

An investigation into the efficacy of strain-counterstrain technique to produce immediate changes in pressure pain thresholds in symptomatic subjects

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A research project submitted in partial fulfillment for the requirements for the degree of Master of Osteopathy at Unitec 2007.

Declaration

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This Research Project is submitted in partial fulfillment for the requirements for the Unitec degree of Master of Osteopathy.

The regulations for the degree are set out in the Master of Osteopathy Programme Schedule and are elaborated in the course handbook.

Candidate's declaration

I confirm that:

- This Research Project represents my own work;
- The contribution of supervisors and others to this work was consistent with the Unitec Regulations and Policies.
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

Research Ethics Committee Approval Number: 2006.611

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DISSERTATION ABSTRACT

Background and objective: Strain counterstrain (SCS) is an osteopathic technique used by osteopaths and manual therapists for the relief of musculoskeletal pain and associated dysfunction. Limited literature exists to support the efficacy of SCS technique. This dissertation is presented in two sections. Section one is a literature review of SCS technique and the proposed outcome measures. Section two is the research conducted presented as a manuscript in the style required by the International Journal of Osteopathic Medicine. The second section is supported by three appendices of material not intended for publication. The aim of this study was to investigate the efficacy of SCS technique on subjects with a history of a recreational sports injury of the upper extremity.

Design: Randomized assessor blinded placebo controlled trial.

Methods: Twenty three subjects (13 males, 10 females; mean age=26.1, SD=6.3) fulfilled the requirements for the study. Subjects were screened to establish the presence of a primary tender point (TeP) around the elbow joint. Subjects were randomly assigned into two groups and received either an SCS intervention or a Sham intervention. The primary outcome measures were pressure pain threshold (PPT) on the primary TeP, and visual analog scale (VAS) assessing local pain intensity elicited by the application of approximately 3kg/cm² of pressure on the primary TeP. The secondary outcome measure was pain-free grip strength (PFGS).

Results: Within group changes showed a significant improvement in VAS for pain intensity following the SCS intervention ($p < 0.001$) compared with the Sham intervention ($p = 0.053$). Pre-post effect sizes for the VAS for pain intensity were 'large' in the SCS intervention group ($d = 1.87$) and 'moderate' ($d = 0.90$) for the Sham intervention group. Both groups surpassed the minimal clinically important difference (MCID) defined as a decrease $\geq 30\%$ in VAS for pain intensity (SCS group=55%, Sham group=31%). Within group changes showed a small improvement for PPT at the TeP following either the SCS intervention ($p = 0.497$) compared with the sham intervention ($p = 0.749$). Pre-post effect sizes for the TeP were small in the SCS intervention group ($d = 0.29$) and trivial ($d = 0.14$) for the sham intervention group. No significant differences were found for the PFGS (SCS: $p = 0.936$ $d = 0.03$, Sham: $p = 0.989$ $d = 0.01$)

Conclusions: The results indicate that SCS technique may be an efficacious technique in treatment of TePs around the elbow in subjects with a history of a recreational sports injury of the upper extremity. SCS technique can produce decreases in pain intensity as reported from mechanical pressure at a primary TeP.

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Abbreviations

SCS	Strain Counterstrain
VAS	Visual Analog Scale
TeP	Tender point
PPT	Pressure Pain Threshold
PFGS	Pain-Free Grip Strength
SEM	Standard Error of Measurement
SDD	Smallest Detectable Difference
MCID	Minimal Clinically Important Difference
SD	Standard Deviation
<i>d</i>	Effect Size (Cohen's <i>d</i>)
OMT	Osteopathic Manipulative Therapy
RCT	Randomized Controlled Trial
ICC	Intra-class Correlation Coefficient

SECTION I – LITERATURE REVIEW

Introduction

Strain-counterstrain (SCS) is an osteopathic treatment technique first developed and described by Lawrence Jones in 1964 (L. H. Jones, 1981). Strain-counterstrain, also known as positional release, is an indirect osteopathic technique, whereby dysfunctional joints and their muscles are moved away from their restrictive barriers into positions of ease in the treatment of both musculoskeletal (D'Ambrogio & Roth, 1997; L. H. Jones, 1981; Ward, 2003) and visceral dysfunctions (Giammatteo & Weiselfish-Giammatteo, 1997). Since Jones' first description there has been a variety of anecdotal evidence presented by assorted therapists in support of the technique but only limited experimental evidence to demonstrate its efficacy in the treatment of musculoskeletal pain and related joint dysfunction (D'Ambrogio & Roth, 1997; Giammatteo & Weiselfish-Giammatteo, 1997; L. H. Jones, 1981; Ward, 2003).

The application of SCS technique requires a practitioner to first palpate a tender point (TeP) in the soft tissues, the patient's limb is then moved in such a way that the pain associated with pressure on the TeP is relieved by at least 70 percent to find the position of ease (D'Ambrogio & Roth, 1997; L. H. Jones, 1981; McPartland & Goodridge, 1997; Wong & Schauer-Alvarez, 2004; Wong & Schauer, 2004). Jones (1981) suggested a minimum period required to hold a position of ease as 90 seconds. It is theorized that the shortening or "folding-over" of aberrant tissues in SCS technique achieves its therapeutic modifications via both proprioceptive (Korr, 1975) and nociceptive mechanisms (Bailey & Dick, 1992), or by the biomechanical principle of nonsequential motion expounded by McPartland & Klofat (1995).

Bailey & Dick (1992) proposed a nociceptive hypothesis that tissue damage in dysfunctional muscles can be reduced by the positional release mechanism utilized by SCS. They suggest that relaxation of the damaged tissues may be achieved by placing patients in a position of ease which may advance local perfusion of fluids (i.e. blood, and lymph) and enhance the removal of sensitizing inflammatory mediators.

In order to use SCS technique a practitioner needs to be able to accurately identify a painful TeP. The TeP can be interpreted using anatomical charts (D'Ambrogio & Roth, 1997; L. H. Jones, 1981) or the "Paracelsus approach" (McPartland & Klofat, 1995), probing a region of patient's pain complaint with the practitioners thumb or finger to locate sensitive TeP's. McPartland & Goodridge (1997) found the SCS method of palpatory diagnosis to be more reliable compared to a traditional osteopathic examination (the tests studied included palpation for restriction of motion, local tissue texture changes and joint capsule tenderness) for subjects with chronic neck pain, demonstrating a 72.2% ($\kappa=0.45$; 'moderate') agreement between examiners.

The essence of SCS is the relief of a painful TeP by moving the patient's limb in order to find a position of ease (L. H. Jones, 1981). Total pain relief is not always the goal, a minimum level of 70% reduction in the (short term) pain associated with the TeP is said to be expected immediately after treatment (D'Ambrogio & Roth, 1997; McPartland & Klofat, 1995).

In 1981 Jones reported diagnostic correlations between joint dysfunction and palpable myofascial tissue TePs (L. H. Jones, 1981). D'Ambrogio & Roth (1997) have subsequently published a list of more than 200 diagnostic TeP locations. The TePs used in SCS are described by Jones (L. H. Jones, 1981) as:

The tender points used in counterstrain techniques are not located in or just beneath the skin as are many acupuncture points, but deeper in muscle, tendon, ligament, or fascia. They measure 1cm across or less, with the most acute point about 3mm in diameter. They may be multiple for one specific joint dysfunction, may extend for a few centimeters along a muscle, or may be arranged in a chain (such as the ones in the muscle and fascia along the lateral surface of the femur) (p. 28)

Other definitions are similar (D'Ambrogio & Roth, 1997; McPartland & Klofat, 1995). When a standardized pressure of 2.6kg/cm^2 is applied to a TeP it has been found to cause a localized sensation of pain (L. H. Jones, 1981; McPartland & Klofat, 1995).

Effectiveness and Efficacy of Strain-counterstrain Technique

A comprehensive search of peer-reviewed literature analyzing the efficacy or effectiveness of SCS identified six experimental studies (Blanco et al., 2006; Howell, Cabell, Chila, & Eland, 2006; Meseguer, Fernández-de-las-Peñas, Navarro-Poza, Rodríguez-Blanco, & Gandia, 2006; Wong & Schauer-Alvarez, 2004; Wong & Schauer, 2004; Wynne, Burns, Eland, Conatser, & Howell, 2006). Three additional experimental studies were identified that utilized SCS as part of an investigation into osteopathic manipulative therapy (Gamber, Shores, Russo, Jimenez, & Rubin, 2002; Noll, Degenhardt, Stuart, McGovern, & Matteson, 2004) or manual therapy (Cleland, Flynn, & Palmer, 2005). The paucity of peer reviewed randomized controlled trial (RCT) articles related to SCS necessitated reference to descriptive case studies and osteopathic and manual medicine texts.

Wong & Schauer (2004) provided evidence of a good correlation between pain reduction (using a visual analog scale (VAS) as a measurement of pain intensity) and SCS pain reduction at TePs (using manual palpation of tender points (TePs) as a measurement). The measurement of TeP sensitivity was performed through manual palpation of TePs to elicit a physical response (visual cue) from subjects, without the aid of pressure algometry to aid reliability. In a follow up study Wong & Schauer-Alvarez (2004) demonstrated an increase in strength in hip musculature following SCS treatment, and a correlated reduction in TeP pain in those muscles.

Meseguer et al. (2006) concluded that the application of SCS technique may be effective in producing hypoalgesia and decreased reactivity of TePs. In their study Meseguer et al (2006) reported moderate effect sizes (as described by Hopkins (2002)) for the VAS for pain intensity between pre –and post- intervention measurement following the application of either the classical or modified application of SCS technique ($p < 0.001$; Cohen's $d = 1.1$). In comparison their control group did not show any change ($p = 0.90$; Cohen's $d = 0.01$). The authors were able to demonstrate an immediate decrease in the sensitivity of a chosen TeP following the application of SCS technique (Meseguer et al., 2006). The results in this study were limited by the choice of outcome measure, the VAS is a valid clinical measure (Reeves, Jaeger, & Graff-Radford, 1986), but could have become a source of error if the subjects were biased by the ability to remember their previous scores due to the short time period between pre- and post- recording (Meseguer et al., 2006). Another potential bias in their group design was the lack of a sham intervention group to investigate the level of placebo attached to their procedure.

Wynne et al. (2006) reported mechanical changes in the peak torque following treatment by SCS technique for various TePs in the lower leg and foot. The treatment effect was considered by the authors to be greater than any changes attributed to the process of repeated measures. They demonstrated a decrease in symptom severity as measured by their adopted four factor ratings scale. The four factors were: pain, soreness, stiffness, and mobility; each factor was scored between 0 (no symptoms) to 9 (extreme symptoms/pain), and the researchers then summed the values for all subjects to give a score out of a maximum range from 0 to 36 (Wynne et al., 2006). This study was not satisfactorily blinded, as the sham treatment chosen was an oral placebo, such that most subjects who took them during the course of the cross-over trial were able to deduce their ineffectiveness.

The data reported by Howell et al. (2006) provides evidence in support of Korr's (1975) hypothesis of somatic dysfunction. Korr (1975) hypothesized that the characteristic restriction-of-motion present in somatic dysfunction was due in part to an alteration in the sensitivity of the monosynaptic stretch reflex, and could therefore be reset to restore range of motion. Howell et al. (2006) did not follow a sufficiently rigorous methodology in order to be able to make any generalized claims as to the effectiveness of SCS for patient's with Achilles' tendonitis. Their procedure compares a symptomatic SCS intervention group with an asymptomatic sham intervention group.

Blanco et al. (2006) compared a muscle energy technique (post-isometric relaxation) with SCS technique in asymptomatic subjects presenting with latent myofascial trigger points. The application of SCS technique was not described as addressing a primary TeP, but rather the therapist located 'a trigger point' in the masseter muscle and proceeded to apply the SCS technique. It would seem plausible to expect a technique that stretches the whole muscle to be more effective in an asymptomatic subject when compared to a technique usually employed to address somatic dysfunction such as SCS. This expectation was upheld with the results reported by Blanco et al. (2006), where they reported an insignificant 'small' effect size ($d=0.32$; $p=0.08$) for the immediate improvements in active mouth opening for asymptomatic subjects treated with SCS for a trigger point identified within the masseter muscle. Blanco et al. (2006) surmised that SCS technique applied to a single randomly chosen latent myofascial trigger point did not improve active mouth opening. The approach employed by Blanco et al. (2006) was a deviation from the recommended method of application for SCS technique, as defined in the regular literature which includes a physical examination of an area for the primary TeP (D'Ambrogio & Roth, 1997; L. H. Jones, 1981; McPartland & Klofat, 1995). Therefore, the findings of this study should not be considered directly applicable to SCS technique as defined in the literature (D'Ambrogio & Roth, 1997; L. H. Jones, 1981; McPartland & Klofat, 1995).

Two additional experimental studies were identified that utilized SCS as part of an investigation into osteopathic manipulative therapy (Gamber et al., 2002; Noll et al., 2004). Gamber et al. (2002) conducted an observer blinded pragmatic randomly assigned clinical trial of osteopathic manipulative therapy (OMT) in patients diagnosed with fibromyalgia syndrome. The SCS techniques were consistently applied in combination with other osteopathic techniques to the TePs the patient identified as most troublesome. The other osteopathic techniques available to the treating osteopath included myofascial release, muscle energy, soft tissue treatment, and craniosacral manipulation (Gamber et al., 2002). The amount of time, and number of points addressed with SCS were not reported. The authors reported significant improvement in pain thresholds post treatment at three locations (left and right second costochondral junction, and the left medial epicondyle) for patients receiving SCS in combination with OMT (Gamber et al., 2002). From the data reported by Gamber et al. (2002) it is not possible to draw any conclusions as to the efficacy of SCS technique.

A number of descriptive articles on SCS have established it is widely utilized clinically as an effective osteopathic manipulative technique, although there is limited evidence substantiating the assumed efficacy of SCS. Several of the descriptive articles have described specific clinical applications for SCS, such as, Complex Regional Pain Syndrome I (CRPS I) following a Grade II ankle sprain (Collins, 2007), iliotibial band friction syndrome (Pedowitz, 2005), sacral torsions (Cislo, Ramirez, & Schwartz, 1991), low back pain (Lewis & Flynn, 2001), chronic myofascial pain (Dardzinski, Ostrov, & Hamann, 2000), foot disorders (L. H. Jones, 1973), and acute ankle injuries (Eisenhart, Gaeta, & Yens, 2003).

Collins (2007) reports on the case of a 14 year old with CRPS I following a Grade II ankle sprain, and the benefits recorded by way of the analgesic effects of SCS and improved function. A decrease of two points on a numeric pain rating scale was reported for overall pain after two months, as was, a decrease in tenderness for 10 out of 13 TePs. These analgesic effects were considered clinically significant, and are suggestive of the need for more formal investigation. Dardzinski et al. (2000) found in a retrospective review of 20 patients suffering from chronic localized myofascial pain, the use of the Jones SCS technique could be beneficial in reducing pain and improving function. Eisenhart et al (2003) found that SCS could be beneficial in the treatment of acute ankle injury. Cleland et al (2005) produced evidence of increased pain free grip strength and decreased pain scores after treatment applied to the area of lateral epicondyle and the cervicothoracic spine. Lewis & Flynn (2001) reported on four case studies of patients with low back pain treated with SCS protocols. The authors reported improvements in the outcomes

measured for disability levels (Oswestry Low Back Pain Disability Questionnaire) and pain (McGill Pain Questionnaire) in all four cases (Lewis & Flynn, 2001).

Domholdt (2000) has proposed that the primary value of case reports is an effective means for practitioners to communicate to scientists. This communication stimulates the progression from theory based on anecdotal evidence to theory based on robust research.

In addition, a number of studies have reported the use of SCS as part of an overall osteopathic manipulative treatment protocol to treat a variety of disorders including shoulder pain and repetitive strain injury of the supraspinatus muscle (Jacobson, Lockwood, Hoefner V, Dickey, & Kuchera, 1989), chronic pelvic pain (Tettambel, 2005), chronic pain (Kuchera, 2005), low back pain (Licciardone, 2004), arthritis related pain (DeAngelo & Gordin, 2004), and cervicothoracic pain (Walko & Janouschek, 1994) and acute or chronically ill hospital patients (Schwartz, 1986). Similarly SCS has been reported beneficial when used in conjunction with massage therapy for the treatment of temporomandibular joint dysfunction (Eisensmith, 2007).

After reviewing the literature there is a large body of anecdotal and descriptive research in support of the effectiveness of SCS technique in clinical practice. To date there are only a few peer reviewed RCT articles that provide substantive evidence as to the efficacy of SCS either in the short term or long term when compared to either a suitable sham (placebo) or control group.

Sports Related Injuries

Recreational sports people offer a broad heterogeneity of age, occupation and socioeconomic group (Stockard, 2001). Recreational sports injuries to the elbow region often involve either epicondylalgia or overuse syndromes (Fulcher, Kiefhaber, & Stern, 1998). These injuries are most frequently the result of activities that require the elbow and forearm to transmit force to a tool; i.e. racquet sports (Gruchow & Pelletier, 1979), rowing (Fulcher et al., 1998), and golf (Stockard, 2001). Or to support the body's weight i.e. cycling (Tucci & Barone, 1988).

The most common injury to amateur golfers is lower back injuries (34.5% of all injuries) followed by injuries to the elbow (33.1%), and hand and wrist injuries (34.5% combined). In female golfers, elbow injury (35.5%) is even more common than lower back injury (27.4%) (McHardy & Pollard, 2005; Stockard, 2001). Stockard (2001) reports a wide range of elbow injuries that may be present in a golf playing population group, such as; lateral epicondylitis, extensor overload injuries, lateral compression injuries, ulnar neuritis associated with medial epicondylitis (up to 20%), flexor carpi ulnaris tenosynovitis, and possible degenerative change (Stockard, 2001). Lateral elbow injuries ('tennis elbow') are more common when compared to medial elbow injuries ('golfer's elbow') at a ratio of 5:1 (lateral:medial) (McHardy & Pollard, 2005). Sevier and Wilson (1999) report that there have been in excess of 40 different treatment methods for lateral epicondylitis described in the literature. Physical therapy has been recommended when the condition becomes chronic or does not respond to initial treatment.

Outcome Measures

Visual Analogue Scale for Pain Intensity

The visual analog scale (VAS) can be used to evaluate a subject's perception of pain level on a horizontal linear scale; this can be interpreted as pain intensity. The VAS is an unmarked horizontal line (generally between 100-130mm in length) with a pain descriptor at each end; "No Pain" at one end to "Unbearable Pain" at the other (Yeomans & Liebenson, 1996).

The validity of the VAS as an outcome measure of pain intensity is well established (Crossley, Bennell, Cowan, & Green, 2004; Merskey, 1973; Ostelo & de Vet, 2005; Price, Bush, Long, & Harkins, 1994; Price, McGrath, Rafii, & Buckingham, 1983; Vicenzino, Collins, Benson, & Wright, 1998; Yeomans & Liebenson, 1997). The VAS has a high level of responsiveness, reliability, and validity permitting detection of clinically relevant changes – an essential measurement for clinical trials (Reading, 1980). Bisset, Paungmali, Vicenzino, Beller & Herbet (2005) report that 25 out the

28 RCTs accepted in the systematic review and meta-analysis of physical treatments for lateral epicondylalgia utilized a VAS for pain as an outcome measure. The VAS measured in millimeters on a 100 mm line has a possible 101 response levels, this increases the sensitivity of the VAS compared to other measures with more limited response categories (Ostelo & de Vet, 2005).

Pressure pain threshold

Pressure algometry is commonly used to quantify measurement of tissue sensitivity (Fischer, 1987; Fryer, Carub, & McIver, 2004; Fryer & Hodgson, 2005; Reeves et al., 1986). The algometer is a calibrated force pressure gauge that can be used to assess the pressure pain threshold (PPT) in an individual. There is a body of evidence (Fischer, 1987; Gold, Punnett, & Katz, 2006; Maquet, Croisier, Demoulin, & Crielaard, 2004; Ohrbach & Gale, 1989; Reeves et al., 1986) supporting the reliability of pressure gauges (algometers) when used to determine PPTs on bony and muscular landmarks. The PPT is highly dependant on anatomical location and gender, as reported by Maquet et al (2004), for the lateral epicondyle healthy males have a mean PPT = 340 kPa (3.5 kg/cm²) and healthy females a mean PPT = 250 kPa (2.6 kg/cm²). Kosek, Ekholm & Hansson (1999) have noted that great inter-individual variability in PPTs exists in healthy subjects.

Fischer (1987) provided evidence of the reproducibility and validity of PPT measurement, with identical results obtained from muscles on opposite sides of the body for both male and female normal subjects. The use of PPT as an outcome measure was reported in six out of the 28 RCTs accepted in the systematic review and meta-analysis of physical treatments for lateral epicondylalgia carried out by Bisset et al. (2005). The PPT can be an accurate measure of change in tissue sensitivity, when sensitivity is defined as the amount of pressure in kg/cm² needed to elicit a change in sensation from pressure to that of discomfort or pain (Nussbaum & Downes, 1998; Potter, McCarthy, & Oldham, 2006; Reeves et al., 1986).

Ylinen et al. (2007) reported intra-class correlation coefficients (ICCs) between 'very large' and 'almost perfect' (0.78-0.93) for the measurement of PPTs of neck muscles. An ICC is considered large (between 0.5 to 0.7), very large (between 0.7 to 0.9) and almost perfect (between 0.9 and 1.0) (Hopkins, 2002). Similarly Paungmali et al. (2003) showed reliability correlation coefficients ranging in the 'very large' category (0.79 to 0.89) for subjects with lateral epicondylalgia. Jones et al. (2007) reported a range of ICCs in the 'almost perfect' category (0.92 to 0.98) for the measurement of PPTs in the upper limb and torso of healthy young women. In a study of PPT for subjects with unilateral shoulder and arm pain Vanderweeën et al. (1996) reported ICCs between 'large' to 'almost perfect' (0.64 to 0.96).

Kosek et al. (1999) showed evidence of lower PPTs over a muscle-nerve site when compared to PPT measurements from either bony or pure muscle sites. Further they gave evidence that these relationships remain irrespective of skin hypoesthesia, and thus are more likely to be reflective of the sensitivity of deeper structures. They conclude that skin pressure pain sensitivity can influence the PPT (Kosek et al., 1999). Slater, Arendt-Nielsen, Wright, & Graven-Nielsen (2003) documented that the most sensitive sites to pressure of various tissues in and around the elbow were the extensor carpi radialis longus origin and the extensor carpi radialis brevis muscle belly. They hypothesized that this phenomenon can be explained partially by the increased density of nociceptors in these regions compared with other tissues around the elbow.

While pressure algometry has been commonly used in clinical practice for the quantitative measurement of tenderness, many variables have been found (such as gender, site of application, and application rate) that lead to a high degree of inter-individual variability (Maquet et al., 2004; Paungmali, O'Leary et al., 2003). With adequate operator training the site of application and application rate can be controlled. Paungmali, O'Leary et al. (2003) demonstrated treatment effects after application of a manual therapy intervention for lateral epicondylalgia with positive changes in the PPT. In a later paper Paungmali, Vicenzino & Smith (2003) demonstrated that repeated application of the manual therapy intervention showed diminished degrees of improvement.

Pain-Free Grip Strength

Pain-free grip strength (PFGS) is defined as the amount of force a subject is able to generate with an isometric gripping action before eliciting pain (Paungmali, O'Leary et al., 2003; Pienimäki, Siira, & Vanharanta, 2002). Pain-free grip strength is commonly used as an outcome measure for the treatment of forearm pain. Bisset et al. (2005) reported that PFGS was employed as an outcome measure in 14 out of the 28 RCTs accepted in the systematic review and meta-analysis of physical treatments for lateral epicondylalgia. Pain free grip strength has previously been used as an outcome measure for physiotherapy RCTs, although it has been noted by Smidt et al. (2002) that the specification of grip strength is sometimes not properly reported.

Measurement of PFGS has been shown to be highly reliable and is robust as a measure of functional disability for subjects with elbow pain (Hillman et al., 2005; Paungmali, O'Leary et al., 2003; Paungmali, Vicenzino et al., 2003; Smidt et al., 2002; Stasinopoulos & Stasinopoulos, 2006). Pienimäki et al. (2002) have shown that increases in grip strength and PFGS correlate well with measures of treatment effectiveness for both medial and lateral epicondylitis. Studies investigating the examiner reliability of PFGS have reported high intra-observer reliability

coefficients (Smidt et al., 2002). Hillman et al. (2005) reported significant differences in PFGS between male and female participants in their study.

Minimal Clinically Important Difference

The minimally clinically important change of the VAS score has been approximated between 30-35 mm (acute subjects) down to 20-25 mm (sub acute to chronic subjects) (Lee, Hobden, Stiell, & Wells, 2003; Ostelo & de Vet, 2005). This is defined as the minimal clinically important difference (MCID).

A variety of studies have returned similar figures for the MCID for VAS for pain intensity scores. In a pragmatic study of chiropractic intervention for low back pain Garner et al. (2007) reported a MCID of 2.3 (95% CI = 1.9-2.6) on a numeric visual analog scale for pain intensity ($p < 0.008$) for 249 subjects. In a prospective observational study of adult emergency department patients with acute pain, Lee et al. (2003) reported a mean reduction in VAS score of 30mm (95% CI = 23.6-36.4) as representing a clinically important difference in pain severity produced by adequate analgesic control in 81% of the subjects. In an investigation of patient's with chronic back pain Mesrian et al. (2007) reported an MCID of 25mm for a VAS for pain intensity. Lee et al. (2003) reported a mean reduction in VAS of 30mm demonstrative of a patient's perception of sufficient pain control in relation to administration of parenteral analgesics. Ries (2005) defined a change in VAS between 10 to 20mm as the MCID in relation to chronic obstructive pulmonary disease.

Bird & Dickson (2001) developed a variable scale for MCIDs for VAS for pain intensity. Bird & Dickson (2001), defined 'a lot better' as a change in VAS correlated to the initial value recorded. A pre-intervention VAS of up to 33mm would require a post-intervention reduction in VAS of >16mm to indicate a perception of 'a lot better' for the patient, whereas a pre-intervention VAS of between 34mm to 66mm would require a post-intervention reduction in VAS of >33mm, likewise an initial VAS of >67mm would require a reduction of >48mm to demonstrate the same change in subjectivity (Bird & Dickson, 2001). An issue for consideration in the comparison of a VAS to other more scalar measures is described by Fosnocht, Chapman, Swanson & Donaldson (2005). The authors report that a change in pain intensity of 10mm as reported on a VAS for pain may not be the same subjective experience when the subject decreases a VAS from 40 to 30mm compared to a change from 90 to 80mm (Fosnocht et al., 2005).

Patients with acute pain in a trauma department were reported as being a 'little better' having a mean MCID of 13mm (95% confidence interval, 10 to 17mm) on a 100mm VAS (Todd, Funk, Funk, & Bonacci, 1996). In their pilot study of acupuncture for low back pain Kennedy et al. (2007) proposed an MCID of 20mm through post hoc power analysis. An MCID of 20mm was reported by Crossley et al (2004) in their paper investigating the responsiveness of outcome measures for the treatment of patellofemoral pain. Kelly (2001) found that there was no statistical difference in the MCID for VAS for pain regardless of the pain severity. Kelly stated the MCID numerically as 12 mm (95%CI 9 mm to 15 mm) for adult patients in an urban emergency department.

The MCID for cancer related break-through pain relief was reported as a 30% decrease in VAS score (Farrar, Portenoy, Berlin, Kinman, & Strom, 2000) and similarly for chronic pain sufferers 30% (Farrar, Young Jr, LaMoreaux, Werth, & Poole, 2001). In a study of myogenous temporomandibular disorders van Grootel et al. (2007) reported further evidence in support of an MCID at a level of 30%. Haas et al. (2004) in a practice based study of interventions for acute or chronic low back pain chose a MCID of 20%.

O'Leary et al. (2007) defined an MCID for pressure pain threshold (PPT) measurement for cervical spine muscles as 20%. Their study reported that specific cervical exercises can produce immediate changes in local mechanical hyperalgesia in the perceived as pain relief by patients with chronic neck pain (O'Leary et al., 2007). In a previous study of reliability of algometry for the measurement of PPTs for spinal muscles, Potter et al. (2006) reported that the algometer was a reliable single pre- and post- intervention measure, with the MCID for spinal muscles between 35-40%. In an earlier study of lateral epicondylalgia the Paungmali et al. (2003) reported an increase of 15% in PPT as being therapeutically effective, this could be interpreted as the MCID.

Sham Protocol

The blinding of subjects is more likely to be successful if the active treatment closely resembles the “light touch” sham intervention (Noll et al., 2004). A potential pitfall in using sham techniques is that the sham could be considered as simply another form of generic manipulation, thus diluting any treatment effect that may occur with the active intervention. All forms of therapeutic touch can elicit beneficial physiological effects, therefore reducing the magnitude of the effect size (Noll et al., 2004). It has been reiterated by McPartland et al. (2005) that the ‘slight application of human touch and attention’ from the practitioner may induce or contribute beneficial physiological responses measurable in the subject. In a review of placebo effects found in pain related studies Licciardone (2004) found that there are small, but consistent effects attributable to placebos.

Noll et al (2004) have previously found that blinding to the treatment protocol can be better achieved if the sham treatment closely mimics the treatment protocol in application to the same body areas, duration and similar sequence of manipulation. A subject’s familiarity with other types of manual therapy will not necessarily make them more difficult to blind (Noll et al., 2004).

Conclusion

After reviewing the literature there is a large body of anecdotal and descriptive research in support of the effectiveness of SCS technique in clinical practice. To date there are only a few peer reviewed randomized controlled trial articles that provide substantive evidence as to the efficacy of SCS either in the short term or long term when compared to either a suitable sham (placebo) or control group.

People with a history of recreational sports injury to the elbow comprise a suitable symptomatic subject group with injuries to areas of the body readily accessible for the collection of data by PPT and palpation. When investigating immediate effects of SCS technique it is possible to consider at least two outcome measures: 1) the subjective level of pain intensity as reported by a VAS (Price et al., 1983); and 2) the objective level of tissue sensitivity as reported by a PPT measurement on a TeP (Fischer, 1987).

The VAS is a valid, reliable and highly responsive measure of pain intensity (Price, Harkins, & Baker, 1987; Reading, 1980), permitting the detection of clinically relevant changes (also known as MCIDs). The VAS for pain intensity has been frequently utilized in studies investigating physical treatments for lateral epicondylalgia (Bisset et al., 2005).

Although pressure algometry has been commonly used to quantify changes in tissue sensitivity (Fryer et al., 2004; Fryer & Hodgson, 2005), it has not been commonly utilized in studies investigating physical treatments for lateral epicondylalgia (Bisset et al., 2005). Random allocation of subjects drawn from a heterogeneous pool into intervention and placebo groups may control for some of the variables that can effect pressure algometry; such as gender, and site of application. The application rate can be partially controlled with prior operator training (Maquet et al., 2004; Paungmali, O'Leary et al., 2003).

The reporting of MCIDs for effectiveness and efficacy studies has become more popular, with a percentage figure for improvement in VAS for pain intensity (a decrease post-intervention) commonly reported (Farrar et al., 2000; Farrar et al., 2001; van Grootel et al., 2007).

The lack of published RCTs analyzing the efficacy of SCS technique to effect pain sensitivity and pain intensity of primary TePs in symptomatic subjects makes it difficult to draw any definitive conclusions from the literature on this topic. Further studies are required investigating the efficacy of SCS technique applied to various body segments of symptomatic subjects.

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SECTION II - MANUSCRIPT

Note: The following manuscript was prepared in accordance with the Instructions for Authors for the International Journal of Osteopathic Medicine [see Appendix C]

An investigation into the efficacy of strain-counterstrain technique to produce immediate changes in pressure pain thresholds in symptomatic subjects

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ABSTRACT

Background and objective: Strain counterstrain (SCS) is an osteopathic technique used by osteopaths and manual therapists for the relief of musculoskeletal pain and associated dysfunction. Limited literature exists to support the efficacy of SCS technique. The aim of this study was to investigate the efficacy of SCS technique on subjects with a history of a recreational sports injury of the upper extremity.

Design: Randomized assessor blinded placebo controlled trial.

Methods: Twenty three subjects (13 males, 10 females; mean age=26.1, SD=6.3) fulfilled the requirements for the study. Subjects were screened to establish the presence of a primary tender point (TeP) around the elbow joint. Subjects were randomly assigned into two groups and received either an SCS intervention or a Sham intervention. The primary outcome measures were pressure pain threshold (PPT) on the primary TeP, and visual analog scale (VAS) assessing local pain intensity elicited by the application of approximately 3kg/cm² of pressure on the primary TeP. The secondary outcome measure was pain-free grip strength (PFGS).

Results: Within group changes showed a significant improvement in VAS for pain intensity following the SCS intervention ($p < 0.001$) compared with the Sham intervention ($p = 0.053$). Pre-post effect sizes for the VAS for pain intensity were 'large' in the SCS intervention group ($d = 1.87$) and 'moderate' ($d = 0.90$) for the Sham intervention group. Both groups surpassed the minimal clinically important difference (MCID) defined as a decrease $\geq 30\%$ in VAS for pain intensity (SCS group=55%, Sham group=31%). Within group changes showed a small improvement for PPT at the TeP following either the SCS intervention ($p = 0.497$) compared with the sham intervention ($p = 0.749$). Pre-post effect sizes for the TeP were small in the SCS intervention group ($d = 0.29$) and trivial ($d = 0.14$) for the sham intervention group. No significant differences were found for the PFGS (SCS: $p = 0.936$ $d = 0.03$, Sham: $p = 0.989$ $d = 0.01$)

Conclusions: The results indicate that SCS technique may be an efficacious technique in treatment of TePs around the elbow in subjects with a history of a recreational sports injury of the upper extremity. SCS technique can produce decreases in pain intensity as reported from mechanical pressure at a primary TeP.

Key words: strain, counterstrain, pressure pain threshold, osteopathy, visual analog scale

INTRODUCTION

Strain-counterstrain (SCS) is an osteopathic technique first developed by Lawrence Jones in the mid 1950s for the treatment of musculoskeletal pain and associated dysfunction.¹ The SCS technique relies on the identification by physical examination of an active TeP (tender point). A TeP has been defined as a small (between 3mm to 10mm in diameter) tense, tender, and edematous zone, located deeper in muscle, tendon, ligament, or fascia.¹ The SCS technique requires a practitioner to position a patient through movement of various joints in three planes so that the primary (or chosen) TeP is placed in a position of ease.¹⁻³ The position of ease was described as the point whereby TeP pain elicited by mechanical pressure was reduced by at least 70% from its original tenderness.¹ The SCS technique offers a modular diagnostic and treatment system that can be practiced in isolation or incorporated as part of other treatment approaches.

Six experimental studies describing the effects of SCS technique in isolation of other osteopathic techniques have been reported in the literature. Of these three studies described the immediate effects of SCS on pain sensitivity. These studies investigated SCS technique for treating myofascial trigger points in the masseter muscle;⁴ the analgesic effects of SCS technique in the treatment of Achilles tendinitis;⁵ and the analgesic effects of SCS technique in the treatment of TePs in the upper trapezius muscle.⁶ The three remaining studies investigated the longer term effects of SCS technique. These studies investigated SCS technique for the treatment of TePs found in the hip abductors and adductors,^{7, 8} and the effectiveness of SCS technique in the treatment of plantar fasciitis.⁹

There have been a number of case reports and other forms of uncontrolled investigation reporting specific clinical applications of SCS in treatment of: foot and ankle disorders;¹⁰⁻¹² iliotibial band friction syndrome;¹³ sacral torsions;¹⁴ low back pain;¹⁵ and chronic myofascial pain.¹⁶ A number of studies have reported the use of SCS as part of an overall osteopathic manipulative treatment protocol to address a variety of disorders including shoulder pain and repetitive strain injury of the supraspinatus muscle;¹⁷ chronic pain;^{18, 19} low back pain;²⁰ arthritis related pain;²¹ cervicothoracic pain,²² and for the treatment of acute or chronically ill hospital patients.²³

We were unable to locate any study in the peer-reviewed literature investigating immediate changes in pressure pain thresholds (PPT) in the soft tissues of the elbow following a single application of SCS technique to a single TeP located around the elbow joint. The aim of this study was to investigate the efficacy of SCS technique on subjects with a history of chronic sports related injury to the upper extremity.

METHODS

Design

A randomized, blinded, placebo controlled experiment, comparing the efficacy of a SCS intervention with a Sham intervention for subjects with an undiagnosed chronic sports related injury to the upper extremity was conducted in a laboratory setting (refer to figure 1).

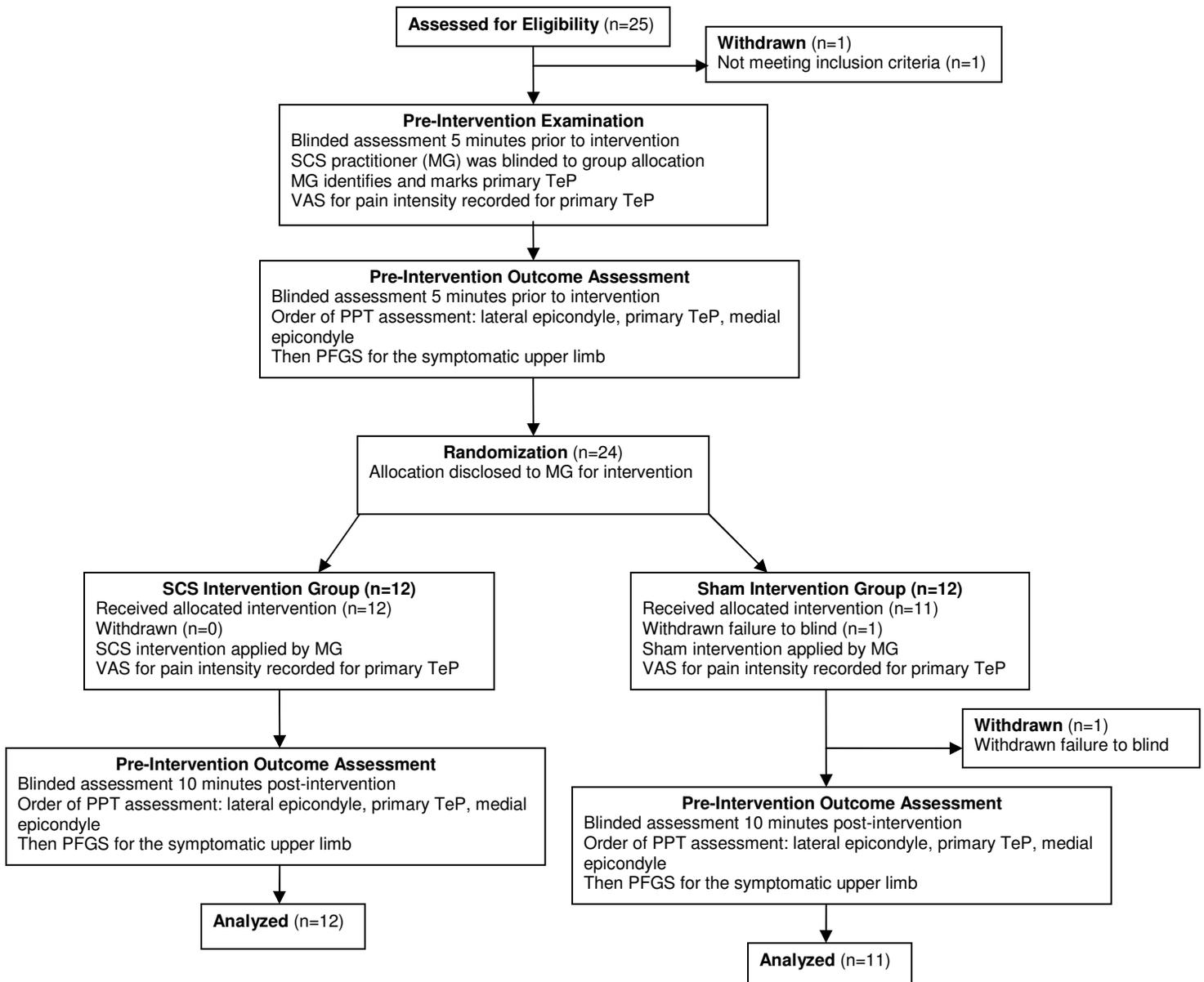


Figure 1 Flowchart of Study Design

Abbreviations: SCS = Strain Counterstrain; TeP = Tender Point; PPT = Pressure Pain Threshold; PFGS = Pain-Free Grip Strength; VAS = Visual Analog Scale

Eligibility Criteria

Twenty five volunteers with a history of chronic sports related injury to the upper extremity responded to written notices distributed at the Unitec NZ Mt Albert campus. Before enrolment all volunteers completed a general medical questionnaire. Volunteers were excluded if they exhibited any of the following: (1) they had signs or symptoms of cervical radiculopathy; (2) they had another medical condition that could interfere with the therapy i.e. cardiovascular disease, systemic inflammatory disorder, nerve root compression, severe arthritis, or recent surgery; (3) they had a history of long term steroid usage; (4) they could not read or write in English; (5) they had used analgesics in the previous 24 hours. All subjects gave written informed consent. The study was approved by the Unitec Research Ethics Committee.

Pre-Intervention Examination

All subjects were physically examined by the practitioner (MG) to screen for the presence of palpable TePs around the elbow. During the pre-intervention scanning process the practitioner was blinded to group allocation (refer to figure 1).

The pre-intervention examination process took approximately 5 minutes, during this time the subjects lay supine on a standard treatment plinth. To be included subjects needed to exhibit a TeP(s) in one or more of the following locations around the elbow: the common extensor origin on the lateral epicondyle; the common flexor origin on the medial epicondyle; the biceps brachii aponeurosis; the belly of brachioradialis; the insertion of brachialis; and the insertion of triceps brachii on the olecranon process of the ulna. The primary TeP was identified using the SCS structural scanning technique for the elbow region, as described by Jones and D'Ambrogio & Roth.^{1,2} The primary TeP was defined as the TeP which elicited the greatest level of pain as reported by the subject in comparison to all other TePs when pressurized by the practitioner's thumb at a level of approximately 3kg/cm.² The primary TeP was located and marked on the skin surface with an ink pen by the practitioner. Subjects completed a visual analog scale (VAS) for pain intensity in the pre-intervention prior to assessment of other outcome measures (refer figure 1).

Pre-Intervention Outcomes Assessment

Following the physical examination subjects moved to a separate assessment cubicle where initial pressure pain thresholds (PPTs) and pain-free grip strength (PFGS) data were collected. The pre-intervention outcomes assessment took approximately 10 minutes.

The order of anatomical locations for the recording of PPTs was the lateral epicondyle, followed by the primary TeP, and then the medial epicondyle. The PPTs for the medial and lateral epicondyles were recorded 1) to provide control data for the assessment of any local or regional changes in pain sensitivity, and 2) to provide data for the assessment of intra-examiner reliability.

The subject was then assessed for initial PFGS. The assessment of PFGS and PPTs was undertaken by a research assistant (RM) who was blinded to group allocation. The principal researcher (JH) recorded all outcomes data. After the initial outcomes measurement the group allocation was revealed to the practitioner (MG) and the principal researcher (JH).

Sample Size

Previous studies investigating the immediate effects of manual therapy techniques on lateral epicondylalgia and the upper trapezius muscle as measured by PPT have returned moderate to large effect sizes.^{24, 25} The effect size ($d=1.20$) for this study was based on the work of Fryer & Hodgson.²⁵ Using G*Power software (v2.0)²⁶ the *a priori* sample size for a two tailed t-test for the difference between two independent means (two groups) was calculated. Based on an alpha error probability of 0.05 and a power (1- β error probability) of 0.80 the minimum sample size required was 24 subjects.

Randomization

Subjects who met all inclusion criteria were randomly assigned using a computer generated randomization list to either 1) the SCS intervention group or 2) the Sham intervention group. The study utilized assessor-blinded outcomes measurement,²⁷ with the research assistant blinded to intervention group assignment for the duration of data collection.

Intervention Protocol

Following pre-intervention measurements, the practitioner (MG), blinded to pre-intervention data, applied the allocated intervention to the subject. The practitioner was a trained manual therapist with over 10 years experience using SCS in a clinical environment, and is completing a postgraduate pre-registration qualification in osteopathy.

SCS Intervention

The SCS intervention was based on the work of D'Ambrogio & Roth² and is described for the primary TeP as used in this study below:

1. Pressure was applied to the marked primary TeP site with either one fingertip or the thumb to determine the degree of tissue tension; subjects were asked to confirm the presence of tenderness. The patient was instructed to relax throughout the intervention.
2. The practitioner combined movements of the upper limb in several planes while monitoring the primary TeP site with either one fingertip or the thumb for relaxation of the myofascial tissues. The range of movements employed to effect the elbow joint consisted of a selection from the following: compression or distraction, flexion or extension, supination or pronation, translation (anterior and posterior), and wrist flexion or wrist extension. The practitioner sought verbal confirmation of a reduction in pain intensity when applying approximately 3kg/cm² pressure with either one fingertip or the thumb at the primary TeP.
3. With minimal movements in all directions the practitioner refined the subject's positioning to maximize the reduction of pain as reported by the subject at the primary TeP. The subject's arm was held in this position for a period of approximately 90 seconds.
4. The subject was instructed to "remain relaxed and not try to help" as the practitioner slowly returned the upper limb to a neutral position.
5. After the intervention the subject then completed another VAS for pain intensity at the primary TeP before returning to the assessment cubicle for post-intervention outcomes measurement.

Sham Intervention

The Sham intervention was based around the work of D'Ambrogio & Roth² and is described for the primary TeP as used in this study below:

1. Pressure was applied to the marked primary TeP site with either one fingertip or the thumb to determine the degree of tissue tension; subjects were asked to confirm the presence of tenderness. The patient was instructed to relax throughout the intervention.
2. The practitioner combined movements of the upper limb in several planes while monitoring the primary TeP site with either one fingertip or the thumb in order to maintain tension of the myofascial tissues. The range of movements employed to effect the elbow joint consisted of a selection from the following: compression or distraction, flexion or extension, supination or pronation, translation (anterior and posterior), and wrist flexion or wrist extension. The practitioner sought verbal confirmation that the pain intensity remained unchanged when applying approximately 3kg/cm² pressure with either one fingertip or the thumb at the primary TeP.
3. With minimal movements in all directions the practitioner refined the subject's positioning to maximize the tissue tension and maintain the original level of pain intensity at the primary TeP, when approximately 3kg/cm² pressure was applied. The subject's arm was held in this position for a period of approximately 90 seconds.
4. The subject was instructed to "remain relaxed and not try to help" as the practitioner slowly returned the upper limb to a neutral position.
5. After the intervention the subject then completed another VAS for pain intensity at the primary TeP before returning to the assessment cubicle for post-intervention outcomes measurement.

There was a 10 minute interval between the intervention phase (SCS or Sham) and post-intervention outcomes assessment.

Outcome Measures

The immediate effects of SCS were investigated using two primary outcome measures: 1) visual analog scale (VAS) for pain intensity; 2) algometry for pressure pain threshold (PPT). A strain gauge hand dynamometer was used to measure the secondary outcome measure of pain-free grip strength (PFGS). The combination of the VAS for pain intensity and PPT for the primary TeP offered both a subjective measure and an objective measure of tissue sensitivity.

Visual Analogue Scale

The VAS used was a 130mm horizontal line marked 'no pain' to 'worst pain possible'. Previous studies have demonstrated the reliability and construct validity of the VAS by demonstrating strong correlations with other self-reported measures of pain intensity.²⁸⁻³⁰

Subjects were asked to indicate by marking the line at the point that best represented their pain intensity when pressure of approximately 3kg/cm² was applied to their primary TeP by the practitioner's thumb. The subjects were blinded to the result of their pre-intervention VAS when completing their post-intervention VAS. The distance from the 'no pain' end to the mark made by the patient was measured to the nearest millimeter, converted to a score out of 100 and recorded as their VAS score of pain intensity.

Pressure Pain Threshold

The mechanical pressure algometer (Activator Methods Algometer, Activator Methods International Ltd, Phoenix AZ) used in this study consisted of a round rubber disk (area 1cm²) attached to a pressure (force) gauge. The gauge displays values in kilograms but, the readings are expressed in kg/cm². The range of values of the pressure algometer is 0 to 10 kg/cm², with 0.1 kg/cm² divisions. The rate of pressure increase was maintained at approximately 1kg/cm²/s, as described by Fischer³¹ for mechanical analogue algometers. Downwards pressure was applied via the head of the algometer which was perpendicular to the surface of measurement (either the marked primary TeP, or the medial and lateral epicondyles).

Subjects were instructed to say 'now' or 'stop' when they "first began to feel the sensation of pressure change to a sensation of discomfort or pain". The research assistant ceased applying pressure at this moment and the principal researcher recorded the pressure value (kg/cm²). Prior to measurement the algometer display was covered so that the research assistant could not inadvertently see the value; it was uncovered and re-covered by the principal researcher after each measurement. The PPT was recorded three times at each point under investigation, with a 15 second interval between each measurement. The mean PPT was calculated for each of the three measurement points in the symptomatic arm and used for analysis.

The PPT measurement was performed 5 minutes prior to the intervention and 10 minutes after the intervention by the research assistant. The PPT measurements were recorded while the subjects lay in a lateral recumbent position on a standard treatment plinth with their elbows in 90° of flexion.³² The examination sequence began with the lateral epicondyle while the subject was positioned with their upper limb supported above their flank by a pillow. After measurement of the

lateral epicondyle, PPTs were recorded over the primary TeP site, followed by the medial epicondyle. To expose the medial surface of the arm the subject was instructed to lie on the side of the symptomatic arm.

Pain-Free Grip Strength

The strain gauge hand dynamometer (Smedley's Dynamometer, TTM, Tokyo) selected for this study measured a range from 0 to 100 kg with 0.5kg divisions. The subject was instructed to lie supine with the symptomatic arm at rest on the treatment plinth, when prompted they were asked to maximally squeeze the strain gauge hand dynamometer. The symptomatic arm was positioned with elbow extended and forearm pronated so that the grip dynamometer could be held perpendicular to the treatment table. The research assistant stabilized the dynamometer while the principal researcher recorded the maximum effort for PFGS in kg. Subjects received verbal encouragement at a consistent level to perform at their maximum effort as described by Martel et al.³³ Three consecutive measurements were recorded for the symptomatic arm, with a 30 second rest period between each. The mean PFGS was calculated and used for analysis.

Reliability

Intra-class correlation coefficients (ICC) were used to examine the relative reliability of PPT measurement for the single blinded assessor, and as a measure of reproducibility.³⁴ The pre-intervention PPT values from the primary TeP and the medial and lateral epicondyles were considered viable data for the calculation of individual ICCs.

ICCs were required for the calculation of the standard error of measurement (SEM) and the smallest detectable difference (SDD). The SEM reflects the variability of measurements due to repetition and random error, and gives an indication of the absolute reliability of the measures used.^{32, 35} The SDD for the measurements reflects the smallest valid change between the two independent measurements that can be detected in a subject.^{35, 36} The SDD is a clinically relevant measure that represents the change that might be expected because of an intervention rather than sampling error at the 0.05 level of statistical significance.

DATA ANALYSIS

All VAS for pain intensity data was converted to percentages. Mean and standard deviations (SD) were calculated for each variable. Baseline and within-group differences were assessed with a paired t-test. Within-group and between group effect sizes (Cohen's d) were calculated using standardized differences in means. The standardized differences in means were calculated by taking the difference in the means divided by the mean standard deviation of the groups.³⁴ Effect sizes were interpreted according to the following guidelines: $d > 2.0$ was considered 'very large'; d between 1.2 and 2.0 was considered 'large'; d between 0.6 and 1.2 was considered 'moderate'; d between 0.2 and 0.6 was considered 'small'; and $d < 0.2$ was considered 'trivial'.³⁴

The ICCs were calculated using a two-way mixed effects model with a single measure, as all subjects were examined by the same assessor (ICC model (3,1)).³⁷ The ICCs were interpreted according to the following guidelines: an ICC between 0.0 to 0.1 was considered 'trivial'; an ICC between 0.1 to 0.3 was considered 'small'; an ICC between 0.3 to 0.5 was considered 'moderate'; an ICC between 0.5 to 0.7 was considered 'large'; an ICC between 0.7 to 0.9 was considered 'very large'; and between 0.9 to 1.0 'almost perfect'.³⁴

The standard error of measurement (SEM) was calculated as the square root of the absolute error variance ($SEM = SD \cdot \sqrt{1 - ICC}$).^{35, 36} The smallest detectable difference (SDD) was calculated using the formula ($SDD = 1.96 \cdot \sqrt{2} \cdot SEM$).

Based on earlier studies, it was decided that a MCID $\geq 30\%$ would be likely to demonstrate a therapeutically important change in the VAS for pain intensity.³⁸⁻⁴¹ The MCID for the VAS for pain intensity was compared at a group level and on an individual subject level.

An MCID $\geq 20\%$ was selected for changes in PPT measurement. This is similar to the level of change reported by Paungmali et al.⁴² for changes in PPT for subjects with lateral epicondylalgia. It was considered that the sensitivity of the tissues around the elbow more closely reflected the responsiveness of cervical spine musculature described by O'Leary et al,⁴³ compared to the larger spinal muscle groups assessed by Potter et al.³⁵

Microsoft Office Excel 2003 was used to tabulate raw data, calculate means, SD, effect size, SEM and SDD. The ICCs were calculated using SPSS statistical software (SPSS Inc. v 14.0, Chicago, Illinois, USA). A p-value less than 0.05 was considered statistically significant.

RESULTS

Subjects

One volunteer was withdrawn from the study before allocation due to recent anti-inflammatory medication use. One subject was withdrawn after allocation to the sham intervention group as a result of failure to blind. There were 12 subjects in the SCS intervention group and 11 subjects in the sham intervention group (refer to table 1). No significant differences were found between the groups for the pre-intervention measures; VAS ($p=0.737$), PPT for the TeP ($p=0.866$), PFGS ($p=0.851$). Therefore, it could be assumed that all groups were comparable at the start of the study.

Table 1 Baseline Characteristics of Subjects

	SCS Intervention	Sham Intervention	p-value
Number of subjects (n)	12	11	
Age range: years	18-39	18-40	
Mean (SD) age years	28 (6)	25 (6)	0.285
Gender: Female	5	5	
Gender: Male	7	6	
Height range: cm	161-189	163.5-179	
Mean (SD) height cm	175.3 (8.8)	172.1 (5.3)	0.296
Weight range: kg	47-81.5	60-100	
Mean (SD) weight kg	69.6 (10.8)	72.8 (13.4)	0.542
Dominant Arm Right	12	9	
Dominant Arm Left	0	2	
Symptomatic Arm Right	5	7	
Symptomatic Arm Left	7	4	
VAS between group pre-intervention			0.737
PPT for Primary TeP pre-intervention			0.866
PFGS pre-intervention			0.851

Notes

VAS = Visual Analog Scale

PPT = Pressure Pain Threshold

PFGS = Pain-Free Grip Strength

VAS for Pain Intensity

When the data was compiled by group (SCS or Sham intervention), both groups showed a reduction in pain intensity according to the VAS for pain intensity (refer figure 2). Both groups satisfied the reduction in $VAS \geq 30\%$ to achieve a MCID (the SCS group showed a 55% reduction and the Sham group a 31% reduction). There was a significant and large effect for the SCS group ($p < 0.001$; $d = 1.87$) and a less significant but moderate effect for the Sham group ($p = 0.053$; $d = 0.90$). At baseline the two groups showed no difference in VAS ($p = 0.737$), whereas the SCS group showed a significant lower post-intervention VAS compared to the Sham group ($p = 0.047$; $d = 0.89$). Thus, the SCS intervention reduced pain intensity significantly more than the sham intervention.

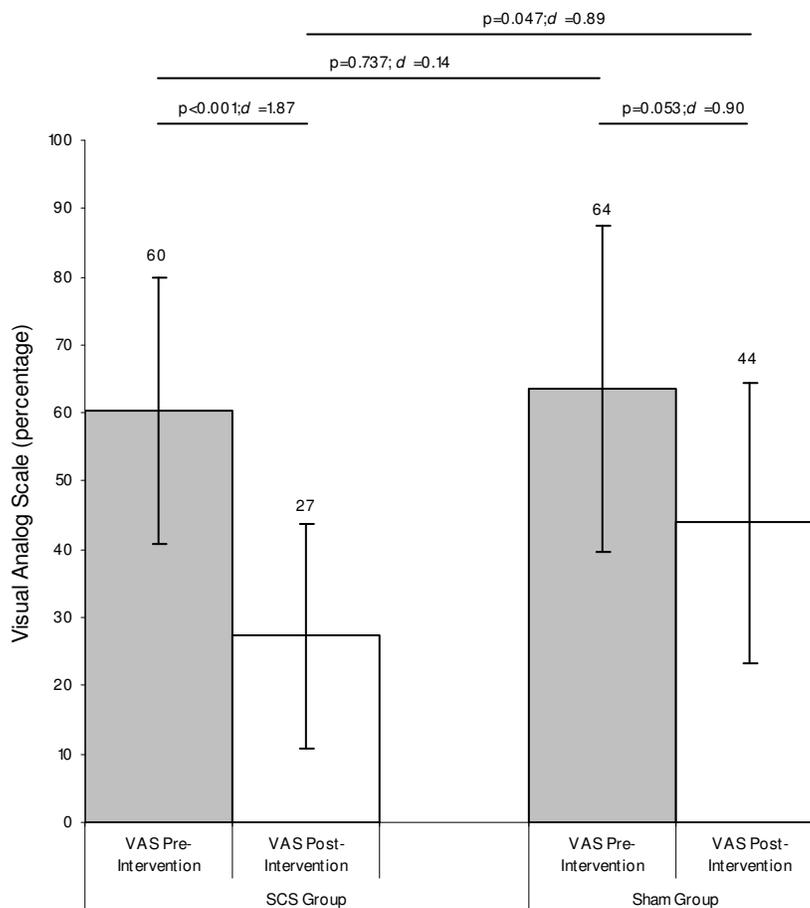


Figure 2 Mean group VAS for pain intensity.

Within group mean scores and the within group effect sizes for both interventions are shown. Both groups showed a mean change in VAS for pain intensity that met the criteria for $MCID \geq 30\%$ change. The SCS group showed a mean reduction in VAS for pain intensity of 55% ($p < 0.001$; $d = 1.87$). The Sham group showed a mean reduction in VAS for pain intensity of 31% ($p = 0.053$; $d = 0.90$). P values were generated using a two-tailed paired t-test, and effect size (d) was generated by standardized difference in means.³⁴

Individually each subject in the SCS group showed a reduction in VAS for pain intensity, of these, 10 met the criteria for a MCID \geq 30% change in VAS (refer figure 3). Nine of the subjects in the Sham group showed a decrease in VAS for pain intensity, of these 6 met the criteria for a MCID \geq 30% change in VAS. Two of the subjects in the Sham group showed either no change or a minimal increase.

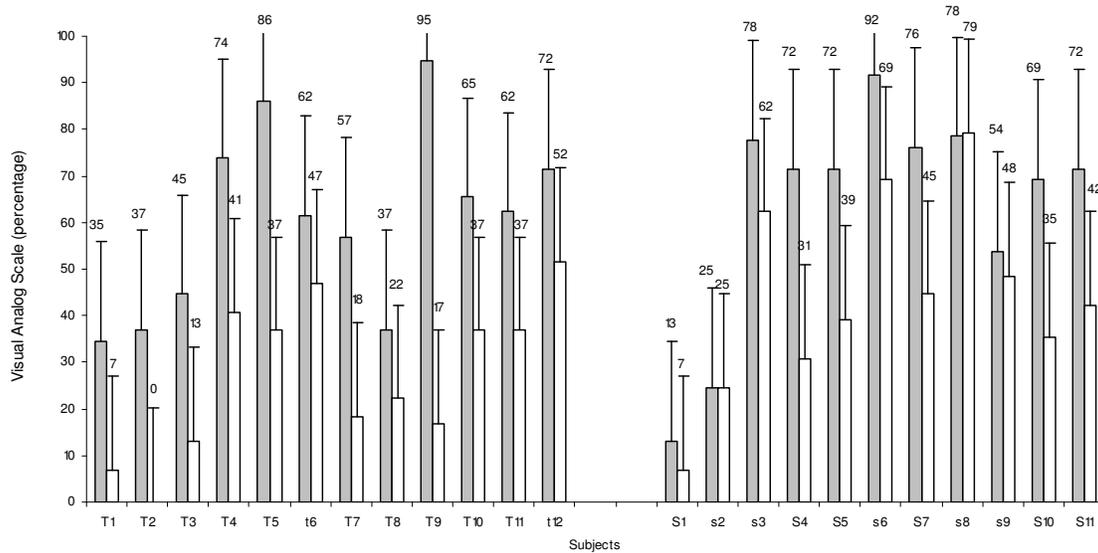


Figure 3 Individual mean VAS for pain intensity.

Individual mean scores and standard deviations for both interventions are shown. Individuals that met the criteria for MCID \geq 30% change are capitalized. Ten subjects in the SCS group showed an individual MCID \geq 30% in VAS for pain intensity (all in a direction that demonstrated a reduction in subjectively assessed pain intensity). Six subjects in the Sham group showed individual MCID \geq 30% in VAS for pain intensity (all in a direction that demonstrated a reduction in subjectively assessed pain intensity).

Changes in PPT levels

As a group there was no statistically significant difference in the primary TeP PPT after either the SCS intervention ($p=0.497$) or the Sham intervention ($p=0.749$) (refer figure 4). There was a 'small' increase in the threshold (11%; $d=0.29$) following the SCS intervention, whereas there was a 'trivial' decrease in the threshold (-3%; $d=0.14$) following the Sham intervention.

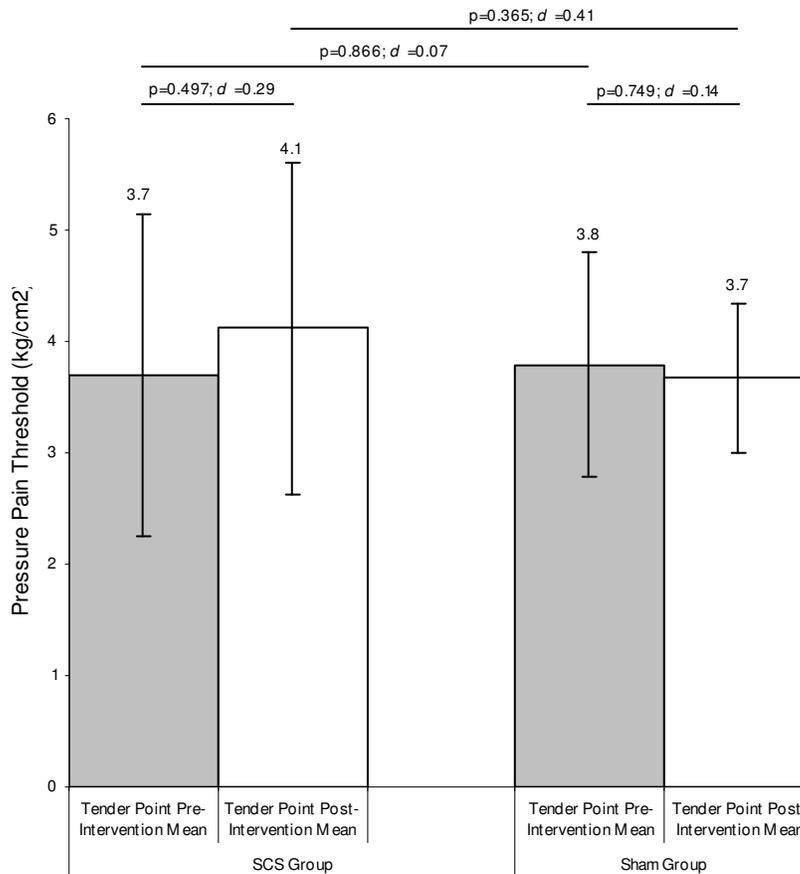


Figure 4 Group Means for Primary Tender point PPTs.

Within group mean scores and the within group effect sizes for both interventions are shown. The SCS group showed a mean increase in PPT for TeP of 11% ($p=0.497$; $d=0.29$). The Sham group showed a mean reduction in PPT for TeP of 3% ($p=0.749$; $d=-0.14$). P values were generated using a two-tailed paired t-test, effect size (d) was generated by standardized difference in means.³⁴ On a group level neither group met the criteria for MCID \geq 20% change.

Individually 5 out of 12 subjects in the SCS group showed a mean change in PPT at the primary TeP meeting the criteria of the MCID \geq 20%, all showed an increase in PPT following the intervention [refer figure 6, appendix A]. In the Sham group 2 out of 11 subjects showed a mean change in PPT at the primary TeP meeting the criteria of the MCID \geq 20%, of these one showed an increase in PPT, and the other a decrease.

As a group there was no statistically significant difference in the PPT for the medial epicondyle after either the SCS intervention ($p=0.803$; $d=0.10$) or the Sham intervention ($p=0.924$; $d=0.13$) [refer figure 7, appendix A]. Individually 2 out of 12 subjects in the SCS group showed a mean change in PPT at the medial epicondyle meeting the criteria of the MCID \geq 20%, one showed an increase in PPT following the intervention, the other a decrease [refer figure 8, appendix A]. In the Sham group 1 out of 11 subjects showed a mean change in PPT at the medial epicondyle meeting the criteria of the MCID \geq 20%, recording an increase in PPT following the intervention.

As a group there was no statistically significant difference in the PPT for the lateral epicondyle after either the SCS intervention ($p=0.568$) or the Sham intervention ($p=0.778$). There was a modest decline of 8% ($d=0.24$) following the SCS intervention, whereas a trivial improvement of 4% was noted following the Sham intervention ($d=0.12$) [refer figure 9, appendix A]. Individually, 6 out of 12 subjects in the SCS group showed a mean change in PPT at the lateral epicondyle meeting the criteria of the $MCID \geq 20\%$. Two showed an increase in PPT following the intervention; the other four a decrease [refer figure 10, appendix A]. In the Sham group 1 out of 11 subjects showed a mean change in PPT at the primary TeP meeting the criteria of the $MCID \geq 20\%$, recording an increase in PPT following the intervention.

When all subjects were considered, three subjects allocated to the SCS intervention group (subjects T3, T4, and T8) and one subject allocated to the Sham intervention group (subject S7) recorded a clinically significant (as defined by the MCID) improvement in both pain intensity and PPT for the primary TeP.

Changes in PFGS levels

As a group (refer figure 5) there was no statistically significant difference in the PFGS after either the SCS intervention ($p=0.936$; $d=0.03$) or the Sham intervention ($p=0.989$; $d=0.01$). With no significant difference recorded after intervention between the groups ($p=0.778$).

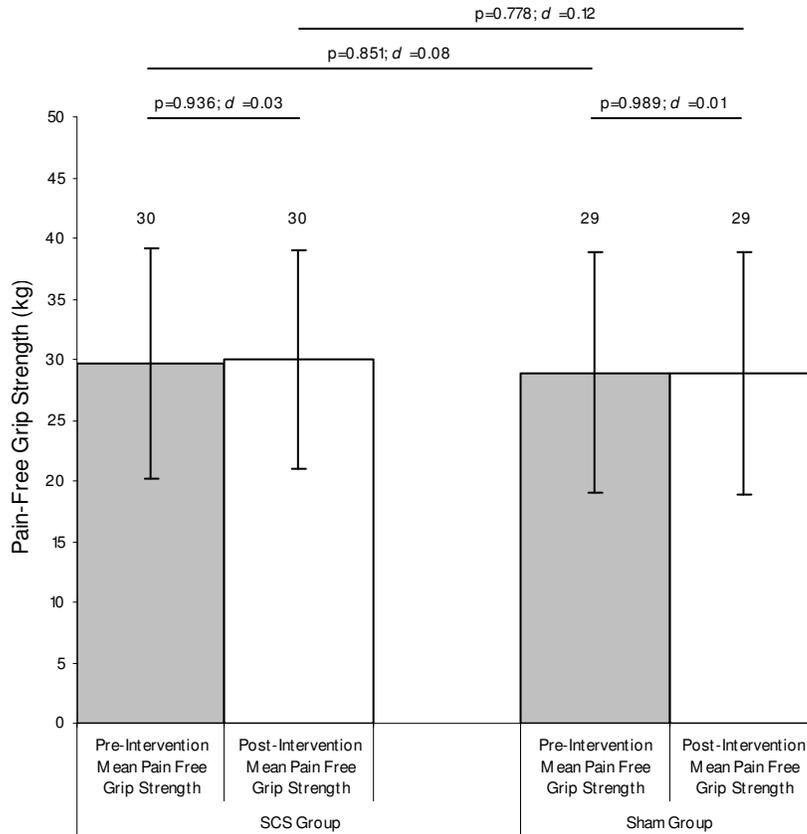


Figure 5 Group Pain Free Grip Strength.

Within group mean scores and the within group effect sizes for both interventions are shown. Neither the SCS nor the Sham group showed any change in PFGS, SCS group ($p=0.936; d=0.03$), and Sham group ($p=0.989; d=0.01$). P values were generated using a two-tailed paired t-test; the effect size (d) was generated by standardized difference in means.³⁴

Reliability

The ICCs, SEM and SDD for the PPT measurements of the primary TeP, and the medial and lateral epicondyles are displayed in table 2. The reliability of the research assistant using the pressure algometer was 'very high'.³⁴

Table 2 Reliability indices

Measure	ICC _{3,1} (LCL-UCL)	SEM	SDD
PPT medial epicondyle (kg/cm ²)	0.841 (0.712-0.923)	0.806	2.2
PPT lateral epicondyle (kg/cm ²)	0.851 (0.730-0.928)	0.886	2.5
PPT Primary TeP (kg/cm ²)	0.839 (0.709-0.922)	0.519	1.4

Notes

PPT = Pressure Pain Threshold

ICC_{3,1} = Intra-class Correlation Coefficient

SEM = Standard Error of Measurement ($SEM = SD \cdot \sqrt{1 - ICC}$)

SDD = Smallest Detectable Difference ($SDD = 1.96 \cdot \sqrt{2} \cdot SEM$)

Table 3 Group and Individual Changes in Context of Smallest Detectable Differences and Minimal Clinically Important Difference

	SDD	SCS Intervention	Sham Intervention
Measure by Group			
PPT medial epicondyle (kg/cm ²)	2.2	0.1 *	-0.1 *
PPT lateral epicondyle (kg/cm ²)	2.5	-0.6 *	0.3 *
PPT Primary TeP (kg/cm ²)	1.4	0.4 *	-0.1 *
Number individuals Surpass SDD from		Improved(Total)	Improved(Total)
PPT medial epicondyle		0	0
PPT lateral epicondyle		1(5)	1(1)
PPT Primary TeP		2(2)	0(1)
Number individuals Surpass MCID from		Improved(Total)	Improved(Total)
PPT medial epicondyle		1(2)	1(1)
PPT lateral epicondyle		2(6)	1(1)
PPT Primary TeP		5(5)	1(2)

Notes

PPT = Pressure Pain Threshold

SDD = Smallest Detectable Difference ($SDD = 1.96 \cdot \sqrt{2} \cdot SEM$)

MCID = Minimal Clinically Important Difference for PPT defined as a difference in means (Pre to Post) $\geq 20\%$

Improved(Total) = number of subjects who show beneficial clinical affect (total number of subjects surpassing either SDD or MCID whether beneficial or not).

* Difference in group means to enable comparison with SDD (post-intervention mean – pre-intervention mean)

No group surpassed the SDD required to indicate a clinically significant change in PPT after either intervention (refer to table 3). All the individual subjects who surpassed the SDD for PPT at either the primary TeP, or medial and lateral epicondyles also surpassed the pre-selected level of 20% for the MCID (by between 5-58%).

DISCUSSION

In this study we measured an immediate decrease in pain intensity (using VAS) for both groups, and an increase in PPT for the SCS group. Effect sizes for the SCS were 'very large' for the change in pain intensity and 'small' for the change in PPT, whereas the effect sizes of the Sham group were 'moderate' for the change in pain intensity and 'trivial' for the change in PPT.

Many previous studies have described the use of SCS in combination with other osteopathic techniques for the treatment of a variety of disorders.^{5, 15, 16, 44, 45} However, only one paper has assessed the immediate effects of SCS on TeP sensitivity.⁶ Meseguer et al.⁶ dealt with a specific muscle, the upper trapezius, in subjects with mechanical neck pain. In the present study, the application of the SCS technique was not to a specific muscle, but rather was to the primary TeP which was found in a variety of locations around the elbow joint between the different symptomatic subjects. The diagnostic TePs in the upper extremity are well suited to experimental investigation since they are readily accessible for PPT measurement. Three outcomes measures were selected as a means of decreasing the likelihood of a single outcome measure giving rise to misleading impressions, as well providing the ability to assess different aspects of the subject's pain experience.⁴⁶

The position adopted for delivery of the SCS intervention concurs with previous descriptions of SCS application where the relevant body segments around the TeP are arranged so as to maximize relaxation and reduce tenderness.^{1, 2} The moderate improvement in pain intensity reported by the subjects in the Sham intervention group may be attributed to the effectiveness of the Sham intervention producing a placebo effect. Well designed Sham interventions in manual therapy should yield only marginal clinical benefits, and should be inactive and nonspecific in comparison to the intervention.⁴⁷ Due to the nonspecific beneficial effects of touch, the change in pain intensity for the Sham group could be attributed to an otherwise unquantified treatment effect. Fernández-de-las-Peñas et al.⁴⁸ reported findings consistent with an earlier review by Hey and Helewa⁴⁹ that no reviewed manual therapy intervention had been more effective than the placebo intervention.

VAS for Pain Intensity

Both SCS and Sham groups surpassed the minimal clinically important difference (MCID) of 30% for change in VAS for pain intensity, suggesting a strong clinical effect. Several studies have reported evidence in support of an MCID for pain intensity (via VAS) as $\geq 30\%$.^{38, 40, 41, 50, 51}

Our results agree with those of Meseguer et al.⁶ who found that SCS was effective in reducing tenderness represented by an increase in pressure pain thresholds of TePs in the upper trapezius muscle of subjects with mechanical neck pain. Our data is also consistent with the findings of Wong & Schauer-Alvarez,⁸ who found that SCS reduced pain intensity in response to manual palpation of TePs in hip musculature.

Changes in PPT levels

The application of SCS is thought to decrease tissue tenderness by altering nociceptor activity in the soft tissues.⁵² An increase in PPT is synonymous with a decrease in tissue sensitivity,^{35, 53, 54} thus the increase in PPT in response to SCS technique provides a measure of the analgesic effect of SCS.^{35, 55} Based on previous literature and our current findings, it appears that SCS techniques have the capacity to provide immediate relief of tenderness and local pain provoked by TePs.

Other authors investigating the effectiveness of manual therapy techniques to increase PPT levels at the elbow have reported improvements ranging from 10% to 20%.^{24, 42, 56} Such findings provide evidence that manual therapy directed to the cervical spine, or to the elbow joint, can both result in analgesic effects at the elbow.

Bailey & Dick⁵² proposed a nociceptive hypothesis that tissue damage in dysfunctional muscles can be reduced by the positional release mechanism utilized by SCS. They suggest that relaxation of the damaged tissues may be achieved by placing patients in a position of ease which may advance local perfusion of fluids (i.e. blood, and lymph) and enhance the removal of sensitizing inflammatory mediators.

Jones et al.⁵⁷ reported a decrease in PPT levels when assessing repeated outcome measurements on the same anatomical locations over successive days. They reported no significant change in PPT levels after repeated pressure algometry measurements on the same anatomical location on the same day.⁵⁷ It is therefore reasonable to conclude that an improvement in PPT demonstrated immediately after an intervention can be attributed to a treatment effect rather than an effect of the testing process.

Changes in PFGS levels

In our study the maximal grip strength, as represented by the pain free grip strength, showed no significant changes between pre- and post- intervention measurement. This could be a reflection of the limited sensitivity of the measuring instrument, or the level of discomfort reported by the subjects before reaching what they felt was a true maximum effort.

Our results concur with the findings of Slater et al.⁵⁸ who were unable to demonstrate an increase in maximal force post treatment in subjects with experimentally induced lateral epicondylgia. Authors of previous studies have been able to demonstrate a clinically important improvement in PFGS after treatment for subjects with lateral epicondylgia.⁵⁹⁻⁶¹

Reliability

The intra-class correlation coefficient (ICC) for our baseline data recorded for both the medial and lateral epicondyles showed good test re-test reliability for our single blinded assessor. The ICCs compare favorably with those described in earlier studies utilizing PPT measurement.^{42, 55, 57, 62}

The smallest detectable difference (SDD) for the lateral and medial epicondyles was similar to that reported by Smidt et al.,³⁶ and the SDD for the primary TeP was higher than the MCID \geq 15% reported by Paungmali et al.⁴² for lateral epicondylgia which may reflect the level of sensitivity associated with our choice of subjects.

All the individual subjects who surpassed the SDD for PPT at either the primary TeP, or medial and lateral epicondyles also surpassed the pre-selected level of MCID. This would suggest that the MCID was at a suitable level for the sensitive tissues around the elbow in subjects with a chronic sports related injury to the upper extremity.

Limitations

This study has several limitations. Only the TePs pertaining to the elbow joint were included for treatment. Interestingly, there has been evidence of beneficial effects in treating the cervical spine in relation to elbow pain.⁶¹ Therefore, further studies are needed to examine the distal effects of SCS interventions when applied to TePs found in the spine.

It was sometimes difficult to accurately apply the algometer to match the angle of the TeP palpated in soft tissues; this was due in part to the shape of the algometer applicator head but was also related to difficulty localizing the algometer to precisely the same point. The increase of pressure for the measurement of PPT was maintained at an approximate rate. The research assistant had received prior training in the application of the algometer at approximately 1kg/cm²/s. Future studies utilizing finger tip flexible pressure meters as described by Marcotte et al.⁶³ may circumvent these problems as: 1) the application of a finger tip sensor allows the assessor a greater degree of sensitivity to accurately locate the pressure sensor, and 2) an electronic device can accurately display the rate of increase in pressure.

There is not yet a strong enough body of evidence to rule out the likelihood the perception of TeP pain can be changing over time for symptomatic subjects. It follows that in order to rule out the negative changes for pressure algometry reported in this study as being due to possible irritation caused by the of the testing process a third group is required. Future studies could include a third group to compare against the sham and SCS intervention groups. This group could act as a control receiving no intervention, so as to quantify the placebo effect attributable to the sham intervention.

The results in this study may have been limited by the choice of outcome measure; the VAS is a valid clinical measure,⁵⁴ but could have become a source of error if the subjects were biased by the ability to remember their previous scores due to the short time period between pre- and post-recording.⁶ Future studies could investigate the longer-term effects of this intervention, so that outcome measurement would occur after greater time periods.

Conclusion

We have demonstrated a significant decrease (54%) in VAS for pain intensity with an associated increase in PPT for the SCS group in our study. The improvement in PPT for the SCS and Sham groups was below the MCID. Our results suggest that SCS was efficacious in reducing tenderness of TePs around the elbow in subjects presenting with mechanical pain related to a sports related injury.

ACKNOWLEDGEMENTS

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Appendix A - Figures

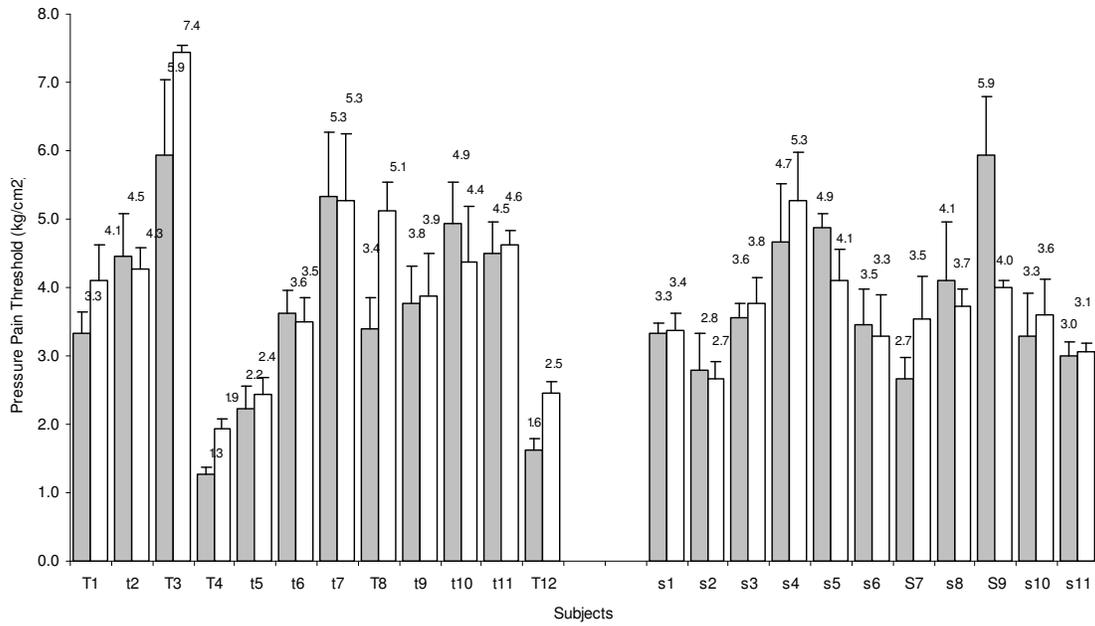


Figure 6 Individual mean PPT for tender point.

Individual mean scores and standard deviations for both interventions are shown. Individuals that met the criteria for MCID \geq 20% change are capitalized. Five subjects in the SCS group showed an individual MCID \geq 20% in PPT for the primary TeP (all in a direction that demonstrated a reduction in objectively assessed pain intensity). Two subjects in the Sham group showed individual MCID \geq 20% in PPT for the primary TeP (one in a direction that demonstrated a reduction in objectively assessed pain intensity, the other showed an objective increase in assessed pain intensity).

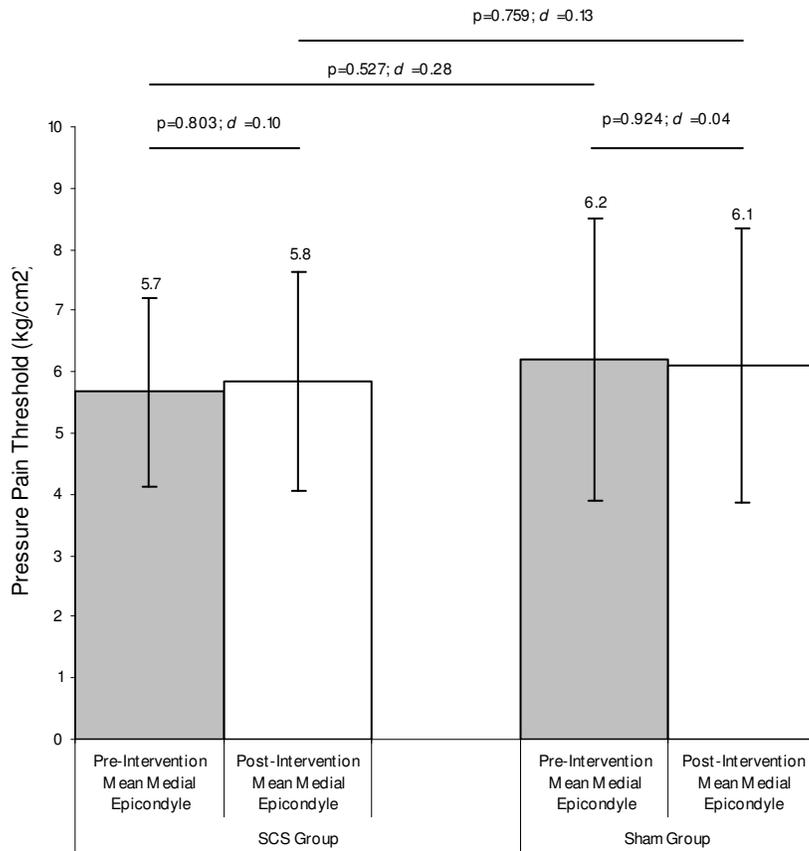


Figure 7 Group Means for Medial Epicondyle PPTs.

Within group mean scores and the within group effect sizes for both interventions are shown. P values were generated using a two-tailed paired t-test, effect size (d) was generated by standardized difference in means.³⁴ On a group level neither group met the criteria for MCID \geq 20% change.

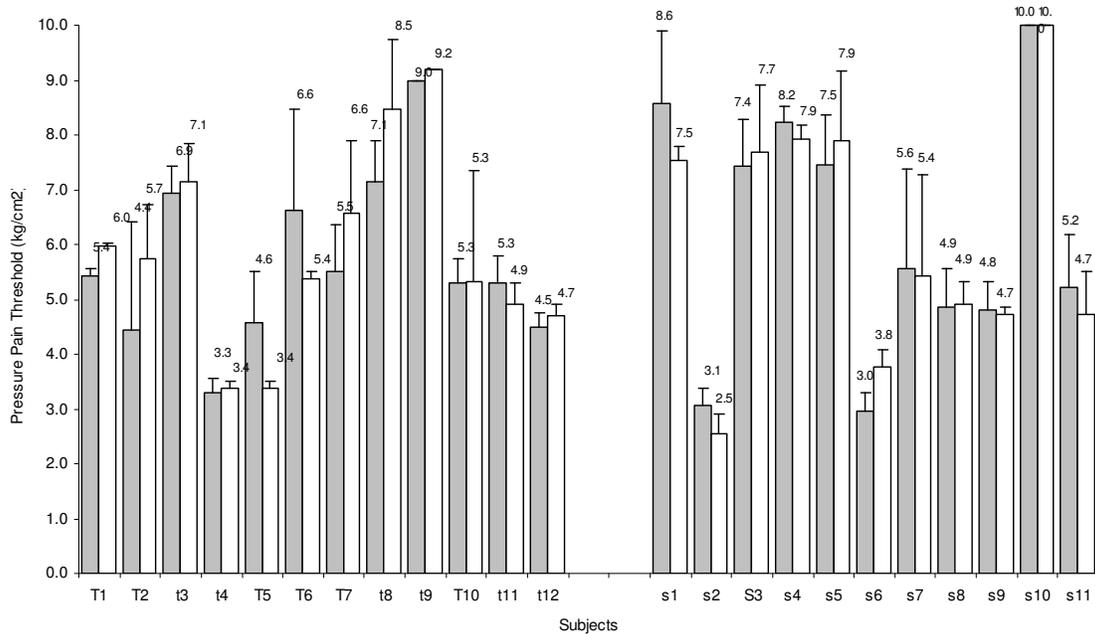


Figure 8 Individual mean PPT for medial epicondyle.

Individual mean scores and standard deviations for both interventions are shown. Individuals that met the criteria for MCID \geq 20% change are capitalized. Two subjects in the SCS group showed an individual MCID \geq 20% in PPT for the medial epicondyle (one in a direction that demonstrated a reduction in objectively assessed pain intensity, the other showed an objective increase in assessed pain intensity). One subject in the Sham group showed individual MCID \geq 20% in PPT for the medial epicondyle (in a direction that demonstrated a reduction in objectively assessed pain intensity).

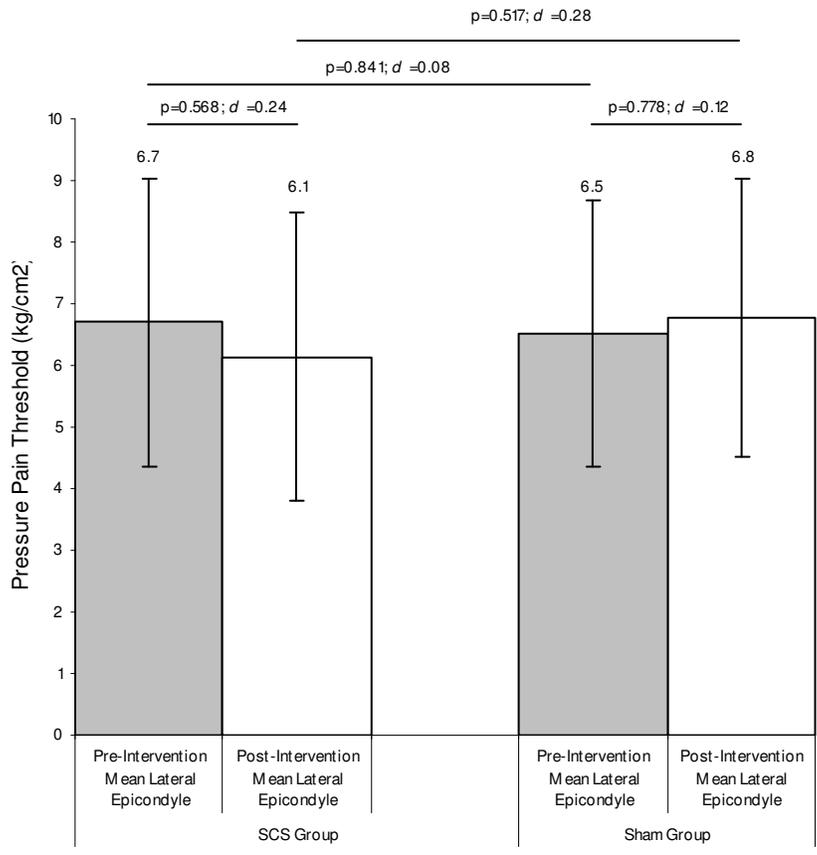


Figure 9 Group Means for Lateral Epicondyle PPTs.

Within group mean scores and the within group effect sizes for both interventions are shown. P values were generated using a two-tailed paired t-test, effect size (d) was generated by standardized difference in means.³⁴ On a group level neither group met the criteria for MCID \geq 20% change.

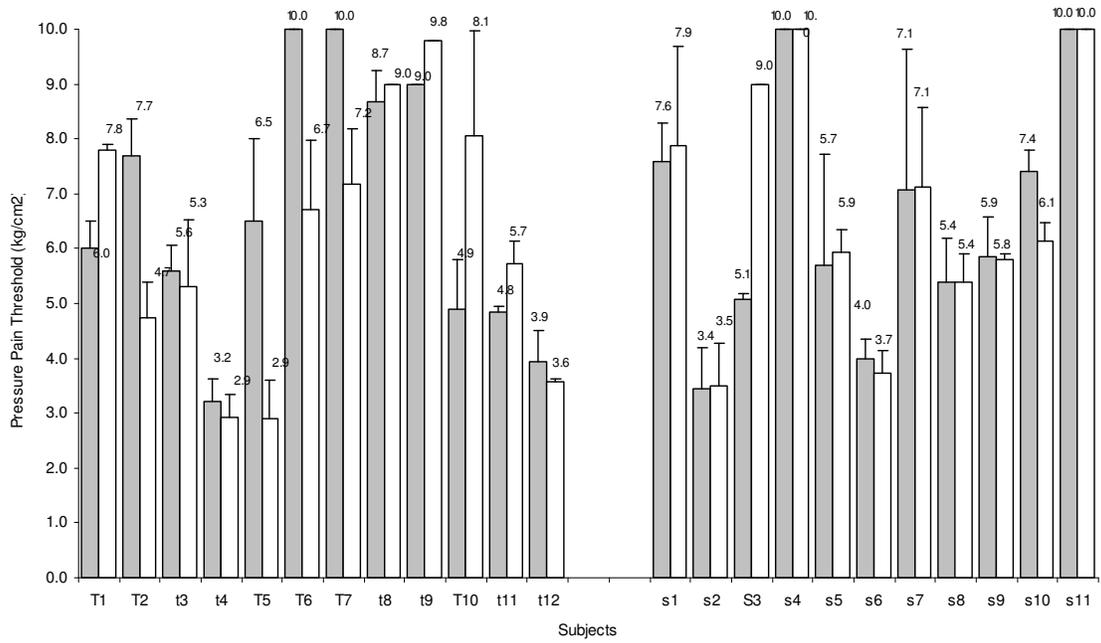


Figure 10 Individual mean PPT for lateral epicondyle.

Individual mean scores and standard deviations for both interventions are shown. Individuals that met the criteria for MCID \geq 20% change are capitalized. Six subjects in the SCS group showed an individual MCID \geq 20% in PPT for the lateral epicondyle (two in a direction that demonstrated a reduction in objectively assessed pain intensity, four showed an objective increase in assessed pain intensity). One subject in the Sham group showed individual MCID \geq 20% in PPT for the lateral epicondyle (in a direction that demonstrated a reduction in objectively assessed pain intensity).

Appendix B - Ethics Resources



An Investigation into the Efficacy of Strain Counterstrain Technique to Produce Hypoalgesic Effects in Symptomatic Subjects

Information Sheet

About the research

You are invited to take part in a research project being undertaken as part of the Masters of Osteopathy Degree. This information sheet is designed to inform you as to the nature of the research and what will happen should you choose to take part.

The purpose of this research is to investigate how well an osteopathic technique called Strain-Counterstrain can reduce pain and improve the functioning of a forearm injury sustained by a recreational sports person. We are recruiting subjects who have sustained such a sports related injury. It is hoped that the information gained from this research will help osteopaths when making technique decisions in the treatment of patients. Strain-Counterstrain is an indirect technique, this means that the patient's arm will be moved by a trained practitioner into a position of comfort, and held in this position for 90 seconds and returned to a rest position. During the Strain-Counterstrain technique the participant is only required to relax.

The researchers

The researcher is James Hutchinson. Dr Carol Horgan and Dr Graham Fordy are supervising the research project.

What will participation involve?

- To currently have a forearm injury sustained while playing some form of recreational sports.
- Read and complete a screening questionnaire on General Health and Musculoskeletal Injuries that may prevent you from receiving a Strain-Counterstrain technique.
- Be available for one data collection session lasting up to 1 ½ hours.
- The research will require you to grip a measurement instrument to test your grip strength before you feel pain. A trained assessor will also apply pressure to an identified tender point on your forearm until you experience discomfort. This testing process will be repeated before and after treatment in order to assess the treatment's effectiveness. Data will be collected from both of your arms for comparison.
- As this is an experimental design research you may be randomly assigned to either a treatment group to receive the Strain-Counterstrain technique or another osteopathic technique. You will not be informed of the type of technique you received until the end of data collection, as the experimental method requires that this information is concealed from you until after treatment and data collection has finished.
- All participants will receive one complementary follow-up treatment session with the principal researcher, one week after data collection or at a later date that suits.
- In order to participate all subjects are required to sign a consent form.
- The research requires a participant to remove any superficial clothing covering the upper body (shirts/blouses etc), from the waist up [NOT underwear].

- For the purpose of data collection three to five anatomical landmarks will be marked with coloured non-permanent (non-toxic) felt tipped pens on various parts of your forearms.
- There will be no sudden movements and your comfort will be monitored. You will be allowed rest breaks, as you require them. You are free to withdraw from the sessions at any point and do not need to state a reason for doing so.
- Consent to the research team's use of the research data in preparing both a research project dissertation and an article for publication (all data will be anonymous).
- Consent to the storage of your anonymous research data indefinitely for future research.

Getting help

Please contact either one of us should you require help with this research project.

James Hutchinson	Email: jamesrhutchinson@gmail.com	Phone: 027 3498919
Dr Carol Horgan	E- mail chorgan@unitec.ac.nz	
Dr Graham Fordy	Email: gfordy@unitec.ac.nz	Phone: (09) 815 4321 ext 7908

Potential risks to research participants

There is no known published data indicating any risks associated with this research. However, the researcher accepts that it is possible there may be some undetermined risks involved in the research process. In the case that any potential risk of harm should arise for any research participant, it will be treated on an individual basis. In any such case the research process will be halted immediately.

Confidentiality

Confidentiality and your anonymity will be protected in the following ways:

- Only the researchers will see completed questionnaires and consent forms.
- All forms will be stored in a locked file. Only the researchers will have access to this file.
- Any data derived from the research will be anonymous and your identity will be kept confidential.

You have the right not to participate, or withdraw from this research project at any time up until the point of data analysis (2 weeks after the last session). Contact James Hutchinson or Dr Carol Horgan that you no longer wish to participate by telephone or email, or by telling us when we contact you.

A copy of the final report will be available at the Unitec New Zealand library. All participants are welcome to view this. Summaries and recommendations may be published in research journals.

Information and concerns

If you want further information about the project, you can call or email the above addresses.

At anytime if you are concerned or confused about the research project you may contact James Hutchinson, the primary researcher on the details above.

If you have concerns about the way in which the research is being conducted you can contact the following:

Health Advocates: Advocates Network Services Trust, Phone (09) 623 5799, 0800 205 555, Fax (09) 623 5798, PO Box 9983, Newmarket, Auckland.

Finally, we would like to thank you for your valuable contribution to this research.

This study has been approved by the Unitec Research Ethics Committee from March 2007 to December 2007. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the Secretary (ph: 09 815-4321 ext 8041). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Screening Questionnaire for General Health and Musculoskeletal Injury History

1. **Are you between the ages of 20 to 70 years old?**
2. **Have you currently or are you receiving treatment for another musculoskeletal disorder that is more “troublesome” than your upper limb pain?**
3. **Have you experienced any neck pain that travels past the tip of your shoulder? Have you experienced any pins & needles or numbness in your arm since the injury?**
4. **Are you currently taking any prescription pain medication or unable to refrain from using any over the counter analgesics?**
5. **Have you been diagnosed, treated and/or medicated for any circulatory, blood or heart conditions in the last 10 years?**
Including any of the following:
Arteriosclerosis/Atherosclerosis
Coronary Artery Disease / Angina / Aneurysm
High Blood Pressure (Hypertension), if controlled by diet leave blank
Pericarditis / Rheumatic Fever
Blood Clots / Deep Vein Thrombosis (exclude single attack)
6. **Have you been diagnosed, treated and/or medicated for any serious digestive conditions in the last 10 years?**
7. **Have you been diagnosed, treated and/or medicated for endocrine, lymphatic or metabolic conditions in the last 10 years?**
Including the long term use of steroids.
8. **Are you currently receiving treatment or have received treatment within the last month for any muscle, skeletal or skin conditions?**
Including any of the following:
Arthritis (chronic or severe osteo- or rheumatoid arthritis includes Ankylosing Spondylitis, Degenerative Disk Disease, and Psoriatic Arthritis; includes conditions that are controlled by aspirin or over-the-counter non-steroidal anti-inflammatory agents)
Bone Disorders (includes Osteoporosis, hip dysplasia, fractures, or bone spurs)
Cartilage/Ligament/Tendon Conditions (includes Chondritis, or Dupuytren’s Contracture (in hands)
Synovitis (which is a joint lining inflammation, includes Tendonitis or Tendinitis;
Tendonitis of Thumb (De Quervain’s Disease)
Surgery
9. **Have you been diagnosed, treated and/or medicated for any non-psychiatric nervous system conditions in the last 10 years?**
Including any of the following:
Carpal Tunnel Syndrome
Thoracic Outlet Syndrome
10. **Have you been diagnosed, treated and/or medicated for any respiratory system conditions in the last 10 years?**



An Investigation into the Efficacy of Strain Counterstrain Technique to Produce Hypoalgesic Effects in Symptomatic Subjects

Consent Form

This research project investigates the efficacy of strain counterstrain technique to improve function and pain-free status of the forearm in a symptomatic population. The research is being undertaken by James Hutchinson from Unitec New Zealand, and will be supervised by Dr Carol Horgan and Robert Moran.

Name of Participant:.....

I have seen the Information Sheet dated October 2006 for people wishing to participate in the project investigating the efficacy of Strain Counterstrain technique to produce hypoalgesia in symptomatic subjects.

I have had the opportunity to read the contents of the information sheet and to discuss the project with the researchers and I am satisfied with the explanations I have been given.

I understand that taking part in this project is voluntary (my choice) and that I may withdraw up until the point at which data analysis is started and this will in no way affect my access to the services provided by Unitec New Zealand or any other support service.

I understand that I can withdraw from the experiment if, for any reason, I want this.

I understand that my participation in this project is confidential and that no material that could identify me will be used in any reports on this project.

I have had enough time to consider whether I want to take part.

I know whom to contact if I have any questions or concerns about the project

The principal researcher and first contact for this project is:
James Hutchinson
027 349 8919
mailto:jamesrhutchinson@gmail.com

Signature.....participant (Date)

Project explained by.....

Signature..... (Date)

The participant should retain a copy of this consent form.

This study has been approved by the Unitec Research Ethics Committee from March 2007 to December 2007. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the Secretary (ph: 09 815-4321 ext 8041). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Do you have a sports related injury?

Contact: James Hutchinson (Principal Researcher) on 027 3498919

You are invited to participate in a research project investigating how well an osteopathic technique called Strain-Counterstrain can reduce pain and improve the functioning of a forearm injury sustained by a recreational sports person. The research project is being undertaken as part of the Masters of Osteopathy Degree, Unitec, Auckland.

All eligible candidates will receive a free follow-up treatment after participating in the research project.

For further information about your eligibility to participate and the project please contact James Hutchinson.

Contact: James Hutchinson (Principal Researcher) on 027 3498919

Email:
jameshutchinson@gmail.com

Phone: 027 3498919

This study has been approved by the Unitec Research Ethics Committee from October 2006 to December 2007. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the Secretary (ph: 09 815-4321 ext #041).



Two free treatments for all accepted participants.

Appendix C – Instructions for authors for manuscript submission

INTERNATIONAL JOURNAL OF OSTEOPATHIC MEDICINE

Former title: Journal of Osteopathic Medicine

Guide for Authors

The journal Editors welcome contributions for publication from the following categories: Letters to the Editor, Reviews and Original Articles, Commentaries and Clinical Practice case studies with educational value.

Online Submission

Submission to this journal proceeds totally online. (☞ <http://ees.elsevier.com/ijom>) you will be guided stepwise through the creation and uploading of the various files. The system automatically converts source files to a single Adobe Acrobat PDF version of the article, which is used in the peer-review process. Please note that even though manuscript source files are converted to PDF at submission for the review process, these source files are needed for further processing after acceptance. All correspondence, including notification of the Editor's decision and requests for revision, takes place by e-mail and via the Author's homepage, removing the need for a hard-copy paper trail.

The above represents a very brief outline of this form of submission. It can be advantageous to print this "Guide for Authors" section from the site for reference in the subsequent stages of article preparation.

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, without the written consent of the Publisher.

Types of contributions

Letters to the Editor As is common in biomedical journals the editorial board welcomes critical response to any aspect of the journal. In particular, letters that point out deficiencies and that add to, or further clarify points made in a recently published work, are welcomed. The Editorial Board reserves the right to offer authors of papers the right of rebuttal, which may be published alongside the letter.

Reviews and Original Articles These should be either i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works. The report will normally be divided into the following sections: abstract, introduction, materials and methods, results, discussion, conclusion, references. Or ii) critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.

Short review The drawing together of present knowledge in a subject area, in order to provide a background for the reader not currently versed in the literature of a particular topic. Shorter in length than and not intended to be as comprehensive as that of the literature review paper. With more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

Research Note Findings of interest arising from a larger study but not the primary aim of the research endeavour, for example short experiments aimed at establishing the reliability of new equipment used in the primary experiment or other incidental findings of interest, arising from, but not the topic of the primary research. Including further clarification of an experimental protocol after addition of further controls, or statistical reassessment of raw data.

Preliminary Findings Presentation of results from pilot studies which may establish a solid basis for further investigations. Format similar to original research report but with more emphasis in discussion of future studies and hypotheses arising from pilot study.

Commentaries Include articles that do not fit into the above criteria as original research. Includes commentary and essays especially in regards to history, philosophy, professional, educational, clinical, ethical, political and legal aspects of osteopathic medicine.

Clinical Practice Authors are encouraged to submit papers in one of the following formats: Case Report, Case Problem, and Evidence in Practice.

Case Reports usually document the management of one patient, with an emphasis on presentations that are unusual, rare or where there was an unexpected response to treatment eg. an unexpected side effect or adverse reaction. Authors may also wish to present a case series where multiple occurrences of a similar phenomenon are documented. Preference will be given to reports that are prospective in their planning and utilise Single System Designs, including objective measures.

The aim of the Case Problem is to provide a more thorough discussion of the differential diagnosis of a clinical problem. The emphasis is on the clinical reasoning and logic employed in the diagnostic process.

The purpose of the Evidence in Practice report is to provide an account of the application of the recognised Evidence Based Medicine process to a real clinical problem. The paper should be written with reference to each of the following five steps: 1. Developing an answerable clinical question. 2. The processes employed in searching the literature for evidence. 3. The appraisal of evidence for usefulness and applicability. 4. Integrating the critical appraisal with existing clinical expertise and with the patient's unique biology, values, and circumstances. 5. Reflect on the process (steps 1-4), evaluating effectiveness, and identifying deficiencies.

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Your article should be typed on A4 paper, double-spaced with margins of at least 3cm. Number all pages consecutively beginning with the title page.

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Both qualitative and quantitative research approaches should be accompanied by a structured abstract. Commentaries and Essays may continue to use text based abstracts of no more than 150 words. All original articles should include the following headings in the abstract as appropriate: *Background, Objective, Design, Setting, Methods, Subjects, Results, and Conclusions*. As an absolute minimum: *Objectives, Methods, Results, and Conclusions* must be provided for all original articles. Abstracts for reviews of the literature (in particular systematic reviews and meta-analysis) should include the following headings as appropriate: *Objectives, Data Sources, Study Selection, Data Extraction, Data Synthesis, Conclusions*. Abstracts for Case Studies should include the following headings as appropriate: *Background, Objectives, Clinical Features, Intervention and Outcomes, Conclusions*.

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The text of observational and experimental articles is usually, but not necessarily, divided into sections with the headings; introduction, methods, results, results and discussion. In longer articles, headings should be used only to enhance the readability. Three categories of headings should be used:

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Responsibility for the accuracy of bibliographic citations lies entirely with the Authors.

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Examples:

Reference to a journal publication:

1. Van der Geer J, Hanraads JAJ, Lupton RA. The art of writing a scientific article. *J Sci Commun* 2000;**163**:51-9.

Reference to a book:

2. Strunk Jr W, White EB. *The elements of style*. 3rd ed. New York: Macmillan; 1979.

Reference to a chapter in an edited book:

3. Mettam GR, Adams LB. How to prepare an electronic version of your article. In: Jones BS, Smith RZ, editors. *Introduction to the electronic age*. New York: E-Publishing Inc; 1999, p. 281-304

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Present results in logical sequence in the text, tables and illustrations. Do not repeat in the text all the data in the tables or illustrations. Emphasise or summarise only important observations.

Discussion

Emphasise the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the introduction or the results section. Include implications of the findings and their limitations, include implications for future research. Relate the observations to other relevant studies. Link the conclusion with the goals of the study, but avoid unqualified statements and conclusions not completely supported by your data. State new hypothesis when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

Acknowledgments

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