THE EFFICACY OF SPINAL MANIPULATIVE THERAPY IN THE MANAGEMENT OF MECHANICAL THORACIC SPINE PAIN

By

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I, Linda Schiller, do hereby declare that this dissertation represents my own work in both conception and execution.

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DEDICATION

I would like to dedicate this work to my supervisor Dr Nook. Not only is he an excellent teacher of chiropractic but also a great inspiration to chiropractic students of Technikon Natal. I thank him for his help and endless knowledge that was shared. Knowledge that will certainly not be lost for students and patients in the future. I thank him too, for his dedication to the chiropractic profession and to humanity.

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ABSTRACT

Objectives

To investigate the efficacy of spinal manipulative therapy (SMT) in the management of mechanical thoracic spine pain. It was postulated by the researcher that with manipulation of the affected thoracic spinal segment, there would be a significantly greater improvement than by only applying placebo treatment.

Summary of background data

There have been no substantiated studies performed up to this date to investigate the efficacy of SMT on thoracic syndromes.

Study design

A single-blind, randomised, comparative, controlled pilot study .

Methods

Thirty subjects selected from the general population, diagnosed as having mechanical thoracic spine pain, were randomly divided into two different treatment groups. Each group consisted of fifteen patients between the ages of 16 and 60 years. The first group received thoracic spine manipulation. The second group received placebo treatment only.

The research project was carried out where both groups received a maximum of six treatments over a minimum period of two weeks. Thereafter a follow-up appointment

was scheduled one month after the final treatment to assess the long-term benefits of the two treatments.

The objective measurements collected were the thoracic spine ranges of motion with the BROM II goniometer and pain threshold with an algometer . Readings were taken before the first treatment and final treatments and again at the one-month follow-up consultation.

The subjective information required completion of the Oswestry Back Pain Disability Index, Short-form McGill Pain Questionnaire and Numerical Pain Rating Scale-101 Questionnaire by the patient. These three forms were completed before the first and final treatment and again at the one month follow-up consultation.

The data gathered at the relevant appointments was then statistically analyzed , using a 95% confidence level. The non-parametric Mann-Whitney U-Test and the Wilcoxon's Signed Rank Test were used for comparing inter-group and intra-group data respectively. This was conducted at $\alpha=0.05$ level of confidence. Further assessment of the data was conducted using power analysis. These data as well as the descriptive statistics are presented in tables and bar charts.

Results

This study suggests that SMT may be more effective than placebo therapy in the short-term management of mechanical thoracic spine pain. Statistically significant results ($p \leq 0.025$) were noted on inter-group comparison at the final treatment on right and left lateral flexion, as well as the percentage pain experienced. It was noted that the power

was weak; so the probability of committing Type II error for the other measurements was high (falsely accepting the null hypothesis).

The intra-group analysis showed statistically significant improvements in the SMT group both subjectively and objectively between the first to final treatment and the first treatment to the one-month follow-up. The placebo group analysis showed statistically significant improvements in subjective measurements only and for sensory pain only between the first treatment to the final treatment and for all subjective measures between the first treatment to the one-month follow-up.

Conclusions

This pilot study suggests that SMT has greater benefits than placebo treatment. Due to the small sample size, the findings of this trial study should not be considered conclusive, but rather used as a foundation to plan future studies.

In further studies a larger sample size is necessary to identify subtle changes in measurement parameters and to add to the validity of the results.

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DEFINITION OF TERMS

Fixation

The state whereby an articulation has become temporarily immobilised in a position that it may normally occupy during any phase of physiological movement (Haldeman 1992:623). Fixation is caused by muscular spasm, a shortened ligament, or by intra-articular blocking (Gatterman 1990:408).

Goniometer

An instrument for measuring angles, used for measuring the range of motion of a joint or a set of joints in degrees (Gatterman 1990:408). Used as an objective clinical finding in this trial study.

Mechanical spine pain

Mechanical spine pain, is pain not due to organic causes, but is associated with degenerative changes of the spine. It is associated with phase one joint degeneration for example facet joint syndrome, hypomobility and early disc degeneration (Kirkaldy Willis 1992:63).

Placebo

An intervention designed to simulate medical therapy, but not believed (by the researcher) to be a specific therapy for the target condition. It is used either for it's psychological effect or to eliminate observer bias in an experimental setting. (Turner et al.1994.)

Note:- for the purpose of this study the placebo treatment will be the application of a non-functional ultrasound head over the area of pain.

Spinal manipulative therapy (SMT)

A passive manual maneuver during with the joint complex is suddenly carried beyond the normal physiological range of movement and through the elastic barrier without exceeding the boundaries of anatomical integrity. The usual characteristic is a dynamic specific thrust of controlled velocity and amplitude given at the end of normal passive range of movement to exceed this elastic barrier into the range of the paraphysiological space. It is usually accompanied by a cracking noise.(Sandoz,R. 1976)

Subjective clinical findings

Diagnostic procedures, as completed by the patient, that subjectively assess the condition of the same patient. This was achieved through the use of three questionnaires (_Oswestry_Back Pain Disability Questionnaire, Short-form McGill Pain Questionnaire, Numerical Pain Rating Scale-101 Questionnaire).

Thoracic spine

Twelve bony segments of the spinal column including the intervertebral discs, zygapophysial joints and accompanying soft tissue of the upper back designated T1 to T12 T1 is below C7 the last cervical spine vertebra and T12 above L1 the first lumbar spine vertebra.

CHAPTER ONE

1.0 INTRODUCTION

1.1 The problem and its setting

Spinal manipulative therapy has been widely recognised and successfully used in the medical fields as a conservative treatment modality for spinal joint dysfunction and pain during the past century (Herzog et al.1993).

Although the first successful chiropractic adjustment recorded was in the thoracic spine by D.D. Palmer in 1910, most of the spinal manipulative therapy (SMT) research has focused on the lumbar spine (Di Fabio 1992). The thoracic spine has been conspicuously absent from the picture (Plaugher 1991:243).

In reviewing the literature relating to the thoracic spine it is apparent that in comparison to the cervical and lumbar regions it has largely been neglected. This may be attributed to the technical difficulties associated with movement analysis in this region and the belief that the thoracic spine is less commonly implicated in clinical pain syndromes (Edmondston and Singer 1997). Thoracic spine pain plays a much more important role in the differential diagnosis of chest pain than expected, being third in frequency. Thoracic spine pain can be easily overlooked and result in a number of false diagnoses and insufficient treatment. (Bechgaard 1981.) Thoracic spine pain is a common complaint which can be as disabling as cervical and lumbar pain and deserves wider recognition (Bruckner el al. (1987), Dreyfuss et al.1994, Edmondston and Singer 1997).

It is well documented that SMT has become one of the most widely used treatment methods for vertebral column pain (Senstad 1997, Herzog1993, Lee 1993) and perhaps is the most well studied remedy for spinal related disorders (Triano 1992) . However the effect that SMT has on various spinal structures is still unknown, therefore chiropractic research will have to expand to determine exactly what role it plays (Haldemann 1992).

SMT is just beginning to define it's role in the thoracic spine. All healing techniques undoubtedly involve placebo factors, but relative proportions of "active" vs. "passive" influences of SMT on the thoracic spine can only be demonstrated in a clinical controlled trial study. This must not be confused with chiropractic practice, as ignoring placebo effects is to deprive patients of the maximum clinical benefits (Keating 1987).

This study will attempt to address the apparent gaps in the literature regarding the interaction of biomechanics and physiology of SMT; and provide clinical evaluation of manipulative and placebo interventions on the thoracic spine.

1.2 The statement of the problem

The purpose of this placebo controlled study is to investigate the efficacy of spinal manipulative therapy in the management of mechanical thoracic spine pain, in terms of objective and subjective clinical findings.

1.2.1 The first sub-problem

The first sub-problem of this placebo controlled study is to investigate the efficacy of spinal manipulative therapy in the management of mechanical thoracic spine pain, in terms of objective clinical findings.

1.2.2. The second sub-problem

The second sub-problem of this placebo controlled study is to investigate the efficacy of spinal manipulative therapy in the management of mechanical thoracic spine pain, in terms of subjective clinical findings.

1.2.3. The third sub-problem

The third sub-problem is to integrate the results of sub-problems one and two to establish the efficacy of spinal manipulative therapy in the management of mechanical thoracic spine pain.

1.3 Hypotheses

1.3.1 The first hypothesis

It is hypothesised that spinal manipulative therapy will be effective in the management of mechanical thoracic spine pain, in terms of objective clinical findings.

1.3.2. The second hypothesis

It is hypothesised that spinal manipulative therapy will be effective in the management of mechanical thoracic spine pain, in terms of subjective clinical findings.

1.3.3. The third hypothesis

It is hypothesised that on integration of the results of hypotheses one and two there would be a statistically significant difference in the subjective and objective clinical findings, showing that spinal manipulative therapy is effective in the management of mechanical thoracic spine pain.

1.4 Benefits of study

There has been a resurgence of interest in the thoracic spine from a clinical perspective that may be explained by: the recognition of the thoracic spine as an important source of local and referred pain, the role of the thoracic curvature in determining overall spinal posture, and the influence of thoracic mobility on movement patterns in other regions of the spine and shoulder girdle (Edmondston and Singer 1997). However much of the clinical theory, particularly in relation to the effects of SMT on thoracic spine pain, is untested.

It is important to determine what role SMT plays in the management of thoracic spine pain, owing to the diversity of treatment protocols and personal opinions. Furthermore SMT has been shown to be beneficial in the treatment of cervical and lumbar spine pain (Hadler et al.1987, Koes et al.1992, Mennell 1990). SMT has not yet been proven to be beneficial for the thoracic spine. SMT cannot be assumed to relieve thoracic spine pain because of similar findings in the cervical and lumbar spine. With the use of a placebo controlled study, the effects of SMT will be more evident and conclusive.

To our knowledge, the present study is unique and opens the way for further research into the management of thoracic spine pain.

CHAPTER TWO

2.0 REVIEW OF THE RELATED LITERATURE

2.1 PREVALENCE AND INCIDENCE OF THORACIC SPINE PAIN

An intensive literature search of Medline, Mantis, in journals and relevant books was conducted by the author. Despite the scientific and clinical research that has taken place over the past decade no epidemiological survey addressing the incidence or prevalence of thoracic spine pain in the adult population, alone without combining lower back pain could be found.

A study by Fairbank et al. (1984) on 446 pupils aged 13-17 years, found 26% to have a history of back pain. In 77 of the 115 pupils complaining of a history of back pain, the anatomic site of pain was identified: 15 had thoracic, 24 thoracolumbar, and 38 lumbar pain.

Another study among 1178 school children was conducted by Troussier et al. (1994) to determine the prevalence of back pain. The cumulative prevalence of back pain was 51,2%. Lumbar pain (41%) and thoracic pain (34%) were more common than cervical pain (27%).

As part of a prospective study of overuse injuries, 395 male infantry recruits were evaluated for back pain during a single basic training course. During the course of 14 weeks of training, 70 recruits (18%) were diagnosed as having overexertional back pain: 32 (8%) had thoracic pain and 40 (10%) had lumbar pain. Two recruits had both lumbar and thoracic pain. (Milgrom et al.1993.)

In the results of a feasibility study by Triano et al. (1993) using 186 patients, thoracic spine pain constituted 13.1% of the distribution of main complaints, while lumbar spine pain constituted 35%, cervical spine pain 18.6% and peripheral joints 6.2%.

In the USA, a comparative survey between six chiropractic college clinics indicated that the number of patients seen for lower back pain ranged between 31%-41%, neck pain ranged between 19-27% and midback pain ranged between 10-15% (Nyiendo et al. 1989).

An epidemiological survey was made of the prevalence of back pain in a sample of 320 Canadian chiropractors. The overall prevalence of back pain was 87%. It was found that male chiropractors complained most frequently of lumbar pain, while among female respondents thoracic pain was most common. The combined frequency of regional complaints was 59% in the lumbar spine, 50% in the thoracic spine and 30% in the cervical spine. They concluded that the overall prevalence of back pain among chiropractors is not only at the upper end of the scale reported for the general population, but also appears to be the highest among health professionals (dentists 57% and nurses 52%). (Mior and Diakow 1987.)

Bechgaard (1981) investigated the frequency of segmental thoracic pain in 1097 patients admitted to a medical department and coronary unit complaining of chest pain. Specific examination of the thoracic vertebrae and segments was preformed with minimal risk to possible coronary patients. Segmental thoracic pain accounts for 13% of chest pains, making it the third most common chest pain (behind coronary thrombosis pain 39%, angina pectoris 20%).

2.2 CONTRIBUTING AND RISK FACTORS OF THORACIC SPINE PAIN

Interactions between thoracic spine posture and mobility are believed to play a role in the development of spinal pain syndromes (Edmondston and Singer 1997).

A pilot study on 10 healthy subjects done by Harms-Ringdahl and Ekholm (1986) identified a possible cause for thoracic spine pain. Extreme flexion positions of the lower-cervical-upper-thoracic spine, resembling the sitting posture in some common work conditions, caused pain in all 10 experimental subjects within 15 minutes. This pain disappeared within 15 minutes after the end of provocation, but was experienced again by 90% of subjects that same evening or next morning and lasted up to 4 days. The recorded electromyographic levels from the splenius, thoracic spinae, rhomboid and lower trapezius muscles also increased during provocation. As expected, activity levels were higher during writing compared to when the arms were at rest. It was thus concluded that pain does occur in healthy persons in common work sitting postures.

Milgrom et al. (1993) in a prospective study for possible risk factors and efficacy of drug treatment regimes for overexertional back pain, found that an increase in lumbar lordosis was a risk factor for overexertional thoracic pain. The thoracic inclination angle, body mass index and waist circumference however had no relationship to thoracic spine pain in all groups. No statistically significant difference in improvement was found between Ibuprofen, Paracetamol or no treatment groups.

The study of back pain in adolescents may give insight into the risk factors of much more frequent complaints of back pain among adults. Fairbank et al. (1984) identified 39 pupils

(8.4%) from a total of 466 with thoracic spine pain. The peak age of onset is 13 years in boys and 14 years in girls. Back pain was more common in those that avoided sport, unlike those pupils with knee pain, who had a higher proportion of sports enthusiasts. Femoral and tibial rotation were significantly less in the pupils with back pain. This finding is consistent with a concept of reduced suppleness in the lower limbs putting an increased strain on the spine during activity. Body weight was also found to be higher in the group with back pain. Increased trunk length was associated with lumbar pain but not with thoracic pain.

Troussier et al. (1994) found, among 1178 pupils, five statistically significant variables that correlated with back pain. There is an important increase in back pain after the age of 12 years, particularly among girls; the prevalence of back pain is less than 42% before 11 years and increases to 60% amongst those aged 12 years or more. The prevalence of back pain significantly increases for those pupils who participated in vollyball (78%), who had previous back injury (9%), who smoked (83%) and who spent more than 1 hour a day watching television (50%).

Mior and Diakow (1987) found no apparent correlation between back pain and operating postures or table heights in 320 Canadian chiropractors. Yet, 82% of the chiropractors believed their back pain was aggravated by practice and made these kind of changes to avoid pain. No clear relationship between the amount of back pain experienced and the total hours worked per week could be established.

2.3 ANATOMY OF THE THORACIC SPINE

In reviewing the literature relating to vertebral column anatomy and biomechanics it is apparent that, in comparison to the cervical and lumbar regions, the thoracic spine has been largely neglected. Appropriate and effective spinal manipulative therapy is dependent on a sound knowledge of anatomy and biomechanics of this region of the vertebral column.

Panjabi et al. (1991) studied the three-dimensional surface anatomy on 144 thoracic vertebrae. The thoracic spine was found to have three distinct regions according to width-to-depth ratios: upper T1-T4, middle T4-T9/T10, and lower T10-T12. The middle thoracic region is characterised by a relatively narrow end-plate and spinal canal. A small spinal canal makes this region susceptible to cord impingement, although rib articulations add significant stiffness to the region. This middle region has been called the critical vascular zone, because the blood supply to the spinal cord is the least profuse at this level.

The kyphotic curve is approximately 45,6° for the entire thoracic spine, that is a vertebral wedge angle of 3,8° per vertebra (Panjabi et al. 1991). Muscle activation has little effect on the thoracic kyphosis which is determined more by the osseous asymmetry of the vertebral bodies. This limits the potential for spinal extension during active and passive movement i.e. SMT. (Edmondston and Singer 1997.)

Oda et al. (1996) investigated the role of the posterior elements, costovertebral joints, and rib cage in the stability of the thoracic spine in eight canine rib cage-thoracic spine complexes. A large increase in the range of motion in flexion-extension was observed after resection of the posterior elements and lateral bending and axial rotation after resection of the costovertebral

joints. The role of the costovertebral joints and rib cage in stabilising the thoracic spine is significant (especially in lateral bending and rotation) and can be called the "fourth column". The thoracic spine may become unstable when the posterior elements and bilateral costovertebral joints are destroyed. It was concluded that the costovertebral joints are important stabilisers and should be assessed when evaluating the thoracic spine.

Thoracic disc height, relative to vertebral body height, is less than that in the cervical and lumbar regions and the ratio of disc diameter to height is 2-3 times higher in the thoracic than the lumbar segments. This reduces the mobility of a functional spinal unit in the thoracic spine. (Edmondston and Singer 1997.)

Dreyfuss et al. (1994) based on the results obtained from a pilot study stated that the thoracic zygapophyseal joints can produce both local and referred pain in a reproducible manner. In all 9 subjects tested, each joint caused the most intense area of evoked pain one segment inferior and slightly lateral (unilateral only) to the joint injected with a contrast medium only. The zygapophyseal joints of the thoracic spine are smaller and hold less volume than the cervical and lumbar counterparts. Thus it appears that their joint pain pattern is more localised and closer to it's origin than zygapophyseal pain in other spinal regions.

The thoracic spine is a common site for normal anatomical variations. Deviations of a thoracic spinous process away from the midline is common, and can be mistaken for fixed segmental rotation. (Edmonston and Singer 1997, Gatterman 1990:182). Manipulative attempts of these static "misalignments" can cause considerable discomfort to the patient. This mistake can be avoided by using motion palpation to determine the correct site to apply SMT. (Gatterman 1990:182.)

2.3 BIOMECHANICS OF THE THORACIC SPINE

The primary mechanical function of the skeleton is to withstand and distribute the forces encountered during weight-bearing and locomotion (Edmondston and Singer 1997). Biomechanical aspects of the thoracic spine are different from those of the cervical and lumbar spine due to the attachment to the rib cage by the costovertebral joints (Oda et al. 1996) and the persistence of the primary kyphotic curve (Gatterman 1990:176).

The compressive load at T1 is about 9% of body weight, increasing to 33% at T8 and 47% at T12 (Edmondston and Singer 1997). The majority of this load is transferred to the vertebral bodies and to accommodate this, the height, end-plate cross-sectional area and bone mass of the vertebral bodies increases caudally, particularly in the middle and lower levels (Panjabi et al.1991).

Thoracic kyphotic curvature will most certainly influence patterns of load-bearing and movement, and the greater the stiffness of the thoracic spine the more it may produce compensatory changes and pain in the more mobile lordotic regions (Edmondston and Singer 1997). This kyphotic curve makes the thoracic spine more prone to be unstable in flexion (White and Panjabi 1990:328).

Willems et al. (1996) provided preliminary data on primary and coupled rotations of the thoracic spine in vivo on 60 subjects. Sagittal motion was almost pure plane motion. Coupling was most evident between lateral flexion and axial rotation. The middle and lower regions of the thoracic spine presented with predominantly ipsilateral coupled patterns. However there was relatively equal incidence of ipsilateral and contralateral patterning in the

upper thoracic region in lateral flexion and coupled axial rotation. While it is well known that scoliosis displays an abnormal coupled relationship between axial rotation and lateral flexion in the thoracic region (White and Panjabi 1990:130). When axial rotation was the primary movement, the couple of lateral flexion was predominantly contralateral. Axial rotation is the dominant motion of the thoracic region with half of the total occurring in the middle thoracic region.(Willems et al. 1996.)

Intervertebral disc degeneration and reduced disc height is greatest in the mid-thoracic segments, while an age related reduction in disc height is much less common in the lumbar spine (Edmondston and Singer 1997). Radial fissures occur most frequently in the thoracic spine. Degenerative disc disease causes anterior disc thinning due to the increased compressive loads encountered here, which leads to altered posture and compensatory changes. Maintenance of normal joint movement is likely to limit the degenerative processes of this joint. (Plaugher 1993 :243.) The influence of motion segment degeneration on the mobility of the thoracic spine has yet to be established.

2.5 EFFICACY OF SPINAL MANIPULATIVE THERAPY

A review study, the efficacy of manual therapy by Di Fabio (1992) provides clear evidence that SMT can be an effective modality when used to treat patients with somatic pain syndromes. Only 22% of studies reviewed show negative results (no difference between control and SMT groups). In the treatment of lower back pain 11 valid studies demonstrated the efficacy of SMT.

Hadler et al. (1987) demonstrated, in a structured and controlled trial study over a period of two years, rapid pain reduction and increased mobility in those patients receiving SMT for acute lumbar spine pain (≤ 4 weeks duration). Fifty-four patients were randomly assigned to one of 2 groups. One group received SMT and the control group was given mobilisation of the lumbar spine. A total of 5 treatment sessions were given over a 2 week period. In the first week following manipulation, the SMT group reported a greater and more rapid improvement of mobility and a decrease in pain (P=0.009) when compared to the control group. No long-term follow-up was included in the study.

Triano et al. (1992) researched differences in treatment history with SMT in 241 patients. Regions from the cervical spine to lumbarsacral spine were treated. One hundred and eighty one patients met the criteria for mechanical spine pain, 42 for muscular and 17 for entrapment. Results have revealed that complaints of the thoracic spine responded twice as quickly to manipulation as have complaints of the cervical, lumbar and lumbosacral areas. Thoracic spine regions required approximately 3 treatments, while cervical required 5.9 and lumbar region 6.7.

In a randomised trial Koes et al. (1992) compared the effectiveness of manual therapy, physiotherapy, continued treatment by a general practioner (GP) and placebo therapy (detuned ultrasound and short-wave diathermy) on 256 patients with nonspecific back and neck complaints. Both manual therapy and physiotherapy showed the greatest improvement in score for the main complaint at a 3 and a 6 week follow-up. There was no difference in effectiveness between the two groups for all outcome measures, except that the manual therapy group required considerably less treatments than the physiotherapy group.

This finding might be regarded as a considerable advantage. The placebo group showed a larger improvement in the main complaint than the GP group but had a score just below that for the manual therapy and physiotherapy groups.

Koes et al.(1996) in a Medline computer aided search identified 36 randomised clinical trials comparing SMT with other treatments. The objective of the study was to assess the efficacy of SMT in the treatment of back and neck complaints on a score system of a maximum of a hundred points. The highest score of a trial was 60 points (maximum score was 100), indicating that most were of poor quality. Nineteen studies (53%) showed favorable results for SMT. In addition, five studies (14%) reported positive results in one or more subgroups only. Among the five studies with 50-60 points 3 were positive and 2 were positive for a subgroup only. Eleven trials compared SMT with placebo therapy, there were 7 positive studies, 1 positive only in a subgroup, and 3 negative studies. In addition all 3 studies with a score of 50 or higher reported positive results with SMT in comparison with placebo treatment for chronic lower back pain. There appeared to be no clear relation between methodological score and the over all outcome of the study results. However Koes et al.(1995) found methodological quality to be associated with the outcome of studies in 69 different randomized clinical trials.

2.6 BIOMECHANICAL STUDIES OF SPINAL MANIPULATIVE THERAPY

Spinal manipulative therapy is a mechanical intervention. Therefore, if SMT can achieve beneficial results for the patient it is mechanical. (Gal et al.1994.) SMT causes in part, at least, a physical reaction of the vertebrae or a physiological response (induced neuromuscular reflex or immunological response) or a combination thereof induced by a mechanical

intervention. Spinal manipulation is preformed by chiropractors, physiotherapists, osteopaths, and medical practitioners. Each of these professions has hypothesised various mechanisms to explain the clinical effects of manipulation. A popular hypothesis is that SMT works by altering spinal stiffness.(Lee et al.1993.)

In a controlled study of 30 asymptomatic subjects Lee et al.(1993) investigated the proposal that thoracic spinal stiffness is altered by manipulation. The manipulation studied was a posteroanterior thrust applied to the T4-T5 spinal level. A t-test comparing the changed scores between interventions revealed no significant difference. However, the posteroanterior stiffness at T5 was found to be significantly greater than at T4. These results do not provide support for the hypothesis that posteroanterior stiffness is altered by manipulation in asymptomatic subjects.

Gal et al. (1994) quantified the movements of thoracic vertebral bodies during SMT. The relative movements between T10 and T11, T11 and T12 were measured during clinical type SMTs to T11 in two unembalmed post-rigor human cadavers. Displacements were measured for 10 treatments in the first specimen and 20 treatments in the second specimen, using two bone pins embedded in each of the three target vertebrae and high speed motion pictures. A chiropractor administered a posterior-to-anterior adjustment to the right transverse process of T11, using a reinforced hypothenar contact. Significant relative movements between target and adjacent vertebrae occurred primarily in axial rotation and sagittal rotation during the thrust phases of SMT and not as expected, in the direction of the primary thrust (posterior to anterior) . The results showed that the absolute movements of all vertebral bodies during SMT were significantly underestimated.

Force studies found that peak and preload forces are considerably smaller for SMT preformed on the cervical spine when compared to values obtained on the thoracic spine and sacroiliac joint. The force-time histories of prone SMT on the sacroiliac joint and thoracic spine are similar, however the mean peak and preload forces recorded for SMT on the thoracic spine (T4) were about 60N larger than those recorded on the sacroiliac joint. Force measurements were obtained using a thin flexible pressure mat consisting of pressure sensors. (Herzog 1994.)

Herzog et al. (1993) also demonstrated that approximately 66% of the variations in peak load forces for SMT on the thoracic spine may be attributed to changes in the corresponding preload forces. It appears that preload forces are of major consequence to the forces administered during the actual treatment part of SMT. This factor may be considered when teaching the techniques for successful SMT on the thoracic spine. Peak forces on the thoracic spine may also exceed the body weight of the treating chiropractor (Herzog et al.1995).

Neurophysiological theories suggest an activation of articular mechanoreceptors and muscle spindles during SMT, leading to reflex inhibition of spastic muscles in the treatment area (Suter et al.1994). Herzog et al. (1995) conducted a pilot study on two asymptomatic subjects, investigating reflex responses associated with SMT on the thoracic spine. Bipolar surface electrodes placed on the opposite side of the spine of the treatment area were used. It was demonstrated that a normal/fast (100ms) SMT administered in a posterior to anterior direction at T3, T7 and T9 levels produced a consistent electromyographic (EMG) response in muscles immediately adjacent and opposite the treatment area, whereas slow SMTs (3-5 sec) did not. This study indicates that the speed of the treatment is important in evoking an EMG response, whereas cavitation is not important in evoking such a response. Suter et

al.(1994) found very similar results for the reflex responses associated with SMT of the thoracic spine. They concluded that the characteristics of the EMG responses suggest that they originate from type II articular mechanoreceptors, located in the capsule of the spinal joints.

Clinically, stretch reflexes have long been used as an index of spinal cord integrity being ideally suited for this purpose by their relative ease of elicitation. Tyler et al. (1994) investigated the effects of cervical and thoracic manipulation on the amplitude of the achilles tendon reflex on 22 subjects. Eleven trial-group subjects were treated for their existing cervical or thoracic fixations and the 11 control subjects received a sham adjustment. Paired t-tests of the amplitude values within and unpaired t-tests between each group showed a significant decrease in the achilles tendon reflex in the trial group compared with the control group at 5, 10, 15, 30 minute intervals. These results are compatible with the decrease in lumbar motoneurone activity following manipulation.

The immunological response to manipulation of the thoracic spine is clearly demonstrated by data collected in 46 subjects by Brennan et al. (1992). A single thoracic manipulation was given in the segment exhibiting the least flexibility by motion palpation. The effect of priming polymorphonuclear neutrophils for an enhanced respiratory burst, isolated from blood collected 15 minutes after the manipulation was significantly higher than those isolated from blood 15 minutes before as well as 30 and 45 minutes after the manipulation. It was also shown that thoracic manipulation primes mononuclear cells for enhanced production of endotoxin-stimulated tumour necrosis factor. The above effects are accompanied by significantly elevated levels of plasma neuroimmunomodulator (Substance P). It was

found that neither a sham manipulation nor a thrust to the gluteal region elicited an enhanced respiratory burst.

2.7 FACET JOINT DYSFUNCTION

" The term dysfunction implies that at one level the components of the joint are not functioning normally." (Kirkaldy-Willis 1992:105)

Joint dysfunction is known as a mechanical cause of pain from zygopophyseal synovial joints. Joint dysfunction presupposes the presence of mechanical play, which is a prerequisite for normal efficient motion in any joint that moves in the human body. When joint play is lost, joint function becomes impaired and painful.(Mennell 1990.) The findings of Taylor et al. (1990), in a study of spinal joint dysfunction in the thoracic spine, suggest a moderate level of support for the validity of the notion that spinal dysfunction is characterised by loss of joint play and contiguous paraspinal tenderness.

SMT is hypothesised to restore joint play. Mennell (1990) treated 83 patients diagnosed with cervical spine joint dysfunction with SMT. Thirty percent reported cessation of symptoms and another 34% felt they had markedly improved. Such findings help to validate the presence of joint dysfunction as a manipulable condition.

2.8 MOTION PALPATION OF THE THORACIC SPINE

The primary indication for SMT is a reversible mechanical derangement of the intervertebral joints which produces a barrier to normal motion. This joint fixation is clinically determined by motion palpation. (Gatterman 1990:50.) Haas et al.(1995) determined the reliability of motion palpation on the thoracic spine on 73 first year chiropractic students in a randomised control trail. Two chiropractic faculty members with 15 years practice experience, conducted the motion palpation assessments. Results showed interexaminer reliability was poor overall (K=0,14). Intraexaminer reliability results revealed moderate self consistency and is quite adequate for clinical practice (K=0.55 and 0.43). Reliability for the thoracic spine is comparable with findings of previous studies in other regions of the spine (Haas et al.1995).

Haas et al. (1995) in another journal article took the study described above a step further to evaluate the short term responsiveness of manual thoracic end-play assessment to spinal manipulation and, thereby construct validity of motion palpation. The treatment group (30 subjects) received manual high velocity, low amplitude rotatory manipulation. The control group (30 subjects) received no intervention. End-play response is defined as the change from restricted to normal end-play immediately after intervention. The response of motion restriction to SMT was 60%, in contrast with the 37% response in the control group. This difference was statistically significant. More than a third of the response in the treatment group was attributable to SMT. For end-play restoration to be palpable, end-play restriction itself must be palpable. This study provides supporting evidence for the construct validity of manual end-play evaluation in the thoracic spine.

2.9 DIAGNOSIS OF MECHANICAL THORACIC SPINE PAIN

Neck and lower back sprain are diagnoses well known to practitioner's. A similar pain from the thoracic spine is generally not acknowledged and scarcely mentioned in medical textbooks and literature.(Bechgaard 1981.) The misdiagnosis of chest pain can easily happen as it mimics a diverse number of musculoskeletal conditions, one of which is thoracic spine dysfunction. The ominous significance of chest pain can cause unnecessary worry when biomechanical joint dysfunction goes undiagnosed (Gatterman 1990:186). Simulated visceral disease (referred pain) still causes endless difficulty by way of repeated misdiagnosis and pointless treatment, even unnecessary surgery six times repeated (Grieve 1994:401). It is important to determine quickly whether a significant coronary, pulmonary or visceral source of the pain exists so that the appropriate treatment may be rendered.

The evaluation of chest pain consumes a tremendous amount of economic and medical resources. It is usually possible to differentiate cardiac or visceral disorders from musculoskeletal on the basis of clinical characteristics and a detailed physical exam. The history taking must focus on location, pattern, character and duration. It is also important to determine exacerbating factors, relieving factors and associated symptoms of the pain. A meticulous examination of the ribs, spine, sternum and their articulations will help establish a correct diagnosis. Diagnostic studies are only necessary when the origin of the chest pain remains in doubt. (Kaye 1993, Fam 1988.)

For the purpose of this study the forced descriptive classifications by Triano et al. (1992) was used to diagnose mechanical spine patients apart from entrapment and muscular spine pain.

Mechanical spine pain - Midline back pain

- Nondermatomal referred pain difficult to localise
- No signs of nerve root tension
- No major neurological deficit
- Pain with compression into spine extension
-Reduced range of motion

2.10 PLACEBO EFFECT

Placebo effects have often been raised as a rival explanation for the proposed biomechanical and neurological value of SMT in general and specific cases (Keating 1987). Koes et al. (1995) concluded from a study that a substantial part of the effect of manual therapy and physiotherapy appeared to be due to placebo effects. Placebo effects have been know to relieve depression, premenstrual tension, the common cold, asthma, chronic headache or backache, as well as prevent migraines and induce sleep in patients with insomnia (Gowdey 1983). Turner et al. (1994) calculated that placebo responses ranged from 15% to 58% and on average , symptoms were "satisfactorily relieved" by placebo in 35% of patients.

Psychoneuroendoimmunology provides a model in which placebo responses are not "mystical" but are rather seen to link psychological and physical processes through common anatomical pathways. The mind and body are linked by well described neural and hormonal pathways.(Jamison 1996.) Measurable objective effects that can follow placebo

administration include changes in gastric acidity, pupil diameter, serum lipoprotein levels, eosinophil and lymphocyte counts as well as lower blood pressure in patients with essential hypertension (Gowdey 1983).

Placebos have time-effect curves, and peak, cumulative and carry-over effects similar to those of active medications. Placebos have also been associated with side effects especially drowsiness, headaches, insomnia, nausea, and constipation. (Turner et al.1994.)

There are many misconceptions about placebos, including the following beliefs: (1) about one third of patients will have a placebo response in any clinical trial; (2) placebo effects are brief; (3) certain personality types are more likely to be placebo responders; (4) Placebo responders have nothing wrong with them to begin with; and (5) giving a placebo is the same as doing nothing.(Turner et al.1994, Jamison 1996.)

Highly compliant patients may have better outcomes than noncompliant patients, even when complying with a placebo. There is also some evidence that highly anxious patients show the greatest placebo responses.(Turner et al. 1994.) High expectancy in both the practitioner and patient, and a satisfactory practitioner-patient relationship potentiates the placebo effect (Jamison 1996).

There are placebo effects whenever the patient and the clinician perceive the treatment as effective. These effects can be potent and can lead to erroneous claims of efficacy for any type of treatment.(Turner et al. 1994.) Randomised controlled trials can establish the efficacy of a treatment above and beyond the natural history of the condition and nonspecific (placebo) effects.

2.11 SIDE EFFECTS OF SPINAL MANIPULATIVE THERAPY

It is important to cover all clinical aspects of SMT, including the negative ones. In the thoracic spine, rib fractures can occur due to SMT (Senstad et al.1996), however, it is rare for SMT to cause life-threatening or severely crippling accidents (Senstad et al.1997, Dvorak et al. 1993). Dvorak et al.(1993) calculated that a physician will encounter a severe complication due to SMT once in every 47 years of practice in the cervical spine and once every 38 years in the thoracic and lumbar spine. Nonetheless, it is a well accepted fact that SMT often results in other less severe side effects.

Senstad et al.(1997) in a clinic-based survey collected information on the side effects of SMT after 4712 treatments on 1058 new patients by 102 Norwegian chiropractors. At least one reaction was reported by 55% of the patients some time during the course of a maximum of six treatments. The most common side effects were local discomfort (53%), headache (12%), tiredness (11%), or radiating discomfort (10%). Reactions were mild (35%) to moderate (50%) in most patients. Sixty-four percent of reactions appeared within 4 hours of treatment and 74% had disappeared within 24 hours.

Leboeuf-Yde et al. (1997) found similar results to Senstad et al.(1997), in her study of 1858 treatments by 66 Swedish chiropractors. In addition results showed that reactions are most commonly reported by women (66%) and at the beginning of the treatment series. Patients with long standing problems are more likely to report treatment reactions, however, patients with no prior experience of chiropractic care did not report more reactions than patients previously treated by chiropractors.

Some treatment related predictors were identified. More reactions occurred when more than one spinal region was treated, or when the thoracic spine only was treated. When only one spinal area was treated the percentage of reactions for the thoracic spine was 39%, cervical spine 32% and lumbar spine 23%. This could be because the thoracic spine is more sensitive to SMT than other areas or because patients have conditions in that area that react more strongly to SMT. The thoracic spine would certainly not be the most stressful area of treatment for the patient or chiropractor. (Senstad et al.1996.) This helps diminish psychological reactions of SMT on the thoracic spine. The forces required to cause cavitation in the thoracic spine are greater than in any other area of the spine, therefore it is thought by the researcher that post manipulative discomfort is due to physiological responses and the forces involved during SMT on the thoracic spine.

2.12 CONCLUSION

In summary the literature indicates that thoracic spine pain is a common complaint that deserves wider recognition. It is shown that both placebo intervention and SMT have some benefits in the treatment of spinal dysfunction, but evidence especially for the thoracic spine is lacking. SMT seems to have advantage over placebo in that it has added benefits of the mechanical, physiological and reflexogenic effects. SMT is a biomechanically complex event yet safe enough to use in practice, rarely resulting in severe complications. This pilot study should add to the current body of knowledge and open the way to future research in this region.

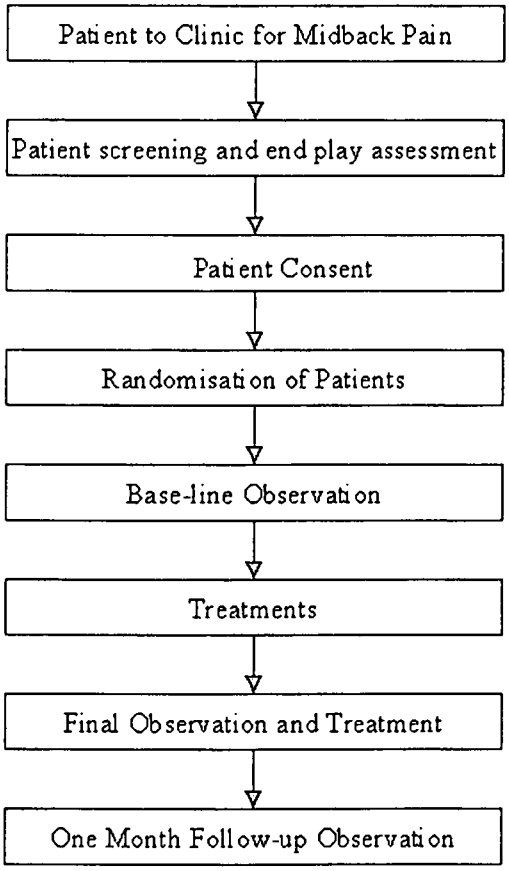
CHAPTER THREE

2.0 MATERIALS AND METHODS

3.1 Introduction

This chapter deals with the details of the research study undertaken. This includes the study design, the subjects (patients) used and a detailed account of the interventions they received. Measurements and observations obtained as well as statistical procedures for assessment of data are also discussed.

Figure 3.1 Flow chart of experimental chronology



3.2 The study design

This study was designed to be a randomised comparative clinical controlled pilot study

3.2.1 Objectives of the study

The aim was to compare two different treatment groups (spinal manipulative therapy versus placebo) and to identify the effectiveness of each treatment group (intra-group analysis) in terms of the objective and subjective measurements. An inter-group statistical analysis was also preformed to determine whether one treatment protocol was more effective than the other. Thus, the more effective treatment method could then be used as either a primary treatment or as an adjunct to other treatment protocols for mechanical thoracic spine pain.

3.2.2 Selection of subjects

Patients were obtained by consecutive sampling, using advertisements posted around the Technikon Campus, on local community boards and by word of mouth, inviting free participation in a clinical trial for people with midback pain. No restrictions were placed on the patient's sex, racial group, occupation, income bracket or area of residence.

Any patient presenting to the clinic with thoracic spine pain was considered a potential candidate for the study. These patients were briefly screened and further investigations took place only if the researcher deemed the patient suitable for the study. The screening procedure involved questioning the patient on the exact location of pain, onset of pain, any

radiation of pain and any associated symptoms as well as palpation of the painful area and motion palpation of the spine.

Those initially accepted had a standard case history (Addendum D) taken and also had full physical (Addendum E) and regional thoracic spine (Addendum F) examinations preformed.

3.2.3 Inclusion and exclusion criteria

1) The patient had to be between the ages of sixteen and sixty years to be included.
2) Only patients diagnosed by the researcher as having mechanical thoracic spine pain were included in the study. Diagnostic criteria as from Triano et al.(1992), as listed in chapter 2, page 22 .
3) Using motion palpation a thoracic fixation had to be found in one or more directions for inclusion of the subject into the study.
4) Patients were not allowed to take any analgesics, nor receive any other treatment for their condition or any other co-existing condition during the research period, if they did they were excluded from the study.
5) Radiographs, where deemed necessary, were taken to exclude patients with contraindications to manipulation or other complicating pathology.
6) Patients randomised to the placebo group had to be "naive" to their treatment, if they were not they were automatically excluded from the study.
6) Patients receiving workers compensation, disability insurance or were involved in litigation for their thoracic spine pain were excluded from the study.
7) Those patients with active or latent myofascial trigger points were not excluded from the study.

3.2.4 Allocation of subjects

Once the patients had signed an informed consent form (Addendum G); a sample of thirty patients were randomly divided into two groups; fifteen in the SMT (experimental) group 1 and fifteen in the placebo (control) group 2. This was accomplished by placing 30 pieces of paper, fifteen marked 1 and fifteen marked 2 into an envelope. The patient then drew a folded piece of paper from the envelope. This determined to which group they were assigned.

3.3 The data

The data in the study consisted of primary and secondary data.

3.3.1 The primary data

The subjective measurement parameters for this study were:

-The patient's perceived amount of their disability (Oswestry Back Pain Disability Index);

-The patient's perception of intensity and quality of their pain, a sensory dimension of pain (Short-form McGill Pain Questionnaire);

-The patient's perception of their pain intensity level (Numerical Rating Scale-101 Questionnaire).

The objective means of measurement for the study were:

-The range of motion in the thoracic spine measured with a goniometer (BROM II);

-Pain threshold measured with an algometer.

3.2.2. The secondary data

This consisted of the literature reviewed. Documents were obtained that covered topics which consisted of previous studies similar to this one or studies which contained applicable information relating to this study.

3.4 Methods of measurements

3.4.1 **Oswestry Back Pain Disability Index** (Addendum A) (Fairbanks et al.1980)

This questionnaire indicates how the everyday life of the patient is affected by the thoracic spine pain. It determines the amount of disability experienced by the patient. This self administered questionnaire avoids interviewer bias and ensures uniformity of presentation. Triano et al. (1993) used 145 patients to test-retest the reliability and validity of six questionnaires. Overall, the Oswestry and Visual Analogue pain scale were both more reliable and valid than other questionnaires. They were also the most responsive to clinical change for musculoskeletal disorders. Fairbanks et al.(1980) in a group of 25 patients found this questionnaire to be a valid and reliable indicator of the disability experienced by the patient.

The patient answers 10 sections, each with 6 questions on the Oswestry questionnaire. Each question scores a maximum of 5 points and a minimum of 0. The total score is therefore out of 50 and is represented as a percentage disability. This percentage was recorded for statistical analysis.

3.4.2 McGill Short-Form Pain Questionnaire (Addendum B) (Melzack 1987)

This questionnaire is designed to assess the quality and intensity of pain and has become one of the most widely used tests for measurement of pain. The McGill short-form questionnaire was developed to be used where detailed information regarding pain is required quickly, as well as to reduce patient fatigue. The short form consists of 15 descriptive words (11 sensory; 4 affective) each consisting of a type of pain and its severity (mild, moderate or severe). Only the first 11 sensory words were used for statistical analysis, the last 4 affective words were ignored in this study. Each description marked by the patient was ranked on an intensity scale. The total score was divided by 91,89 and reflected as a ratio. The maximum score was one. This form correlates very highly with the sensory and total indices of the McGill Long Form Questionnaire and is sensitive to clinical therapies.

3.4.3 Numerical Pain Rating Scale-101 Questionnaire (Addendum C) (Jensen et al.1986)

This questionnaire is extremely simple to administer (written or verbal) and score, it assesses with ease the patient's perceived level of pain intensity. Jensen et al. (1986) established its validity and reliability when providing subjective information about pain levels. The Numerical Pain Rating Scale-101 Questionnaire consists of asking the patient to rate their perceived level of pain intensity on a numerical scale from 0 to 100, with 0 being no pain and 100 being the worst pain. The patient indicates by means of a percentage on a 10cm line, when the pain was at its worst and again when at its least. The average of these two figures indicates the average pain experienced by the patient as a percentage. This percentage was used for statistical analysis.

3.4.4 Thoracic Spine Range of Motion (Breum et al.1995)

The BROM II goniometer produced by Performance Attainment Associates (St Paul, MN) was used to measure thoracic ranges of motion in flexion, extension, bilateral rotation and bilateral lateral flexion. The ranges of motion were measured in degrees according to the protocol laid out in the manufacturers procedure manual. The BROM II was found to be a reliable instrument in the measurement of mobility in forward flexion and lateral flexion in a study conducted by Breum et al.(1995) using 47 asymptomatic subjects. Rotation and extension received less support.

3.4.5 Algometer Measurements (Fischer 1987)

The algometer produced by Wagner Instruments (Greenwich, CT) was used to measure the pain threshold of patients. Fischer (1987) found that the reliability of the algometer as a tool for the diagnosis of tender spots and the assessment of treatment results have been well documented in previous articles. Fischer (1987) states that changes in the patient's pressure threshold under standard clinical conditions can be regarded as reliable data. An increase in pressure tolerance would indicate improvement of the patient's condition.

The algometer was placed over the area of most discomfort in this study. The patient was instructed to indicate, through vocal feedback, when the sensation changed from pressure to pain, at which point the reading was taken. The reading was measured in terms of kg/cm^2 and was recorded as such for statistical analysis.

3.5 The location of the data

The primary data were obtained from 3 questionnaires, the BROM II goniometer readings and algometer readings (as detailed in 3.4).
The data were collected before the first treatment, before the last treatment and at the one month follow-up consultation.

The secondary data were sourced from current journal articles, books and the Internet (Medline and Mantis).

3.6 Interventions

The patients were treated with their randomly selected intervention. The patients received treatment until symptom free or up to a maximum of 6 treatments over a minimum period of two weeks or a maximum period of 3 weeks with 2 to 3 treatments per week. A follow-up consultation for reassessment took place one month after the last treatment.

3.6.1 Experimental Group 1: Spinal Manipulative Therapy

The experimental group received standard, manual thrust, chiropractic adjustments to the thoracic spine. The levels of dysfunction to apply manipulation was determined using motion palpation. With all manipulative techniques the joint slack was taken out to the elastic barrier and a high velocity, low amplitude thrust was delivered at the level, and in the direction, of the loss of joint motion (fixation).

For purposes of this study the author felt a cavitation sound was necessary for a successful manipulation technique. It appears that cavitation may be measured during SMT using accelerometry and that a practitioner's perception of the occurrence of cavitation during SMT is very accurate (Herzog et al.1993).

The manipulations employed were diversified techniques according to the "Compendium of Chiropractic Technique" (Szaraz 1990: 96,98,102,103) and Clinical Practice and Principles IV class notes (Technikon Natal, Dr Nook 1997). These are all summarised below:

Hypothenar Thenar Transverse (Dr Nook 1997)

This technique is indicated for either extension or rotation dysfunctions from T1-T12. The patient is prone lying with headpiece adjusted in neutral. Contact with the hypothenar eminence is made with the caudad hand by the doctor on the side of the lesion. Contact hand is against the facet joint (transverse process) while the indifferent hand is placed on the contralateral TVP of the same vertebra. Line of drive is posterior to anterior. A body drop thrust is applied at the point of joint resistance.

Hypothenar Spinous-Thenar Transverse (Dr Nook 1997)

This technique is indicated for lateral flexion fixations from T1-T12. The patient is prone lying with headpiece adjusted in neutral. Contact with the hypothenar eminence is made with the caudad hand by the doctor on the side of the lesion. The contact hand is against the spinous process of the fixated segment, while the indifferent hand is placed on the contralateral TVP of the same vertebra. The spinous is pushed medial to lateral and thrust

medial to lateral and posterior to anterior. A body drop thrust is applied at the point of joint resistance.

Crossed Bilateral (Szaraz 1990)

This technique is used for rotation type dysfunctions of T4-T12. The patient lies prone with the doctor on the side of the lesion facing cephalad. The final position for the doctor's torso is determined by the level of the lesion and the patient's dorsal curve. A pisiform contact onto the ipsilateral TVP is taken up. The indifferent hand (superior hand) is crossed over contact hand and placed on contralateral TVP. Joint and soft tissue slack is taken up in a cephalad direction with contact hand. A single, high velocity body drop type thrust in a cephalad direction along the facet facings is executed. Compliance of the rib cage must be carefully evaluated for each patient.

Sternal Spinous-Standing or Seated (Dr Nook 1997)

This technique is indicated for extension, rotation, or lateral flexion fixations. The patient is standing or seated with arms crossed, neck and upper thoracic spine is flexed. Doctor stands behind the patient. A sternal contact onto the tip of the fixated spinous process is taken up by the doctor. Both hands of the doctor wrap around the patient and contract their folded arms. Thrust is inferior to superior and posterior to anterior. Patient is positioned into the direction of the fixation i.e. with extension fixation, the patient is positioned in extension. Joint slack is taken out till resistance is felt and a thrust with the sternum is applied by the doctor, hyperextending his thoracic spine

3.6.2 Control group 2: Placebo

The patients in this group received placebo treatments. The appropriate choice of placebo treatment had to be trustworthy for patients and have no specific effects. The next best solution to finding a placebo treatment like the "real" treatment was the use of de-tuned ultrasound therapy (Koes et al. 1995). The placebo treatment consisted of the application of a non-functional ultra-sound head over the area of pain, for a total of 10 minutes. Those patients randomised to the placebo group had to be "naive" to their treatment. The researcher identified those patients that were not naive to their treatment by means of careful questioning during the Case History and again during the research period whilst consulting. Those patients that were not naive to placebo treatment had to be excluded from the study. The patients in this group were told that the treatment would benefit them and the same amount of time and enthusiasm was spent with them as those in the experimental group.

3.7 Statistical procedures (van den Honert 1997)

3.7.1 The Sample Size of the Study

To take part in the study, the patient had to have mechanical thoracic spine pain. In view of the shortage of time and resources encountered, only the first 30 eligible patients were chosen for the study. Group 1 contained 15 patients that make the experimental group. Group 2 contains the remaining 15 patients that make the placebo group. The sample size per group is small ($n1=15, n2=15$). Hence, non-parametric methods were used for statistical data analysis. There were 3 consultations (beginning, end and follow-up) for each of the clinical experiments: OSW, NRS-101, McGill, ALG and ROM.

3.7.2 Inter-group comparison (experimental versus placebo)

The Mann-Whitney unpaired two-tailed test was used to compare groups 1 and 2 with respect to each variable of interest. In each test, the null hypothesis states that there is no significant difference between groups 1 and 2 with respect to the variable in charge, at the α=0,05 level of significance. The alternative hypothesis states that there is a significant difference.

The decision rule: The null hypothesis is rejected at the α level of significance if $p \geq \alpha/2$ where p is the observed level of significance or P-value. Otherwise, the null hypothesis is accepted at the same level.

3.7.3 Experimental: intra-group comparison

The Wilcoxon's sign ranked test was used to compare results from related samples in each of the 10 clinical procedures in the study. In each test, the null hypothesis states that there is no significant improvement between the two related samples being compared, at the α level of significance. The alternative hypothesis states that there is a significant improvement.

Decision rule: The null hypothesis is rejected at the α level of significance if $p \leq \alpha/2$ where p is the observed significance level or P-value. Otherwise, the null hypothesis is accepted at the same level.

3.7.4 Control: intra-group comparison

The procedure in 3.7.3. was repeated within the control group with the same decision rule.

3.7.5 Summary statistics

The summary statistics consisted of medians, averages and variances for each variable of the study. These results were needed for power analysis and the construction of barcharts.

3.7.6 Comparison using barcharts

Selected visual summaries of analytical findings were given by the use of barcharts to compare groups 1 and 2 with respect to selected variables of interest. Median readings were used to construct barcharts.

3.7.7 Power analysis (Portney and Watkins 1993)

The power of each Mann-Whitney unpaired test was determined by using power analysis. Power analysis was done at a UCLA web site using summary statistics results.

Statistical package: The statistical package **Statgraphics** was used for data entry and analysis. This package is manufactured by Manugistics Inc. (2115 East Jefferson Street, Rockville, Maryland, 20852, U.S.A.)

CHAPTER FOUR

4.0 THE RESULTS

4.1 Introduction

This chapter will represent the data and attempt to analyse the data in tabular form in order to accept or reject the null hypothesis. This study concluded with a total of 30 subjects: 15 in group one and 15 in group two. This sample size was small, therefore non-parametric test methods were used for statistical analysis. Two volunteers were rejected as they had complicating problems of : neurological symptoms and another with a thoracic disc herniation. Three volunteers had to be rejected due to non-compliance to the study protocol (2 in the SMT group and 1 in the placebo group). And lastly, another two in the placebo group had to be withdrawn from the study after the final treatment due to continuous pain and inability to wait for the one-month follow-up.

The Mann-Whitney U-test was used for inter-group comparisons. In each Mann-Whitney U-test the null hypothesis stated that there was no significant difference between groups 1 and 2 with respect to the variable in charge, at the $\alpha=0.05$ level of significance. The alternative hypothesis stated that there was a significant difference.

The Wilcoxon's Signed Rank Test was used for intra-group comparisons. In each Wilcoxon's Signed Rank Test the null hypothesis stated that there was no significant

improvement between the two related samples being compared, at the α=0.05 level of significance. The alternative hypothesis stated that there was a significant improvement.

The null hypothesis was rejected for both tests at the α level of significance if $P \leq 0.025$ where P was the observed significance level or P-value. Otherwise, the null hypothesis was accepted at the same level ($P \geq 0.025$).

The power of each test is a measure of test sensitivity. The power of a test depends on the sample size, the accuracy of measurements involved in the study and the level of significance of the study, α (0.05). The power of a statistical test is the probability of detecting a difference between the two groups. Therefore, power value should be as close to one as possible. Thus, if a test has a low power of 0.10, it would mean that the probability of detecting a result could be purely chance, 10 times out of a hundred. The smaller the power of a test, the larger becomes the likelihood of a type II error, i.e. accepting a false null hypothesis. (Portney and Watkins 1993.)

The power of non-parametric tests is usually low, thereby indicating that results obtained from non-parametric tests are not necessarily reliable as a decision-making tool (Portney and Watkins 1993).

The tables in this chapter display the median, mean, standard deviation, standard error, P-value and the results from the Mann-Whitney U-Test power analysis .

In addition demographic data was obtained from the study and represents the age, gender, race, region and occupation distributions in a sample of thirty.

Key for abbreviations in tables

Group 1 : received spinal manipulative therapy

Group 2 : received placebo therapy

OSW: Oswestry Back Disability Index

NRS-101: Numerical Pain Rating Scale-101 Questionnaire

McGill: Short-Form McGill Pain Questionnaire

ALG: algometer reading

ROM: Range of Motion

S.D.: Standard deviation

S.E.: Standard error of mean

Bold numbers: significant

4.2 Demographic data

Table 4.1 The age distribution within the sample of 30

Age	Group 1	Group 2	Total %
16-24	6	8	47
25-34	6	3	30
35-44	1	3	13
45-55	2	1	10

Table 4.2 The gender distribution within the sample of 30

Gender	Group 1	Group 2	Total %
Male	7	7	47
Female	8	8	53

The male to female ratio was 1:1

Table 4.3 The race distribution within the sample of 30

Race	Group 1	Group 2	Total %
Caucasian	13	7	67
Asian	1	5	20
Black	1	3	13

Table 3 Region distribution of the thoracic spine primary fixation within the sample of 30

Region	Group 1	Group 2	Total %
T1-T4	0	4	13
T5-T9	14	9	77
T10-T12	1	2	10

Table 4.5 Occupation within a sample of 30

Occupation	Group 1	Group 2
Student	5	5
Sales reps	2	2
Secretaries	2	2
Technicians	2	1
Housewife	1	1
Waitress	1	0
Programmer	1	0
Clerk	0	1
Co-ordinator	0	1
Mechanic	1	0
Lifeguard	1	0
Ground hostess	0	1

From the above tables it is shown that there is a fairly even distribution between the two groups for age, gender and occupation.

4.3 The analysed data

4.3.1 The Inter-group analysis using Mann-Whitney Unpaired tests:

Table 4.6 Comparison of groups 1 and 2 using the Mann-Whitney's U-test to analyse results collected from the subjective data at treatment one

TREATMENT 1									
	GROUP 1					GROUP 2			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	12	14.1	2.5	9.7	0.0474	18	19	1.6	6.5
NRS-101	50	48	3.7	14.5	0.7549	45	46.8	3.04	11.7
McGill	0.17	0.22	0.04	0.18	0.6036	0.16	0.23	0.04	0.16

POWER	
OSW	0.3401
NRS-101	0.0560
McGill	0.0532

The null hypothesis is accepted for the Oswestry Back Disability Index, Numerical Pain rating Scale 101-Questionnaire and McGill Pain Questionnaire, which indicates that at the α=0.05 level of significance there was no significant difference between groups 1 and 2 at treatment one.

Table 4.7 Comparison of groups 1 and 2 using the Mann-Whitney's U-test to analyse results collected from the subjective data at the final treatment

FINAL TREATMENT									
	GROUP 1					GROUP 2			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	4	7.6	2.2	8.6	0.1085	8	12.2	2.3	9.2
NRS-101	20	21.9	2.9	11.4	**0.0146**	35	35.6	3.7	14.2
McGill	0.06	0.1	0.05	0.1	0.0610	0.09	0.17	0.04	0.16

POWER	
OSW	0.2908
NRS-101	0.7885
McGill	0.0627

The null hypothesis is rejected for the Numerical Pain Rating Scale-101 Questionnaire at the α=0.05 level of significance, as there was a significant difference between groups1 and 2 at the final treatment.

In contrast, the null hypothesis is accepted for the Oswestry Back Disability Index and the McGill Pain Questionnaire, indicating no significant difference between groups 1 and 2 at the final treatment.

Table 4.8 Comparison of groups 1 and 2 using the Mann-Whitney's U-test to analyse results collected from the subjective data at the one-month follow-up

ONE-MONTH									
	GROUP 1					GROUP 2			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	4	6.5	2.7	10.5	0.0630	8	8.9	5.8	34.2
NRS-101	22	20.5	4.5	17.4	0.0458	37	33.8	4.7	18.4
McGill	0.03	0.08	0.04	0.18	0.0297	0.09	0.13	0.02	0.11

POWER	
OSW	0.1107
NRS-101	0.4953
McGill	0.1437

In all of the above cases, the null hypothesis is accepted for both groups at α=0.05 significance level. There was thus no statistically significant difference in the efficacy of the two treatment protocols at the one-month follow-up.

Table 4.9 Comparison of groups 1 and 2 using the Mann-Whitney's U-test to analyse results collected from the objective data at treatment one

TREATMENT 1									
	GROUP 1					GROUP 2			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	3.5	3.8	0.45	1.74	0.3075	4	5.7	1.4	5.5
Flex	20	17.6	1.6	6.5	0.7803	20	19.5	2.1	8.3
Ext	10	12	1.06	4.14	0.9303	10	12.5	1.47	5.71
R. Lat Flex	40	41.3	3.1	12	0.6676	45	44	2.08	8.06
L. Lat Flex	45	43	2.6	10.3	0.3494	50	47	1.6	6.21
R. Rot	35	36.6	2.9	11.2	0.9826	40	37.3	2	7.76
L.Rot	40	37.6	2.79	10.8	0.7153	40	39.3	2	7.7

POWER	
ALG	0.2119
Flex	0.0998
Ext	0.0582
R. Lat Flex	0.1015
L. Lat Flex	0.2277
R. Rot	0.0538
L.Rot	0.0741

The null hypothesis is accepted for the algometer readings and all thoracic ranges of motion , as there was no significant difference at treatment one for both groups.

Table 4.10 Comparison of groups 1 and 2 using the Mann-Whitney's U-test to analyse results collected from the objective data at the final treatment

FINAL TREATMENT									
	GROUP 1					GROUP 2			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	5.5	5.2	0.5	0.05	0.0910	4	4.03	0.39	1.5
Flex	15	18	1.27	4.9	0.6935	15	18.3	2.1	8.1
Ext	15	13.3	0.9	3.6	0.1894	10	11.5	1.18	4.58
R. Lat Flex	50	47.6	1.8	7	**0.0191**	40	40.6	1.75	6.77
L. Lat Flex	50	48.6	1.3	5.1	**0.0157**	45	43	1.7	6.76
R. Rot	50	43	2.8	10.2	0.0304	30	35.6	2.2	8.6
L.Rot	40	43	2.9	11.3	0.2172	40	38	2.4	9.4

POWER	
ALG	0.3918
Flex	0.0515
Ext	0.1969
R. Lat Flex	0.7643
L. Lat Flex	0.6907
R. Rot	0.5163
L.Rot	0.2363

The null hypothesis is rejected at the α=0.05 level of significance for right and left lateral flexion. Hence, there was a statistically significant difference in efficacy between groups 1 and 2 for lateral flexion at the final treatment. It was noted that the power for right and left lateral flexion was close to 1, this is good as it shows that the likelihood of committing a type II error was small (accepting a false null hypothesis).

The null hypothesis is accepted for the algometer, flexion, extension, right and left rotation. Thus, there was no statistically significant difference for these readings between groups 1 and 2 at the final treatment.

Table 4.11 Comparison of groups 1 and 2 using the Mann-Whitney's U-test to analyse results collected from the objective data at the one-month follow up.

ONE-MONTH									
	GROUP 1					GROUP 2			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	5	5.2	0.49	1.9	0.0331	3.5	3.8	0.4	1.5
Flex	20	19.6	1.4	5.5	0.2663	15	18.3	2.05	7.9
Ext	15	13.3	0.9	3.6	0.5627	10	12.5	1.1	4.2
R. Lat Flex	45	45.6	1.7	6.5	0.1928	40	41.6	2.3	9
L. Lat Flex	50	48	1.3	5.2	0.0703	45	44.3	1.75	6.8
R. Rot	50	42.6	2.9	11.2	0.0339	30	34.3	2	7.8
L.Rot	50	43	3.1	12.2	0.0826	30	36	1.9	7.6

POWER	
ALG	0.7522
Flex	0.0769
Ext	0.0781
R. Lat Flex	0.2605
L. Lat Flex	0.3538
R. Rot	0.6231
L.Rot	0.4359

The null hypothesis is accepted for the above results, as there was no significant difference between both groups, thus indicating that both treatment approaches had similar efficacy at the one-month follow up.

4.3.2. The Intra-group analysis using Wilcoxon's Signed Rank tests:

Table 4.12 Comparison of results within group 1 using the Wilcoxon's signed rank test to analyse subjective data collected between treatment 1 and the final treatment

GROUP 1									
	TREATMENT 1					FINAL TREATMENT			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	12	14.1	2.5	9.7	**0.0055**	4	7.6	2.2	8.6
NRS-101	50	48	3.7	14.5	**0.0005**	20	21.9	2.9	11.4
McGill	0.17	0.22	0.04	0.18	**0.0019**	0.06	0.1	0.05	0.1

POWER	
OSW	0.4598
NRS-101	0.9991
McGill	0.3331

The null hypothesis is rejected for the Oswestry Back Disability Index, Numerical Pain rating Scale 101-Questionnaire and McGill Pain Questionnaire, which indicate that at the α=0.05 level of significance there was a statistically significant subjective improvement between treatments one and the final treatment for group 1. The power for the Numerical Pain rating Scale 101-Questionnaire is close to 1, therefore there was only a small chance of committing a type II error (accepting a false null hypothesis).

Table 4.13 Comparison of results within group 1 using the Wilcoxon's signed rank test to analyse subjective data collected between treatment 1 and the one-month follow-up

GROUP 1									
	TREATMENT 1					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	12	14.1	2.5	9.7	**0.0008**	4	6.5	2.7	10.5
NRS-101	50	48	3.7	14.5	**0.0005**	22	20.5	4.5	17.4
McGill	0.17	0.22	0.04	0.18	**0.0008**	0.03	0.08	0.04	0.18

POWER	
OSW	0.5034
NRS-101	0.9933
McGill	0.5813

The null hypothesis is rejected for the Oswestry Back Disability Index, Numerical Pain rating Scale 101-Questionnaire and McGill Pain Questionnaire, which indicate that at the α=0.05 level of significance there was a statistically significant subjective improvement between treatments one and the one-month follow-up for group 1. The power for the Numerical Pain rating Scale 101-Questionnaire is close to 1, therefore there was only a small chance of committing a type II error (accepting a false null hypothesis).

Table 4.14 Comparison of results within group 1 using the Wilcoxon's signed rank test to analyse subjective data collected between the final treatment and the one-month follow-up

GROUP 1									
	FINAL TREATMENT					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	4	7.6	2.2	8.6	0.3427	4	6.5	2.7	10.5
NRS-101	20	21.9	2.9	11.4	0.7892	22	20.5	4.5	17.4
McGill	0.06	0.1	0.05	0.1	0.5464	0.03	0.08	0.04	0.18

POWER	
OSW	0.0509
NRS-101	0.0656
McGill	0.0916

The null hypothesis is accepted for the Oswestry Back Disability Index, Numerical Pain rating Scale 101-Questionnaire and McGill Pain Questionnaire, which indicates that at the α=0.05 level of significance there was no statistically significant subjective improvement between the final treatment and the one-month follow-up for group 1.
It was noted that the power for all the measurements was low, therefore, the chance of committing a type II error was high (accepting a false null hypothesis).

Table 4.15 Comparison of results within group 1 using the Wilcoxon's signed rank test to analyse objective data collected between treatment 1 and the final treatment

GROUP 1									
	TREATMENT 1					FINAL TREATMENT			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	3.5	3.8	0.45	1.74	**0.0008**	5.5	5.2	0.5	0.05
Flex	20	17.6	1.6	6.5	0.7236	15	18	1.27	4.9
Ext	10	12	1.06	4.14	0.1336	15	13.3	0.9	3.6
R. Lat Flex	40	41.3	3.1	12	**0.0233**	50	47.6	1.8	7
L. Lat Flex	45	43	2.6	10.3	0.0412	50	48.6	1.3	5.1
R. Rot	35	36.6	2.9	11.2	**0.0076**	50	43	2.8	10.2
L.Rot	40	37.6	2.79	10.8	0.2888	40	43	2.9	11.3

POWER	
ALG	0.4840
Flex	0.0525
Ext	0.1412
R. Lat Flex	0.3816
L. Lat Flex	0.4416
R. Rot	0.3243
L.Rot	0.2387

The null hypothesis is rejected at the α=0.05 level of significance for the algometer, right lateral flexion and right rotation, therefore demonstrating a statistically significant improvement between treatment one and the final treatment for group 1.

The null hypothesis is accepted for flexion, extension, left lateral flexion and left rotation, and therefore there was no statistically significant improvement between treatment one and the final treatment for group 1. The powers of all the objective measurements are low and thus there was a large likelihood of accepting a false null hypothesis (committing a type II error).

Table 4.16 Comparison of results within group 1 using the Wilcoxon's signed rank test to analyse objective data collected between treatment 1 and the one-month follow-up

GROUP 1									
	TREATMENT 1					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	3.5	3.8	0.45	1.74	**0.0025**	5	5.2	0.49	1.9
Flex	20	17.6	1.6	6.5	0.1305	20	19.6	1.4	5.5
Ext	10	12	1.06	4.14	0.2206	15	13.3	0.9	3.6
R. Lat Flex	40	41.3	3.1	12	0.1305	45	45.6	1.7	6.5
L. Lat Flex	45	43	2.6	10.3	0.0736	50	48	1.3	5.2
R. Rot	35	36.6	2.9	11.2	0.0455	50	42.6	2.9	11.2
L.Rot	40	37.6	2.79	10.8	0.2888	50	43	3.1	12.2

POWER	
ALG	0.5141
Flex	0.1354
Ext	0.1412
R. Lat Flex	0.2114
L. Lat Flex	0.3551
R. Rot	0.2832
L.Rot	0.2219

The null hypothesis is rejected at the α=0.05 level of significance for the algometer, therefore demonstrating a statistically significant improvement between treatment one and the one-month follow-up for group 1.

The null hypothesis is accepted for all ranges of motion, and therefore there was no statistically significant improvement between treatment one and the one-month follow-up for group 1.

Table 4.17 Comparison of results within group 1 using the Wilcoxon's signed rank test to analyse objective data collected between the final treatment and the one-month follow-up

GROUP 1									
	FINAL TREATMENT					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	5.5	5.2	0.5	0.05	1.0000	5	5.2	0.49	1.9
Flex	15	18	1.27	4.9	0.6170	20	19.6	1.4	5.5
Ext	15	13.3	0.9	3.6	0.4794	15	13.3	0.9	3.6
R. Lat Flex	50	47.6	1.8	7	0.2206	45	45.6	1.7	6.5
L. Lat Flex	50	48.6	1.3	5.1	0.6170	50	48	1.3	5.2
R. Rot	50	43	2.8	10.2	1.0000	50	42.6	2.9	11.2
L.Rot	40	43	2.9	11.3	1.0000	50	43	3.1	12.2

POWER	
ALG	0.0507
Flex	0.1285
Ext	0.0500
R. Lat Flex	0.1167
L. Lat Flex	0.8176
R. Rot	0.0510
L.Rot	0.0500

The null hypothesis is accepted at the α=0.05 level of significance for all of the above cases, and therefore there was no statistically significant improvement between the final treatment and the one-month follow-up for group 1. The power was close to 1 for left lateral flexion. This indicates that there was only a small chance of committing a type II error (accepting a false null hypothesis) for left lateral flexion. The remaining power values are low and thus there was a large likelihood of accepting a false null hypothesis (type II error).

Table 4.18 Comparison of results within group 2 using the Wilcoxon's signed rank test to analyse subjective data collected between treatment 1 and the final treatment

GROUP 2									
	TREATMENT 1					FINAL TREATMENT			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	18	19	1.6	6.5	0.0960	8	12.2	2.3	9.2
NRS-101	45	46.8	3.04	11.7	0.0388	35	35.6	3.7	14.2
McGill	0.16	0.23	0.04	0.16	**0.0032**	0.09	0.17	0.04	0.16

POWER	
OSW	0.5818
NRS-101	0.6028
McGill	0.1962

The Short-Form McGill Pain Questionnaire demonstrates a significant improvement between treatment one and the final treatment. The null hypothesis was thus rejected at the α=0.05 level of significance.

For the Oswestry Back Disability Index, Numerical Pain Rating Scale-101 Questionnaire, there was no significant improvement between treatment one and the final treatment. The null hypothesis was thus accepted at the α=0.05 level of significance.

Table 4.19 Comparison of results within group 2 using the Wilcoxon's signed rank test to analyse subjective data collected between treatment 1 and the one-month follow-up

GROUP 2									
	TREATMENT 1					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	18	19	1.6	6.5	**0.0019**	8	8.9	5.8	34.2
NRS-101	45	46.8	3.04	11.7	**0.0055**	37	33.8	4.7	18.4
McGill	0.16	0.23	0.04	0.16	**0.0019**	0.09	0.13	0.02	0.11

POWER	
OSW	0.9801
NRS-101	0.6001
McGill	0.1024

For the Oswestry Back Disability Index, Numerical Pain Rating Scale-101 Questionnaire and McGill Pain Questionnaire, the null hypothesis is rejected at α=0.05 level of significance. This indicates that there was a statistically significant improvement between treatment one and the one-month follow-up within group 2. The powers for the Oswestry Back Disability Index and the Numerical Pain Rating Scale-101 Questionnaire was high, this indicates that the likelihood of committing a type II error (accepting a false null hypothesis) was small.

Table 4.20 Comparison of results within group 2 using the Wilcoxon's signed rank test to analyse subjective data collected between the final treatment and the one-month follow-up

GROUP 2									
	FINAL TREATMENT					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
OSW	8	12.2	2.3	9.2	0.3864	8	8.9	5.8	34.2
NRS-101	35	35.6	3.7	14.2	0.1213	37	33.8	4.7	18.4
McGill	0.09	0.17	0.04	0.16	0.2672	0.09	0.13	0.02	0.11

POWER	
OSW	0.2137
NRS-101	0.0585
McGill	0.1360

In all of the above instances, the null hypothesis is accepted at α=0.05 level significance. This indicates that there is no statistically significant subjective improvement between the final treatment and the one-month follow-up within group 2. The powers for all three subjective measurements was low, this indicates that the likelihood of committing a type II error (accepting a false null hypothesis) was large.

Table 4.21 Comparison of results within group 2 using the Wilcoxon's signed rank test to analyse objective data collected between treatment 1 and the final treatment

GROUP 2									
	TREATMENT 1					FINAL TREATMENT			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	4	5.7	1.4	5.5	0.5049	4	4.03	0.39	1.5
Flex	20	19.5	2.1	8.3	0.3710	15	18.3	2.1	8.1
Ext	10	12.5	1.47	5.71	1.0000	10	11.5	1.18	4.58
R. Lat Flex	45	44	2.08	8.06	0.3864	40	40.6	1.75	6.77
L. Lat Flex	50	47	1.6	6.21	0.3427	45	43	1.7	6.76
R. Rot	40	37.3	2	7.76	0.2206	30	35.6	2.2	8.6
L.Rot	40	39.3	2	7.7	0.4496	40	38	2.4	9.4

POWER	
ALG	0.1853
Flex	0.0656
Ext	0.0778
R. Lat Flex	0.2108
L. Lat Flex	0.3629
R. Rot	0.0808
L.Rot	0.0667

The null hypothesis is accepted for the algometer and all ranges of motion at $\alpha=0.05$ level of significance. This indicates that there was no statistically significant objective improvement between treatment one and the final treatment within group 2.

The powers for all objective measurements was low, this indicates that the likelihood of committing a type II error (accepting a false null hypothesis) was large.

Table 4.22 Comparison of results within group 2 using the Wilcoxon's signed rank test to analyse objective data collected between treatment 1 and the one-month follow-up

GROUP 2									
	TREATMENT 1					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	4	5.7	1.4	5.5	0.0704	3.5	3.8	0.4	1.5
Flex	20	19.5	2.1	8.3	0.3710	15	18.3	2.05	7.9
Ext	10	12.5	1.47	5.71	0.6830	10	12.5	1.1	4.2
R. Lat Flex	45	44	2.08	8.06	1.0000	40	41.6	2.3	9
L. Lat Flex	50	47	1.6	6.21	0.4496	45	44.3	1.75	6.8
R. Rot	40	37.3	2	7.76	0.0770	30	34.3	2	7.8
L. Rot	40	39.3	2	7.7	0.1305	30	36	1.9	7.6

POWER	
ALG	0.2214
Flex	0.0660
Ext	0.0500
R. Lat Flex	0.1070
L. Lat Flex	0.1868
R. Rot	0.1676
L.Rot	0.1970

The null hypothesis is accepted for the algometer and all ranges of motion at $\alpha=0.05$ level of significance. This indicates that there was no statistically significant objective improvement between treatment one and the one-month follow-up within group 2. The powers for all objective measurements was low, this indicates that the likelihood of committing a type II error (accepting a false null hypothesis) was large.

Table 4.23 Comparison of results within group 2 using the Wilcoxon's signed rank test to analyse objective data collected between final treatment and the one-month follow-up

GROUP 2									
	FINAL TREATMENT					ONE-MONTH			
	MEDIAN	MEAN	S.E	S.D	P-VALUE	MEDIAN	MEAN	S.E	S.D
ALG	4	4.03	0.39	1.5	0.5049	3.5	3.8	0.4	1.5
Flex	15	18.3	2.1	8.1	0.4794	15	18.3	2.05	7.9
Ext	10	11.5	1.18	4.58	0.2482	10	12.5	1.1	4.2
R. Lat Flex	40	40.6	1.75	6.77	0.7236	40	41.6	2.3	9
L. Lat Flex	45	43	1.7	6.76	0.5049	45	44.3	1.75	6.8
R. Rot	30	35.6	2.2	8.6	0.6170	30	34.3	2	7.8
L. Rot	40	38	2.4	9.4	0.3710	30	36	1.9	7.6

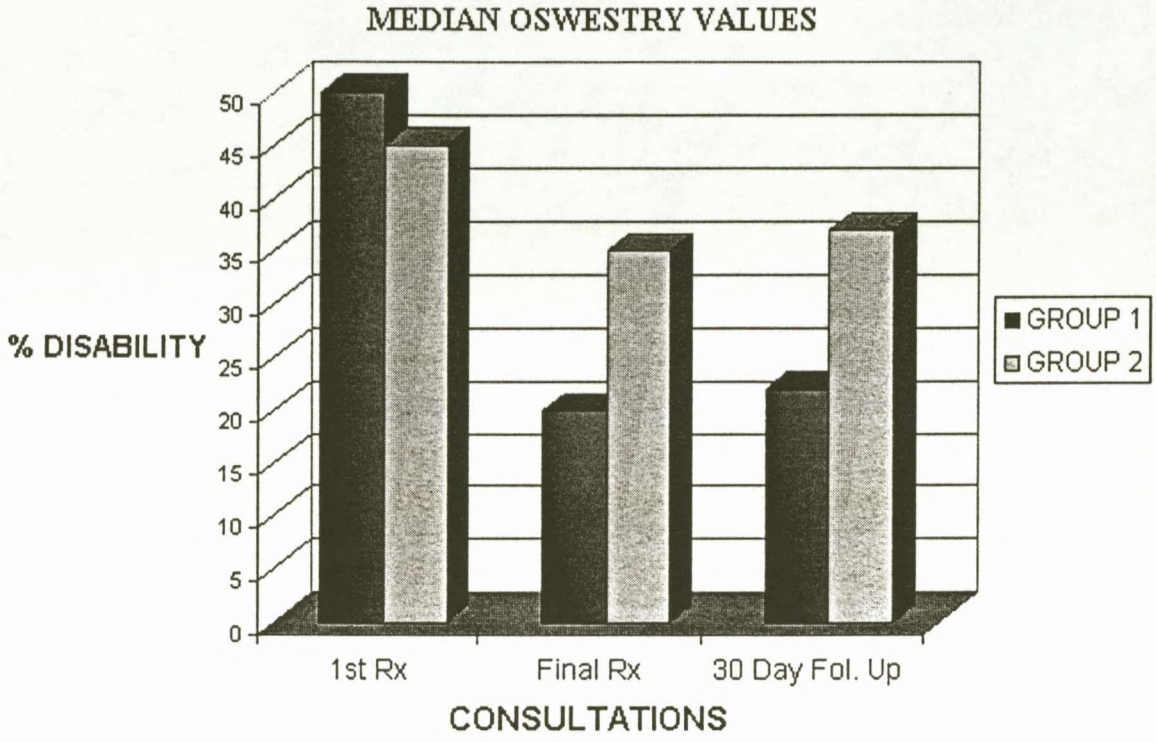
POWER	
ALG	0.0627
Flex	0.0500
Ext	0.0883
R. Lat Flex	0.0630
L. Lat Flex	0.0774
R. Rot	0.0694
L.Rot	0.0911

The null hypothesis is accepted for the algometer and all ranges of motion at α=0.05 level of significance. This indicates that there was no statistically significant objective improvement between the final treatment and the one-month follow-up within group 2. The powers for all objective measurements was low, this indicates that the likelihood of committing a type II error (accepting a false null hypothesis) was large.

4.4 Barcharts

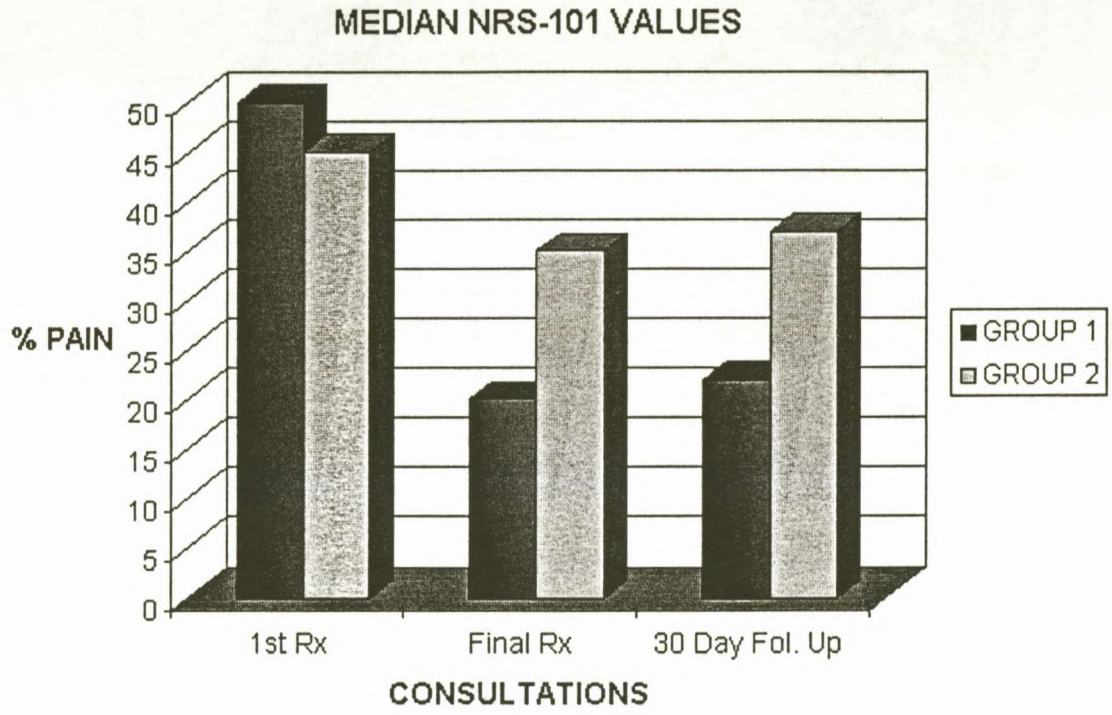
Figures 4.1-4.8 are visual representations of the median value changes of group 1 and group 2 found within the first, final, and one month follow-up consultations. These values were taken from the summary statistics and are not intended as a comparison between the two study groups as this could not be done from median values. However, they serve to indicate possible trends within the two groups.

Fig 4.1 This figure indicates the changes in the median disability values over the period of evaluation



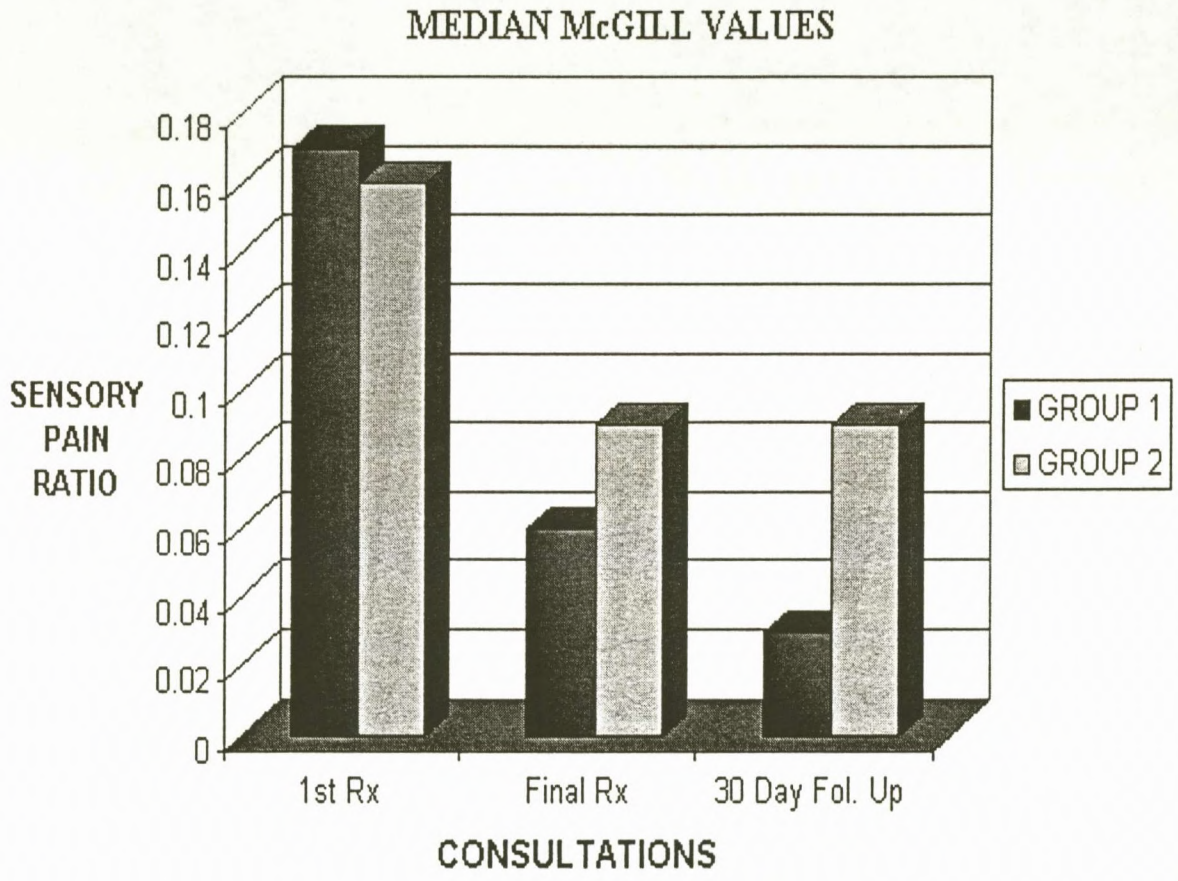
There is a large decrease in percentage disability for the SMT group at the final consultation and only a slight decrease for the placebo group. Little change occurred from the final treatment to the one-month follow-up for both treatment groups.

Fig 4.2 This figure indicates the changes in the median percentage pain values over the period of evaluation



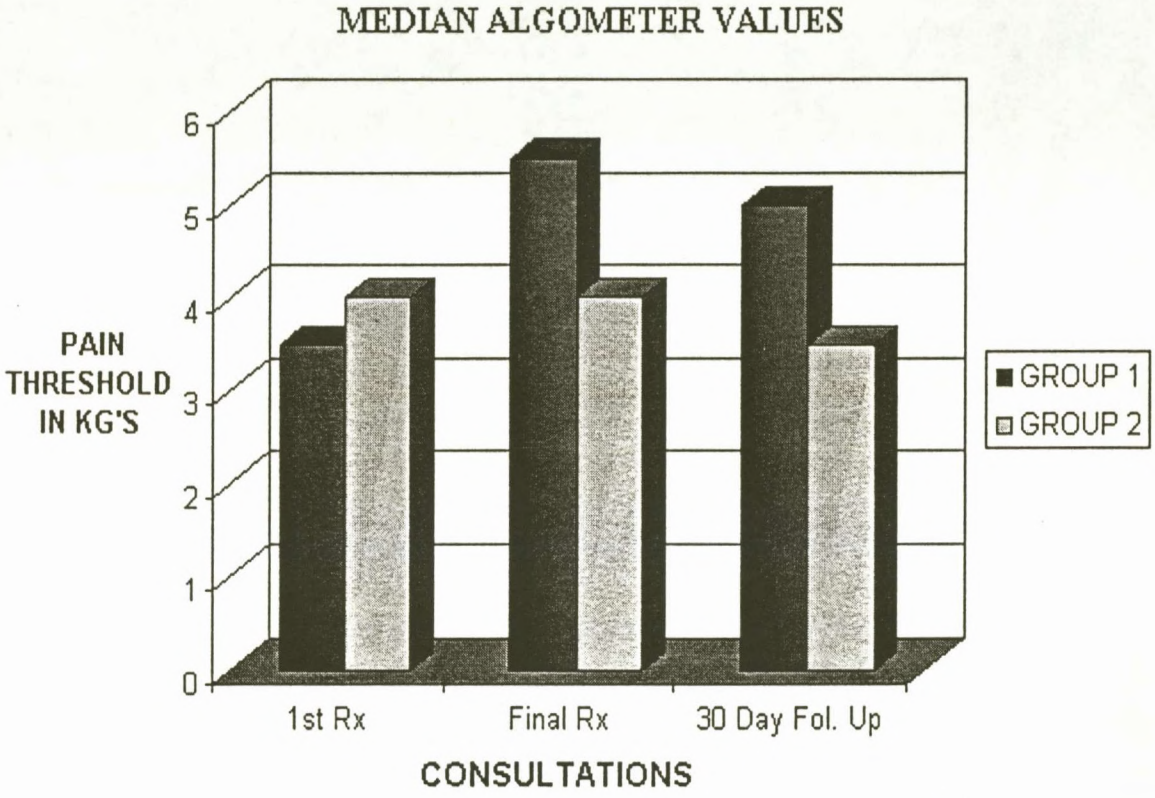
There is a large decrease in the percentage pain experienced by the SMT group and in comparison only a slight decrease is experienced by the placebo group, at the final consultation. For both groups, little change in percentage pain occurred at the one-month follow-up. This finding has a similar trend as the median Oswestry values.

Fig 4.3 This figure indicates the changes in the median sensory pain ratio values over the period of evaluation



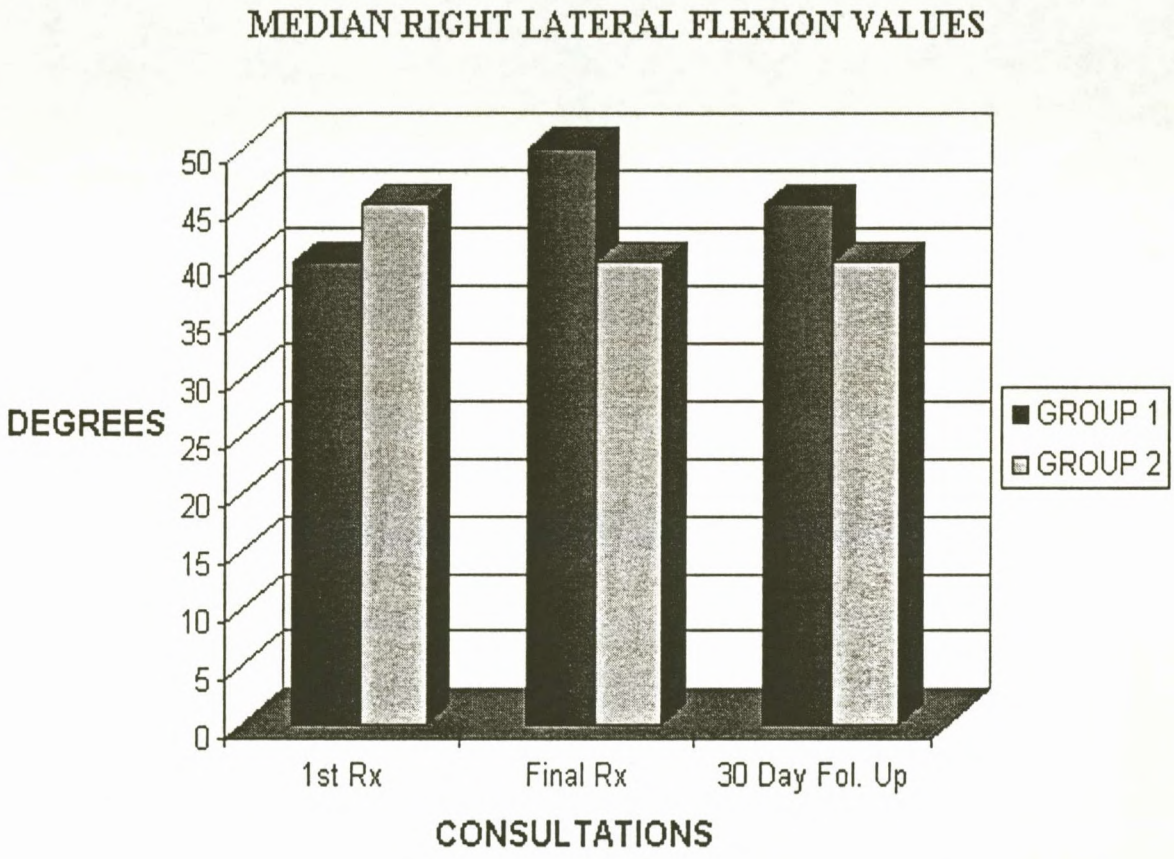
A decrease in sensory pain occurred for both groups at the final consultations. A slightly greater decrease is seen for the SMT group. The sensory pain ratio did not increase between the final treatment and the 30 day follow-up, therefore, long term benefits of both groups are noted.

Fig 4.4 This figure indicates the changes in the median pain threshold values over the period of evaluation



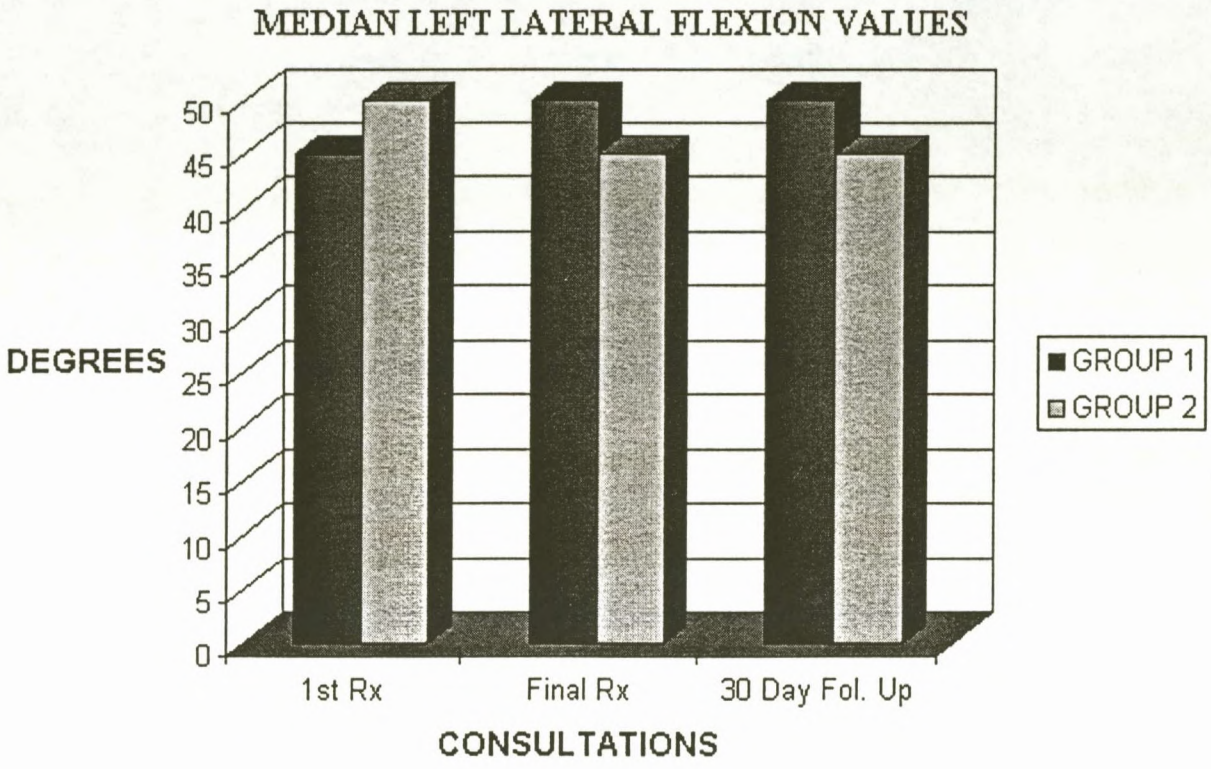
An increase in pain threshold occurred for the SMT group only, while the placebo group values remained constant. A slight decrease in pain threshold occurred at the one-month follow-up for both groups, however, the benefits of SMT are still evident at this stage.

Fig 4.5 This figure indicates the changes in the median right lateral flexion values over the period of evaluation



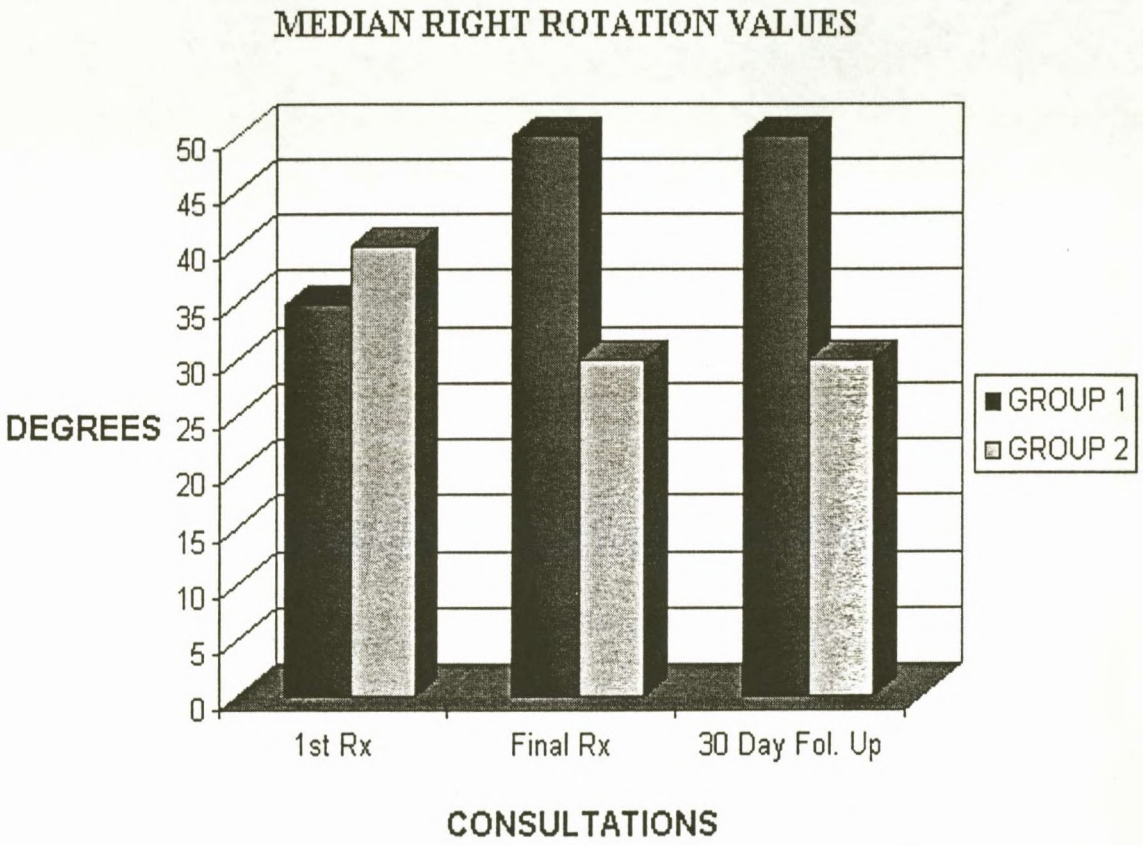
A 10° increase in median right lateral flexion values occurred for the SMT group at the final consultation. The placebo group in comparison showed a 5° decrease at the final consultation. At the 30 day follow-up there is a slight loss in gain for the SMT group only, however, the benefits of the treatment period are still evident.

Fig 4.6 This figure indicates the changes in the median left lateral flexion values over the period of evaluation



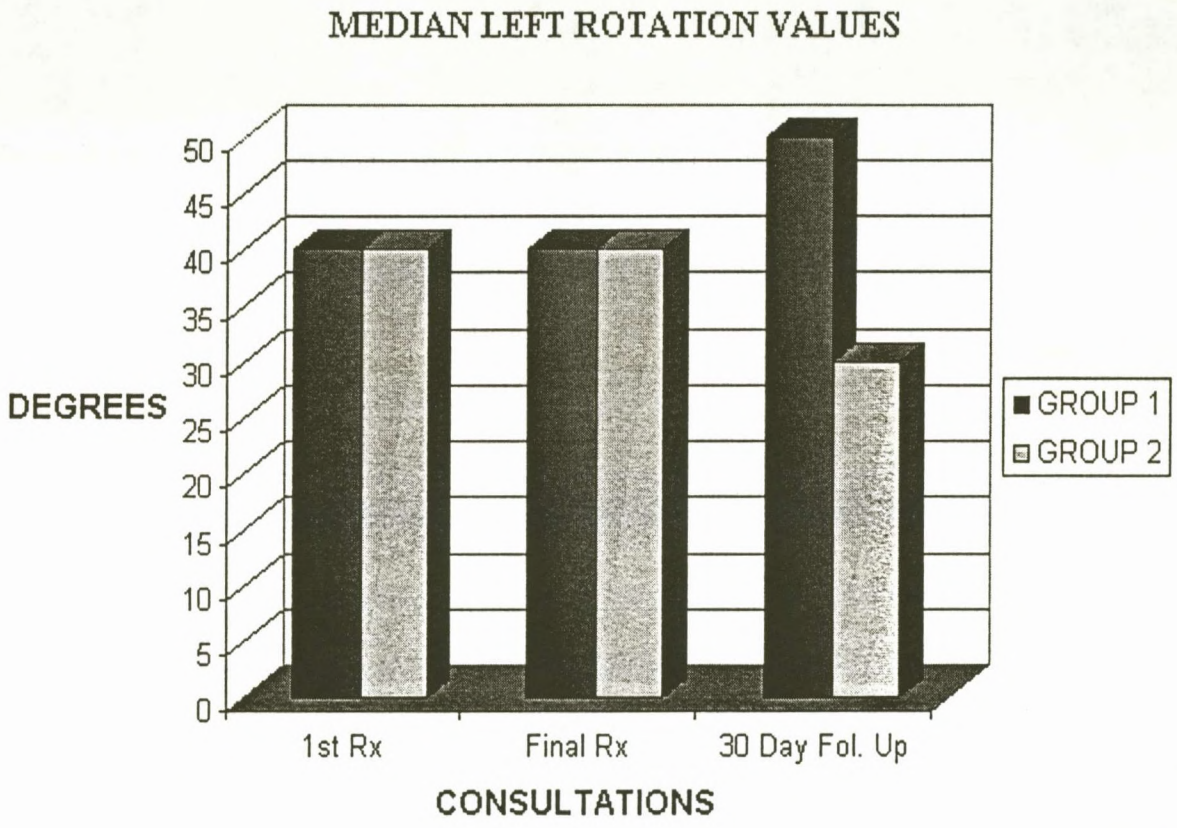
A 5° increase in median left lateral flexion values is seen for the SMT group at the final treatment and still evident at the 30 day follow-up. In contrast a 5° decrease is seen for the placebo group at the final treatment and the 30 day follow-up in comparison to the first treatment. This difference between the placebo and SMT groups could be due to a deterioration in the condition of some patients without "active" treatment.

Fig 4.7 This figure indicates the changes in the median right rotation values over the period of evaluation



There is a 15° increase in median right rotation values at the final consultation which remains at the 30 day follow-up for the SMT group. A slight decrease is noted for the placebo group at the final consultation which remains at the 30 day follow-up. This difference shows the relative long term benefits of SMT in increasing right rotation as compared to the placebo treatment.

Fig 4.8 This figure indicates the changes in the median left rotation values over the period of evaluation



Unlike the previous graphs there is no change between the first treatment and the final treatment for both groups for median left rotation values. However, a 10° increase for the SMT group and a 10° decrease for the placebo group is seen at the 30 day follow-up. This finding can not be easily explained.

CHAPTER FIVE

5.0 DISCUSSION OF RESULTS

5.1 INTRODUCTION

This chapter will discuss the results obtained from the subjective and objective data presented in chapter four.

In the evaluation of the inter-group data the assessment from measurements of the first treatment gives an indication of any baseline differences in subjective and objective findings between the two groups, in terms of their original signs and symptoms. The inter-group comparison at the final treatment indicates which treatment protocol is more effective. The assessment of the results at the one-month follow-up consultation indicates differences in the relative long-term treatment benefits between the two groups.

The analysis of the subjective and objective intra-group results between treatments one and the final treatment represent the efficacy of each treatment regime. Evaluation of the results between the final treatment and the one-month follow-up consultation gives an indication of the long-term benefits of each treatment regime.

5.2 INTER-GROUP COMPARISON

5.2.1 The subjective data

The statistical data can be found in tables 4.6, 4.7 and 4.8.

On statistical analysis, no significant difference could be detected between the two groups at the first treatment suggesting that the symptomatology caused by mechanical thoracic spine dysfunction was similar between the two groups initially. A significant difference could be detected for Numerical pain Rating Scale-101 Questionnaire at the final treatment, suggesting that SMT was more effective than placebo therapy at the final treatment, but only for percentage pain experienced by the subjects. No significant difference could be detected between the two groups at the one-month follow-up for the percentage pain experienced, indicating that the two treatment approaches were equally effective in the relative long term.

Statistical analysis of the Short-form McGill Pain Questionnaire and Oswestry Back Disability Index revealed no significant difference between the two groups at any period of time throughout the study. This indicates that both treatment approaches were both effective in the amount of disability and sensory dimensions of pain experienced by the patient.

The power for all three assessment periods were not close to 1, this is especially true for the Short-form McGill Pain Questionnaire, indicating that even if significant changes were present, they would not have been detected due to the small sample size. The smaller the power of a test, the larger becomes the likelihood of a type II error, i.e. accepting a

-vomitting of food eaten long before (Boericke, 1998).

Ipecacuahna

-nausea from the smell of food, improved by eating

-empty eructations with excessive salivation - gastritis, not even a drop of food will stay down

- rumbling in the abdomen, accompanied by distention

- cutting, gripping pains especially around umbilicus

- after vomitting must sleep (Vermeulen, 2000).

2.8 The Placebo Enigma

Placebo refers to a medical treatment, which has no specific medicinal activity and is just a dummy. Placebo effect dates back to Hippocrates who observed that certain gravely ill patients seemed to recover through sheer "contentment". Placebo accounts for much of the benefit people get from anti- depressants and all the benefit from anti-biotics taken for viral infections which are not affected by the drugs (Grady, 2004).

It is often considered as a classic example of body- mind relation that depends on largely sub-conscious interactions between the doctor, the treatment process and the patient. Evidence will be adduced that it depends on the patient's belief or expectation that treatment is effective; it often operates without deliberate intention, and, it affects physiological and psychological processes (Linde, 2006).

present for the other values, they would not have been detected due to a increased likelihood of committing a type II error i.e. accepting a false null hypothesis.
The median values (Figs 4.4-4.8) for the groups tend to show differences in treatment response at the final treatment and slight differences at the one-month follow-up, favouring SMT.

5.3 INTRA-GROUP COMPARISON

5.3.1 The subjective data

The statistical data can be found in tables 4.12, 4.13, 4.14, 4.18, 4.19 and 4.20.

Statistical analysis within the SMT group revealed significant improvements for all subjective measurements taken during the first to final treatments and first treatment to the one-month follow-up. This suggests that SMT is an effective treatment for reduction of disability, percentage pain and sensory dimensions of pain for mechanical thoracic spine pain. There were no statistically significant improvements between the final treatment and the one-month follow-up, indicating that no further subjective improvement was experienced once treatment had stopped.

Within the placebo group statistical analysis revealed no significant improvements for the Oswestry Back Disability Index and the Numerical Pain Rating Scale-101 Questionnaire during the first to final treatments, in contrast to the SMT group that did. This indicates that only the SMT group was successful in significantly reducing disability and amount of

pain. However, the Short-Form McGill Pain Questionnaire revealed a significant improvement during the first treatment to the final treatments within the placebo group. Therefore placebo therapy did significantly reduce sensory dimensions of pain during the treatment period. This is possibly due to the fact, that in this study, sensory pain could be the most subjective measurement.

Within the placebo group all subjective measurements were statistically significant between the first treatment and the one-month follow-up, as with the SMT group, suggesting that there are significant long-term benefits of the placebo treatment. These long-term benefits are similar to SMT.

No statistically significant improvement within the placebo group was noted between the final treatment and the one-month follow-up. Indicating that no further statistically significant improvement occurred once treatment had stopped.

5.3.2 The Objective data

The statistical data for the algometer measurements and thoracic spine ranges of motion can be found in tables 4.15, 4.16, 4.17, 4.21, 4.22 and 4.23.

The SMT group showed a significant improvement in algometer pain threshold measurements, right lateral flexion and right rotation during the period between the first treatment and the final treatment. When viewing the period between the first treatment and the one-month follow-up, a significant increase in algometer pain threshold measurements

was found, indicating a substantial increase in pain threshold over the six week treatment period.

In comparison, no statistically significant improvement could be found within the placebo group in all objective measurements during the period between the first treatment to the final treatment and the first treatment to the one-month follow-up, indicating that placebo therapy is ineffective in improving pain threshold and thoracic spine ranges of motion.

In the period between the final treatment and the one-month follow-up consultation no statistically significant improvement was noted within both groups, indicating that once treatment had stopped no further objective improvement took place.

On comparison between the two groups, the SMT group showed a greater number of significant findings. It is of potential clinical significance that SMT caused a substantial increase in range of motion and pain threshold as these are the most often affected in mechanical thoracic spine pain.

The intra-group comparison suggests that SMT was more effective in universally increasing thoracic ranges of motion as well as being more effective in increasing pain thresholds during the course of the treatment protocol. Placebo therapy had no significant influence on objective measurements during the course of the study period.

5.4 STUDY LIMITATIONS

From the statistical analysis of this study there seems to be no overall significant difference between SMT and placebo therapy in the treatment of mechanical thoracic spine pain.

Both treatment approaches improved subjectively to such a degree that it was not possible to distinguish a better treatment modality at the one-month follow-up. The SMT group improved significantly on objective measures at the final treatment, showing that SMT does have more clinical benefits than placebo therapy, but may not have lasting effects.

Having stated the above, the following factors must be considered for future studies of this nature.

5.4.1 Cross-over study design

A shortcoming of this study was the lack of a cross-over design. Two patients in the placebo treatment group discontinued the study after the final treatment due to inability to wait one month for any further treatment. These two patients had not improved with placebo treatment and their condition caused them to seek further treatment. If this was a cross-over study design, these data could have been included into the statistical analysis, and thus more valid trial conclusions obtained.

Uncontrolled clinical trials may contribute to drawing erroneous conclusion from results due to the placebo effect. However, a placebo controlled clinical trial may lead to poor patient compliance, putting the validity of study results in jeopardy. One way to avoid this catch-22 situation is to change the placebo group patients that have not improved to a certain degree after the final treatment, over to the SMT group.

5.4.2 Study size and power

The most profound shortcoming of this study is the sample size of 15 patients in each group. In the criteria list for the methodological assessment of a clinical trial for back and neck manipulation Koes et al. (1996) sub-divided their list into four subsections. The sub-section addressing the study population counted for 30 out of a possible 100 points. The authors attach a value of 12 points to any clinical trial with a sample size of $\geq$100 subjects. This indicates the strength that a larger study population lends to a study. This is evident from the higher power of the larger study.

There is a close connection between sample size and the power of a statistical test. The smaller the sample size the greater the likelihood of a type II error occurring (i.e. accepting a false null hypothesis). This results from the low power of the study to detect small but clinically relevant treatment differences. (Koes et al.1995.) In view of a shortage of time and resources encountered it was not possible to use a larger study population in this study. However, this is a pilot study that can be utilized for a larger study.

5.4.3 Homogeneity

In any randomized clinical trial the goal is that the study groups should be similar in relevant patient characteristics. A higher degree of comparability between the two groups allows for more valid trial conclusions. (Haldeman 1992:418.) However it is not always possible to have a study group with comparable baseline characteristics and still have a random allocation of subjects. This study used a randomised allocation of subjects to ensure that researcher bias did not influence the results. When larger sample sizes are used, random assignment to treatment groups tends to create groups that are more comparable in baseline characteristics.

In this study, when considering the demographic data it can be seen that the two groups were very similar in age, gender and occupation distributions. The main complaint, 77%, occurred in the mid thoracic spinal region (T5-T9) predominantly. It is concluded that this study has comparable baseline characteristics (see tables 4.1- 4.5).

5.4.4 Blinding

To reduce bias, some measurement of blinding must be introduced into a clinical trial. Blinding of patients was established in this study by including placebo therapy to naive patients (single-blind study). Thus, this study gave information about the nonspecific effects involved during interventions. Only statistically significant subjective improvements occurred within the placebo group.

The study was conducted solely by the author; thus the possibility of practitioner bias exists. An independent observer taking the measurements before, during and after treatments would minimize investigator bias. It is important that the independent observer not know which group the subject is assigned to. It was not practically possible to include an independent observer effectively into this study, which may reduce the validity of the study due to the lack of double blinding.

5.4.5 Significance

There is a consensus that outcome measures should be valid, precise and sensitive for measuring small but clinically relevant changes (Koes et al.1995). Significance may not be revealed by statistical analysis of objective and subjective data if this is not so. We cannot be sure of which of the many available outcome measures and instruments should be used for the investigation of mechanical thoracic spine pain. It was shown from the method discussion in chapter three that the objective and subjective measurements used in this study represent valid methods of capturing changes within test subjects. However, true clinical changes of dysfunctional joints undergoing SMT could have been incompletely measured.

Another weakness stands in the lack of human understanding in correctly completing subjective questionnaires, bringing about error. The patient may have felt the need to please the researcher and thus recorded results that they thought the researcher desired, which brings about biased subjective results. The patients in this study were told to

complete the questionnaires as honestly as possible, however the researcher cannot be sure that the patient did.

The objective measurements may have been subject to observer bias. The increments of the algometer and goniometer are $1kg/cm^2$ and 2° respectively and thus the observer may not have noticed subtle changes in the readings. Electronic measuring devices would have been more accurate. However due to resource constraints this was not possible in this study.

5.5 POSSIBLE EFFECTS ON EXISTING KNOWLEDGE AND PRACTICES

Although this study could only find a few significant differences (Numerical Pain Rating Scale-101 Questionnaire, Right and Left Lateral Flexion) between the two treatment groups on inter-group analysis, it was shown that SMT is an effective tool in the treatment of mechanical thoracic spine pain.

Placebo therapy did have statistically significant benefits, however they were limited to subjective improvements only. SMT proved to have greater significant subjective improvements than the placebo group with intra-group statistical analysis.
This seems to be the trend when viewing the barcharts using the median values (figs 4.1-4.3), especially when the first treatment is compared to the final and thirty day follow-up.

Most patients in this study required all six treatment sessions to improve, with the exception of one patient in the SMT group who was symptom free after two treatments. It is the author's clinical impression that most patients showed improvement after the fourth treatment, however they were still not symptom free. This finding does not correlate with Triano et al's (1992), where it was found that thoracic spine disorders needed a mean of 3 treatments for clinical resolution. However, their study cannot be directly compared with this study as they used co-interventions to SMT such as physical therapy modalities, exercise and home care advice. It was also noted by Triano et al.(1992) that chronic conditions require more treatment than acute conditions, and in this study most subject's condition was chronic in nature for both groups.

Although placebo therapy is not always considered a legitimate part of a clinical practice, it was shown in this study that placebo therapy did statistically benefit patients subjectively. All physicians are using the placebo effect merely by prescribing any therapeutic intervention. The author's impressions, after the study was completed, are that physicians should utilise placebo effects to maximize possible treatment benefits for the patient.

Side effects of SMT were noted to be common in patients following treatment to the thoracic spine. Moderate local discomfort was a common complaint, especially after the first treatment. This incidental finding correlates with Senstad et al.(1996). They found that 39% of patients treated with SMT to the thoracic spine reported side effects. It is clinically important to remember, when treating the thoracic spine with SMT, that patients be informed of possible side effects.

Due to the small sample size used in this study, the results can only be used as a guide line for further studies and cannot be recognized as having a significant impact on the current body of knowledge.

CHAPTER SIX

6.0 RECOMMENDATIONS AND CONCLUSIONS

6.1 RECOMMENDATIONS

With greater financial and time freedom the author would recommend a study that could investigate the possible differences between SMT and placebo treatment in the management of chronic or acute thoracic spine pain, with the following improvements suggested below.

Sample size:

A larger sample size should be selected using a stratified randomization procedure, taking into account age, gender, race, location and occupation. These factors could aid in making the sample more linear in distribution and thus produce more valid trial conclusions. Parametric statistical analysis should be used with a chance of a type II error limited to a set level.

Homogeneity:

Duration of patients' symptoms should be taken into account. Patients should be divided into acute, subacute, chronic or recurrent thoracic spine pain categories due to the differences noted in treatment history (Triano et al. 1992). This would allow for greater accuracy and reliability of results.

The study should be limited to only the middle region of the thoracic spine (T5-T9), due to the differences in anatomy and biomechanics of the three regions (Edmondson and Singer 1997); this would also allow for greater accuracy and specificity of results.

Blinding:

Researcher bias can be eliminated by not informing the independent observer collecting and collating the data as to which group the patient falls.

Follow-up period:

An adequate follow-up period of six months or more is recommended. This gives a clearer indication of the long-term benefits associated with the treatment.

Cross-over design:

A cross-over study design should be considered to limit the possibility of drop-outs during the follow-up period. Those patients not showing a certain degree of improvement by the final treatment should be switched over to the opposite group to see if any improvement occurs.

Accuracy of measurements:

As technology advances more sensitive instrumentation should be introduced into clinical trials. This should allow for more accurate readings and greater detection of small but significant differences in effects of treatments.

If only another pilot study was possible due to limited resources the author would recommend a study to investigate treatment differences between mobilization and

manipulation for thoracic spine pain. Also needed is research investigating the demographic effects on the incidence of, and risk factors for, thoracic spine pain.

6.2 CONCLUSIONS

This controlled clinical trial study comprised a sample size of 30. All patients had to be diagnosed with mechanical thoracic spine pain according to certain criteria. These patients were randomly divided into two groups of 15 each. Group 1 received spinal manipulative therapy and group 2 received non-functional ultra-sound over the area of pain. Both groups received a maximum of six treatments over a three week period and had a one-month follow-up.

Analysis of the data revealed statistically significant differences between the SMT group and the placebo group in terms of percentage pain, right and left lateral flexion after the treatment period. However these differences were not evident at the one-month follow-up. This leads to the conclusion that the SMT group responded more favorably in terms of subjective and objective measures immediately after the treatment period.

Further analysis revealed statistically significant improvements within the SMT group subjectively and objectively, after the treatment period. These changes were still evident at the one-month follow-up.

The placebo group also showed significant improvements within the group, however they were limited to subjective improvements only. The median values (Figs 4.1-4.3) for the

placebo group revealed subjective improvements to a lesser degree than the SMT group. No group showed significant improvements between the final treatment and one-month follow up.

The study thus indicates that SMT and placebo therapy are not equally effective in the short-term treatment of mechanical thoracic spine pain.

Further trials, using a larger sample size and parametric analysis may find variations in results from this study. The findings in this study should not be considered conclusive, but rather used as a foundation to plan larger studies.

There are no clear treatment protocols that exist yet for the treatment of mechanical thoracic spine pain. The treatment of mechanical thoracic spine pain is complex due to the number of variables involved i.e. stress, posture, nutritional inadequacies and functional factors. Constant re-evaluation of patients must be used in order to clinically monitor patient response. In the author's opinion, uncomplicated mechanical thoracic spine pain treated with SMT should improve significantly after four treatments. If this does not happen further investigations into the possible etiology of the condition is suggested.

In view of the prevalence of back pain and its pervasive impact in so many social spheres, the ability to decrease an episode of back pain, even by a few days, can have major ramifications.

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ADDENDUM A

OSWESTRY BACK DISABILITY INDEX

PATIENT NAME:_____ FILE #:_____ DATE:___ ___

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 the 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 have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

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 walking any distance.
- ☐ Pain prevents me walking more than 1 mile (2.2 km).
- ☐ Pain prevents me walking more than ½ mile (1.1 km).
- ☐ Pain prevents me walking more than ¼ mile (0.5 km).
- ☐ 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 1 hour.
- ☐ Pain prevents me from sitting more than ½ hour.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 - Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want, but it gives me extra pain.
- ☐ Pain prevents me from standing for more than one hour.
- ☐ Pain prevents me from standing for more than 30 minutes.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 - Sex Life

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 8 - Social Life

- ☐ My social life is normal and gives me no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting any more energetic interests, for example, dancing.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 9 - Sleeping

- ☐ I have no trouble sleeping.
- ☐ I can sleep well only by using pills.
- ☐ Even when I take pills I have less than six hours sleep.
- ☐ Even when I take pills I have less than four hours sleep.
- ☐ Even when I take pills I have less than two hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 10 - Travelling

- ☐ I can travel anywhere without extra pain.
- ☐ I can travel anywhere but it gives me extra pain.
- ☐ Pain is bad but I manage trips over two hours.
- ☐ Pain restricts me to trips of less than one hour.
- ☐ Pain restricts me to trips under 30 minutes.
- ☐ Pain prevents me from travelling, except to the doctor or hospital.

ADDENDUM B

PATIENT NAME : _____

FILE # : _____ DATE : _____

		NONE	MILD	MODERATE	SEVERE
1	THROBBING	0) ____	1) ____	2) ____	3) ____
2	SHOOTING	0) ____	1) ____	2) ____	3) ____
3	STABBING	0) ____	1) ____	2) ____	3) ____
4	SHARP	0) ____	1) ____	2) ____	3) ____
5	CRAMPING	0) ____	1) ____	2) ____	3) ____
6	GNAWING	0) ____	1) ____	2) ____	3) ____
7	HOT-BURNING	0) ____	1) ____	2) ____	3) ____
8	ACHING	0) ____	1) ____	2) ____	3) ____
9	HEAVY	0) ____	1) ____	2) ____	3) ____
10	TENDER	0) ____	1) ____	2) ____	3) ____
11	SPLITTING	0) ____	1) ____	2) ____	3) ____
12	TIRING-EXHAUSTING	0) ____	1) ____	2) ____	3) ____
13	SICKENING	0) ____	1) ____	2) ____	3) ____
14	FEARFUL	0) ____	1) ____	2) ____	3) ____
15	PUNISHING-CRUEL	0) ____	1) ____	2) ____	3) ____

McGILL PAIN QUESTIONNAIRE

ADDENDUM C

NUMERICAL PAIN RATING SCALE 101.

Patient Name:_____

File number:_____ Date:_____

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, when it is at its WORST. A zero (0) would mean "no pain at all" and one hundred (100) would mean "pain as bad as it could be".

Please write only one number.

0 _____ 100

Please indicate on the line below the number between 0 and 100 that best describes the pain of your major problem at this point, when it is at its LEAST. A zero (0) would mean "no pain at all" and one hundred (100) would mean "pain as bad as it could be".

Please write only one number.

0 _____ 100

ADDENDUM D

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:_____ Date: _____
file #:_____ X-Ray#:_____
Age:_____ Sex:_____ Occupation:_____
Intern:_____ Signature:_____

FOR CLINICIAN'S USE ONLY
Initial visit clinician:_____Signature:_____

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. lab:
Previous: Current:

Case Status:

PTT: Conditional: Signed Off: Final Sign out:

Recommendations:

Intern's Case History

1. Source of History:

2. Chief Complaint: (patient's own words)

3. Present Illness:

- Location
- Onset
- Duration
- Frequency
- Pain (Character)
- Progression
- Aggravating Factors
- Relieving Factors
- Associated S & S
- Previous Occurrences
- Past Treatment and Outcome

4. Other Complaints:

5. Past Medical History:

- General Health Status
- Childhood Illnesses
- Adult Illnesses
- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests
- Environmental Hazards (Home, School, Work)
- Safety Measures (seat belts, condoms)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
- Tobacco
- Alcohol
- Social Drugs

7. Immediate Family Medical History:

- Age
- Health
- Cause of Death
- DM
- Heart Disease
- TB
- Stroke
- Kidney Disease
- CA
- Arthritis
- Anaemia
- Headaches
- Thyroid Disease
- Epilepsy
- Mental Illness
- Alcoholism
- Drug Addiction
- Other

8. Psychosocial history:

- Home Situation and daily life
- Important experiences
- Religious Beliefs

9. Review of Systems:

- General
- Skin
- Head
- Eyes
- Ears
- Nose/Sinuses
- Mouth/Throat
- Neck
- Breasts
- Respiratory
- Cardiac
- Gastro-intestinal
- Urinary
- Genital
- Vascular
- Musculoskeletal
- Neurologic
- Haematologic
- Endocrine
- Psychiatric

ADDENDUM E

TECHNIKON NATAL

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:_____File#: _____Date:_____
Clinician:_____Signature:_____
Intern:_____Signature:_____

1. VITALS

Pulse rate:
Respiratory rate:
Blood pressure: R L
Temperature:
Height:
Weight:

2. GENERAL EXAMINATION

General Impression:
Skin:
Jaundice:
Pallor:
Clubbing:
Cyanosis (Central/Peripheral):
Oedema:
Lymph nodes - Head and neck:
- Axillary:
- Epitrochlear:
- Inguinal:

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in **Cardiac Failure** ?
2) Does this patient have signs of **Infective Endocarditis** ?
3) Does this patient have **Rheumatic Heart Disease ?**

Inspection - Scars
- Chest deformity:
- Precordial bulge:
- Neck -JVP:

Palpation: - Apex Beat (character + location):
- Right or left ventricular heave:
- Epigastric Pulsations:
- Palpable P2:
- Palpable A2:

Pulses:
- General Impression:
- Radio-femoral delay:
- Carotid:
- Radial:
- Dorsalis pedis:
- Posterior tibial:
- Popliteal:
- Femoral:

Percussion: - borders of heart

Auscultation:
- heart valves (mitral, aortic, tricuspid, pulmonary)
- Murmurs (timing,systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

1) Is this patient in **Respiratory Distress** ?

Inspection
- Barrel chest:
- Pectus carinatum/cavinatum:
- Left precordial bulge:
- Symmetry of movement:
- Scars:

Palpation
- Tracheal symmetry:
- Tracheal tug:
- Thyroid Gland:
- Symmetry of movement (ant + post)
- Tactile fremitus:

Percussion
- Percussion note:
- Cardiac dullness:
- Liver dullness:

Auscultation
- Normal breath sounds bilat.:
- Adventitious sounds (crackles, wheezes, crepitations)
- Pleural frictional rub:
- Vocal resonance
  - Whispering pectoriloquy:
  - Bronchophony:
  - Egophony:

5. ABDOMINAL EXAMINATION

1) Is this patient in **Liver Failure** ?

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

Auscultation - Bowel sounds:
- Arteries (aortic, renal, iliac, femoral, hepatic)

Rectal Examination
- Perianal skin:
- Sphincter tone & S4 Dermatome:
- Obvious masses:
- Prostate:
- Appendix:

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

Gait and Posture
- Abnormalities in gait:
- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Rombergs test (Pronator Drift):

Higher Mental Function
- Information and Vocabulary:
- Calculating ability:
- Abstract Thinking:

G.C.S.:
- Eyes:
- Motor:
- Verbal:

Evidence of head trauma:

Evidence of Meningism:
- Neck mobility and Brudzinski's sign:
- Kernigs sign:

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

II External examination of eye:
- Visual Acuity:
- Visual fields by confrontation:

- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:

b. Motor - Masseter:
- Jaw lateral movement:

c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

VII a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance:
- Show teeth:
- Blow out cheeks:

b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function - Nystagmus:
- Rombergs:
- Wallenbergs:
Otoscope examination:

IX & X Gag reflex:
Uvula deviation:
Speech quality:

XI Shoulder lift:
S.C.M. strength:

XII Inspection of tongue (deviation):

Motor System:

a. Power
- Shoulder = Abduction & Adduction:
  = Flexion & Extension:
- Elbow = Flexion & Extension:
- Wrist = Flexion & Extension:

- Forearm = Supination & Pronation:
- Fingers = Extension (Interphalangeals & M.C.P's):
- Thumb = Opposition:
- Hip = Flexion & Extension:
  = Adduction & Abduction:
- Knee = Flexion & Extension:
- Foot = Dorsiflexion & Plantar flexion:
  = Inversion & Eversion:
  = Toe (Plantarflexion & Dorsiflexion):

b. Tone
- Shoulder:
- Elbow:
- Wrist:
- Lower limb - Int. & Ext. rotation:
- Knee clonus:
- ankle clonus:

c. Reflexes
- Biceps:
- Triceps:
- Supinator:
- Knee:
- Ankle:
- Abdominal:
- Plantar:

Sensory System:

a. Dermatomes
- Light touch:
- Crude touch:
- Pain:
- Temperature:
- Two point discrimination:

b. Joint position sense
- Finger:
- Toe:

c. Vibration:
- Big toe:
- Tibial tuberosity:
- ASIS:
- Interphalangeal Joint:
- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:
= Intention Tremor:
= Nystagmus:
= Truncal Ataxia:

Finger-nose test (Dysmetria):
Rapid alternating movements (Dysdiadochokinesia):
Heel-shin test:
Heel-toe gait:
Reflexes:
Signs of Parkinsons:

8. **SPINAL EXAMINATION:**(See Regional examination)

Obvious Abnormalities:
Spinous Percussion:
R.O.M:
Other:

9. **BREAST EXAMINATION:**

Summon female chaperon.

Inspection
- Hands rested in lap:
- Hands pressed on hips:
- Arms above head:
- Leaning forward:

Palpation
- masses:
- tenderness:
- axillary tail:
- nipple:
- regional lymph nodes:

ADDENDUM F

REGIONAL EXAMINATION - THORACIC SPINE

Patient: _____ File #: _____ Date: _____

Intern: _____ Signature: _____

Clinician: _____ Signature: _____

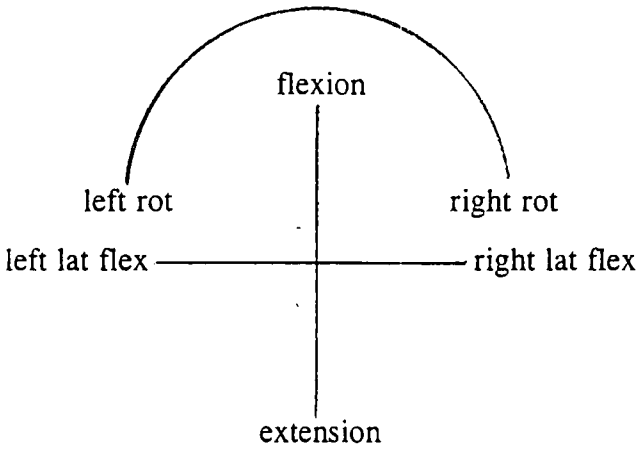
STANDING

Posture (incl. L/S & C/S):
Muscle Tone:
Skyline view - Scoliosis
Spinous Percussion
Breathing (quality, rate, rhythm, effort):
Deep inspiration

Scars:
Chest Deformity
(pigeon, funnel,
barrel):

RANGE OF MOTION

Forward flexion	20 - 45 degrees (15cm from floor)
Extension	25 - 45 degrees (15cm from floor)
L/R Rotation	35 - 50 degrees (15cm from floor)
L/R Lateral Flexion	20 - 40 degrees (15cm from floor)



RESISTED ISOMETRIC MOVEMENTS: (in neutral)

Forward flexion
Extension
L/R Rotation
L/R Lateral Flexion

SEATED:

Palpate Auxillary Lymph Nodes
Palpate Ant/Post Chest Wall
Costovertabral Expansion (3 - 7cm diff. at 4th intercostal space)
Slump Test (dural stretch test)

SUPINE:

Rib Motion
Soto Hall Test (#, sprains)
SLR
Palpate Abdomen

PRONE:

Passive Scapular Approximation
Facet Joint Challenge
Vertebral Pressure (P-A central, unilateral, transverse)
Active Myofascial Trigger Points:

- Rhomboid Major
- Rhomboid Minor
- Lower Trapezius
- Spinalis Thoracic
- Serratus Posterior
- Serratus Superior
- Pectoralis Major
- Pectoralis Minor
- Quadratus Lumborum

COMMENTS: _____

_____

NEUROLOGICAL EXAMINATION:

DERMATOMES

	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
Left												
Right												

Basic LOWER LIMB neuro: Myotomes:
Dermatomes: Reflexes:

KEMPS TEST:

MOTION PALPATION:

Ribs: Calliper: Left:
Right:
Joint Play:
Bucket handle: Left:
Right:
Joint Play:
Motion Palpation and Joint Play: Left:
Right:

Basic Lumbar Exam:
History:
ROM:
Neuro/Ortho:

Basic Cervical Exam:
History
ROM:
Neuro/ortho:

ADDENDUM G

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject*) *Delete whichever is not applicable.

TITLE OF RESEARCH PROJECT

_____

_____

NAME OF SUPERVISOR

_____

NAME OF RESEARCH STUDENT

_____

Date:_____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO

2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO

4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO

6. Who have you spoken to? _____

7. Do you understand the implications of your involvement in this study? YES/NO

8. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time
   b) without having to give a reason for withdrawing, and
   c) without affecting your future health care.

9. Do you agree to voluntarily participate in this study? YES/NO

PATIENT/SUBJECT* Name_____ Signature_____
(in block letters)

PARENT/GUARDIAN* Name_____ Signature_____
(in block letters)

WITNESS Name_____ Signature_____
(in block letters)

RESEARCH STUDENT Name_____ Signature_____
(in block letters)