Declaration

Name of candidate: Gail Hanson

This Research Project is submitted in partial fulfilment 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 Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by said Committee.

Approval Reference Number: 2008.850

Candidate Signature: ............................................Date: 19 December 2013

(Gail Hanson)

Student number: 1187686
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The effectiveness of the ‘Bruce Jones sacroiliac technique’ in treatment of people with chronic low back pain: A single cohort design

Gail Hanson

A research project submitted in partial fulfilment for the requirements for the degree of Master of Osteopathy at Unitec 2013
# Section 1: Literature Review

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Section 2: Manuscript

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Overview

This thesis is organised in three sections. Section 1 reviews the literature, with an emphasis on the prevalence of chronic low back pain and economic burden to society. The first aim of the literature review was to investigate current treatment and management of chronic low back pain including pharmacological, surgical and manual therapy options. The literature review then focuses on the sacroiliac joint as a source of chronic low back pain. The controversy around the sacroiliac joint as a pain generator and current treatment of sacroiliac pain will conclude the literature review. A description of the Bruce Jones sacroiliac joint technique (BJS) will be given at the end of this part. The low back pain research has been reviewed using the PEDro system for critical evaluation of scientific articles.

Section 2 reports a single cohort study investigating the effects of BJS technique on people with chronic low back pain including preliminary results. This section is structured as a manuscript in the format specified for submission to the International Journal of Osteopathic Medicine (IJOM). The intent is for this to be included in the IJOM Clinical Practice section and the Guidelines for Authors are included in the thesis appendix.

Section 3 contains appendices that include ethics approval notification, participant information sheet, screening questions, consent form, questionnaires, medical history form and the guidelines for authors to the International Journal of Osteopathic Medicine.
Section 1: Literature Review
1. Introduction to Part 1

Low back pain (LBP) is a major health and significant economic burden in Western society (Walker, Muller, & Grant, 2003). LBP is multi-factorial in presentation and is typically associated with activity limitations for people experiencing it, but also has broader impacts such as carer burden, use of health-care resources and financial encumbrance (Hoy, March, Brooks, Woolf, Blyth, Vos, & Buchbinder, 2010b). LBP has a multitude of causes and precipitating factors (Janwantanakul, Sitthipornvorakul, & Paksaichol, 2012) and one anatomical source from which pain may be generated is the sacroiliac joint (SIJ).

Therapeutic interventions used for SIJ pain include intra-articular SIJ injections, and radiofrequency neurotomy, although there is limited evidence of short and long-term relief with these treatments (Hansen, McKenzie-Brown, Cohen, Swicegood, Colson, & Manchikanti, 2007). Manual therapy treatments for the SIJ are poorly researched and little is known about the effects these treatments (Oldreive, 2000). This literature review initially discusses the prevalence, cost and treatment of chronic LBP, and then focuses on sacroiliac pain and current manual therapy used to treat SIJ dysfunction.

1.1. Definition of Chronic LBP

Chronic LBP is defined by the International Association for the Study of Pain (IASP) as LBP lasting longer than three months. However, for research purposes six months duration is preferred when used as a research study inclusion criterion (Malliou, Gioftsidou, Beneka, & Godolias, 2006). Acute LBP is pain experienced for less than three months (Bogduk, 1999) and subacute is pain lasting longer than six weeks but less than three months (M. W. van Tulder, Koes, Bouter, & Metsemakers, 1997).
1.2. Prevalence and Economic cost of LBP

The estimated point prevalence of LBP appears to be variable in different countries, reported as 6.8% in North America, 14% in the United Kingdom, 28.4% in Canada and 17.5% in New Zealand (Kent & Keating, 2005; Laslett, Crothers, Beattie, Cregten, & Moses, 1991). These apparent geographical differences in LBP prevalence are probably best explained by methodological difficulties in obtaining true population estimates and methodological heterogeneity across studies (Hoy, Bain, Williams, March, Brooks, Blyth, Woolf, Vos, & Buchbinder, 2012; Hoy, Brooks, Blyth, & Buchbinder, 2010a). The lifetime prevalence of LBP is reported as over 70% in industrialised countries, one-year prevalence is 15% to 45% and as Kent and Keating (2005) and M. van Tulder, Becker, Bekkering, Breen, del Real, Hutchinson, Koes, Laerum, and Malmivaara (2006) state peak prevalence occurs between ages 35 and 55 years. World prevalence data reviewed by Volinn (1997) suggested that the rates of prevalence were 2 — 4 times higher in developed countries than in developing countries but the review did not determine whether the differences reflected demographic, cultural or research methodological factors.

Prevalence studies of LBP in New Zealand are scarce but a cross sectional study (Coggan, Norton, Roberts, & Hope, 1994) investigating the prevalence of back pain related to nursing showed similar percentages to the international data. Specifically the New Zealand nursing study found that the lifetime prevalence was 62%, with an annual and point prevalence of 37% (Coggan et al., 1994). Certain industries appear to be more susceptible to LBP and one New Zealand study found that the farming industry, a major contributor to New Zealand’s economy, has the fourth highest LBP claim rate and the lifetime prevalence is 90%, with over half (54.6%) having suffered a LBP episode in the last 12 months (Firth, Herbison, McBride, & Feyer, 2002).
1.2.1. **Direct Costs**

Direct costs related to LBP are for general practitioner (GP) visits and capitation subsidies, therapy treatment costs, medications, medical imaging, surgery and work-related compensation. In the United Kingdom direct LBP healthcare yearly costs (NZD) are $307 per capita (Waddell, 1996) and in the United States it is estimated the economic burden is $48 – $359 per capita (Dagenais, Caro, & Haldeman, 2008). A systematic review of LBP cost of illness studies in the United States and internationally provided a breakdown of direct costs with the largest proportion of direct medical costs for LBP being spent on physical therapy (17%), inpatient services (17%), followed by pharmacy (13%) and primary care (13%) (Dagenais et al., 2008). Specific statistics relevant to LBP costs in New Zealand are not routinely collected within the health sector (Bossley C J, 2009), but it has been estimated that the annual economic cost of LBP is $349 per capita (National Health Committee, 2007), although this data is likely to have increased since 2007 due to inflationary pressures.

1.2.2. **Indirect Costs**

Among studies providing additional estimates of total costs, the indirect cost resulting from lost work productivity represented a majority of the overall costs associated with LBP (Dagenais et al., 2008; How-Ran, Tanaka, Halperin, & Cameron, 1999). The economic burden of LBP is mainly in the large number of work days lost by the percentage of patients who develop chronic LBP (Maetzel & Li, 2002). In the United Kingdom 116 million work days, 2 days per capita per year, were lost due to back pain (Maniadakis & Gray, 2000) and in the United States 101.8 million work days, 0.5 days per capita per year, were lost (How-Ran et al., 1999).

Data for work days lost are not available for New Zealand. However, data for the number of Accident Compensation Corporation (ACC) claims reported for 2005-2006 shows 10,006 new claims costing (NZD) $39 million and 5702 ongoing claims costing $119 million (ACC, 2006). These statistics include some funding of direct treatment costs as well as income compensation and do not account for LBP that is
not accident-related, as treatment of non-injury related back pain is not covered by ACC, and therefore the true cost of LBP is underestimated in New Zealand. Globally, the cost of LBP treatment and income compensation make treatment and management of LBP a priority for government health agencies and insurance companies, and also makes it one of the major health issues in the developed world (Deyo, Cherkin, Conrad, & Volinn, 1991; Maetzel & Li, 2002; Maniadakis & Gray, 2000).

1.3. Anatomical Sources of LBP

LBP can arise from the lumbar or sacral spine or a combination of both. Each area has defined topographical borders but pain can radiate from these areas to elsewhere (Bogduk, 2001). There are a number of anatomical structures that LBP may arise from, including intervertebral discs, ligaments, muscles, bones and joints (Hoy et al., 2010a). Bogduk (2001) postulates that for a structure to cause back pain it must satisfy several criteria: structure must be innervated, be susceptible to injury or disease, and clinically the structure must be shown to be a source of pain using reliable and valid diagnostic techniques. According to Murtagh (2007) the ‘probability diagnosis’ (a reflection of prevalence) for LBP in general medical practice is vertebral dysfunction especially facet joint and disc, musculo-ligamentous strain and spondylosis in that order of prevalence. One area that is an accepted source of LBP and meets Bogduk’s criteria is the SIJ. Although treatment of this area is relatively poorly researched, it has been reported that 10 – 27% of LBP relates to this area (McKenzie-Brown, Shah, Sehgal, & Everett, 2005; Rupert, Lee, Manchikanti, Datta, & Cohen, 2009).

Hansen et al. (2007) describes the SIJ as a diarthrodial synovial joint with abundant innervations which therefore has the capability of being a source of LBP. It is variously described as receiving innervations from the ventral rami of L4 and L5, the superior gluteal nerve, and the dorsal rami of L5, S1, and S2, or that it is almost exclusively derived from the sacral dorsal rami (Forst, Wheeler, Fortin, & Vilensky, 2006).
The SIJ is made up of the sacrum sitting at the base of spine and the two innominate bones on each side which form the joint and is strategically placed in the pelvic ring at the site of maximum torsional stress (DiGiovanna & Schiowitz, 1997). This enables forces to be transmitted from the vertebral column laterally into the pelvis and thence into the lower limbs. Conversely, forces from the lower limbs can be transmitted through the pelvis to the sacrum and then to the vertebral column (Bogduk, 2001).

There is debate as to the functional significance of the sacroiliac joint as its ranges of movement are small compared to other joints of the axial skeleton, and it does not have muscles that directly execute active movements on the joint (Bogduk, 2001; McGrath, 2004). However, it does move passively and this is illustrated in the mechanics of walking. When one leg moves back, the pelvis on that side tends to ‘twist’ forwards, and tension in the iliofemoral ligament draws the anterior ilium downwards. On the contra lateral side, the pelvic half of the forward moving leg twists backwards with tension in the hamstring muscle group drawing the pelvis downwards and forwards. This alternating flexion and extension of the lower limbs conveys twisting forces on the pelvis around its transverse axis. The SIJ being the most mobile joint of the bony pelvis means that it acts as ‘stress relieving’ joint buffering these twisting forces, a characteristic that may increase susceptibility to injury (Bogduk, 2001).

1.4. **Chronic LBP Treatment**

The most common nonsurgical treatment for chronic LBP is pharmacotherapy (Chou, 2010; Keller, Hayden, Bombardier, & Van Tulder, 2007). The primary drugs used for to alleviate back pain are analgesics, non-steroidal anti-inflammatory drugs (NSAID’s), muscle relaxants and antidepressants. A pharmacotherapy systematic review found that chronic LBP symptoms were more effectively reduced by a combination of NSAID’s and antidepressants as opposed to studies where these drugs were taken individually (Schnitzer, Ferraro, Hunsche, & Kong, 2004).
Other pharmacotherapy interventions for example, drug injection therapy have limited efficacy for treating chronic LBP (Nelemans, deBie, deVet, & Sturmans, 2001), but have been shown to be beneficial for short-term relief of chronic LBP (Shen, Samartzis, & Andersson, 2006) but limited for long term relief (Conn, Buenaventura, Datta, Abdi, & Diwan, 2009). Effectiveness of trigger point and sacroiliac injections for management of chronic LBP have not been substantiated by research (Shen et al., 2006).

When LBP is not effectively managed with pharmacotherapy and physical and manual therapies, surgery may be considered if an appropriate surgical lesion can be identified. Surgical interventions for chronic LBP are generally of two types: fusion, or the more recent total disc replacement. Jacobs, Van der Gaag, Tuschel, de Kleuver, Peul, Verbout, and Oner (2012) recent systematic review found that disc replacement showed slightly greater improvement in pain and disability compared to fusion, but was not statistically different. The possible long term advantages of total disc replacement are that lumbar mobility is preserved in contrast to spinal fusion and it also may prevent degeneration of adjacent lumbar segments, although computer models show that it may place increase loading on adjacent facets (Chen, Zhong, Chen, Chen, & Hung, 2009; Zander, Rohlmann, & Bergmann, 2009). Surgery is generally considered as a last resort due to its invasive nature and the financial costs associated with it.

1.5. Manual Therapy for Chronic LBP

One common treatment method for chronic LBP is manual and manipulative therapy and this is predominantly provided by osteopaths, chiropractors and physiotherapists (Kent, Mjosund, & Petersen, 2010; Ong, Doll, Bodeker, & Stewart-Brown, 2004). The effect of manual therapy interventions have been well researched, particularly spinal manipulative therapy. Spinal manipulation is a passive technique during which a practitioner applies a manual impulse to a joint near the end of passive range of motion (Triano, 2001). Cochrane searches for systematic reviews of manual therapy treatment for chronic LBP identified only one systematic review which evaluated
spinal manipulative therapy (Rubinstein, Van Middelkoop, Assendelft, De Boer, & Van Tulder, 2011). The review initially concludes that spinal manipulative therapy (SMT) has a statistically significant short-term effect on pain relief and functional status compared to other interventions. However, after considering the risk of bias, blinding to sham treatments and clinical important differences, the authors conclude that SMT only produces small clinical benefits that are equivalent to those of other commonly used therapies such as acupuncture and massage therapy.

Five studies from the Rubinstein et al. (2011) review examined the effectiveness of manual treatment on pain and disability including short-, intermediate- and long-term outcomes for adults with chronic LBP. In the review presented here, these studies have been assessed further with regards to design, back pain duration, therapy used and outcome measures (Hemmilä, Keinänen-Kiukaanniemi, Levoska, & Puska, 2002; Hondras, Long, Cao, Rowell, & Meeker, 2009; Hsieh, Adams, Tobis, Hong, Danielson, Platt, Hoehler, Reinsch, & Rubel, 2002; Skillgate, Bohman, Holm, Vingård, & Alfredsson, 2010; UKBeam, 2004).

In the following section, these five studies have been evaluated using the Physiotherapy Evidence Database (PEDro) methodology (Sherrington, Herbert, Maher, & Moseley, 2000). Although, the PEDro system is a validated tool for evaluating research quality, the scoring scale and weighting allocated to some of the assessment criteria has been questioned (Bhogal, Teasell, Foley, & Speechley, 2005; Colle, Rannou, Revel, Fermanian, & Poiraudeau, 2002; de Morton, 2009) so for this review the evaluation methodology was used but not the scoring scale. Detailed information from the PEDro analysis is shown in Table 2.

### 1.5.1. Hondras et al (2009)

Hondras et al. (2009) study randomly assigning 240 participants aged 55 years and older with subacute or chronic LBP to one of three treatment groups in a 2:2:1 ratio. The three treatment groups were high velocity low amplitude spinal manipulation (HVLA-SM), low velocity variable amplitude spinal mobilisation (LVVA-SM) and minimal conservative medical care (MCMC). All groups received exercise instruction
to be performed at home from week three.

The primary outcome variable was LBP-related disability measured by a 24-item Roland Morris Disability (RMD) questionnaire at weeks 3, 6, 12, 24. The RMD is a valid and sensitive measure of disability and is widely used in clinical trials for LBP (Kovacs, Abraira, Royuela, Corcoll, Alegre, Cano, Muriel, Zamora, Gil Del Real, Gestoso, & Mufraggi, 2007). Secondary outcome measures were Fear Avoidance Beliefs Questionnaire (FABQ), physical function subscale of the SF36, Visual Analogue Scale (VAS) for pain intensity, with the last two variables measured only at weeks 3 and 6 then global improvement was assessed using a verbal rating scale (VRS) was used at weeks 12 and 24.

The inclusion criteria of pain experienced for at least four weeks does not meet the International Association of Pain (IAP) definition of chronic pain, which is, LBP of at least 3 months duration. Therefore, the RMQ scores from baseline to end for the LVVA group of 2.9 points (95% Confidence Intervals (CI): 2.2, 3.6) and HVLA group of 2.7 points (95% CI: 2.0, 3.3) that are attributed to the therapy could actually be related to the natural course of back pain. The study does have a 24-week follow-up period which does help assuage this potential problem of using decreased back pain criteria for inclusion. There was also a mean change of 1.6 points (95% CI: 0.5, 2.8) for the non-intervention MCMC group but was not statistically significant or clinically important as the MCID for RMQ is a two point decrease.

Exercises were prescribed to all groups at week 3 but it was unclear if the patients maintained records of how often they performed the exercises and if these data were collated and analysed by the researchers. It is unclear from this study if the exercise component had to be performed concurrently with the manual therapy for the treatment to be beneficial to patients. It was also unclear as to why outcome variables changed at week 12 which may leave readers drawing unjust conclusions.

Although the sample size was reasonable (n=200) the age range (≥55y) could be a limiting factor in the applicability of the therapy to the general population. In summary this study supports manipulation in its different forms as a useful treatment for older patients with LBP.
1.5.2. *Hsieh et al. (2002)*

This study investigated the effectiveness of three manual treatments and back school for patients with subacute LBP, defined as pain longer than two weeks and less than six months. The research question was whether combined joint manipulation and myofascial therapy was more effective than joint manipulation or myofascial therapy alone and secondly, whether specific manual procedures more effective than the back school program. The study was a randomised clinical trial performed at two locations with a total of 200 participants for all sites. Outcome variables were measured by blinded assessors and performed 1-2 days before treatment started, after 3 weeks of care and after 6 months of care. The outcome variables were:

*Primary Outcome Variables*

- Roland-Morris activity scale for LBP
- Visual Analog Scale (VAS) for pain

*Secondary Outcome Variables*

- MOS 36-Item Short-Form Health Survey
- Confidence and Satisfaction Score

Five monthly phone assessments were also performed by blinded assessors and they included the following variables:

- Roland-Morris activity (primary efficacy value)
- Current pain level (0-10) (primary efficacy value)
- Work or school days lost
- Use of health care services

All four groups showed significant reductions in pain and activity scores after 3 weeks of care, but no further significant changes at the 6 month follow-up, shown in
Individual contrasts showed a significant difference between the combined myofascial and joint manipulation treatment group and myofascial therapy group at 3 weeks for both VAS and RMAS but Tukey post hoc tests which adjust for multiple comparisons showed no significant effects. Analyses of the monthly phone follow-up assessments found statistically significant differences in activity scores between the combined group and myofascial group. The secondary outcome variables produced scattered non-significant statistical effects.

**Table 1**: VAS and RMAS Mean Scores (SD) at baseline, three weeks and six month follow-up, redrawn using results from (Hsieh et al., 2002)

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Combined Group</th>
<th>n</th>
<th>Joint Manipulation</th>
<th>n</th>
<th>Myofascial Therapy</th>
<th>n</th>
<th>Back School</th>
</tr>
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<tr>
<td><strong>VAS (cm)</strong></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>Baseline</td>
<td>52</td>
<td>3.75 (2.18)</td>
<td>48</td>
<td>3.66 (1.90)</td>
<td>51</td>
<td>4.05 (2.15)</td>
<td>48</td>
<td>4.14 (2.10)</td>
</tr>
<tr>
<td>3 weeks</td>
<td>48</td>
<td>2.04 (1.35)</td>
<td>45</td>
<td>2.58 (1.93)</td>
<td>49</td>
<td>2.78 (1.82)</td>
<td>42</td>
<td>2.13 (1.28)</td>
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<tr>
<td>6 months</td>
<td>49</td>
<td>2.24 (2.01)</td>
<td>40</td>
<td>2.40 (2.41)</td>
<td>47</td>
<td>2.99 (2.28)</td>
<td>42</td>
<td>2.29 (1.98)</td>
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<tr>
<td><strong>RMAS</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>52</td>
<td>7.62 (4.58)</td>
<td>48</td>
<td>8.40 (5.16)</td>
<td>49</td>
<td>8.35 (4.57)</td>
<td>48</td>
<td>7.92 (4.15)</td>
</tr>
<tr>
<td>3 weeks</td>
<td>48</td>
<td>3.73 (3.76)</td>
<td>45</td>
<td>4.42 (4.92)</td>
<td>49</td>
<td>5.80 (5.12)</td>
<td>42</td>
<td>4.26 (3.52)</td>
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<tr>
<td>6 months</td>
<td>48</td>
<td>3.56 (3.46)</td>
<td>41</td>
<td>3.29 (4.73)</td>
<td>47</td>
<td>5.06 (4.78)</td>
<td>42</td>
<td>3.48 (3.86)</td>
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Although the myofascial group had a list of muscles (sites) that would be treated as part of the trial, clinicians were also allowed to treat additional body sites if they deemed it necessary. The allowing of treating additional sites makes it difficult for the myofascial treatment to be replicated and applied to others. In contrast the manual therapy groups followed a “prescribed procedure” and the practitioners were not permitted to give their patients additional advice. Both these factors cause issues, the lack of standardisation makes it difficult to replicate a study whereas a strict standardisation compromises generalisation to population group.

The key finding was similar effective outcomes in all four groups but the ability of these treatments being applied globally to a chronic and acute back pain population cannot be determined and would require further research.
1.5.3. **Skillgate et al. (2010)**

Skillgate et al. (2010) carried out a pragmatic randomised control trial investigating the long-term effects of naprapathic manual therapy on non-specific back and neck pain. Naprapathic therapy is a combination of manual techniques such as massage, muscle stretching, and spinal manipulation. Patients were recruited (n=409) and randomly allocated to two groups; the first group (index group) were treated with a combination of naprapathic, massage, stretching, spinal manipulation, naprapathic manual techniques and when required, preventive and rehabilitative advice for applicable physical activities and ergonomics. Patients were given a maximum of six treatments over a six-week period. The second group (control group) were given advice on staying active and on pain coping strategies (Skillgate et al., 2010). Outcome measures were:

**Primary outcome measures**
- Pain and disability were assessed using the Chronic Pain Questionnaire (CPQ)
- Back and neck disability were determined using a modified Whiplash Disability Questionnaire (WDQ)

**Secondary outcome measures**
- Health status was evaluated by a Medical Outcomes Study Short Form-36 Health Survey (SF-36)

Inclusion criteria were unclear, the authors describe a self-administered questionnaire that potential participants completed but failed to give any details and this would make replicating the study difficult. The statistical analysis was performed by an independent statistician and the initial results state that the naprapathic treatment showed significant improvement in pain and disability.

It is only when back pain results are isolated from the neck pain results and then analysed in comparison to the control group that naprapathic treatment is shown not
to significantly improve back pain, 95% CI and mean changes from baseline were
0.1 ((-0.6)-0.8), $p = 0.712$ and disability 0.5 ((-0.4)-1.4), $p = 0.282$. The SF-36 results
showed improvement in only 2 of the 5 quality of life subscales, bodily pain, $p =
0.045$ and social function, $p = 0.018$. One secondary finding of note is that the
number of dropouts were similar between groups, (control =12, index= 10) but the
control group had a much higher incidence of dissatisfaction (10 versus 1) which can
negatively influence pain perception.

The above Skillgate et al. (2010) study provided a long term follow-up with a large
participation rate for the duration of the study but the naprapathic treatment for the
LBP subjects did not prove to be more effective than the control group.

1.5.4. UKBeam (2004)

The United Kingdom back pain exercise and manipulation (UK BEAM) pragmatic
randomised control trial was one of the largest undertaken including osteopaths
(Vogel, Dear, & Evans, 2005) with over 1334 participants and follow-ups at 3 and 12
months. This study investigated the effects of six treatments: general practice care,
exercise, spinal manipulation, a combination of manipulate and exercise with the last
two groups being further sub-divided between two sites of delivery, NHS premises or
private practices.

Baseline data was captured as part of the eligibility questionnaire at least four weeks
prior to randomisation. Minimum treatment was defined an initial assessment, at
least two manipulation sessions and for the exercise groups at least one class.
Practitioners were given a package of techniques that could be used to perform
spinal manipulations.

Main outcome measures

- Roland disability questionnaire (RDQ)
- Modified Von Korff scale (MVK)
Secondary outcome measures

- Back belief questionnaire (BBQ)
- Fear avoidance beliefs questionnaire (FABQ)
- SF-36

Both the manipulation and exercise groups showed small and statistically significant positive effects for RDQ, MVK, BBQ, and FABQ. The combination treatment group had a moderate effect. There was a large loss of participants (25%) by the end of trial but no reasons for loss to follow-up were provided.

The group that had largest statistically significant effect from baseline to 12 months, 1.3 (0.5 to 2.1), was the combination treatment group but cost could be prohibitive to making this standard practice for LBP sufferers. Interestingly enough, the location of the clinic i.e. where the treatments were provided had no effect on outcomes and this is useful for future studies as site of delivery has been a concern for bias as it was considered that private clinics provided superior treatment to hospital outpatient care.

1.5.5. Hemmilá et al. (2002)

Hemmilá et al. (2002) undertook a randomised trial of 114 participants to investigate the effect of 3 therapies: bone-setting, light exercise, and physiotherapy. Bone-setting is a traditional Finnish manipulation considered to be a precursor to contemporary chiropractic and osteopathic manipulation practiced today.

Participants were allowed a maximum of 10 one-hour therapy sessions for each of the therapy groups. The bone-setting was performed by four folk healers and they were free to choose their own methods. The authors reported that the methods resembled a gentler version of chiropractic and osteopathy adjustments. The physiotherapy group had a number of technique options they were allowed to use and these consisted of massage, traction, thermal and electrotherapies. The exercise group was shown how to “rhythmically bend their backs” in three planes.
The outcome variables were ODI and subjective improvement on a 5-point scale. These variables were measured at 6 weeks, 3, 6 and 12-months after therapy was completed. The bone-setting group was the only group to show a statistically significant improvement in ODI at 12 months, mean change improvement = 8.4 points (95% CI = 5.2 to 11.6), \( P = .04 \). As a result of the randomization process the other two groups had lower ODI measurements at baseline and therefore the difference at 12 months is not as great.

Interestingly, two thirds of participants across all groups sought additional therapies during the follow-up period with the bone-setting group having the highest number of participants seeking massage (n=19) versus 13 patients in the physiotherapy group and 11 patients in the exercise group. Sub-group analysis was performed to remove the patients who sought additional therapy and the bone-setting group had the highest disability score at baseline but then the lowest at one year.

No patient information was reported except that they were ambulatory patients of working age and must have experienced back pain for more than 7 weeks. This lack of detail makes it difficult to ascertain the mean age for patients and applicability to the general population. This study was supposed to be an RCT but it was not clear from the information provided whether the exercise group constituted a control or comparison condition.

1.6. **Summary of Manual LBP Therapy Studies**

All the studies performed between group analyses to ensure baseline characteristics were similar but inter-study patient characteristics were quite different as can be seen in the different inclusion criteria. The wide range of demographics could impact on the natural history of participant’s LBP as the risk of chronic back pain increases with older age and has also been found to have a negative effect on recovery (Andersson, 1999; J, Miedema, Verkerk, Pool-Goudzwaard, & Koes, 2012). All of the studies applied very different selection requirements as to the length of back pain history in patients who fulfilled the inclusion criteria, which makes a direct comparison questionable. As previously discussed chronic LBP is defined as back
pain lasting longer than three months yet the Skillgate et al. (2010) study required participants to have back pain longer than two weeks only whereas Hemmilä et al. (2002) study required back pain longer than 7 weeks. Back pain of short duration can resolve spontaneously (Hoy et al., 2010a) and inclusion of participants in intervention studies with short term duration could lead to overestimation of the effect of treatment. A further weakness is that treatment periods last between 3 and 12 weeks (6-12 treatments in total) with follow up periods ranging from six months to one year. Any potential treatment effect could be attributable to natural history or normal pain fluctuation within an individual patient if long follow up periods were coupled with a short duration of LBP prior to randomization. It appears there is limited consensus about what treatment timeframes are appropriate and this may have to be addressed in future studies.

Overall the exercise and education groups in the studies that included these groups seemed to exhibit the smallest decrease in terms of pain and disability compared to the treatment groups, but there is mixed information within individual studies as to whether this could be more of a compliance issue as opposed to an actual effect. Dropout rates were mostly due to dissatisfaction and were higher for all the studies’ exercise groups or minimal care groups 9-83% versus the therapy groups 8-12%.

Most studies showed only small clinically important differences in primary outcome measures with the exception of Hemmilä et al (2002) and Skillgate et al. (2012), where no clinically important differences were found. Interestingly, combined interventions did not prove more effective than single intervention and the groups that received advice only did not improve significantly.

Overall the conclusion from the systematic review that SMT therapy is no better or worse than other therapies seems to be the only one that can be drawn from these results. However, the points raised in the above discussion of the individual studies beg the question whether more defined timeframes for the duration of back pain prior to selection and set treatment numbers and follow-up periods are required to usefully evaluate effectiveness of SMT.
**Table 2: Part 1** Comparison of Hondras et al. (2009), Hsieh et al. (2002), Skillgate et al. (2010), UKBeam et al. (2004), Hemmilä et al. (2002) to PEDro criteria.

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<tbody>
<tr>
<td>1.</td>
<td>Inclusion criteria were the following were at least 55 years old, (2) presented with non-specific LBP of at least 4 weeks duration, and (3) met the diagnostic classification of 1 (pain without radiation), 2 (pain plus radiation to extremity, proximally), or 3 (pain plus radiation to extremity, distally)</td>
<td>Inclusion criteria was 18 years of age or older, LBP of more than 3 weeks and less than 6 months for the current episode or a pain-free period of at least 2 months in the preceding 8 month for recurrent LBP. Comprehensive list of exclusion criteria was detailed.</td>
<td>Back pain now and in the previous two weeks or longer. Extensive self administered questionnaire</td>
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<td>2.</td>
<td>Computer generated randomisation software, 2:2:1 ratio</td>
<td>Randomisation of Patients into one of four treatments groups was achieved by using a computer program designed to balance allocation of patients according to a number of factors: age, gender, LBP duration and treatment preference for physical therapy or chiropractic.</td>
<td>Subjects assigned by computer randomisation to two groups by assistant not involved in research.</td>
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<td>3.</td>
<td>Allocation was not concealed</td>
<td>Not discussed</td>
<td>Researchers and patients blinded to group assignment until after baseline data collected.</td>
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<td>4.</td>
<td>Participant characteristics between groups were balanced by minimising on the baseline characteristics of sex age, baseline RMD score, duration of LBP, prior use of chiropractor, FABQ score.</td>
<td>The four groups were similar at baseline in regards to demographic characteristics</td>
<td>Differences in baseline factors between groups were evaluated using the Mantel Haenszels (Ahlbom, 1993) method to assess confounding effect and there was no need to adjust for confounding from these factors.</td>
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<td>5.</td>
<td>Blinding of participants to therapy not possible</td>
<td>The subjects were not blinded as treatment was obvious.</td>
<td>Subjects were blinded until after baseline data was collected.</td>
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<td>6.</td>
<td>Therapists were aware of therapy administered.</td>
<td>Therapists performing manual therapy were not blinded.</td>
<td>Therapists were not blinded as they applied a combination of naprathic techniques.</td>
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<td>7.</td>
<td>Blinding of assessors not undertaken</td>
<td>Blinded independent examiners performed assessments 1 to 2 days before the treatment was started, 1 to 2 days after 3 weeks of care and 6 months after care.</td>
<td>A statistician using SAS (version 9.1.3.) performed all analyses.</td>
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<td>8.</td>
<td>Five monthly phone follow-up evaluations were also conducted</td>
<td>Key outcomes: VAS &amp; RMAS, N=199</td>
<td>Of the naprapathy group 90% (n=186) completed the 52-week follow-up and the evidence base care group 79% (n=160) completed the 52-week follow-up and details of dropout reasons were given. Dissatisfied: Group 1 n=1, group 2 n=10</td>
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<tr>
<td>9.</td>
<td>All analyses used an intention to treat approach</td>
<td>Intention to treat methodology was used and all data was analysed regardless of patient compliance</td>
<td>Intention to treat analysis was performed and additional sensitivity analysis for the impact of missing responses was done using &quot;predictive mean matching method&quot; (Rubin, 1987).</td>
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<tr>
<td>10.</td>
<td>Between group analyses performed.</td>
<td>Individual contrasts showed a significant difference between the combined treatment and myofascial therapy at 3 weeks for both VAS (P = 0.027) and RMAS (p = 0.022) but Tukey tests which adjusts for the multiple comparisons showed no significant effects</td>
<td>Changes between groups were calculated using t-tests and relative risks and risk differences with 95% confidence intervals were also calculated.</td>
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<td>11.</td>
<td>Unstructured covariances were used in each model to account for within participant correlation over time. Any participant who had a non missing data for at least 1 end point was included in the analyses.</td>
<td>Effect sizes were calculated for VAS and RMAS</td>
<td>Effect sizes were calculated for CPQ, WPQ, and SF-36</td>
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Table 2: Part 2 Comparison of Hondras et al. (2009), Hsieh et al. (2002), Skillgate et al. (2010), UKBeam et al. (2004), Hemmilä et al. (2002) to PEDro criteria

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<td>1.</td>
<td>Inclusion criteria were the following were at least 55 years old, (2) presented with non-specific LBP of at least 4 weeks duration, and (3) met the diagnostic classification of 1 (pain without radiation), 2 (pain plus radiation to extremity, proximally), or 3 (pain plus radiation to extremity, distally)</td>
<td>Ambulatory patients of working age with back pain longer than 7 weeks. No therapies were allowed 1 month prior to study.</td>
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<td>2.</td>
<td>Computer generated randomisation software, 2:2:1 ratio</td>
<td>General practitioner was blinded to randomisation until the six month examination was completed.</td>
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<td>3.</td>
<td>Allocation was not concealed</td>
<td>Only ODI was tested for differences between the baseline characteristics of the therapy groups and the bone-setting group had a slightly higher result but was not statistically significant.</td>
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<td>4.</td>
<td>Participant characteristics between groups were balanced by minimising on the baseline characteristics of sex, age, baseline RMD score, duration of LBP, prior use of chiropractor, FABQ score.</td>
<td>Participants were aware of group allocation</td>
</tr>
<tr>
<td>5.</td>
<td>Blinding of participants to therapy not possible</td>
<td>Physiotherapist and bone-setters were aware of the therapy administered.</td>
</tr>
<tr>
<td>6.</td>
<td>Therapists were aware of therapy administered.</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Blinding of assessors not undertaken</td>
<td>General practitioner was blinded to group allocation until the six month examination.</td>
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<tr>
<td>8.</td>
<td>Primary outcome: RMD questionnaire Secondary outcome: FABQ, VAS, SF-36 (Weeks 3 and 6), VRS (Weeks 12 and 24)</td>
<td>ODI and subjective improvement on a five point scale were completed at six weeks by 101 patients (89%), three months 111 patients (97%), six months 113 patients (99%) and 12 months 108 patients (95%).</td>
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<tr>
<td>9.</td>
<td>All analyses used an intention to treat approach</td>
<td>All analyses were completed with the intention to treat approach.</td>
</tr>
<tr>
<td>10.</td>
<td>Between group analyses performed.</td>
<td>Changes between groups were analysed for ODI.</td>
</tr>
<tr>
<td>11.</td>
<td>Unstructured covariances were used in each model to account for within participant correlation over time. Any participant who had a non missing data for at least 1 end point was included in the analyses.</td>
<td>Point measures and standard deviations for effects were given for all groups.</td>
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Notes:
PEDro Criteria (Sherrington et al., 2000)
1. Eligibility criteria were specified
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)
3. Allocation was concealed
4. The groups were similar at baseline regarding the most important prognostic indicators
5. There was blinding of all subjects
6. There was blinding of all therapists who administered the therapy
7. There was blinding of all assessors who measured at least one key outcome
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”
10. The results of between-group statistical comparisons are reported for at least one key outcome
11. The study provides both point measures and measures of variability for at least one key outcome
2. SIJ Pain and Treatment

According to a questionnaire of Australian osteopaths, two of the more common hypotheses regarding the SIJ in LBP are that asymmetry within the pelvic ring results in areas of increased stress and subsequent production of pain, or that hypomobility at either sacroiliac joint results in tissue stress and pain (Peace & Fryer, 2004). This view held by the Australian osteopaths is consistent with earlier authorities who considered that relative hypomobility with altered anatomical relationship between sacrum and ilium to be the more common cause of SIJ pain (Dreyfuss, Dreyer, Griffin, Hoffman, & Walsh, 1994).

Diagnosing SIJ–mediated pain is clinically difficult because the presenting complaints are similar to those of other causes of low back (Laslett, 2008; van der Wurff, Hagmeijer, & Meyne, 2000a). While imaging and radionuclear bone scans of the SIJ cannot reliably determine whether the joint itself is the source of the pain there is moderate evidence for the accuracy of controlled analgesic injections (Hansen et al., 2007). Anaesthetic injection studies have determined that approximately 13% (95% CI: 9-26%) of patients with persistent LBP have the SIJ confirmed as the origin of pain (Maigne, Aivaliklis, & Pfefer, 1996). However, reliability is questioned as the anaesthetic block implicates intra-articular sources of pain and not the whole SIJ complex including the ligaments (Laslett, 2008). Another discussion point is the variation in the visual analogue scale (VAS) cut off points for discriminating whether an anaesthetic block procedure is successful or not. It has been recommended that the VAS score should be close to 0mm or no more than 10mm if the procedure is considered successful (Dreyfuss et al. 1996), however, some studies have used higher cut-off points e.g. Slipman et al. (1998) used 20mm; and Maigne et al. (1996) used 25mm. The cut-off point used by investigators can be a major influence on the conclusions. For instance, if the cut-off point in the Broadhurst and Bond (1998) study was changed from 30mm to 10mm the positive outcome would decrease by 50% (van der Wurff, Meyne, & Hagmeijer, 2000b). Although the SIJ anaesthetic block is considered the ‘gold standard’ for identifying the SIJ as a source of pain (van der Wurff et al., 2000b) due to its invasive nature and debatable reliability it is not routinely used in clinical practice.
2.1. Treatment for Sacroiliac Dysfunction

Conservative management of SIJ dysfunction includes manual medicine techniques, pelvic stabilization exercises to allow dynamic postural control and muscle balancing of the trunk and lower extremities (Forst et al., 2006). Interventional treatments include sacroiliac intra-articular joint injections and radiofrequency neurotomy but evidence has shown these to be limited in managing SIJ pain (Dreyfuss, Dreyer, Cole, & Mayo, 2004; McKenzie-Brown et al., 2005).

There is a large amount of research literature discussing the diagnosis of sacroiliac dysfunction but very little on the treatment of sacroiliac dysfunction with manual therapy (Fryer, Johnson, & Fossum, 2010). A number of systematic reviews of the SIJ interventions highlight the paucity of literature for manual therapy treatment of the SIJ (Hansen et al., 2007; Rupert et al., 2009). A critical review of the literature of the treatment of SIJ syndromes by Oldreive (2000) revealed the use of a large number of techniques but many were incompletely described. Oldreive (2000) reported that there were relatively few investigations into the effectiveness of treatment of the SIJ. Oldreive also stated that more comprehensive descriptions of treatment regimes would be helpful and more clinical trials of these techniques are needed.

Only two studies, both randomised clinical trials, have investigated the efficacy of manual therapy interventions for SIJ pain and found beneficial changes (Kamali & Shokri, 2012; Shearar, Colloca, & White, 2005). The two studies applied different techniques. The more recent study (Kamali & Shokri, 2012) compared SIJ manipulation with combined treatment of SIJ manipulation and lumbar manipulation, whereas the earlier study (Shearar et al., 2005) investigated manually delivered chiropractic thrust versus instrument delivered thrust. Both studies lacked control groups, used a small number of interventions and short follow-up periods. Kamali and Shokri (2012) study performed one treatment with an immediate, 48 hour and 1 month follow-up while Shearar et al. (2005) had four chiropractic adjustments over a 2-week period and were re-evaluated at a 1-week follow-up.
Improvements in indices of pain and disability were observed in both studies, the Kamali and Shokri (2012) study showed improvement in both lumbar and SIJ and lumbar combined groups for the visual analogue pain scale (VAS) one month after final treatment compared to before (Z scores -3.1 – 3.3; p = 0.001 – 0.002) and the numerical pain rating scale (NRS) used in the Shearar et al. (2005) study showed improvement in both groups (mean NRS; group 1, 49.1-23.4; group 2, 48.9-22.5; p <.001). The Oswestry Disability Index (ODI) results showed similar improvements the Kamali and Shokri (2012) study (Z = - 3.0 – 3.5; p = < 0.004) and the Shearar et al. (2005) study (mean ODI; group 1, 37.4-18.5; group 2, 36.6-15.1; p = <.001).

These pain and disability improvements were shown in two quite different population groups; whereas the Kamali and Shokri (2012) study included females aged 20 – 30 years the Shearar et al. (2005) study included men and women aged 18 – 59 years.

The Shearar et al. (2005) study included more outcome measures, the orthopaedic rating score (mean, group 1, 7.6-0.6; group 2, 7.5-0.8; p ≤.001) and algometry measure (mean, group 1, 4.8-6.5; group 2, 5.0-6.8; p ≤ .001). The Kamali and Shokri (2012) study found that combined treatment was shown to be more effective than the SIJ manipulation alone whereas the Shearar et al. (2005) study found that neither intervention was more effective than the other.

Both studies had small numbers of participants and a lack of control groups, with the Kamali and Shokri (2012) study limited to young females, questioning whether these treatments are applicable to the general SIJ syndrome population. Additionally SIJ pain can be variable in nature and revert to a chronic form after a period of time similarly to LBP hence the short follow-up periods in both studies make it impossible to predict the efficacy of the investigated treatments long term.

3. Brief Overview of Osteopathic Treatment and Research

Osteopathic treatment is based on four key principles: (1) the body is a unit; (2) the body possesses self-regulatory mechanisms; (3) structure and function are reciprocally interrelated; and (4) rational therapy is based on an understanding of body unity, self-regulatory mechanisms, and the interrelationship of structure and
function (Licciardone, 2008; Ward, 2003). Osteopathic treatment incorporates diagnostic and manually delivered treatments to enhance the homeostatic mechanisms, and maximize structure-function interrelationships (Kuchera, 2007).

Within the osteopathic profession technique preferences for the treatment of SIJ dysfunction has been researched. The most commonly reported techniques were passive joint articulation, soft tissue, prescription of patient self-stretches, muscle energy techniques (MET) and HVLA (Fryer et al., 2010; Fryer, Morse, & Johnson, 2008; Orrock, 2009) but there is little research into the effectiveness of these treatments (Ferrante, King, Roche, Kim, & et al., 2001). It has been suggested that further research to validate a specific manual therapy intervention for SIJ dysfunction remains a research priority (Huijbregts, 2005).

There is agreement amongst osteopathic authors on the lack of research literature on osteopathic techniques in general and has been a common criticism of osteopathy (Phillips & Cobbin, 2001). The paucity of literature can be traced as far as back the origins of osteopathy. Dr Still the founder of osteopathy was a skilled practitioner but some techniques he used were unknown or lost. It is thought this was intentional on his part as he believed that each practitioner should use his own judgment and that the core of osteopathy was having a detailed knowledge of anatomy and applying this knowledge to help restore health (Van Buskirk, 2000).

Licciardone (2007) points out that the osteopathic profession has been challenged over the past decade to provide clinically relevant research and that evidence-based osteopathic research is imperative not only for scientific, economic, and professional reasons, but also to drive health care policy and clinical practice guidelines. This is not the first time the research challenge has been mentioned. Gibbons and Tehan (1997) wrote in the late 1990s that the responsibility for the scientific credibility of osteopathic medicine rests solely with the osteopathic profession. Today, the priority in research within the osteopathic profession has shifted towards outcome studies to measure the impact of osteopathic treatment on pain and disability (Franke, 2010; Kent et al., 2010; Licciardone, Kearns, & Minotti, 2013).
4. Bruce Jones SIJ Technique

The lack of osteopathic research in general and SIJ treatment in particular prompted an Auckland based osteopath, Bruce Jones to develop a novel mobilisation technique which he suggests improves SIJ movement and reduces patient's LBP (Bruce Jones, personal communication 2007). Jones’ technique has not previously been described or documented in any publically available document, but involves the patient lying supine with their hip and thigh rotated medially over a large firm bolster. The SIJ is then articulated by using a downward force on the patient’s upper leg in a rhythmic manner while palpating the joint posteriorly. Jones indicates that to target different areas of the SIJ the angle of hip flexion is changed. Jones has observed through long term use of the technique in his private practice, that following application of this technique in his clinic, patients reported improvements in pain and function after 4-5 treatments.

Given the established need to develop effective treatment interventions for people with LBP, and in the context of scarce literature investigating the application of osteopathic manual techniques, and combined with a claim made by a local practitioner about observed clinical success, an opportunity to investigate Jones’ novel mobilisation technique was identified. Therefore, the research aim of the study reported in Section 2 of this thesis was: To evaluate the efficacy of Bruce Jones’ technique on function, pain and disability in people presenting to a private practice with LBP.
References


Physician, 12(2), 399-418.


Section 2: Manuscript
The effectiveness of a novel mobilisation technique for treatment of chronic low back pain: A single cohort design

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Abstract

Aim: To investigate the effect of a novel manual sacroiliac mobilisation technique on pain intensity, disability and function in people with chronic low back pain. Immediate changes in lumbar range of motion were also investigated between pre and post-treatment for the first treatment session.

Setting: Participants were recruited from patients attending for a new consultation at a suburban private clinic. Treatment was delivered by an osteopath who was also the developer of the novel technique.

Design: Single cohort series

Methods: Participants (n=24) who suffered from chronic low back pain and whose baseline score on the Oswestry Disability Index was higher than 22% were recruited from people attending the practice. Primary outcome measures were: change from baseline to eight weeks on the Oswestry Disability Index (ODI); Quadruple Visual Analog Scale (QVAS) and the Patient Specific Functional Scale (PSFS). The intervention was a side-lying joint mobilization technique targeting the sacroiliac joint with a median of five treatments per participant. The mobilisation technique has not previously been described.

Results: Analysis with repeated measures ANOVA revealed significant changes in pain and disability scores, with mean reductions in Oswestry score of 15 points, \( p < 0.0001 \) (95% CI: 9.2, 22.7); QVAS 1.9 points; \( p < 0.0001 \) (95% CI: 1.0, 3.0); and PSFS of 3.1 points, \( p < 0.0001 \) (95% CI: 1.9, 4.3).

Conclusions: The results of this study indicate that pain intensity, disability and function improved in most participants following treatment. Consequently further investigation using more robust research designs to compare this approach with other treatment approaches and usual care for the treatment of chronic low back pain is indicated.

Key words: Osteopathy; sacroiliac; chronic low back pain; double-inclinometer
**Introduction**

Low back pain (LBP) is one of the most common musculoskeletal conditions (51%) in New Zealand and is a substantial cost to society.\(^1\) Accident Compensation Corporation (ACC) statistics show that most common site of injury of people who require time off work each year is the lower back/spine, with approximately 8000 cases resulting in over 250,000 paid sick days per year.\(^2\) It is estimated that in New Zealand alone, there are economic losses of (NZD) $1.5 billion per year in New Zealand as a direct result of back pain and this does not take into account personal expenditure on medications and other therapies.\(^3\) Chronic LBP contributes 20–25%\(^1\) of the economic burden of LBP mainly because of the number of work days lost.\(^4\)

Chronic LBP has significant negative effect on an individual’s function as it can reduce their physical leisure activities, and their ability to perform work duties and household activities. Function and disability are now considered important research outcomes and are useful indicators of the effectiveness of an intervention. Besides the physical impact on quality of life there is the emotional toll that occurs.\(^5\) Those suffering from chronic LBP are more likely to experience adverse psychological effects\(^6\) which may impede their recovery.

There is little consensus about how chronic LBP should be best managed.\(^7\) Current treatments for chronic LBP include manual therapy, exercise, cognitive behavioral therapy, electrotherapy, thermotherapy, and pharmacotherapy.\(^8\) The sacroiliac joint (SIJ) is considered an important source of LBP\(^9\) and has been implicated as the primary source of LBP in 10% to 27% of patients utilising controlled comparative local anaesthetic blocks.\(^10\) SIJ dysfunction can mimic discogenic or radicular LBP and is frequently overlooked as a cause of LBP.\(^11\)

A critical review of the literature on the treatment of SIJ syndromes by Oldreive\(^12\) revealed the use of a large number of techniques but many were incompletely described. There were relatively few results of research into the effectiveness of these various techniques. Bruce Jones Sacroiliac technique (BJST) is a manual
osteopathic technique that is thought to improve back pain and disability by improving SI movement. The aim of this study was to investigate the effectiveness of the BJST in the treatment of chronic LBP.

**Methods**

**Sample size**

G*Power software (v3.0.1)\(^{13}\) was used to calculate the *a priori* sample size for a two-tailed t-test for the difference between two means. Based on α error probability of 0.05, a power (1-β error probability) of 0.80 the minimum required sample was 26 participants to detect an effect size of 0.5.

**Design and Recruitment**

A single cohort design was used as this type of study is an observational design that reports on data from a single group without a comparison population\(^{14,15}\) and was deemed best suited for application in a clinical practice.

Participants were recruited by convenience sampling of new patients from a clinical practice operated by the developer of the intervention. Any new patients to the clinic were approached by an independent researcher over a three month period until sample size was achieved. Prospective participants were briefed by the researcher and then given an information sheet to read [Appendix C]. To ascertain if they met the criteria for the study they completed an Oswestry Disability Index Questionnaire (ODI) [Appendix D] and a medical screening [Appendix E]. If eligible for the study they were then provided with an informed consent form to read and sign [Appendix F]. The study was approved by Unitec Research Ethics Committee, reference 2008.850 [Appendix G]

To be eligible participants needed to be aged 18 – 65 years old, have experienced chronic LBP longer than six months, have an Oswestry Disability Index Score greater than 22%, a positive SIJ standing flexion test and be able to read and understand English. Participants were not eligible if they had (1) known pathologies;
(2) had recent surgery; (3) had hip or knee replacement surgery; (4) were pregnant.

Once eligibility was confirmed the participants then completed the Patient Specific Functional Scale (PSFS) and Quadruple Visual Analog Scale (QVAS) questionnaires [Appendix H & I]. These questionnaires were also mailed to participants 4 and 8-weeks after their final treatment and were the components of the long term outcome measures. Lumbar flexibility was measured using a digital inclinometer before and after the first treatment session only (see Figure 1).
Assessed for Eligibility (n=33)

Ineligible (n=6)

1st Treatment
Outcome Assessments
Oswestry Disability Questionnaire (ODI)
Quadruple Visual Analog Scale (QVAS)
Patient Specific Functional Scale (PSFS)
Lumbar Flexibility (inclinometer) before and after 1st treatment

Sacroiliac Assessment and Treatment

Treatments (n=27)
(Range = 3-9, Median= 6)

Withdrawn (n=3)
Referred to specialist (n=2)
Relocated (n=1)

Week Four follow-up *

ODI
QVAS
PSFS

Week Eight follow-up *

ODI
QVAS
PSFS

Analysed (n=24)

Figure 1: Flowchart of Study Design
* Follow-up questionnaires were completed 4 and 8 weeks from participants final treatment
Measurements

The 10-item ODI questionnaire which has been validated by the Medical Research Council \(^{16},^{17}\) was used to measure back pain disability. Each item refers to daily living activities and has 6 statements ranging from being able to perform activity to being unable to perform activity. For each item of six statements the maximum score is 5 and the total score for the questionnaire is 50 which is expressed as a percentage.\(^{18}\)

The intensity of back pain was measured using QVAS which is a reliable and valid assessment of the intensity of back pain covering the previous four weeks\(^{19}\). Respondents rate their pain intensity from 0 (no pain) to 10 (worst possible pain) on four different scales: 1) pain right now; 2) typical or average pain; 3) pain level at its best; 4) pain level at its worst.

The PSFS is considered to be a valid, reliable \(^{20}\) and highly responsive outcome measure \(^{21}\) which measures functional status using a patient-specific approach [Appendix I\]. Participants are asked to identify 3 daily activities they find difficult to perform as a result of their back pain and rate each of these on an 11 point numerical scale, with 0 indicating that they are unable to perform activity to 10 that they are able to perform activity at the same level before injury or problem.

Lumbar spine flexibility measurements were performed using two 3-axis (roll, pitch and yaw) digital inclinometer sensors (Microstrain 3DM Digital). Manufacturer specification sheets state the accuracies of these sensors are \(\pm 1.5^\circ\) for yaw and \(\pm 0.7^\circ\) for pitch and roll \(^{22}\). These sensors were connected to a Windows XP Dell Laptop via Serial to USB cables. Microstrain proprietary software was used to capture raw data from both sensors simultaneously and then later imported to Microsoft Excel prior to analysis.

The sensors were placed on the participants while they were standing in an upright position, T12-L1 and L5-S1 inter-spinous points were identified and marked. Self-adhesive hook and loop fastening tape was placed at these levels and the sensors were then attached (Figure 2). A line of tape was placed on the floor and
participants were asked to stand behind and close to this line. Pre-conditioning was performed prior to measurement to decrease the effect of tissue creep deformation. To achieve a stable measure of range of movement six repetitions for each movement were required, which was validated in a previous study. ²³ For flexion, participants were asked to reach down to touch toes with fingertips, going as far as comfortable and then coming back to the upright position. For extension, they were asked to arch backwards as far as possible and then return to the upright position. For side-bending, first to the left and then the right, they were asked to side-bend by running their hand down the outside of their leg without rotating, keeping legs straight and then to return to the upright position. Participants repeated each movement six times before changing to the next.

Figure 2: 3DM Sensor Placement at the T12-L1 and L5-S1 inter-spinous levels.
Intervention

The sacroiliac technique was performed by a registered osteopath with 10 years experience. When performing the technique the osteopath asked the patient to lie supine with the opposite hip & knee flexed. The osteopath then placed a large firm bolster between the patient’s thighs. The patient’s flexed leg was then rotated over the bolster towards the osteopath so that patient’s lower half was in lateral recumbent position (Figure 3). The osteopath articulated the SI joint by using a downward force on the patient’s upper leg in a rhythmic manner while palpating the joint posteriorly. To target different areas of the SI joint the osteopath changed the angle of hip flexion to varying degrees.

Participants were seen on a weekly basis, underwent an average of 6 treatments (range 3 – 9) and treatment concluded when the osteopath believed there was sufficient movement in the SIJ. The pain and disability questionnaires were posted to participants 4 and 8-weeks after their final treatment. Participants were requested to refrain from using other treatment modalities during the course of the study.

Figure 3: Technique setup. See text for explanation.
Data Analysis

Tests for normality of the raw data were performed using Shapiro-Wilk statistic and measures of skewness and kurtosis. Stem-and-leaf, histograms and Q-Q plots were constructed and inspected for consistency with normality. Group effects of the intervention on lumbar flexibility and the questionnaire scores were reported as ± 95% confidence intervals and were analysed using paired t-tests and repeated measure analysis of variance (ANOVA). Pooled effect size was calculated using the following formula

\[ d = \frac{X_1 - X_2}{\sqrt{(SD_1^2 + SD_2^2)/2}} \]

Results

Subjects

Of the 33 participants interviewed, 27 met the eligibility criteria. Three people failed to complete the study because they moved (n=1) or were referred to specialist because of suspicion of more serious pathology (n=2). The descriptive characteristics of the 24 participants who completed the trial, 11 female and 13 male, are shown in Table 1.

Table 1: Baseline participant characteristics

<table>
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<tr>
<th></th>
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<th>Males n=13</th>
</tr>
</thead>
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<tr>
<td>Age (years)</td>
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<tr>
<td>ODI at baseline</td>
<td>36.7 (9.9)</td>
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<tr>
<td>PSFS at baseline</td>
<td>6.7 (1.2)</td>
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<tr>
<td>QVAS at baseline</td>
<td>6.2 (1.1)</td>
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</table>

Note: data are mean (SD).
Long term outcome measures

Repeated measures ANOVA showed an overall change in the ODI at week 8 with a mean reduction of 15 points: $p < 0.0001$ (95% CI: 8.5, 21.8) shown in Table 2. Using the minimum clinical important difference (MCID) value of 10 points$^{18}$ for the ODI there were 17 positive responders (71%), 6 non responders (25%) and 1 negative responder (4%). Of the six non-responders two showed improvement in the other long term outcome measurements (LTOM). The negative responder was consistent in all long term measurements by showing no improvement [Appendix B, Table 3].

Table 2: Clinical outcomes measures for pain and disability

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-treatment (n=24)</th>
<th>4 Weeks Post Treatment</th>
<th>8 Weeks Post Treatment</th>
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<tr>
<td></td>
<td>Mean (±SD)</td>
<td>Mean (±SD)</td>
<td>MCID</td>
</tr>
<tr>
<td>ODI</td>
<td>36.7 (9.9)</td>
<td>20.7 (13)</td>
<td>Y</td>
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<tr>
<td>QVAS</td>
<td>6.2 (1.1)</td>
<td>3.9 (1.7)</td>
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<tr>
<td>PSFS</td>
<td>6.7 (1.2)</td>
<td>3.3 (2.3)</td>
<td>Y</td>
</tr>
</tbody>
</table>

Notes: Post treatment surveys were completed 4 and 8 weeks after final treatment session.
Analysis of QVAS with repeated measures ANOVA showed there was a mean reduction of 1.9 points; $p < 0.0001$ (95% CI: 1.0, 3.0) (see Table 2). Further analysis of QVAS using MCID value range of 2 points$^{24}$ found 15 (63%) positive responders, 7 (29%) non responders, four of whom showed improvement in other outcome measures and 2 (8%) negative responders. One of the negative responders showed improvement in the ODI & PSFS measurements while the other worsened in all outcome measurements (see Appendix B, Table 3).

PSFS analysis with repeated measures ANOVA showed an overall mean reduction of 3.1 points; $p < 0.0001$ (95% CI: 1.9, 4.3). Using PSFS MCID value of 2 points$^{25}$ analysis showed that there were 18 (75%) positive responders, four (17%) non responders and two (8%) negative responders (see Appendix B, Table 3).

**Short term outcome measures**

There was little change from pre- to post-treatment in lumbar flexion, extension, left and right side-bending measured with inclinometers (see Figure 5). Effect size analysis showed a small effect across all ranges of movement measured ($Cohen d = 0.3-0.5$). Pearson’s correlation analysis between lumbar mobility and pain and disability results showed small correlation coefficients except for an increase in left side-bending and a decrease in week 4 QVAS, $r = -.429; p < 0.0005$. 


Discussion

The aim of this study was to explore the effectiveness of the Bruce Jones Sacroiliac technique on chronic LBP. Due to time constraints and financial limitations a single cohort design was chosen. This type of design is considered feasible to investigate new treatments because it is easy to conduct and requires less time and resources than more complex designs. The results of this study indicate improvement in pain and functional disability 4 and 8-weeks after completing treatment with the novel Bruce Jones sacroiliac technique. These initial results suggest that a larger more robust study design would be justified.

Back pain disability improved for 71% of participants to a degree that is considered clinically relevant (>10 points on the ODI). For the ODI, at both the four week and eight week follow-up, there was a minimal clinically important difference (MCID), which according to Jevsevar et al., refers to “the smallest amount of change that matters to a patient”. This suggests the treatment decreased the disability experienced for a considerable number of participants. A similar picture emerged for PSFS results in that there was also a MCID at both follow-up points, with 75% of participants reporting an improvement.

It should be noted that QVAS showed a MCID (>2 points) only at 4 weeks and this was not maintained at the 8-week follow-up however, further analysis of this data, considering individual results rather than overall averages shows 63% of participants had an improvement in the QVAS. Taking all clinical outcome measures in combination, the indication is that the treatment had a positive effect on most participants’ LBP.

It is possible that the effect of the treatment could be under represented due to the relatively small sample group, where the impact of the three individuals who did not report improvement could statistically distort results. Axel et al. discusses the dilution effect of results in studies of heterogeneous populations due to those who do not improve and suggests that clustering patients on the basis of their individual
course of back pain to reduce this effect. The nature of LBP is multi-factorial and while analyzing compiled results gives a broad overview of possible effects of the treatment, the analysis of individual results can give a clearer picture of effects of treatment. On this basis reviewing the trends in individual responses for the outcome variables does have merit in helping assess the effect of this treatment.

When analyzing lumbar flexibility measured with inclinometers pre- and post-treatment there was no overall correlation of lumbar flexibility to pain and disability. It is possible that changes may have occurred with later treatments, but further follow-up assessments of flexibility were not logistically feasible. This lack of correlation of lumbar mobility and SIJ pain has also been reported in other studies. Some authors believe that SIJ dysfunction alters the mechanics of lumbar spine function and the lumbar segments should be treated in conjunction with the SIJ. Kamali & Shokri report that lumbar and SIJ manipulation offered no additional benefit in relation to pain and functional disability compared to SIJ treatment by itself. The results of this study support Kamali et al finding given the lack of correlation with lumbar flexibility measurements.

In comparison to the few studies that have examined the efficacy of SIJ manual therapy treatment, Shearar, et al. study investigating manual versus mechanical force manipulation of the SIJ showed comparable results with statistically significant improvements in pain and disability. Shearar, et al. study had similar demographics except that the recent history of LBP only had to be 2-weeks versus 6-months for this study and in conjunction their study only had a one week follow-up so no comparison can be made as to the long term effect of these treatments.

There were several limitations of this study, one being the lack of a control group which meant the natural history of SIJ pain could not be observed in a placebo group. It is also known that studies such as this one, using a single cohort design are considered to be of low strength in the hierarchy of evidence due to the lack of comparison group. However, the purpose of this study was to investigate the potential efficacy of treatment and indicate whether a further study of a stronger design might be justified.
Another limiting factor was the expense and invasiveness of the SIJ block which is the gold standard for confirming the SIJ as a source of symptoms was deemed impractical for this exploratory study. Instead, the patients history and results from the standing flexion test were used to diagnose a SIJ dysfunction accepting that this test has only a moderate intra-examiner reliability (68%) \(^1\) there is potential for false positive and false negative results for a SIJ dysfunction diagnosis in the sample group. Regardless of the nociceptive origins of symptoms, all participants did report the presence of LBP.

Bias can be inherent in a single cohort studies, but by having consecutive enrolment, strict criteria for inclusion and exclusion helped minimize the risk. Bias was also avoided by having outcome measures that were clinically relevant and collected at predetermined intervals with a high follow-up rate. \(^2\) The practitioner performing the treatment was unaware of any baseline information as all questionnaires were handled by the principle investigator, this reduced the risk of bias being created by the treatment provider.

This study had a short follow-up period of 8-weeks but back pain can fluctuate over time \(^3\) as many environmental and personal factors influence the onset and pattern of LBP. \(^4\) It should be noted that one of the criteria for this study was for participants to have experienced LBP for at least 6-months prior to baseline data capture. This may have mitigated some of the risk of distortions as LBP has a natural course with reoccurrence and remissions. Having a longer follow-up period could also address this and identify any chronic patient’s regression to mean. \(^5\) For future studies increasing the sample size and employing a control group would make the results stronger in the hierarchy of evidence \(^6\) and to clearly assess the efficacy of the BJS technique a randomised controlled trial with blinded assessor outcomes would be required.
Conclusion

The results of this single cohort study series indicates that pain and disability improved in most participants following the Bruce Jones Sacroiliac technique. Consequently, further investigation of this technique is required for patients with LBP.
References

18. Ostelo RWJG, de Vet HCW. Clinically important outcomes in low back pain.


Section 3: Appendices
Appendix A: Figures

Figure 4a: Oswestry disability index score (ODI), maximum score 100

Figure 4b: Quadruple Visual Analog Scale for Pain (QVAS), maximum score is 10.

Figure 4c: Patient Specific Functional Scale (PSFS), maximum score 10

All pain and disability questionnaires measured immediately prior to first treatment then four and eight weeks following final treatment. Error bars show 1 Standard Deviation
Figure 5: Lumbar mobility measured using a double inclinometer pre and post-treatment, a. Flexion b. Extension c. Left side-bending d. Right side-bending. Error bars show 1 standard deviation.
### Table 3: Pain & Disability changes

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**+ve Change**  
| ↑16  | ↑18  | ↑20  | ↑17  | ↑15  | ↑18  |

**No Change**  
| ↔7   | ↔3   | ↔3   | ↔6   | ↔7   | ↔4   |

**-ve Change**  
| ↓1   | ↓3   | ↓1   | ↓2   | ↓2   |

Notes:  
MCID's were used for calculating changes(▲): ODI=10, QVAS=2, PSFS=2
Appendix C: Patient Information Sheet

Information for Participants

The effectiveness of the Bruce Jones Sacroiliac Technique
in the treatment of chronic low back pain

You are invited to take part in a research project being undertaken as a part of the Masters of Osteopathy Degree. The research involves investigating the effect of technique developed by Bruce Jones for the treatment of the chronic low back pain. This information sheet is designed to provide information regarding the nature of the research, and what will happen should you decide to participate. We currently need people who have suffered from low back pain for six months or longer and who are aged between 18 to 65 years. Unfortunately, if your back pain is known to be related to diagnosed disc damage or is due to diseases such as cancer or obvious medical conditions such as cauda equina syndrome you cannot be included.

The Researchers
The researcher is Gail Hanson, with supervision from Clive Standen and Dr Craig Hilton.

What will participation involve?

- Having a brief consultation prior to your initial appointment to ensure that you are eligible for this project.
- Discussing the procedure and being informed of what happens in the research. After you have had time to consider participating you will be invited to sign the consent form.
- Being available for nine weeks during the trial, including your 1-2 treatment sessions with Bruce Jones at the Pakuranga Neck and Back Clinic. Immediately prior to your treatment we would like to measure your back flexibility with a digital inclinometer while you bend forward and try to touch your toes. The same procedure will be performed immediately after your treatment and should only take about 5 minutes.
- When Bruce is conducting the osteopathic technique we will require access to your lower back. To do this you will be requested to remove your outer layers of clothing. It is preferable to not to wear restrictive clothing like jeans. If you are a female participant we suggest that a singlet or sports bra would be most suitable.
• Your only other commitment will be to fill in a few questionnaires regarding your pain levels and activities which should take 10-15 minutes to fill out. These forms are filled out prior to treatment then again four weeks and eight weeks after your treatment (prepaid envelopes are provided to send them back).

What is the nature of the intervention and outcome measure?

- Bruce Jones developed his technique to help restore sacral motion as he believes improper sacral motion can be one of the factors causing chronic low back pain. Bruce has found the technique to be very effective in helping reduce low back pain but there has been no research to prove its effectiveness.
- We will be measuring your relative pain levels and how limited you feel you are in completing common day to day activities. In addition we are interested in any changes in your back flexibility so we would like to measure this by you trying to touch your toes and measuring this with a digital inclinometer.

Potential Risks to Research Participants

There are no specific risks associated with this research. However, the researcher accepts that it is possible that there may be some undetermined risks involved in the research process. In the case that any potential risk or harm is identified, for any of the research participants, 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:

• All consent forms and completed questionnaires will be seen only by the researchers.
• All hard copies and information will be stored in a locked file in a secured room. Only the researchers will have access to this file.
• Only anonymous data will be presented in reports related to this research.
• Electronic files will be protected with an electronic password.

You have the right not to participate, or to withdraw from this research project within two weeks of your final data collection. This can be done by contacting Gail Hanson or Clive Standen by telephone or email, or by verbally informing either of them upon contact that you no longer wish to participate.

A final report containing the information from this study will be available at the Unitec Main Library upon completion or by informing the researcher of your desire for a summary of the results to be mailed to you on completion of the study.

Information and Concerns

For further information or concerns please contact the researchers by phone or email.

<table>
<thead>
<tr>
<th>Gail Hanson</th>
<th>Or</th>
</tr>
</thead>
<tbody>
<tr>
<td>School of Health and Community Studies</td>
<td>Clive Standen</td>
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This study has been approved by the Unitec Research Ethics Committee (ref 2008.850) from 23 July 2008 to 31 December 2009. 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.
Appendix D: Oswestry Disability Questionnaire

LOW BACK DISABILITY QUESTIONNAIRE (REVISED OSWESTRY)

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage in everyday life. Please answer every section and mark in each section only ONE box which applies to you. We realize you may consider that two of the statements in any one section relate to you, but please just mark the box which MOST CLOSELY describes your problem.

Section 1 - Pain Intensity
- I can tolerate the pain without having to use painkillers.
- The pain is bad but I can manage without taking painkillers.
- Painkillers give complete relief from pain.
- Painkillers give moderate relief from pain.
- Painkillers give very little relief from pain.
- Painkillers have no effect on the pain and I do not use them.

Section 2 -- Personal Care (Washing, Dressing, etc.)
- I can look after myself normally without causing extra pain.
- I can look after myself normally but it causes extra pain.
- It is painful to look after myself and I am slow and careful.
- I need some help but manage most of my personal care.
- I need help every day in most aspects of self care.
- I do not get dressed, I wash with difficulty and stay in bed.

Section 3 -- Lifting
- I can lift heavy weights without extra pain.
- I can lift heavy weights but it gives extra pain.
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table.
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- I can lift very light weights.
- I cannot lift or carry anything at all.

Section 4 -- Walking
- Pain does not prevent me from walking any distance.
- Pain prevents me from walking more than one mile.
- Pain prevents me from walking more than one-half mile.
- Pain prevents me from walking more than one-quarter mile.
- I can only walk using a stick or crutches.
- I am in bed most of the time and have to crawl to the toilet.

Section 5 -- Sitting
- I can sit in any chair as long as I like.
- I can only sit in my favorite chair as long as I like.
- Pain prevents me from sitting more than one hour.
- Pain prevents me from sitting more than 30 minutes.
- Pain prevents me from sitting more than 10 minutes.
- Pain prevents me from sitting almost all the time.

Scoring: Questions are scored on a vertical scale of 0-5. Total scores and multiply by 2. Divide by number of sections answered multiplied by 10. A score of 22% or more is considered significant activities of daily living disability.

\[
\text{Score} = \frac{\text{Score} \times 2}{\text{Section} \times 10} = \text{ %ADL}
\]

Appendix E: Medical Screening Form

PARTICIPANTS MEDICAL HISTORY FORM

Completion of this form is for the purpose of this research project only. All information obtained will be kept secure and confidential.

Name: .................................................................................................................................

Address: ..............................................................................................................................

.................................................................................................................................

Email Address: ....................................................................................................................

Home No: ......................... Mobile no: ............................................................

Occupation: ...........................................................................................................................

Age: ......................... Sex: .............................

How long have you suffered from back pain? .................................................................

Since the onset of your back pain what is the longest period of time you have been without pain? .................................................................

Do you take medication for your back pain, if yes, what type and how often .................................................................

Please indicate the following with a tick

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is English your first language?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever fractured your spine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever suffered from Cauda Equinae?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have a spondylolisthesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have diagnosed disc damage?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you had recent surgery?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you had hip or knee replacement surgery?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you had any recent changes in bowel or bladder function?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you currently on any medication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you pregnant?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature: ................................................................. Date: .................................
Appendix F: Informed Consent

The effectiveness of the Bruce Jones Sacroiliac Technique in the treatment of chronic low back pain using a prospective case series research design.

Consent Form

This research is being undertaken by Gail Hanson from Unitec New Zealand, with supervision from Clive Standen and Dr Craig Hilton

Name of Participant: .................................................................

I have seen the Information Sheet dated __/__/2008 for participants taking part in the research project that is investigating the effect of Bruce Jones Sacroiliac Technique on chronic low back pain. I have had the opportunity to read the contents of the information sheet and to discuss the project with the project team, and I am satisfied with the explanations I have been given. I agree that anonymised raw data from this research project can be held indefinitely for the purposes of future analysis and research. I understand that taking part in this project is voluntary (my choice) and that I may withdraw from the project if necessary.

I understand that I can withdraw from the project at any time up until a fortnight after the final session, for any reason.

I understand that my participation in this project is confidential and that no material from which I might be identified 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:

Gail Hanson
Master of Osteopathy student
School of Health and Community Studies
Unitec New Zealand
(09) 8383144 or (021) 399710
gail_hanson@xtra.co.nz

Signature..........................................................participant .............. (date)

Project explained by..............................................................

Signature ............................................................ (date)

This study has been approved by the Unitec Research Ethics Committee (ref 2008.850) from 23 July 2008 to 31 December 2008. 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.
Appendix G: Ethics Approval

Gail Hanson
4 Fairbanks Place
Glendene
Waitakere

25 July 2008

Dear Gail

Your file number for this application: 2008.650

Title: The effect of the Bruce Jones Sacroiliac Technique in treatment of chronic low back pain using a prospective case series research design

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 23 July 2008
Finish date: 31 December 2009

Please note that:
1. the above dates must be referred to on the information AND consent forms given to all participants
2. you must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC. We wish you every success with your project.

Yours sincerely

[Signature]

For
Deborah Rolland
Deputy Chair, UREC

cc: Clive Standen
Appendix H: Quadruple Visual Analog Scale

<table>
<thead>
<tr>
<th>QUADRUPLE VISUAL ANALOGUE SCALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
</tr>
</tbody>
</table>

Please read carefully.

Instructions: Please circle the number that best describes the question being asked.

Note: If you have more than one complaint, please answer each question for each individual complaint and indicate the score for each complaint. Please indicate your pain level right now, average pain, and pain at its best and worst.

Example:

<table>
<thead>
<tr>
<th>No pain</th>
<th>Headache</th>
<th>Neck</th>
<th>Low Back</th>
<th>worst possible pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 – What is your pain RIGHT NOW?

<table>
<thead>
<tr>
<th>No pain</th>
<th>worst possible pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

2 – What is your TYPICAL or AVERAGE pain?

<table>
<thead>
<tr>
<th>No pain</th>
<th>worst possible pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

3 – What is your pain level AT ITS BEST (How close to “0” does your pain get at its best)?

<table>
<thead>
<tr>
<th>No pain</th>
<th>worst possible pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

4 – What is your pain level AT ITS WORST (How close to “10” does your pain get at its worst)?

<table>
<thead>
<tr>
<th>No pain</th>
<th>worst possible pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
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<td>6</td>
<td>7</td>
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<td>8</td>
<td>9</td>
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<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

OTHER COMMENTS:

__________________________________________________________

Examiner

Appendix I: Patient Specific Functional Scale

Patient Specific Functional Scale

Id No:

Name: .................................................. Date:.....................

Clinician to Read and Fill in Below: Complete at end of the history and prior to
physical examination.

Initial assessment:

I am going to ask you to identify up to three important activities that you are
unable to do or are having difficulty with as a result of your low back problem.
Today, are there any activities that you are unable to do or having difficulty
with because of your low back problem.

(Clinician: show scale to patient and have the patient rate each activity)

Patient-Specific Activity Scoring Scheme  (Point to one number)

<table>
<thead>
<tr>
<th>Unable to perform activity</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to perform activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activity</th>
<th>Score 1st Week</th>
<th>Score Subsequent Treatments</th>
<th>Score 4th Week</th>
<th>Score 8th Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
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<tr>
<td>3.</td>
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<td></td>
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<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Date
Appendix J: IJOM manuscript submission

INTERNATIONAL JOURNAL OF OSTEOPATHIC MEDICINE
Former title: Journal of Osteopathic Medicine

Online Submission
Submission to this journal proceeds totally online at 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.

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
Short review (1,500-3,000 words) 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 critical or systematic review paper. These papers typically place more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

Preliminary Findings (1,500-2,500 words) 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 (up to 2,000 words) Includes articles that do not fit into the above criteria as original research. Includes commentaries and essays especially in regards to history, philosophy, professional, educational, clinical, ethical, political and legal aspects of osteopathic medicine.

Preparation of the Manuscript

The manuscript with a font size of 12 or 10 pt double-spaced with wide margins (2.5 cm at least) and number pages consecutively beginning with the Title Page. Depending on the paper type (see above) this should include the title, abstract, key words, text, references, tables, figure legends, figures, appendix. Microsoft Word or similar programme should be used.

To facilitate anonymity, the author’s names and any reference to their addresses should only appear on the title page. Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

Papers should be set out as follows, with each section beginning on a separate page:

Title page
To facilitate the blinded peer-review process, two title pages are required. The first should carry just the title of the paper and no information that might identify the author or institution. The second should contain the following information: title of paper; full name(s) and address(es) of author(s) clearly indicating who is the corresponding author; you should give a maximum of four degrees/qualifications for each author and the current relevant appointment only; institutional affiliation; name, address, telephone, fax and e-mail of the corresponding author; source(s) of support in the form of funding.
Keywords
Include four to ten keywords in alphabetical order, which accurately identify the paper's subject, purpose, method and focus. These should be indexing terms that may be published with the abstract with the aim of increasing the likely accessibility of your paper to potential readers searching the literature. Therefore, ensure keywords are descriptive of the study. Use the Medical Subject Headings (MeSH®) thesaurus or Cumulative Index to Nursing and Allied Health (CINAHL) headings where possible (see http://www.nlm.nih.gov/mesh/meshhome.html).

Abstract
Both qualitative and quantitative research approaches should be accompanied by a structured abstract of no more than 250 words. 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, Participants, 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.

Text
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:

• major headings should be typed in capital letter in the centre of the page and underlined (i.e. INTRODUCTION)
• secondary ones should be typed in lower case (with an initial capital letter) in the left hand margin and underlined (i.e. Participants).
• minor ones typed in lower case and italicised (i.e. questionnaire).

Do not use 'he', 'his' etc. where the sex of the person is unknown; say 'the patient' etc. Avoid inelegant alternatives such as 'he/she'.

Statement of Competing Interests
When submitting a manuscript you will need to consider if you, or any of your co-authors, are an Editor or Editorial Board member of the International Journal of Osteopathic Medicine. If this is the case you will need to include a section, at the end of your manuscript immediately before the reference section, called "Statement of Competing Interests". Example statement, which may require editing, is as follows: {Name of author} is an Editor of the Int J Osteopath Med; {Name of author} is a member of the Editorial Board of the Int J Osteopath Med but was not involved in review or editorial decisions regarding this manuscript.

References
Responsibility for the accuracy of bibliographic citations lies entirely with the authors.

Citations in the text: Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Avoid using references in the abstract. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either "Unpublished results" or "Personal communication" Citation of a reference as "in press" implies that the item has been accepted for publication.

Text: Indicate references by superscript numbers in the text. The actual authors can be referred to, but the reference number(s) must always be given.
List: Number the references in the list in the order in which they appear in the text.

Examples:

Reference to a journal publication:

Reference to a book:

Reference to a chapter in an edited book:

For journal articles, the abbreviated title of the journal should be used. Authors should refer to the National Library of Medicine database for journal abbreviations (http://www.ncbi.nlm.nih.gov/nlmcatalog/journals).

Note shortened form for last page number. (e.g., 51-9), and that for more than 6 authors the first 6 should be listed followed by "et al." For further details you are referred to "Uniform Requirements for Manuscripts submitted to Biomedical Journals" (J Am Med Assoc 1997;277:927-934) (see also http://www.nejm.org/general/text/requirements/1.htm).

**Web references** - As a minimum, the full URL and access date should be given. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be provided. Web references should be included in the reference list.

**Tables, Illustrations and Figures**
Tables, illustrations and figures should be placed on separate pages as separate electronic files and not placed within the manuscript. Each table, illustration or figure should be accompanied by a number (e.g. Table 1) and a brief description of the content of the table, figure or illustration, below the table, illustration or figure. All tables, illustrations or figures should be referred to in the manuscript.

**Specific Guidance for Original Research Articles**
The text of *original research* for a quantitative or qualitative study is typically subdivided into the following sections:

*Introduction*
State the purpose of the article. Summarise the rationale for the study or observation. Give only strictly pertinent references and do not review the subject extensively. Do not include data or conclusions from the work being reported.

*Materials and Methods*
Describe your selection of observational or experimental participants (including controls). Identify the methods, apparatus (manufacturer's name and address in parenthesis) and procedures in sufficient detail to allow workers to reproduce the results. Give references and brief descriptions for methods that have been published but are not well known; describe new methods and evaluate limitations.

Indicate whether procedures followed were in accordance with the ethical standards of the institution or regional committee responsible for ethical standards. Do not use patient names or initials. Take care to mask the identity of any participants in illustrative material.

*Results*
Present results in a 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, and 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.

**Conclusion**
A summary of the pertinent findings and, relevance of the study and implications of the study for
future research.