Mechanical stimulation of C5 affecting referred shoulder pain

A prospective, randomized, double blind, placebo controlled clinical trial assessing the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) on referred pain to the shoulder.

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Master of Medicine

February 2015

Originality Statement

'I hereby declare that this submission is my own work and to the best of my knowledge it contains no materials previously published or written by another person, or substantial proportions of material which have been accepted for the award of any other degree or diploma at UNSW or any other educational institution, except where due acknowledgement is made in the thesis. Any contribution made to the research by others, with whom I have worked at UNSW or elsewhere, is explicitly acknowledged in the thesis'.

'I also declare that the intellectual content of this thesis is the product of my own work, except to the extent that assistance from others in the project's design and conception or in style, presentation and linguistic expression is acknowledged'.

Signed…….

Dated……...

Abstract

Background: Manipulating the C5 facet joints is a popular chiropractic treatment for referred shoulder pain, however there are no clinical trials evaluating its efficacy.

Aim: To determine the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) in patients presenting with referred shoulder pain.

Methods: This was a prospective, randomized, double blind, placebo controlled trial to assess the effects of applying a force to the C5 facet joints by a MAI to patients with referred shoulder pain. For this trial; the treatment cohort had the MAI set at the maximum setting (5 rings) to transmit a force into the spine; the placebo cohort had the MAI turned off (0 ring). Primary outcome measures were frequency and severity of extreme shoulder pain obtained via a patient reported questionnaire; secondary outcome measures were patient ranked pain and functional outcomes as well as examiner assessed range of motion and strength. Assessment procedures were completed at 24 weeks post treatment and data were analysed with an intent to treat protocol.

Results: One hundred and twenty-five patients were recruited for this trial, sixty five were in the treatment cohort and sixty in the placebo cohort.

There was a reduction in the frequency but not severity of extreme shoulder pain in the treatment cohort, with average ranking reducing from weekly to monthly ($p<0.05$). Patients treated with the MAI had 10 N ($p=0.04$) better internal rotation strength after 6 months

post-treatment. There were, however, no differences with any other outcome measures between the two cohorts at the 24 week study period.

Conclusion: The major effect of a MAI over placebo applied to the C5 facet joints two times per week for six weeks, then once a week for three weeks in patients who presented with referred shoulder pain was improved shoulder strength in internal rotation at 24 weeks ($p=0.04$).

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A thesis submitted in fulfillment of the requirements for the degree of Master of Medicine

February 2015

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Acknowledgements

First and foremost, I would like to acknowledge and thank Professor George Murrell, my supervisor and mentor, whose unreserved generosity of time and resources and continued advice showed me how to achieve the highest level in my discipline.

I also thank the staff at the Orthopaedic Research Institute at St George Hospital, Dr Patrick Lam for his statistical support and advice and my co-supervisor A/Professor Judie Walton for providing editorial advice on this thesis.

Finally, I would like to thank the patients, who willingly participated in the trial and by having done so made this research possible.

Introduction

1. Neck and shoulder pain

Up to 20% of the adult population experiences shoulder symptoms at any one time [1]. Shoulder pain is the second most common musculoskeletal condition in the upper extremities [2]. Using the Maastricht Upper Extremity Questionnaire (MUEQ) which showed that one third of respondents had disorders of their cervical spine, 31% in the shoulder followed by upper arm (12%), lower arm (8%), elbow (6%), wrist (8%) and hand (11%) [2]. It has also been reported that 23% of patients that attend physiotherapy clinics [3] and 12% of patients that attend chiropractic clinics [4] have shoulder complaints.

Shoulder pain and neck pain are often interrelated. Bogduk et al. [5] have shown that neck and shoulder pain may arise from the C5/C6 facet joints and neck pain and headaches from the C2/C3 facet joints. The sensory innervation of facet joints is derived from the medial branch of the posterior primary division (dorsal ramus) at both the level of the joint and the levels immediately above and below the joint. This multilevel innervation may explain why pain from a facet joint has a broad referral pattern. In experiments evaluating the distribution of pain from the cervical facet joint, Dwyer et al. [6] identified the C5/C6 facet joints. They then inserted a needle until it was felt to pierce the joint capsule and injected contrast medium until pain was elicited. The subject was then examined for tenderness in the cervical and shoulder region. The distribution of evoked pain and tenderness was marked on the skin and the area recorded on a body diagram. The authors found that the pain patterns for C5/C6 covered the shoulder above the level of the spine of the scapula. The authors then injected the medial branches of the dorsal rami of the target joint with

local anaesthetic and noted that the experimentally induced pain was relieved in all subjects. The study demonstrated the cervical facet joints can be a source of neck pain and that the pain extends beyond the immediate vicinity of the stimulated joint to include an element of referred pain into the related limb or limb girdle.

2. Mechanisms of referred pain

Bogduk defined referred pain as "pain perceived as arising from a body region topographically displaced from the site of the stimulus or disorder that produces the pain" [7]. For example a lesion of the C5/C6 facet joints often is associated with pain at the top of the scapula and shoulder above the level of the spine of the scapula [6]. Bogduk hypothesized that referred pain arises when the brain misinterprets, or is unable to interpret the exact origin of a painful stimulus as it receives input from several topographically distinct sites [7]. The body region innervated by a given neuron is known as its receptive field so that primary afferent fibres represent a specific receptive field, dorsal horn neurons a larger receptive field and thalamic neurons an even larger receptive field [7]. Upon entering the spinal cord primary afferent fibres are not simply matched one to one with second order neurons, rather a given cell in the dorsal horn may receive an input from several primary afferent fibres [7]. Further along, thalamic neurons receive an input from several dorsal horn cells. The disadvantage of this convergent system of connections is that the precision as to the origin to the stimulus is lost and any of the primary afferent fibres relaying to a dorsal horn neuron cannot determine which primary afferent is responsible [7]. The dorsal horn neuron simply relays its activation to the thalamus, however the thalamic neurons cannot distinguish which particular dorsal horn neuron is responsible for the activation. Therefore the further transmission of the stimulus from the thalamic neuron to

the cortex is not precise. At best the cortex could infer that the stimulus arose somewhere in the receptive field of the thalamic neuron that activated it. Feinstein et al., Inman and Saunders as well as Kellgren [7] completed studies that produced maps of patterns of referred pain from the cervical and thoracic vertebral column. These maps indicate that the referred pain follows a segmental pattern such that stimulation of progressively caudal levels in the vertebral column produces a progressively caudal distribution of referred pain. [7]. The term "sclerotome" has been adopted to describe the peripheral region in which referred pain from a given vertebral segment is perceived [7].

3. Research for cervical treatment of referred shoulder pain

The hypothesis that the facet joints of the cervical spine can be a source of referred pain to the shoulder and that this referred pain can be alleviated by a treatment consisting of manipulating the C5 facet joints. This is taught in chiropractic departments such as the department of chiropractic in the faculty of science where the Master of Chiropractic degree is offered at Macquarie University. However, there have been very few published clinical research trials testing or supporting this hypothesis. One method of "manipulating" the C5 facet joints is to apply a force using a mechanically assisted instrument (MAI) (described in the hypothesis, p. 20). This device is commonly used by chiropractors. Christensen et al. estimated in 2000 that 45,000 chiropractors used this instrument world wide [8]. It has been reported that 51% American, 40% Canadian, 82% British, 73% Australian and 54% of New Zealand chiropractors use the MAI [9]. I conducted a literature search via Medline, Embase Pubmed and Cinahl using the following key words: referred shoulder pain; treatment of referred shoulder pain; treatment of the cervical spine for referred shoulder pain; medical treatment of referred shoulder pain; chiropractic treatment

of referred shoulder pain; chiropractic-shoulder pain; activator treatment-shoulder pain; shoulder pain-cervical vertebrae; mechanically assisted manipulation for referred shoulder pain; mechanically assisted instrument for referred shoulder pain; physiotherapy treatment of the shoulder; physiotherapy treatment of referred shoulder pain; physiotherapy treatment of the cervical spine for referred shoulder pain. The search produced 64 results. Of these 64 results, 52 of the papers were related to isolated shoulder pain or shoulder pain secondary to visceral sources. Thirteen publications were related to shoulder and neck pain: 2 case reports, 3 case series and 8 randomized clinical trials. These publications are reviewed below.

Case reports

Of the case reports, one reported a patient who had a presentation of a history suggestive of a shoulder disorder. The cervical spine was tested sitting. The patient was shown how to restore his/her lumbar lordosis and retract his/her head. This position abolished their shoulder symptoms [10].

Another case report described a manual physical therapy management approach for a patient with shoulder pain and disability. Cervical spine examination showed increased resistance in a posterior to anterior motion at C5/C6. The patient was seen once a week for 5 weeks for a course of physical therapy intervention. Intervention consisted of posterior to anterior mobilization of the C5/C6 segment combining a large amplitude movement performed into firm resistance or up to the limit of available range and small amplitude movement performed into firm resistance or up to the limit of the available range [11]. The Shoulder Pain and Disability Index and goniometric measurement of shoulder range motion

were used to measure outcomes following the intervention. The patient's Shoulder Pain and Disability Index score improved from 83% to 1.5% over the course of treatment. Active range of motion of shoulder flexion improved from 50º to 155º over this period of time. A 6 month follow-up revealed a full return to usual activity and a Shoulder Pain and Disability Index score of 0%. A 6 month follow-up revealed a full return to usual activity and a ceasing of their symptoms [12].

Case series

De Branche [13] reported 58 patients with local epicondylagia and cervical spine pathology. All patients received 1 to 4 manipulations (unspecified) of the cervical spine at weekly intervals. The authors reported a significant improvement was achieved in 28% of patients for 2 to 4 days and in 43% there was improvement for a longer, but non-specified period. Only 16% of the patients remained pain free.

Maigne [13] reported complete "healing" of symptomatic tennis elbow after "manual therapy" for cervical dysfunction in 51 of 92 patients, and "significant" improvement in another 29 patients. "Only" 2 patients required surgery. Inclusion criteria, outcome assessment, and follow-up were not reported.

A case series by Pribicevic and Pollard [14] of 4 patients presenting with shoulder pain with "restrictions" of the C5/C6, T2/ T3 and T3/T4 levels of the spine and localised cervical pain in response to Kemp's/Quadrant (combined cervical: rotation, lateral flexion and extension). Patient treatment consultations ranged between 4 and 5 sessions. Treatment interventions were multimodal involving: soft tissue therapy (the application of ischaemic

pressure to myofascial pain syndromes), ultrasound, manipulation (peripheral thrust manipulation was applied to the glenohumeral joints, and inferiorly to the acromioclavicular joint and anterior to posterior to the sternoclavicular joints). Mechanically-assisted manipulations were made with the MAI in an inferior direction through the acromioclavicular joint. Diversified spinal manipulations were used to manipulate the thoracic and cervical spine regions at the levels of T3/T4 and C5/C6. Exercise involved isometric strengthening of the supraspinatus and infraspinatus muscles. There was a reported 100% improvement in the Visual Analogue Scale. Follow-up re-assessments revealed full and painless range of motion without subjective symptoms and no abnormalities were detected in Hawkin's test and Neer's impingement test in all 4 subjects between 4 and 8 weeks.

Randomized clinical trials

Vicenzino et al. [15] conducted a randomized, double blind, placebo-controlled, repeated-measures clinical trial to study the initial effects of "cervical spine treatment" in 15 patients with lateral epicondylalgia (tennis elbow). Pressure pain threshold, pain-free grip strength upper limb neurodynamics, pain and function were assessed prior to and following application of treatment and placebo or control conditions. Subjects in the treatment cohort received grade III contralateral lateral glide treatment at the C5/C6 motion segment. This involved one of the therapist's hands depressing the scapula while the other hand cradled the occiput and neck above C5/C6, applying passive lateral movement by the hand cradling the neck until the occiput reaches the limits of range of motion. The placebo cohort received the same manual contact and setting up procedure as the treatment but without the actual application of a grade III lateral glide movement. The control cohort involved no

manual contact by the therapist to the patient. The treatment cohort showed a significant effect immediately after its application as demonstrated for the Upper Limb Tension Test 2b which improved by 44%; Pain-free grip improved by 30%; Pressure Pain Threshold improved by 26%; the Visual Analogue Scale improved by 50%.

McClatchie et al. [16] completed a randomized, blinded, placebo-controlled, cross-over trial to evaluate the immediate effects of cervical lateral glide mobilization on pain intensity and shoulder abduction painful arc in subjects with shoulder pain. Twenty-one subjects received interventions of both cervical mobilization and placebo over two sessions. The lateral cervical glide mobilization involved the examiner's thumb placed on the lateral aspect of the spinous process of C5 applying small amplitude end range movements. The placebo treatment involved the examiner resting their hands/thumb in the same position as the mobilization technique but without the application of force. Assessment was completed immediately after the application of either intervention and showed that the Visual Analogue Scale for pain in the cervical lateral glide mobilization cohort reduced by 35%.

Wood et al. [17] completed a prospective, randomized comparative clinical trial on the effect of instrument versus manual manipulation in the treatment of cervical spine dysfunction in 30 patients. Patients were included if they had neck pain and a restricted cervical spine range of motion for a duration of at least 1 month. Each group received only the specific intervention until asymptomatic status was achieved or a maximum of 8 treatments had been received. One group received treatment to the cervical spine consisting of a mechanical force manually assisted manipulation, delivered by means of a hand held instrument. The other group received specific contact high velocity, low amplitude

manipulation to the cervical spine. Assessments consisted of the following questionnaires; Neck Disability Index Numerical Pain Rating Scale 101 and the McGill Short-Form Pain Questionnaire. The results for all the questionnaires indicated that both treatment groups showed statistically significant improvements and the two treatment methods acted with equal effectiveness both during the treatment period and up to 1 month follow-up.

Gemmell and Miller [18] conducted a randomized comparative trial with patients complaining of sub-acute neck pain. Patients were randomly allocated into 3 groups; manipulation, mobilization and MAI. However, the trial was ceased due to lack of recruitment of participants.

Yurkiw and Mior [19] completed a randomized clinical trial of 14 patients (7 in each group) with subacute unilateral neck pain. The interventions were applied to the region of the cervical spine that showed restrictions by motion palpation in the region of C3-C7. They compared diversified spinal manipulative therapy (high-velocity, low-amplitude adjustment) to the MAI. For the patients in diversified spinal manipulative therapy cohort one "adjustment" was applied from C3-C7, for one session. For the MAI cohort patients the instrument was applied in the two ring setting to the posterior pillar from C3-C7 using one click application for one session. Both interventions showed improvements in all outcome measures but no statistical significance was found between the groups [20].

Another randomized placebo controlled trial by Ma et al. [21] was performed in patients who reported consistent neck and shoulder pain related to computer use for more than 3 months. A total of 60 participants completed the trial and were divided into 4 groups. The

interventions were applied for 6 weeks. One intervention was the use of a biofeedback machine to the upper-left and upper-right trapezius muscles. A threshold amplitude was preset and surface electromyography signals were collected by the biofeedback machine. Electromyographic signals above the threshold would trigger an auditory feedback signal. When these signals were heard the subjects were taught to sit quietly with the eyes closed and to relax/depress their shoulders. The second group was given exercises, the third group was given interferential therapy and hot packs applied to the participant's neck and shoulders. The fourth (control) group was given an educational booklet on office ergonomics. The biofeedback training produced more favourable outcomes at the 6 month follow up in reducing pain and improving muscle activation of neck muscles in patients with work-related neck and shoulder pain. The Neck Disability Index score decreased by 35% at 6 months compared to the active exercise group, and by 50% compared to the passive treatment group and control group; the Visual Analogue Scale had decreased by 50% at 6 months compared to the active exercise group and by 70% compared to the passive treatment and control groups.

Tsai et al. [22] completed a double blind, randomized controlled study to assess the effectiveness of cervical facet joint injection (local anaesthetic) in treating shoulder pain with the myofascial trigger point in the upper trapezius muscle secondary to cervical facet joint lesion. The cervical facet joints that were injected were at the level of C4/C5. There were 46 patients in the experimental group and 43 patients in the control group. A myofascial trigger point was defined as the most sensitive spot in a taut band of skeletal muscle. An active myofascial trigger point is painful, both spontaneously and during movement. There are many sensitive loci (probably sensitized nociceptors) in a myofascial

trigger point region. For the cervical facet irritation test this was seen as a positive facet sign when the patient turned their head to the side of pain followed by extension of the neck and aggravated pain in the upper trapezius myofascial trigger point. In addition, when the ipsilateral C4/C5 facet joint was compressed with the examiner's finger, pain in the myofascial trigger point of the upper trapezius could be aggravated. This was considered positive facet compression. The experimental group consisted of eighty-nine patients with chronic unilateral shoulder pain due to myofascial trigger points in the upper trapezius muscles, they received an injection to the C4/C5 facet joint. The corresponding unilateral multifidi muscle was injected in the control group. The assessment period was for one month. There was an 80% reduction in mean pain intensity in the experimental group compared to the control group and a 56% reduction in the mean pressure pain threshold intensity in the experimental group compared to the control group.

Park and Kim [23] performed a prospective randomized controlled study to investigate the effects of local anaesthetic cervical facet joint injections on 306 patients with long-standing myofascial pain syndrome. Myofascial pain syndrome was defined by regional or widespread myalgia with trigger points in one or more muscles, taught bands, referred pain sensory changes and local twitch response. The injection group received cervical facet joint injections on the bilateral C5/C6 and C6/C7 facet joints using anesthetic blocks in 0.3 ml of 1% lidocaine and 0.25% bupivacaine on their first and second visits, respectively. The non-injection group comprised patients who had not received therapeutic cervical facet joint injections [23]. There was an increase in the symptom-free period in the injection group by 50% compared to the non-injection group.

Mechanically Assisted Instrument (MAI)

As outlined earlier, there is a hypothesis that application of force to the C5 facet joints may alleviate referred pain to the shoulder. One method that can be used to apply this force to the C5 facet joints is traction; applying a generalized pulling force on the spine [24]. Another is mobilization; involving slow non-specific oscillatory movements directed toward multiples segments of the spine. Manipulation; involves the application of a thrusting force to a specific part of the spine in a single direction beyond a joints active and passive movement, remaining within the limit of the joint's anatomical integrity [5, 18]. Another way to apply this force is to use a MAI. The MAI is a hand-held spring- loaded device that is activated by compressing a handle on the shank of the instrument. It delivers a force to a rubber tip which is attached to the end of a stylus. A force is applied to the C5 facet joints using the MAI by placing the MAI on the skin at the level of C5 of the spine, in line with the column of the articular processes that contain the superior and inferior articular facets (on the side of pain). The MAI at this site delivers a force in a posterior to anterior direction.

The MAI has several theoretical advantages over the other methods of which are: (i) the small size of its tip enables specificity and lower force characteristics compared to traction mobilization and manual manipulation; (ii) the force applied by the MAI can be more reproducible compared to manual manipulation; (iii) rotation of the spine is unnecessary; (iv) it does not involve twisting of the body; (v) there are no audible sounds (cavitation/cracking) from joints compared to manipulation; (vi) the force is delivered faster than manual manipulation: 0.1 to 5 milliseconds for the MAI compared to 30 to 150 milliseconds for manual manipulation [25, 26]; and (vii) less force is delivered by the MAI

5 Newtons as outlined later, compared to manual manipulation which can reach up to 300 Newtons [18] for forces applied to the cervical spine.

There are, however, as outlined in the above literature review no studies to show whether an MAI is of any value or not to patients with neck pain and referred shoulder pain.

Aim

To determine if there were any benefits in applying a force to the C5 facet joints by an MAI in patients presenting with referred pain to the shoulder.

Materials and Methods

4.0 Study design

This study was a prospective, randomized, double blind, placebo controlled clinical trial assessing the effects of applying a force to C5 facet joints by an MAI on referred pain to the shoulder.

4.1 Ethics Approval

This study was approved by the South Eastern Sydney & Illawarra Area Health Service Human Research Ethics Committee (HREC) prior to patient recruitment (#06/102 Murrell).

4.2 Assessment

The primary outcome measures were defined as patient-determined frequency and severity of shoulder pain at 24 weeks.

The secondary outcomes were defined as patient-determined: driving ability due to neck pain level of headaches due to neck pain, level of neck pain intensity, participation in recreational activities due to neck pain, neck pain affecting sleep, cervical pain on lateral flexion, cervical pain on extension/rotation/lateral flexion (Quadrant/Kemp's), stiffness on cervical rotation frequency of shoulder pain-during activity, frequency of shoulder pain-during sleep, level of shoulder pain with overhead activities, shoulder strength on internal rotation, shoulder strength of supraspinatus and shoulder impingement on internal rotation. All analyses were made using an intent to treat protocol.

4.3 Patient recruitment

Patients with symptomatic shoulder pain were recruited through advertising in local newspapers, at conferences and presentations, mail-outs to general practitioners and medical specialists. At the initial interview patients were assessed for eligibility criteria and provided information about the study trial. The information was provided both verbally and in a printed handout. If interested a patient signed a consent form.

4.4 Patients were suitable for inclusion if:

1) 16-75 years.

2) their symptoms of shoulder pain had lasted least 2 weeks in duration.

3) they experienced shoulder pain upon movement of their cervical spine.

4) their shoulder pain was unaccompanied by shoulder pathology.

4.5 Patients were excluded if they had:

1) worker's compensation or third party insurance claims and/or litigation in relation to the cervical spine.

2) concurrent facture of the cervical spine/upper limb.

3) concurrent infections of the spine/systemic infection.

4) inflammatory diseases of the spine and or upper limb-rheumatoid arthritis.

5) tumors or other destructive lesions of the cervical spine and or upper limb.

6) frank loss of sensory sensation to the affected upper limb, as tested via pin wheel/light touch.

7) any surgical intervention to the upper limb in the proceeding 12 weeks.

4.6 Information and Consent

Once the patients were satisfied and agreed to participate in the trial they were given a subject information statement and consent form to sign (Appendix A).

4.7 Randomization

All subjects were assigned to one of two groups in a 1:1 ratio. Randomization was completed by preparing 40 cards with the word "treatment" written on them, and 40 cards with the word "placebo" written on them. Each card was then placed in an unmarked envelope and sealed. The envelopes were mixed, then placed in a box. This box was only accessible to the treating physician. On the day of the commencement in the trial the treating physician took out an envelope from the box and opened it to determine which cohort the patient was in. The card was then placed back in the envelope and the patient's name was written on it. The card was then placed in a separate storage compartment.

The treating physician wrote the patient's name and to which cohort they were assigned in a dedicated note book. The physician would refer to this notebook at each consultation to inform him of the patient's cohort. This notebook was then stored in a lockable file cabinet (separated storage compartment) which could only be accessed by that physician.

4.8 Treatment

Patients in both cohorts were placed in the prone position on a treatment table. The MAI was placed on the patient's skin at the level of C5 of the spine, at the level of the column of articular processes that contain the superior and inferior articular facets (on the side of pain).

In the treatment cohort the MAI was set at the maximum setting (5 rings) depressed once transmitting a force into the spine in a posterior to anterior motion.

In the placebo cohort the MAI was not activated. Instead another MAI held in the practitioner's other hand was depressed once, so that the sound of the MAI would be generated, but no force would be delivered to the cervical spine.

The above procedures were completed twice per week for 6 weeks, then once per week for 3 weeks. At 12 and 24 weeks there was no intervention. Assessments by an independent examiner were completed at 1/3/6/9/12 and 24 weeks.

4.9 Outcome measures

Evaluation consisted of assessments at initial (pre-treatment) appointment, 1 week, 3 weeks 6 weeks, 9 weeks, 12 weeks and 24 weeks post treatment. These consisted of patient ranked questionnaires and independent examiner findings (Appendices B,C,D). Shoulder symptoms were patient-ranked for pain and functional outcomes including: the frequency of pain; with activity; whilst sleeping; and extreme pain. Shoulder symptoms were also ranked according to the severity of pain; with rest, during sleep; and activities above the head. (Appendices B and C).

Neck pain symptoms were rated for effects on driving. (Appendix C).

Neck pain symptoms rated the affects of participation in recreation. (Appendix C).

Neck pain symptoms rated the affects on the ability to sleep. (Appendix C).

Neck pain symptoms rated the affects on headaches. (Appendix C).

Independent examiner assessments were completed and recorded (Appendix D) for muscle strength measured via a hand held dynamometer for internal rotation and supraspinatus; cervical range of motion assessments for stiffness and pain in flexion, extension, rotation lateral flexion, extension/rotation/lateral flexion (Quadrant/Kemp's); shoulder impingement on internal rotation.

Figure 1. Mechanically Assisted Instrument

Figure 2. Treatment table

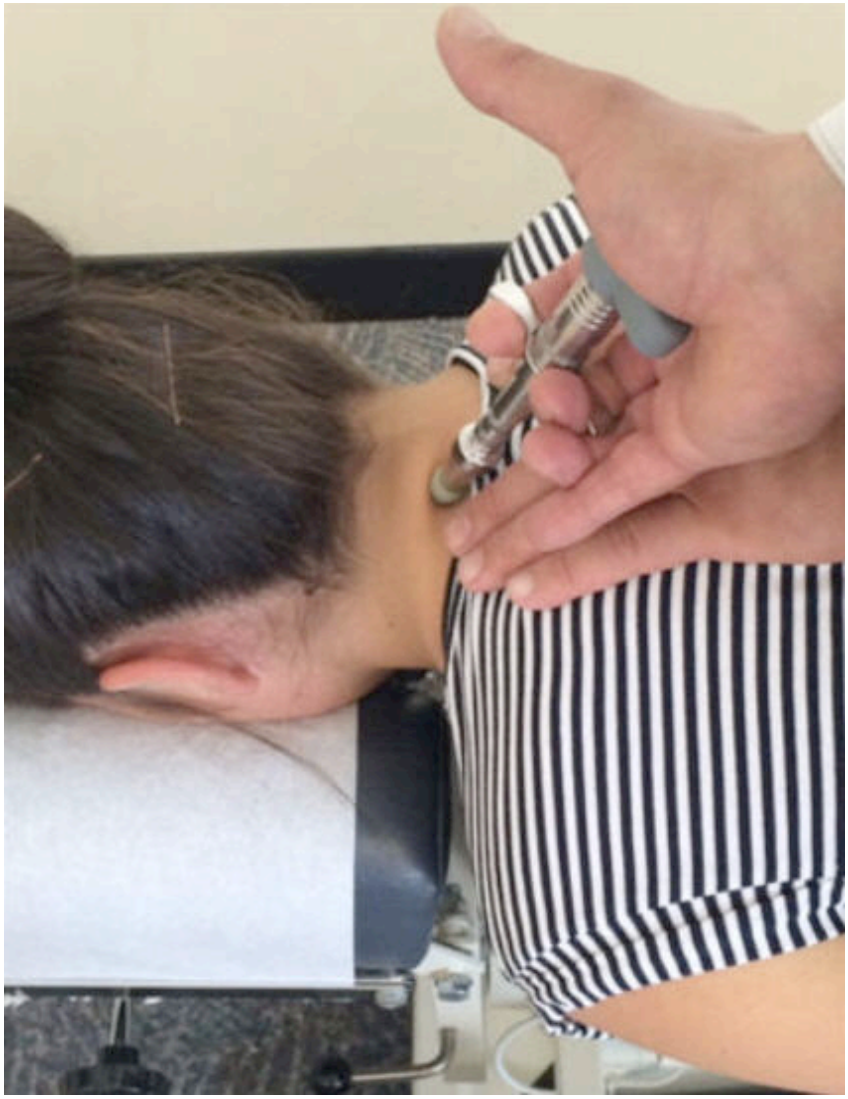

Figure 3. MAI application procedure

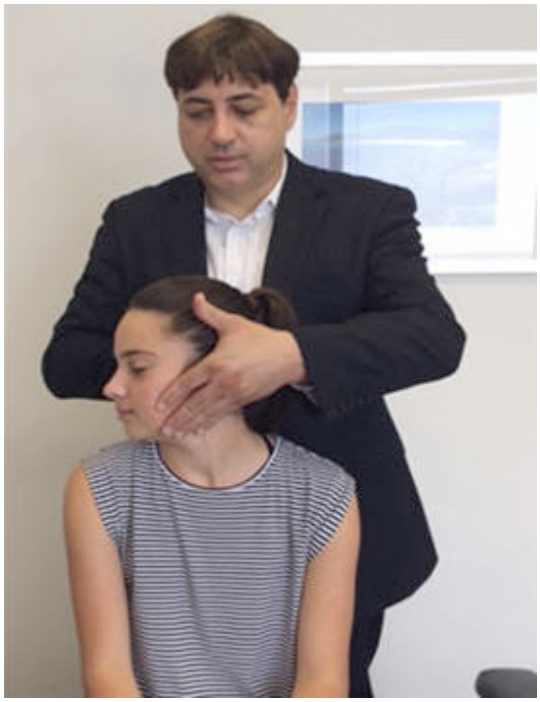

Figure 4. Cervical Spine Rotation

Figure 5. Cervical Spine Lateral Flexion

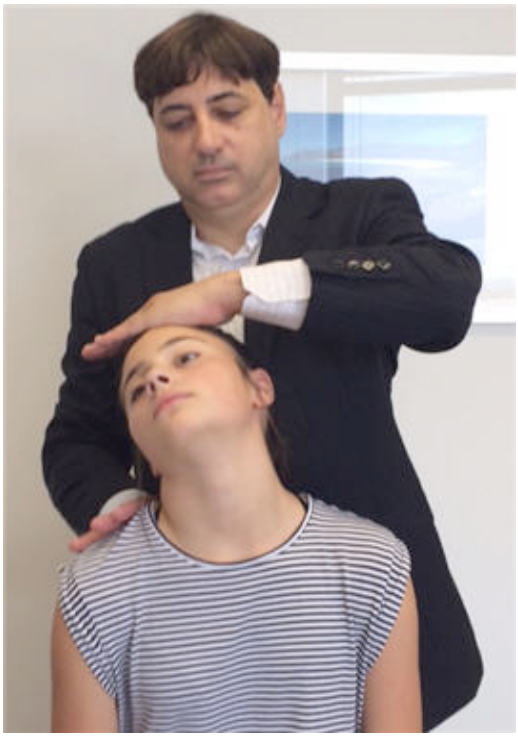

Figure 6. Cervical Spine Extension/Rotation/Lateral Flexion (Quadrant/Kemp's)

Figure 7. The Dynamometer

Figure 8. Internal rotation strength test

Figure 9. Supraspinatus strength test

Figure 10. Impingement test internal rotation

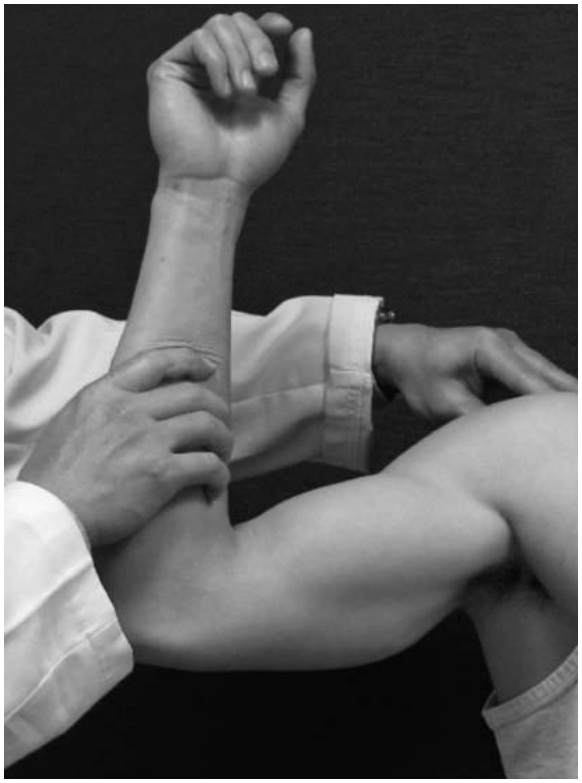

Figure 11. Impingement test external rotation

5.0 Statistical analysis

The outcome measures were analysed with Sigmaplot v 11 (Systat Software, Inc. Chicago IL, SPSS v21, IBM Inc., N.Y., U.S.A.) software using an intention to treat analysis. Parametric data consisting of active range of motion, grip strength and Orthopaedic Research Institute tests of maximal strength were analysed using Student's unpaired t-test for differences between cohorts at different time points with significance level set at $p<0.05$. Mann-Whitney tests were used for non-parametric pain scores, internal rotation (hand–behind-back vertebrae levels) for differences between the cohorts (treatment v placebo) at different time points with significance level set at $p<0.05$. Two-Way ANOVA with Bonferroni corrections was used to assess two factors (effects of time and treatment) between initial and different follow-up time points, with significance level set at $p<0.05$. Chi-square analysis was used to assess dichomatous data, such as patient demographics and impingement signs.

Results

The MAI performance was assessed by a hand-held dynamometer, this indicated that at full setting it delivered a mean force of 5N +/- 0.2 N (Mean +/-SEM).

6.0 Demographics

Two hundred and two patients, presenting with shoulder pain, were recruited through newspaper advertisement, doctor mail-outs and referrals from other health professionals.

Of these recruits 45 did not meet the inclusion criteria and 32 declined to participate resulting in 125 patients meeting the inclusion criteria and agreeing to participate in the trial. There were 65 participants in the treatment cohort and 60 in the placebo cohort. Males totalled 68 of which 35 were in the placebo cohort and 33 in the treatment cohort. There were 57 females of which 25 were in the placebo cohort and 32 in the treatment cohort. The median age of the participants was 61 (range, 28-75 years) (Table 1) and the median duration of symptoms was 21 (range, 1-300 months) (Table 1).

Table 1. Demographic data

No significant differences were found between the placebo and treatment cohorts.

	Placebo Cohort	**Treatment Cohort**
Age	63 (37-75)	56 (28-75)
Gender **M : F**	35 : 25	33 : 32
Affected Shoulder **R : L**	42 : 18	37 : 28
Symptoms Duration **(Months)**	12 (1-300)	24 (1-288)

6.1 Primary outcome measures

Frequency of Extreme Shoulder Pain

Both cohorts experienced a significant improvement in the frequency of shoulder pain at 24 weeks compared to pre-intervention levels. However, there was no significant difference between the two cohorts at 24 weeks.

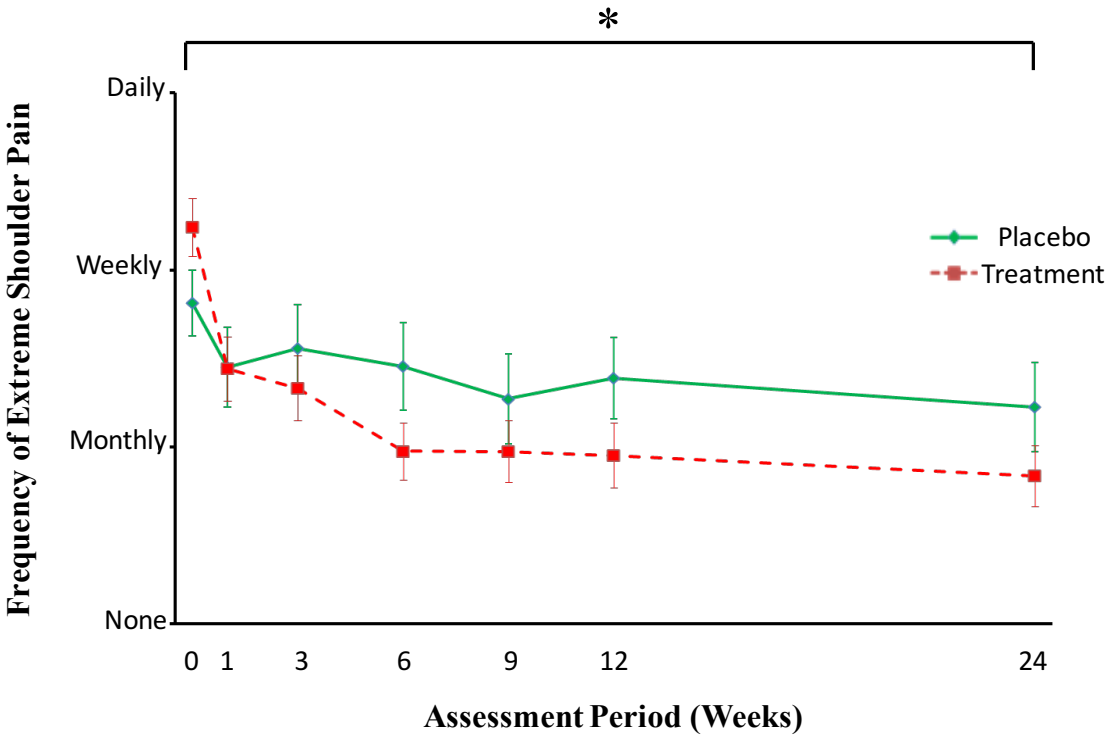

Figure 12. Frequency of Extreme Shoulder Pain.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Level of Shoulder Pain at Rest

Both cohorts experienced a significant improvement in the intensity of shoulder pain at 24 weeks compared to pre-intervention levels. However, there was no significant difference between the two cohorts at 24 weeks.

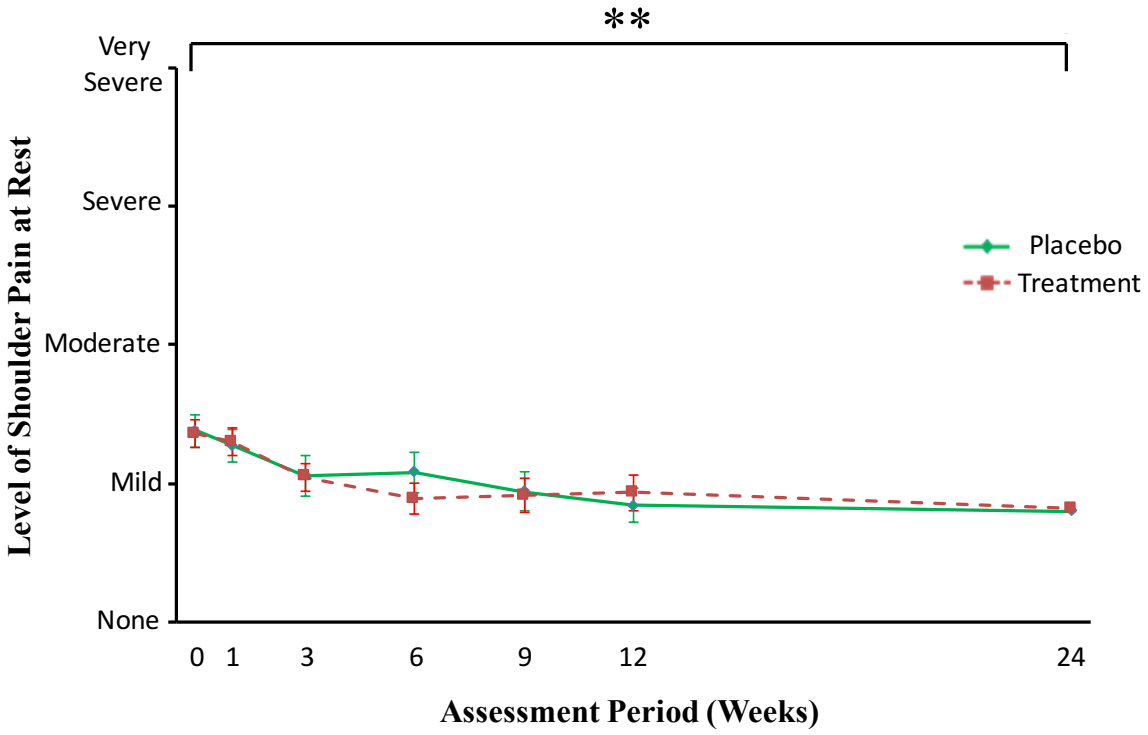

Figure 13. Level of Shoulder Pain at Rest.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.01$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

6.2 Secondary outcome measures

Driving Ability due to Neck Pain

Treatment cohort experienced a significant improvement in driving without neck pain at 24 weeks compared to pre-intervention levels. However, there was no significant difference between the two cohorts at 24 weeks.

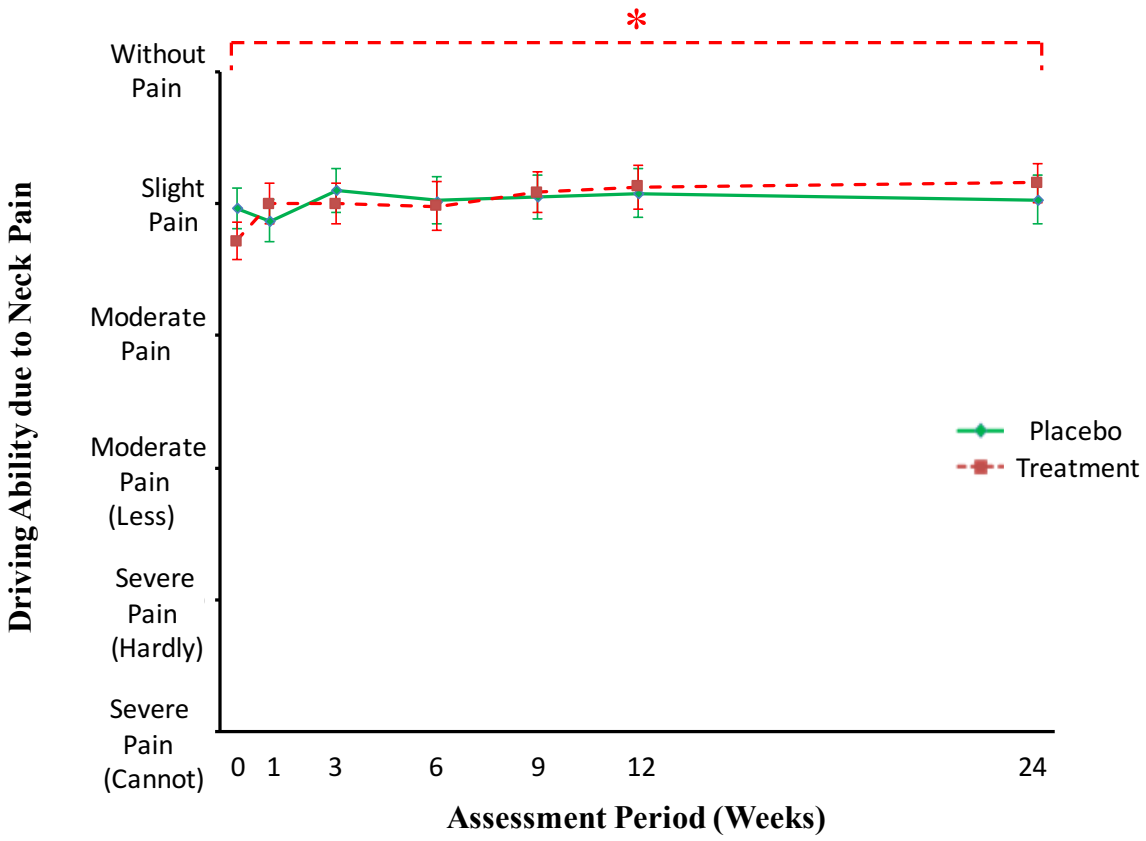

Figure 14. Driving Ability due to Neck Pain.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort p<0.05 using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Level of Headaches due to Neck Pain

Treatment cohort experienced a significant improvement in headaches due to neck pain at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

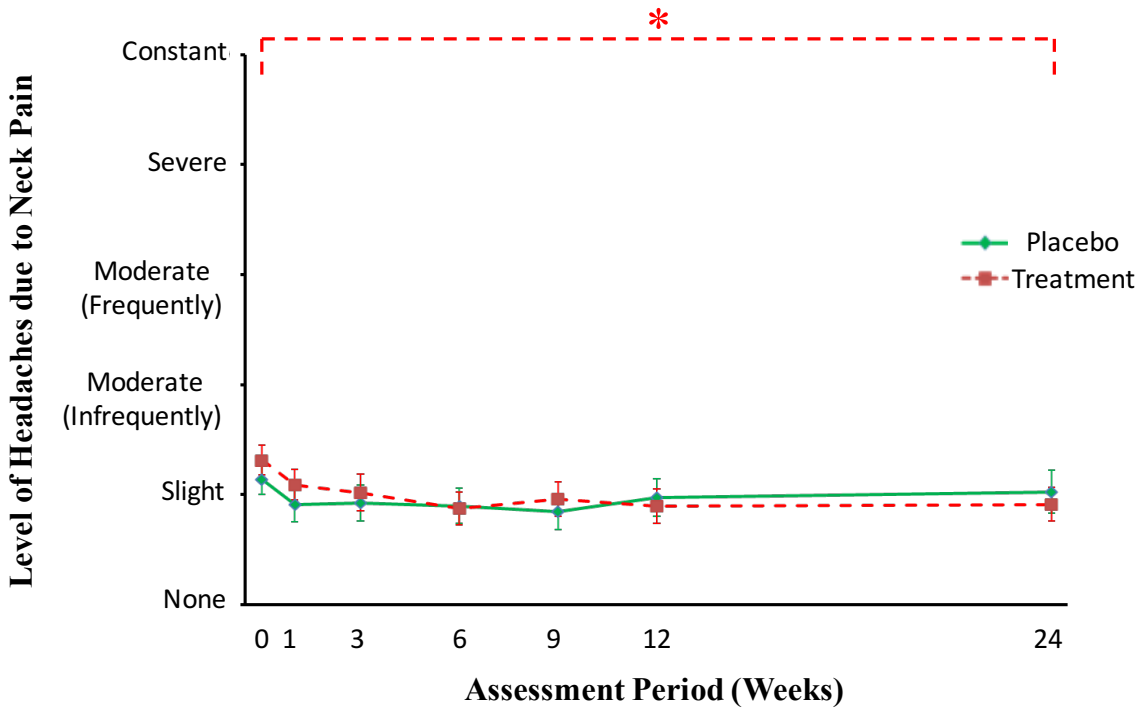

Figure 15. Level of Headaches due to Neck Pain.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Level of Neck Pain Intensity

Both cohorts experienced a significant improvement in the level of neck pain intensity at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

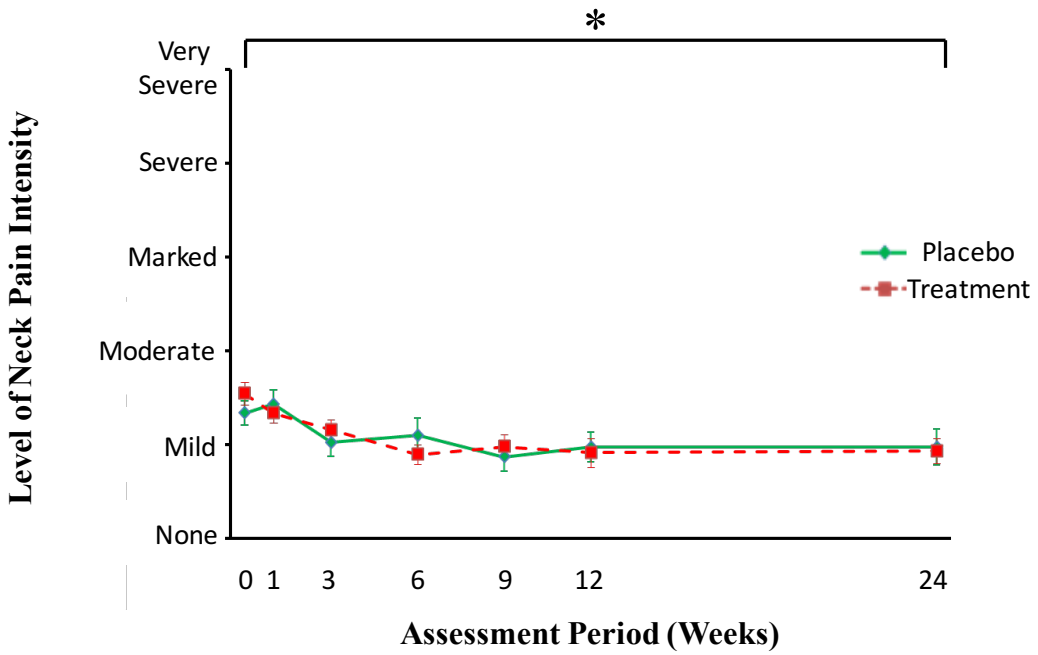

Figure 16. Level of Neck Pain Intensity.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Participation in Recreational Activities due to Neck Pain

Both cohorts experienced a significant improvement in the ability to participate in recreational activities at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

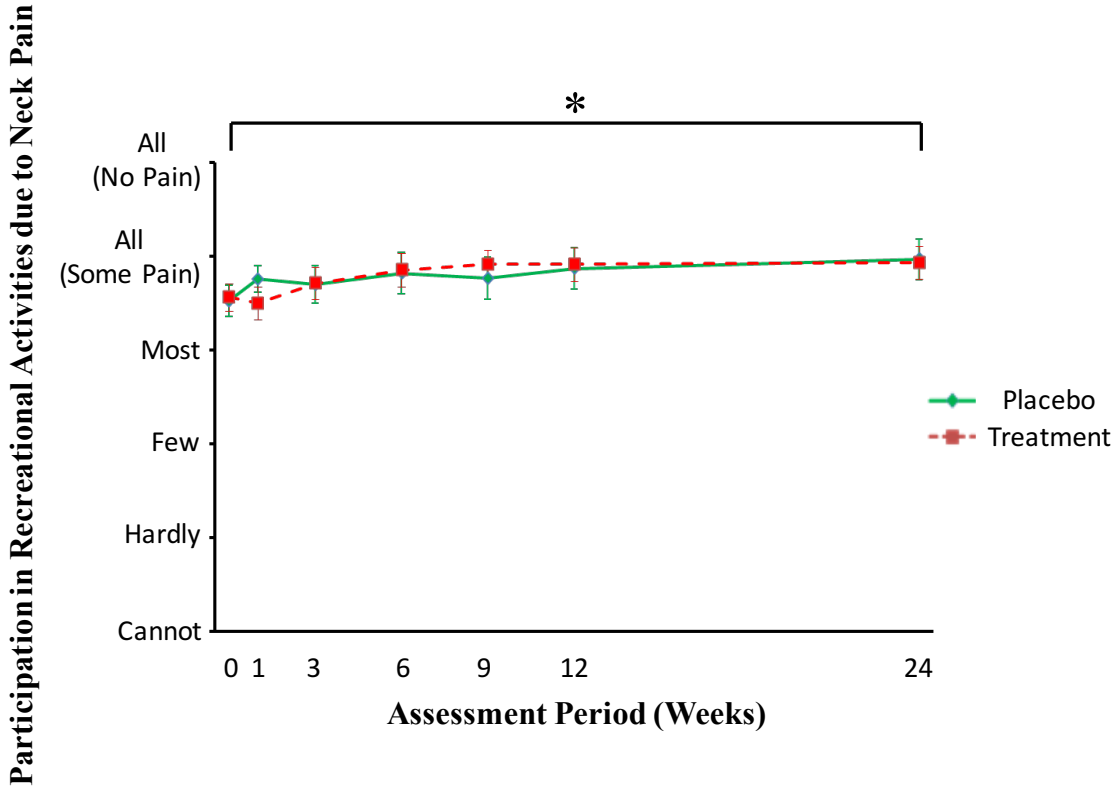

Figure 17. Participation in Recreational Activities due to Neck Pain.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Cervical Pain Affecting Sleep

Treatment cohort experienced a significant improvement in the ability to sleep due to neck pain at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

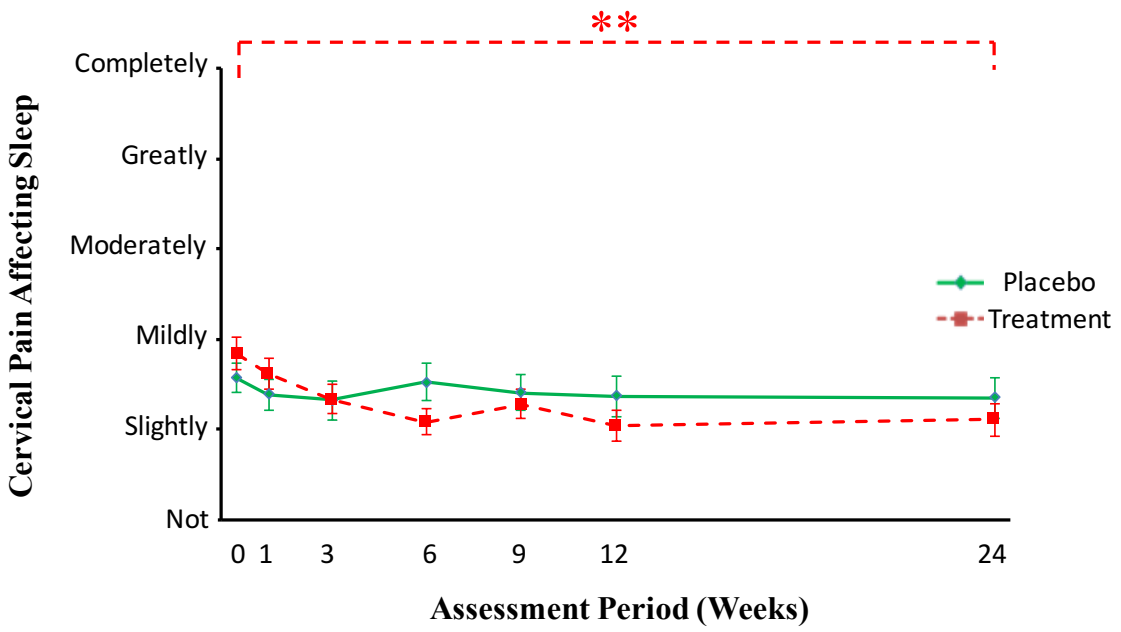

Figure 18. Cervical Pain Affecting Sleep.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort p<0.01 using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Proportion of Patients Experiencing Cervical Pain on Extension/Rotation/Lateral Flexion (Quadrant/Kemp's)

Treatment cohort experienced a significant improvement in the proportion of patients who experienced cervical spine pain in extension/rotation/lateral flexion at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

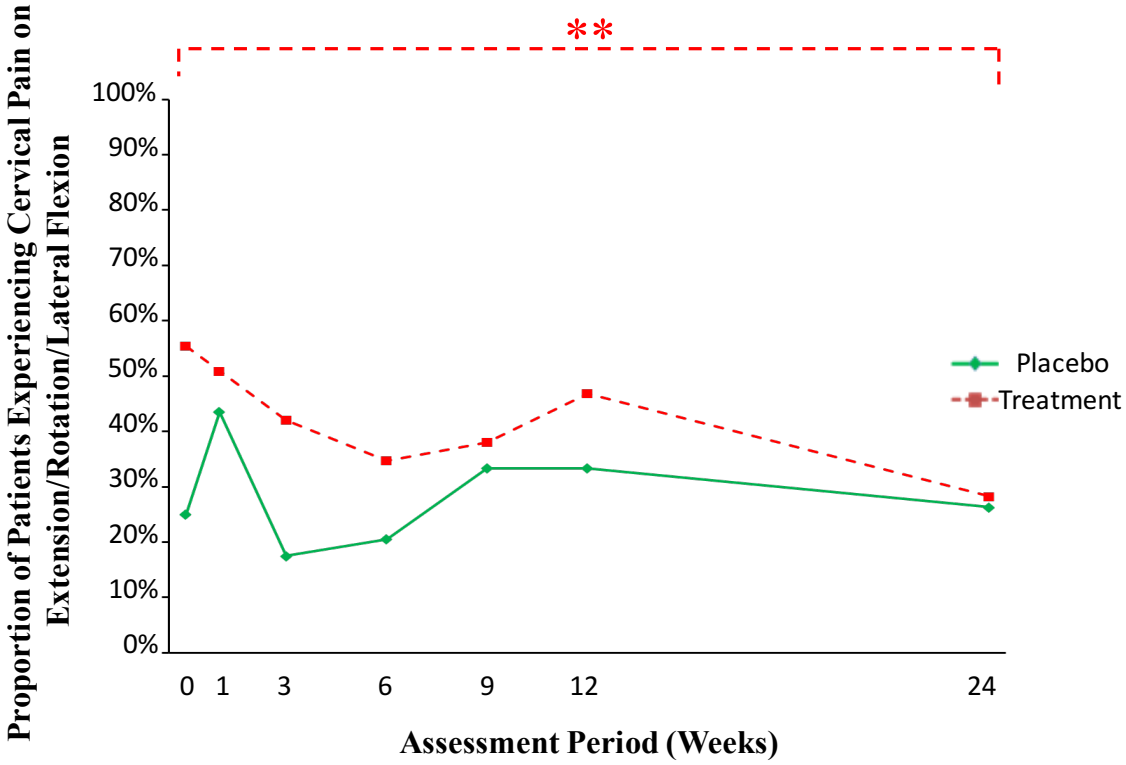

Figure 19. Proportion of Patients Experiencing Cervical Pain (patient ranked) on Extension/ Rotation/Lateral Flexion (Quadrant/Kemp's).

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.01$ between pre-treatment and 24 weeks with Chi square analysis. Chi square analysis at 24 weeks showed no significant difference between the two cohorts.

Proportion of Patients Experiencing Cervical Pain on Lateral Flexion

Treatment cohort experienced a significant improvement in proportion of patients who experienced cervical spine pain in lateral flexion at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

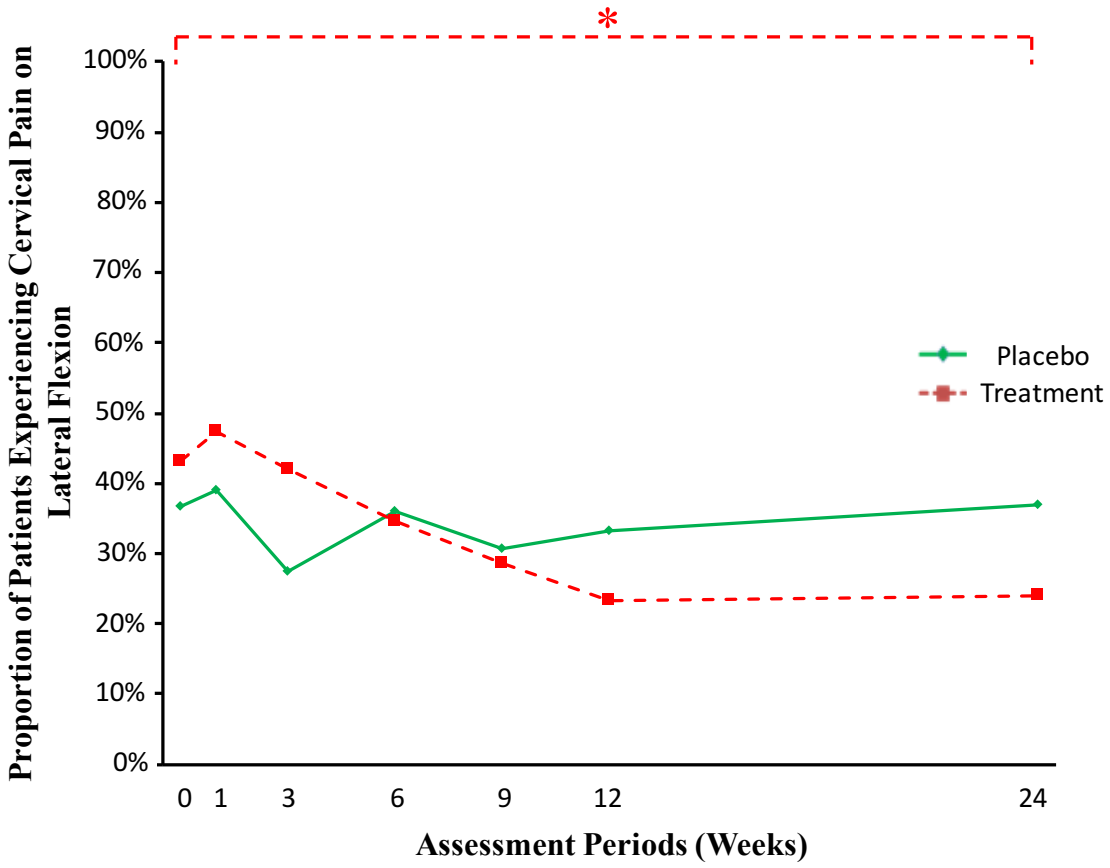

Figure 20. Proportion of Patients Experiencing Cervical Pain (patient ranked) on Lateral Flexion.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ between pre-treatment and 24 weeks with Chi square analysis. Chi square analysis at 24 weeks showed no significant difference between the two cohorts.

Proportion of Patients Experiencing Stiffness on Cervical Rotation

Treatment cohort experienced a significant improvement in proportion of patients who experienced cervical spine stiffness in rotation at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

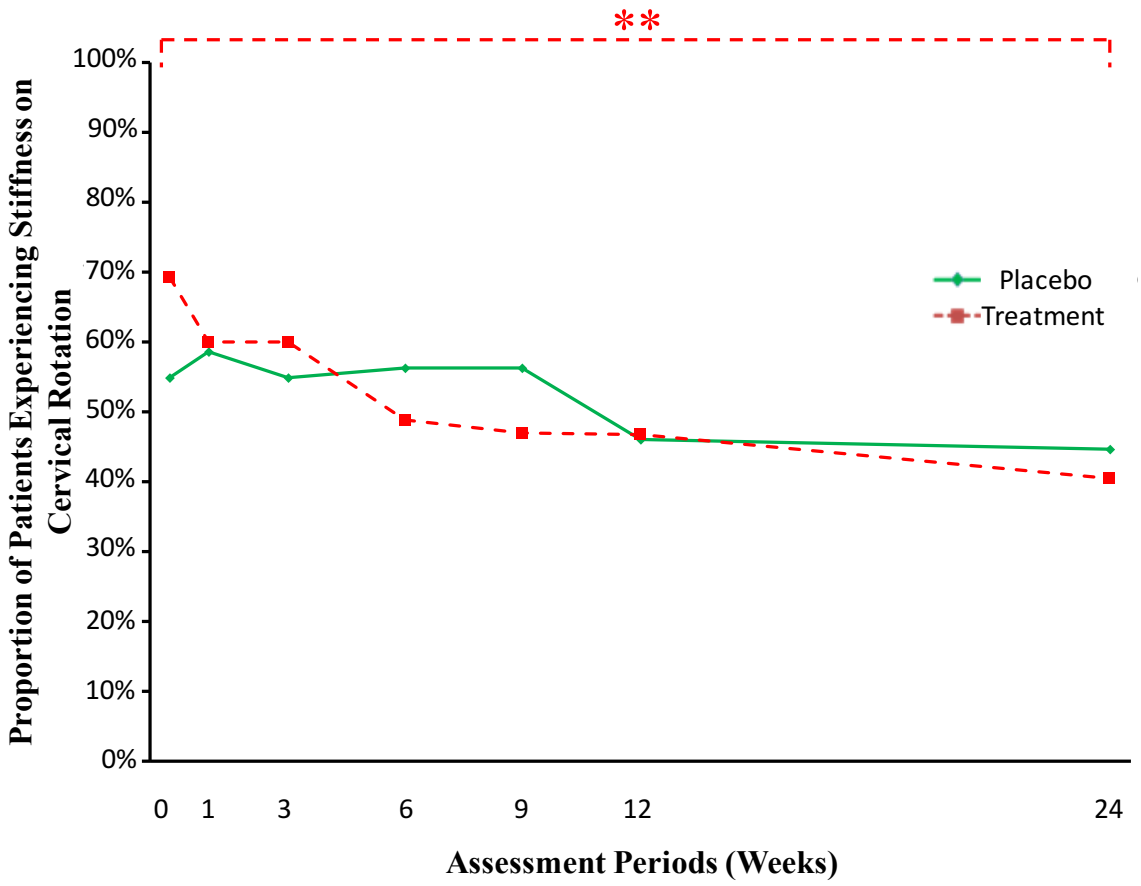

Figure 21. Proportion of Patients with Stiffness (patient ranked) on Cervical Rotation.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. Chi square analysis showed the treatment cohort had a significant improvement p<0.01 between pre-treatment and 24 weeks. Chi square analysis at 24 weeks showed no significant difference between the two cohorts.

Frequency of Shoulder Pain during Activity

Both cohorts experienced a significant improvement in the frequency of shoulder pain during activity at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

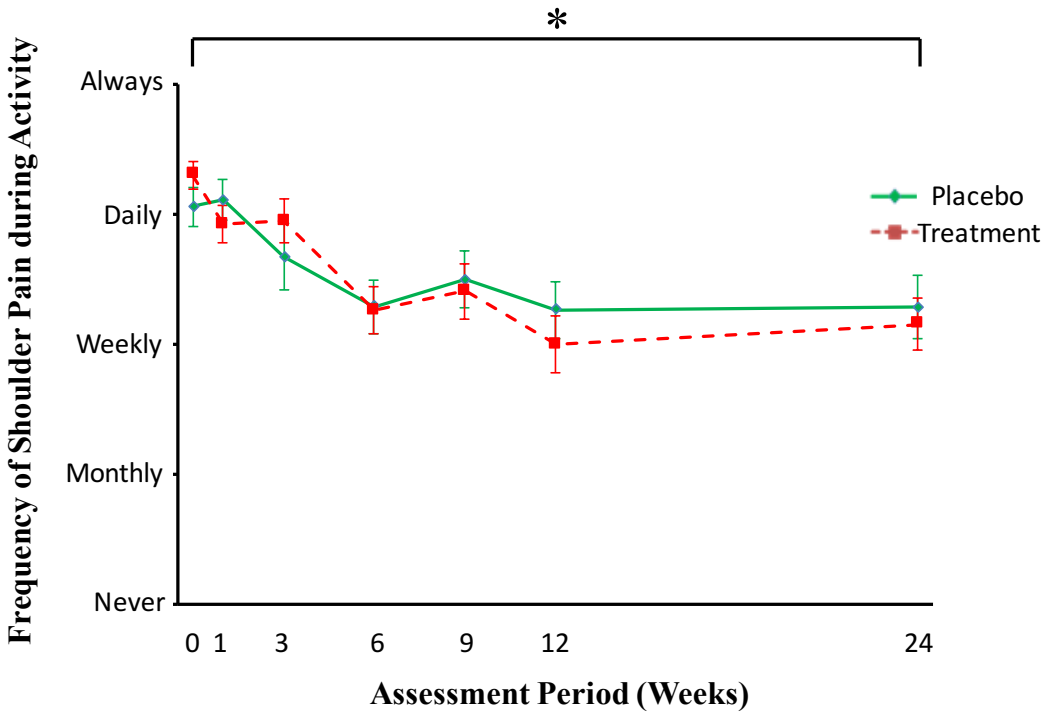

Figure 22. Frequency of Shoulder Pain during Activity.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Frequency of Shoulder Pain during Sleep

Both cohorts experienced a significant improvement in the frequency of shoulder pain during sleep at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

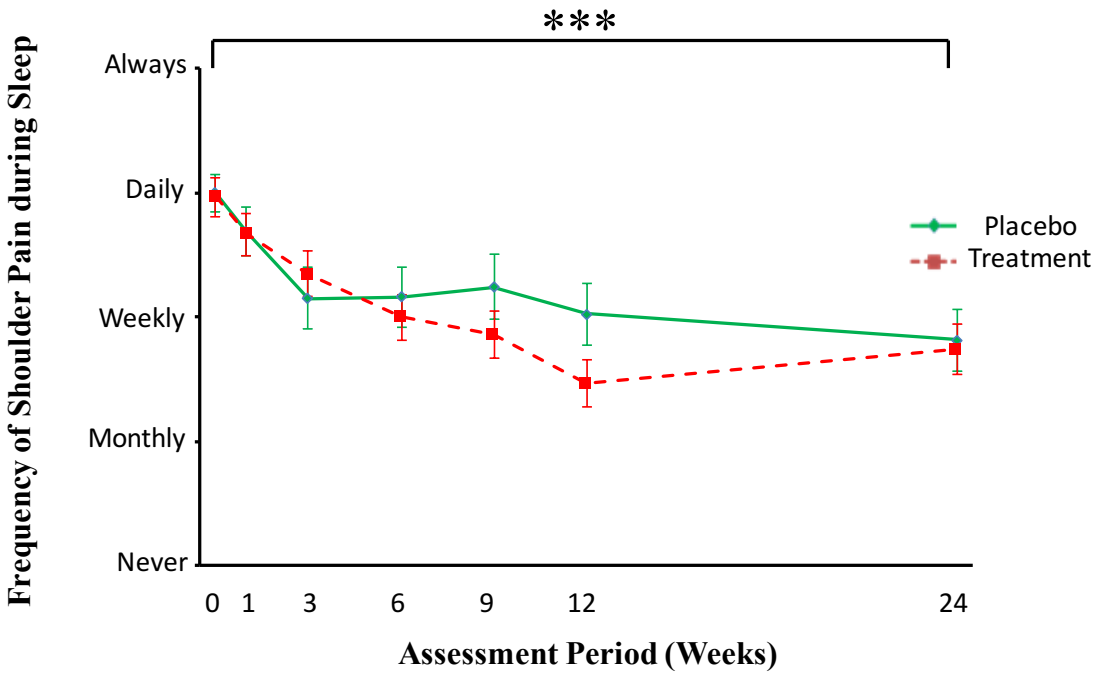

Figure 23. Frequency of Shoulder Pain during Sleep.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort p<0.001 using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Level of Shoulder Pain with Overhead Activities

Both cohorts experienced a significant improvement in the frequency of shoulder pain with overhead activities at 24 weeks compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

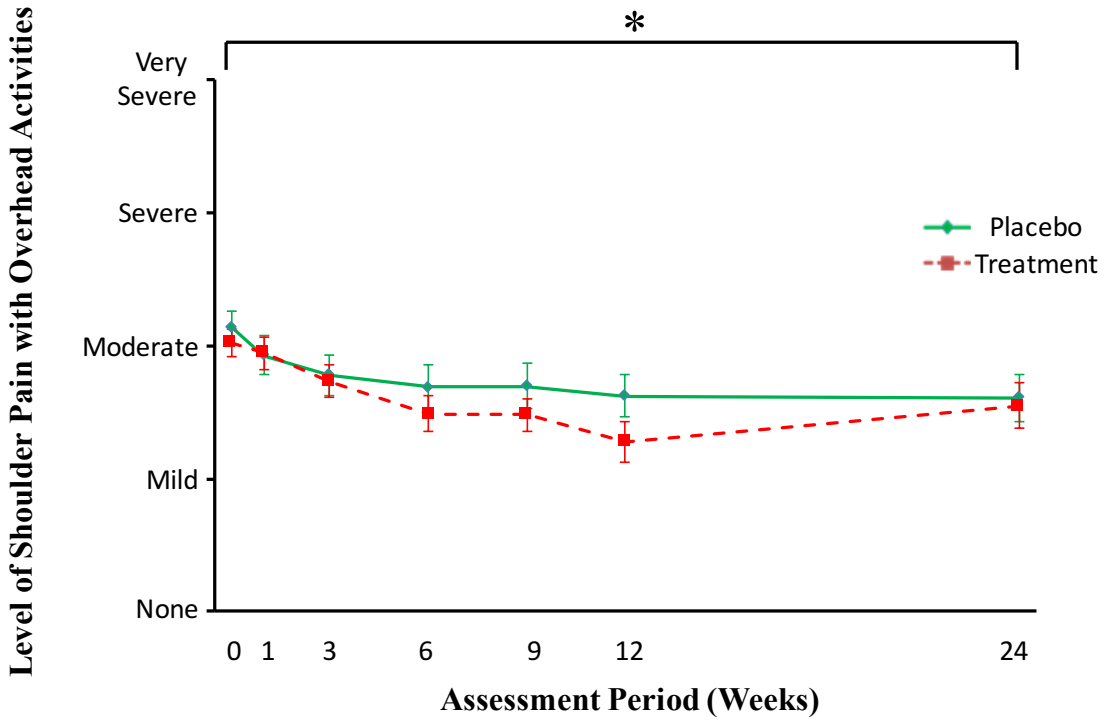

Figure 24. Level of Shoulder Pain with Overhead Activities.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort $p<0.05$ using Wilcoxon signed rank test between pre-treatment and 24 weeks. Mann-Whitney unpaired test showed no significant difference between the 2 cohorts at 24 weeks. Two-way ANOVA showed that time was the significant factor.

Shoulder Strength-Internal Rotation (Newtons)

However there was a significant difference in the two cohorts at 24 weeks, where treatment was a contributing factor.

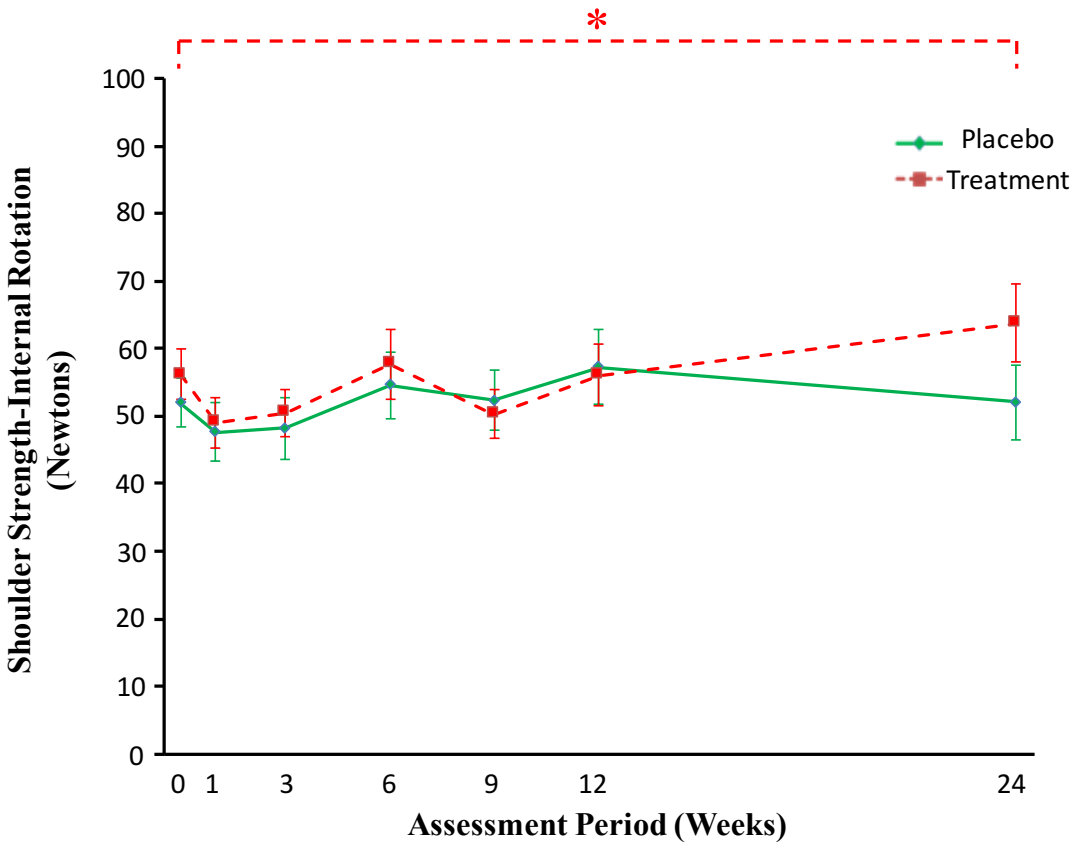

Figure 25. Shoulder Strength-Internal Rotation.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. Student's t-test showed no significant difference for the two cohorts between pre-treatment and 24 weeks. Two way ANOVA showed that the treatment cohort had a significant improvement at 6 months compared to pre-treatment. This improvement was due to the treatment itself p= 0.04 and not a temporal improvement p<0.06.

Shoulder Strength-Supraspinatus (Newtons)

Both cohorts had a significant difference at 24 weeks for shoulder strength-supraspinatus compared to pre-intervention levels. However, there was no significant difference in the two cohorts at 24 weeks.

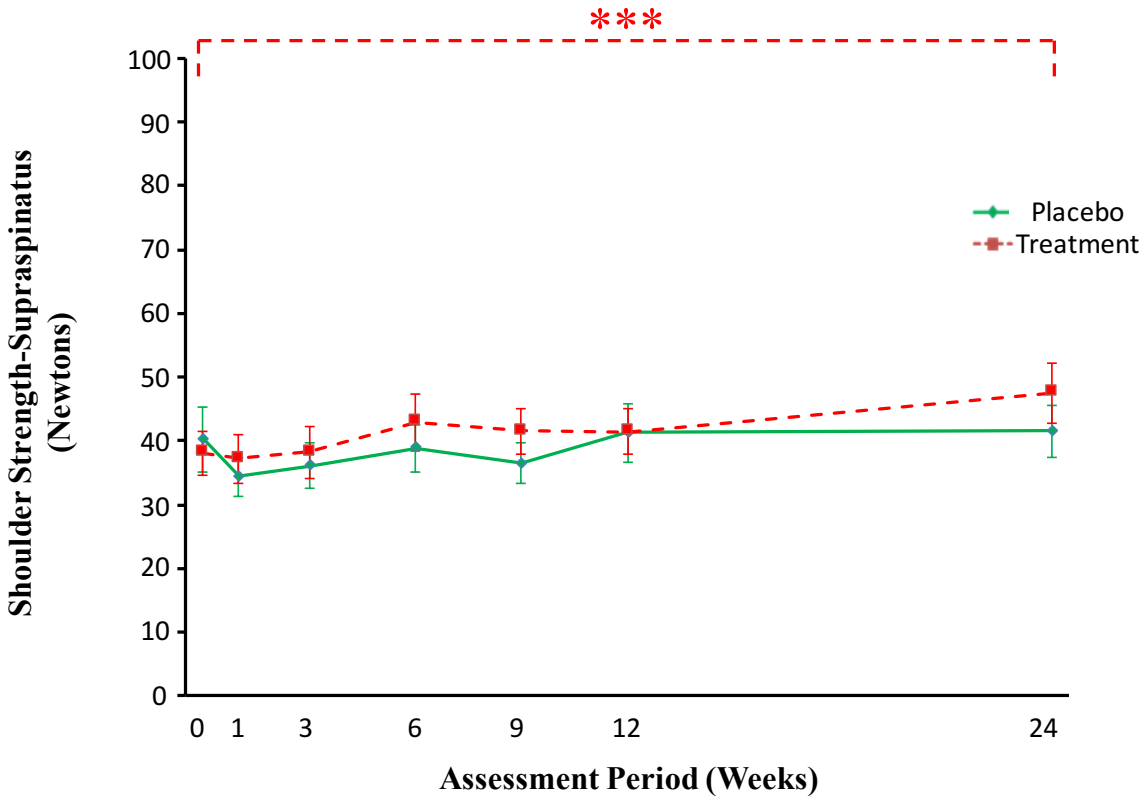

Figure 26. Shoulder Strength-Supraspinatus.

Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort p<0.001 using Student's t-test. Two-Way ANOVA showed that time was the contributing factor.

Proportion of Patients with Positive Impingement on Internal Rotation

Both cohorts had a significant improvement in the proportion of patients with positive impingement on internal rotation at 24 weeks compared to pre-intervention levels. However there was no significant difference in the two cohorts at 24 weeks.

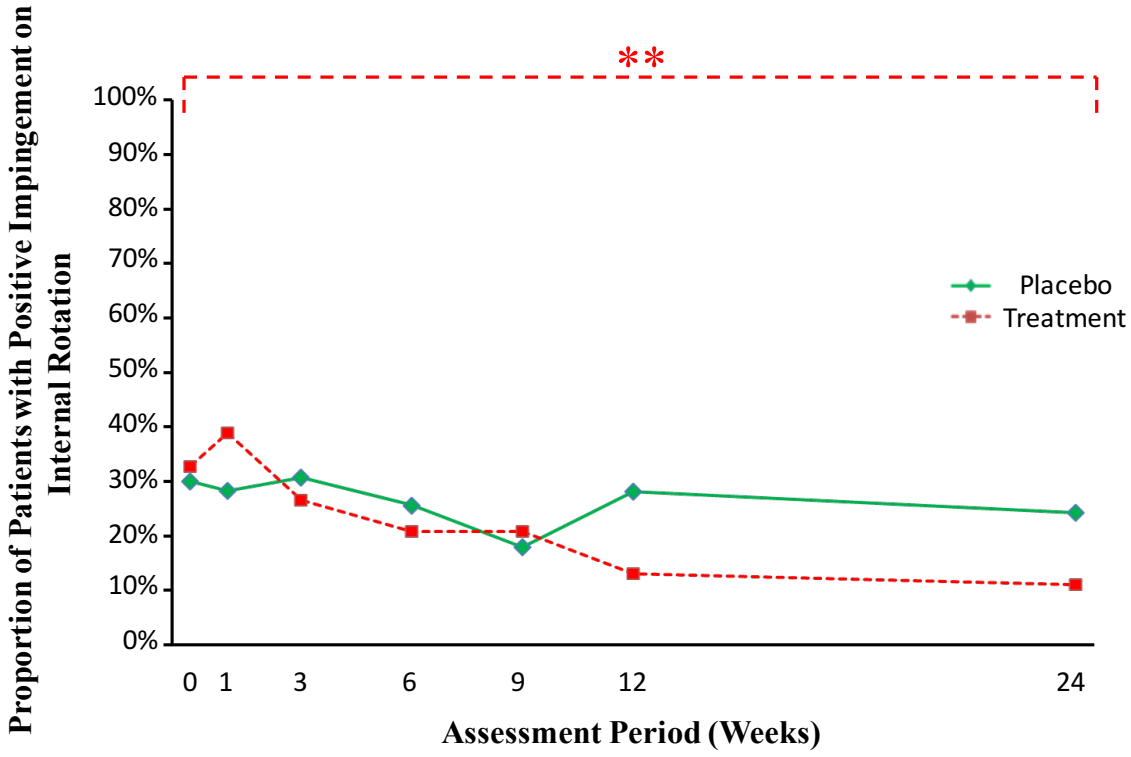

Figure 27. Proportion of Patients with Positive Impingement on Internal Rotation. *Mean +/- S.E.M., n=60 in the placebo cohort, n=65 in the treatment cohort. In the treatment cohort p<0.01 using Chi square. Chi square analysis at 24 weeks showed no significant difference between the two cohorts.*

6.3 Power analysis

No significant differences were observed in the outcome measures between the treatment and control cohorts, except for the increase in shoulder strength in internal rotation in the treatment cohort. It is possible that this may be due to the study being underpowered, i.e. due to type II error. In order to evaluate for this possibility, a post-hoc power analysis was performed, using the difference of the means at 24 weeks, the average of standard deviations of the treatment cohort and the placebo cohort with a power of 0.8 and an alpha of 0.05. The group sizes required to show a statistically significant difference for each outcome measure are summarized in Table 2. The required group sizes to rule out type II was for all of these measures ranged from 312 to 55384 subjects.

Table 2. Post hoc power analysis for size requirements of the treatment and placebo cohorts.

Outcome measure	Group size to see difference
Frequency of Extreme Shoulder Pain	312
Level of Shoulder Pain at Rest	55384
Driving Ability due to Neck Pain	2334
Level of Headaches due to Neck Pain	3090
Level of Neck Pain Intensity	26864
Participation in Recreational Activities	33164
Cervical Pain Affecting Sleep	1072
Proportion of Patients Experiencing Cervical Pain on Extension/Rotation/Lateral Flexion (Quadrant/Kemp's)	29914
Proportion of Patients Experiencing Cervical Pain on Lateral Flexion	762
Proportion of Patients Experiencing Stiffness on Cervical Rotation	5936
Frequency of Shoulder Pain-During Activity	4524
Frequency of Shoulder Pain-During Sleep	11638
Level of Shoulder Pain with Overhead Activities	9802
Shoulder Strength-Internal Rotation	350
Shoulder Strength-Supraspinatus	874
Proportion of patients with Positive Impingement on Internal Rotation	520

Discussion

This trial was a prospective, randomized, double blind, placebo controlled clinical trial aimed to determine if there were any benefits in applying a force to the C5 facet joints twice per week for 6 weeks then once a week for 3 weeks by a mechanically assisted instrument (MAI) in patients with referred pain to the shoulder. It was found that there was no effect on the intensity of pain, however, there were other improvements.

The results showed that in both cohorts the frequency of shoulder pain during activity ($p<0.05$) and sleep ($p<0.001$) decreased from daily to weekly at 24 weeks. In the treatment cohort at 24 weeks; the frequency of extreme shoulder pain decreased from weekly to monthly ($p<0.05$); the proportion of patients experiencing pain on cervical range of motion decreased by 30% ($p<0.01$) in extension/rotation/lateral flexion (Quadrant/Kemp's); the proportion of patients experiencing pain in cervical lateral flexion decreased by 20% ($p<0.05$); the proportion of patients that experienced stiffness in cervical rotation was reduced by 30% ($p<0.01$); shoulder strength increased in internal rotation by 10 N and supraspinatus strength increased by 10 N; the proportion of patients experiencing positive shoulder impingement on internal rotation decreased by 20% ($p<0.01$). Whilst all these outcomes improved in the treatment cohort, the only outcome measure that was statistically significantly better in patients receiving the mechanically assisted instrument (MAI) compared with placebo, was shoulder strength in internal rotation at 24 weeks.

No deterioration in any parameters was detected in either cohorts, and there were no adverse reactions to the procedures reported. One patient had cervical fusion during the trial, this was pre-planned prior to their participation.

To our knowledge no other studies have evaluated the use of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) in referred pain to the shoulder.

The strengths of our study was that it was a double blinded, placebo controlled trial. Both patient-reported and examiner-reported data were collected during the trial process and a single clinician with extensive experience in the use of the MAI applied the MAI treatment. The assessor was blinded as was the patient. This was a relatively large study for a single institution.

The limitations of the study was that although the numbers were large, more differences between cohorts may have been found with larger sample sizes.

Conclusion

The major effect of a mechanically assisted instrument (MAI) over placebo applied to the C5 facet joints two times per week for six weeks, then once a week for three weeks in patients who presented with referred shoulder pain was improved shoulder strength in internal rotation at 24 weeks. There was a reduction in the frequency but not severity of extreme shoulder pain in the treatment cohort, with average ranking reducing from weekly to monthly.

Presentations arising from thesis

Presentation at "What's New, What Works and What Does Not: An UPDATE for Physiotherapists". Orthopaedics and Sports Medicine, Kogarah, Australia, 13th September 2008.

Presentation at "Frontiers in Sports Medicine Conference'. Orthopaedic Research Institute Kogarah, Australia, 28th August 2014.

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Appendix A

St George Hospital Campus
Department Orthopaedic Surgery

Approval No._____

ST GEORGE HOSPITAL AND THE UNIVERSITY OF NEW SOUTH WALES

SUBJECT INFORMATION STATEMENT AND CONSENT FORM

Title of Project: A prospective, randomized, double blind, placebo controlled clinical trial assessing the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) on referred pain to the shoulder.

You are invited to participate in a study to determine the efficacy of using a mechanically assisted instrument (MAI) to treat referred shoulder pain. There is a theory that using the MAI can alleviate referred pain to the shoulder. The MAI is a hand held spring loaded device that is activated by compressing a handle on the shank of the instrument, it then delivers a force to a rubber attachment. The treatment therefore consists of placing the MAI on the skin at the level of C5 of the neck and activating it. However there are no clinical studies to show such effectiveness in the chiropractic and medical literature. Our aim is to show if the MAI can be beneficial in alleviating referred pain to the shoulder. You were selected as a possible participant in this study because you have suffered from referred shoulder pain for at least 2 weeks duration, and have not responded to maximal medical treatment.

If you decide to participate, you will receive treatment of your neck on the affected side, to be performed in the consulting rooms of George Hardas, a chiropractor, at St.George Private Hospital & Medical Complex. You will have a 50% chance of receiving treatment and a 50% chance of receiving "sham" treatment. There will be very minimal to negligible side-effects. We cannot guarantee or promise you will receive any benefits from this study. We will review you at regular intervals after your treatment, and ask you to fill in progress forms. Should any health problem occur as a result of participating in the trial in this research study compensation is available, however you may need to seek legal assistance in order to obtain compensation. If you think that some form of compensation is required we encourage you to discuss your case with the study doctor or hospital ethics committee.

Any information that is obtained in connection with this study and that can be identified with you will be kept strictly confidential. It will be only be disclosed with your permission or except as required by law. If you give us your permission by signing this document, we plan to use this information as the basis for a research thesis at the University of NSW and discuss/publish the results in scientific meetings and literature. In any publications information will be provided in such a way that you cannot be identified.

Complaints may be directed to the Ethics Secretariat, South Eastern Sydney Area Health Service Research Ethics Committee (Southern Section), St George Hospital, Gray Street Kogarah 2217, ph: 02 9350 2481, fax: 02 9350 3968.

Your decision whether or not to participate will not prejudice your future relations with Professor Murrell or St George Hospital. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

If you have any questions, we would like you to ask us. If you have any further questions later, Professor Murrell will be happy to answer them for you on 02 9350 2827.

You will be given a copy of this form to keep.

Signature of patient._____

Approval No._____

ST GEORGE HOSPITAL AND THE UNIVERSITY OF NEW SOUTH WALES

SUBJECT INFORMATION STATEMENT AND CONSENT FORM (CONTINUED)

Title of project: Chiropractic treatment of referred shoulder pain.

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate having read the information provided above.

Signature of patient

Please PRINT name

Date

Signature of witness

Please PRINT name

Nature of witness

Signature of Investigator

Please PRINT name

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardize any treatment or my relationship with the St George Hospital or my medical attendants.

Signature Date

Please PRINT name

The section for Revocation of Consent should be forwarded to Professor Murrell at the Department of Orthopaedics, St George Hospital, Kogarah 2217

Appendix B

All patients to complete the following:

1. Gender: Female □ Male □

2. Age: _____

3. Birthdate: _____

4. Occupation:_____

5. Which shoulder is affected? Right □ Left □

6. Are you? Right handed □ Left handed □ Ambidextrous □

7. Date your shoulder problem began:

   _____

8. Was this related to a specific injury? If so, how?

   _____

   _____

9. Does this injury involve an insurance claim? Yes □ No □

10. What was your level of activity at work before your shoulder problem?

    None □ Light activity □ Moderate activity □ Strenuous labour □

11. What was your highest exercise level before your shoulder problem?

    None □ Light activity □ Moderate activity □ Strenuous labour □

12. How often is your shoulder:	Always	Daily	Weekly	Monthly	Never
a) Painful during activity?	□	□	□	□	□
b) Painful when you sleep?	□	□	□	□	□
c) Extremely painful?	□	□	□	□	□

13. What is your level of shoulder pain:	Very	Severe	Moderate	Mild	None
a) When you are resting?	□	□	□	□	□
b) With activities above your head?	□	□	□	□	□
c) When you sleep?	□	□	□	□	□

14. How much difficulty do you have:	Very	Severe	Moderate	Mild	None
a) With reaching behind your back?	□	□	□	□	□
b) With activities above your head?	□	□	□	□	□

15. How "stiff" is your shoulder?

Very □ Quite □ Moderately □ A little □ Not at all □

16. How is your problem overall?

Very bad □ Bad □ Poor □ Fair □ Good □

17. Do you have neck pain?

Always □ Daily □ Weekly □ Monthly □ Never □

18. What is the level of your neck pain?

Very Severe □ Severe □ Moderate □ Mild □ None □

19. Do you have headaches?

Always □ Daily □ Weekly □ Monthly □ Never □

20. What is the level of your headaches?

Very Severe □ Severe □ Moderate □ Mild □ None □

21. Do you have ‘dizziness’/vertigo?

Always □ Daily □ Weekly □ Monthly □ Never □

22. What is the level of your ‘dizziness’/vertigo?

Very Severe □ Severe □ Moderate □ Mild □ None □

23. What is your current level of activity at work?

None □ Light activity □ Moderate activity □ Strenuous labour □

24. How many times has your shoulder dislocated?

>10x □ 5-9x □ 2-4x □ 1x □ Never □

25. Do you have any allergies? No □ Yes □ If yes, what?

_____

26. Do you take medication regularly? No □ Yes □ If yes, what?

_____

27. Please indicate if you have ever suffered from any of the following:

Heart trouble, chest pain, palpitations?	□
High blood pressure?	□
Shortness of breath?	□
Asthma?	□
Thrombosis or clots?	□
Diabetes?	□
Rheumatoid arthritis?	□
Indigestion, heart burn or ulcers?	□
Hepatitis or jaundice	□
Kidney trouble?	□
Stroke?	□
Fits or funny turns?	□
Bleeding disorder?	□

28. Mark if you have had any previous treatments/interventions to the shoulder:

Treatment/Intervention		How many sessions?	Did the treatment help? Yes	Did the treatment help? No
a) Chiropractic therapy	□	_____	□	□
b) Physiotherapy	□	_____	□	□
c) Acupuncture	□	_____	□	□
d) Injections	□	_____	□	□
e) Surgery	□	_____	□	□

Appendix C

Neck Disability Index (NDI)

Please read: This questionnaire is designed to enable us to understand how much your neck pain has affected your ability to manage everyday activities. Please answer each section by circling the ONE CHOICE that most applies to you. We realize that you may feel that more than one statement may relate to you, but please just circle the one choice that closely describes your problem right now.

Section 1 Pain intensity

A. I have no pain at the moment.
B. The pain is mild at the moment.
C. The pain comes and goes and is moderate.
D. The pain is severe but comes and goes.
E. The pain is severe but comes and goes.
F. The pain is severe and does not vary much.

Section 2 Personal care (washing, dressing, etc.)

A. I can look after myself without causing extra pain.
B. I can look after myself normally, but it causes extra pain.
C. It is painful to look after myself, and I am slow and careful.
D. I need some help but manage most of my personal care.
E. I need help every day in most aspects of self-care.
F. I do not get dressed, I wash with difficulty, and say in bed.

Section 3 Lifting

A. I can lift heavy weights without extra pain.
B. I can lift heavy weights, but it causes extra pain.
C. Pain prevents me from lifting heavy weights off the floor, but I can if they are conveniently positioned, for example on a table.
D. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
E. I can lift very light weights.
F. I cannot lift or carry anything at all.

Section 4 Reading

A. I can read as much as I want to with no pain in my neck.
B. I can read as much as I want to with slight pain in my neck.
C. I can read as much as I want with moderate pain in my neck.
D. I cannot read as much as I want because of moderate pain in my neck.
E. I cannot read as much as I want because of severe pain in my neck.
F. I cannot read at all.

Section 5 Headache

A. I have no headaches at all.
B. I have slight headaches that come infrequently.
C. I have moderate headaches that come infrequently.
D. I have moderate headaches that come frequently
E. I have severe headaches that come frequently.
F. I have headaches almost all the time.

Section 6 Concentration

A. I can concentrate fully when I want to with no difficulty.
B. I can concentrate fully when I want to with slight difficulty.
C. I have a fair degree of difficulty in concentrating when I want to.
D. I have a lot of difficulty in concentrating when I want to.
E. I have a great deal of difficulty in concentrating when I want to.
F. I cannot concentrate at all.

Section 7 Work

A. I can do as much work as I want to.
B. I can only do my usual work, but no more.
C. I can do most of my usual work, but no more.
D. I cannot do my usual work.
E. I can hardly do any work at all.
F. I cannot do any work at all.

Section 8 Driving

A. I can drive my car without neck pain.
B. I can drive my car as long as I want with slight pain in my neck.
C. I can drive my car as long as I want with moderate pain in my neck.
D. I cannot drive my car as long as I want because of moderate pain in my neck.
E. I can hardly drive my car at all because of severe pain in my neck.
F. I cannot drive my car at all.

Section 9 Sleeping

A. I have no trouble sleeping.
B. My sleep is slightly disturbed (less than 1 hour sleepless).
C. My sleep is slightly disturbed (1-2 hours sleepless).
D. My sleep is slightly disturbed (2-3 hours sleepless).
E. My sleep is slightly disturbed (3-5 hours sleepless).
F. My sleep is completed disturbed (5-7 hours sleepless).

Section 10 Recreation

A. I am able to engage in all recreational activities with no pain in my neck at all.
B. I am able to engage in all recreational activities with some pain in my neck at all.
C. I am able to engage in most but not all recreational activities because of pain in my neck.
D. I am able to engage in a few of my usual recreational activities because of pain in my neck.
E. I can hardly do any recreational activities because of pain in my neck.
F. I cannot do any recreational activities at all.

Appendix D

Shoulder/Cervical Assessments

1. Examiner's shoulder assessment

a) Affected shoulder **Right □** **Left □**

b) Passive range of motion **Degrees**

Forward flexion	
Abduction	
External rotation	

c) Internal rotation **Vertebral level**

Thoracic	
Lumbar	
Sacrum	

d) Strength **Meter (N) (Measured via a dynamometer)**

Internal rotation	
External rotation	
Supraspinatus	

e) Tests **(+)** **(-)**

Impingement (internal rotation)		
Impingement (external rotation)		

2. Examiner's cervical spine assessment

Cervical range of motion	Stiffness: Yes/No	Pain: Yes/No
Flexion		
Extension		
(R) Rotation		
(L) Rotation		
(R) Lateral Flexion		
(L) Lateral Flexion		
(R) Extension/Rotation/Lateral Flexion (Quadrant/Kemp's)		
(L) Extension/Rotation/Lateral Flexion (Quadrant/Kemp's)		