial joint pain in this group, as demonstrated by the diagnostic blocks, was 65%. Relying only on diagnostic imaging, all these patients would have remained undiagnosed.

In patients with a history of traumatic injury to the cervical spine and chronic zygoapophysial joint pain (confirmed via diagnostic blocks), post-traumatic arthritic changes were found post-mortem (16). Injuries of intra-articular components of the small joints of the spine may progress to osteoarthritic changes with subsequent irritation of pain sensitive structures. This relates to the stated hypothesis iii. Structures within joints, generally, would be susceptible to the reparative PST effect via the very same mechanisms that have been well documented in radiographic OA of the spine.

In a patient with post-traumatic pain persisting beyond the accepted soft-tissue healing time (3 to 6 months), articular or bony involvement should not be excluded solely based on absence of positive radiographic findings. Indeed, such patients can suffer chronic unrelenting pain without anatomical evidence of cartilage or bony injury or arthritis. In addition, their symptoms resist soft tissue therapeutic modalities. Whether PST exerts its effect on the soft tissue structures (tendon, ligament) or bone and cartilage or both, it seems as effective in the treatment of patients with soft tissue injuries as it is in the treatment of those with clearly defined osteoarthritis. The results obtained with Pulsed Signal Therapy warrant further investigation into the mechanism of reparation as well as the nature of the injury in post-traumatic chronic pain patients.

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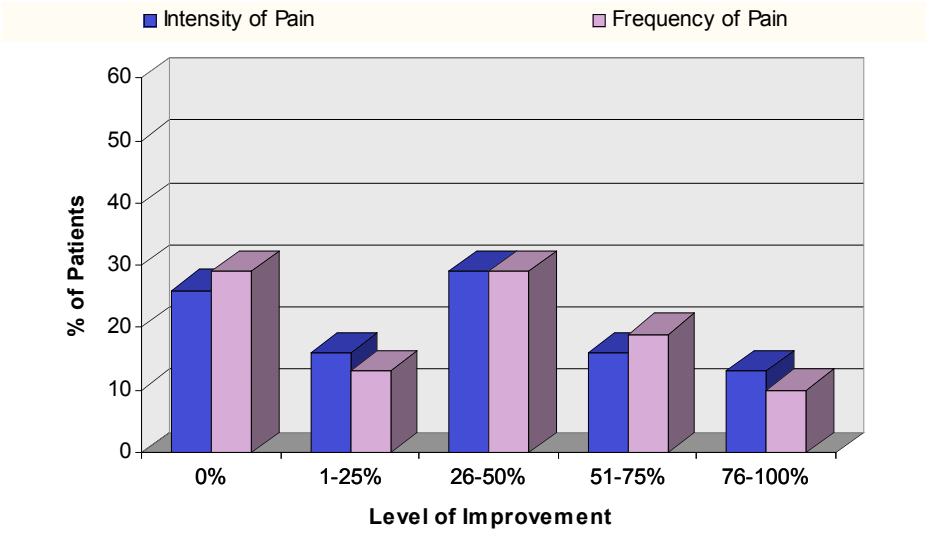

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