THE RELATIVE EFFECTIVENESS OF SPINAL MANIPULATION AND ULTRASOUND IN MECHANICAL NECK PAIN

by

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I, Malany Moodley, do declare that this dissertation is representative of my own work.

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DEDICATION

This work is dedicated to my parents Rani and the late Poobalan Moodley who have through great sacrifice made it possible for me to study Chiropractic.

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ABSTRACT

The aim of this study was to determine the effectiveness of adjustments versus the use of ultrasound in the treatment of mechanical neck pain. It was hypothesized that treatment with adjustments over a four week period, with a further four week follow-up period, would be more effective than ultrasound in terms of improving patients' cervical ranges of motion and their perceptions of pain and disability.

Thirty consecutive patients suffering from mechanical neck pain were randomly assigned to either the adjustment or ultrasound groups. An experimental design was employed, whereby both groups received treatment twice a week for four weeks. After a follow-up period of a month, the patients were re-assessed. Measurements of the cervical spine ranges of motion with the CROM goniometer, algometer readings, and the completion of the Numerical Pain Rating Scale-101, CMCC Neck Disability Index and the Short Form McGill Pain questionnaires were performed before the first, fourth and final treatments as well as at the one month follow-up consultation.

The data were then transferred to spreadsheets and underwent statistical

analyses, using a 95 % confidence level. Analyses within each group were performed, using the Wilcoxon Signed Rank test and various readings were compared. The reading taken before the first treatment was compared to the reading taken before the final treatment. The initial reading was then again compared with the reading taken at the one month follow-up consultation.

Comparison of the results of both treatment groups was statistically evaluated, using the Mann-Whitney U-Test. The comparison was made using the readings of the first, fourth and final treatments, as well as the one month follow-up consultation. This was done for all measurement parameters.

The results indicated that the first treatment group (adjustments) achieved significant improvements with regard to extension and right lateral flexion at the one month follow-up consultation ($p<0.05$). The first treatment group also achieved significant improvements with regard to disability at the final consultation and pain intensity at the final and follow-up consultations ($p<0.05$). The second treatment group (ultrasound) achieved significant improvements in left lateral flexion at the final and one month follow-up consultations ($p<0.05$). Forward flexion was only significantly improved at the final treatment, whereas right lateral flexion, and right and left rotation were significantly improved at the one month follow-up consultation ($p<0.05$). The second treatment group also had significant improvements in pain intensity at the final and one month follow-up consultations ($p<0.05$).

Statistically significant differences were noted between the two treatment groups for left and right rotation at the fourth consultation, right lateral flexion at all four measurement stages of the study, and disability measurements at the final consultation ($p<0.05$).

From the results, it was apparent that ultrasound is effective in treating mechanical neck pain as are adjustments. However, it appears that the first method of treatment, i.e. adjustments was more effective in restoring mobility and decreasing disability than the second. Future research in this field is required to refute or validate this finding.

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LIST OF ABBREVIATIONS

Z = two - tailed probability of equalling or exceeding Z

(sig) = significance

ns = no significant difference in the medians

s = significant difference in the medians

tx1 = first consultation

tx2 = fourth consultation

tx3 = eighth consultation

tx4 = month follow - up consultation

Grp 1 = treatment group 1 - (adjustments)

Grp 2 = treatment group 2 - (ultrasound)

If P = < 0.05 = significant difference

DEFINITION OF TERMS

Cervical Spine - This is the area of the spine extending from the occiput to and including the seventh cervical vertebra (C7). (Moore 1985:570)

Disability - This is the inability to perform normal day to day activities which one can normally perform or a decrease in the ability to perform these functions.

Adjustment - This consists of a high velocity, low amplitude thrust directed beyond the passive range of motion of the joint and is associated with an audible crack, caused by cavitation of the underlying facet joint. (Mierau et al. 1988)

Mechanical Neck Conditions - All conditions causing increased neural activity in muscles and ligaments of the cervical joints due to mechanical causes, but excluding conditions causing hard neurological signs and symptoms and gross pathology due to systemic diseases. Mechanical neck conditions include posterior facet syndromes, myofascial pain and dysfunction syndromes, sub-occipital headaches and shoulder pain and stiffness.

Phonophoresis - A cream emulsion containing drug molecules is placed on the skin and used as a coupling agent while the molecules of medicine are propelled into the body. (Andrew and Harrelson 1991:106)

1.0 INTRODUCTION

The problem and its setting

Neck pain is a common complaint, with a point prevalence of nearly 13% and lifetime prevalence of nearly 50% (Aker et al. 1996). Bland (1994:6) reports that working individuals between 25 and 29 years of age have a 25% to 30% incidence of one or more attacks of stiff neck. This figure rises to 50% for those over 45 years of age, and 45% of working men have had at least one attack .

Despite the common occurrence of neck pain, the exact nature of the pathology remains obscure and the pain is often attributed to mechanical factors. Indeed, when treating patients without knowing the pathological cause underlying the patients' complaints, it comes as no surprise that the results are often unpredictable (Mennell 1990).

The primary treatment modality used by the chiropractic profession since its inception is vertebral manipulation. This is employed to restore normal joint and muscle function. More recently, nonspecific exercises and modalities have been used to help an injured area heal (Fitz-Ritson 1990).

Manipulative therapy involves the application of specific, accurately determined forces to the body. Its objective is to improve mobility in areas where mobility is restricted, whether the restrictions are within the joints, connective tissues or skeletal muscles. The result may be an improvement in posture or locomotion, and the relief of pain and discomfort. Improvement in the functioning of systems elsewhere in the body and a greater sense of well-being may also be evident. (Korr 1978:15).

Ultrasound therapy has achieved recognition as a suitable method in physical medicine to treat acute and chronic musculoskeletal disorders. Ultrasound consists of sound waves with a frequency of more than " 20 000 counts per second ", and well beyond the range of human hearing. The sound waves are absorbed differently in tissue with low and high protein content. It is therefore possible to heat deeper structures, such as joints, muscle and bone with ultrasound (Gam and Johannsen 1995).

Ultrasound is a modality that has been used as a therapeutic agent, mainly as a means of stimulating the repair of soft tissue injuries and relieving pain, for over 40 years. The widespread and apparently increasing use of ultrasound as a therapeutic agent is mainly due to its effectiveness and excellent safety record when correctly used. The types of injuries treated include damage to ligaments, joint capsules, tendons and muscles, inflammation of tendon sheaths, scar tissue tension and sensitivity, fasciitis, pressure sores and varicose ulcers. (Nyborg and Ziskin 1985 :121).

Experimental studies have found that ultrasound accelerates restoration of tissue generation, increases pain threshold, stimulates bone growth and increases tendon extensibility (Gam and Johannsen 1995).

Aker (1995) reviewed the related literature on the conservative management of mechanical neck pain using meta-analysis. This was conducted via research with teams at McMaster University in Canada and through the RAND Corporation in California. Only randomized clinical trials were included in this search. Five studies were found to have been done involving manipulation and one of these studies involved both the use of manipulation and ultrasound. These studies will be discussed in greater detail in Chapter Two.

A wide variety of treatments including manipulation, mobilization, interferential current therapy, ultrasound, trigger point therapy and pharmaceutical intervention is commonly applied for the treatment of neck pain (Howe et al. 1983, Cassidy et al. 1992a, Koes et al. 1992). However, there is little information available from clinical trials to support many of the treatments for mechanical neck pain. Conservative interventions have not been studied in enough detail to assess efficacy adequately (Aker et al. 1996).

No studies appear to have been performed comparing adjustments to ultrasound in the treatment of mechanical neck pain. By evaluating the relative effectiveness of the two treatment protocols, valuable information was obtained from this study. This will allow for improved chiropractic treatment and therefore greater relief of pain and dysfunction associated with the cervical spine.

1.2 Statement of research objective

The purpose of this investigation was to evaluate the relative effectiveness of combined manipulative and soft tissue therapy compared to combined ultrasound and soft tissue therapy, in terms of objective and subjective responses, in order to determine the more effective protocol in the management of mechanical cervical spine pain.

1.2.1. The first objective

The first objective was to evaluate the relative effectiveness of combined manipulative and soft tissue therapy compared to combined ultrasound and soft tissue therapy in terms of subjective responses.

1.2.2. The second objective

The second objective was to evaluate the relative efffectivenes of combined manipulative and soft tissue therapy compared to combined ultrasound and soft tissue therapy in terms of objective responses.

1.2.3. The third objective

The third objective was to analyze and interpret the data obtained and to compare and integrate the conclusions reached in order to determine the more effective protocol in the management of mechanical neck pain.

1.3 Hypotheses

1.3.1 The First Hypothesis

By adjusting the fixated segments of the cervical spine there would be a statistically significant difference in the subjective and objective clinical findings on analysis of the data, showing that this treatment protocol was effective.

1.3.2 The Second Hypothesis

By applying therapeutic ultrasound over the cervical musculature there would be a statistically significant difference in the subjective and objective clinical findings on analysis of the data, indicating that this treatment protocol was effective.

1.3.3 The Third Hypothesis

On integration of the data of Treatment Group One with Treatment Group Two, there would be a statistically significant difference in the subjective and objective clinical findings, indicating that the first treatment protocol (adjustments) was more effective.

It was intended that this study should draw attention to the need for a better understanding of the effects of different treatment protocols commonly employed by chiropractors. The longer the treatment period necessary for satisfactory recovery, the greater the financial burden on the patient, medical aids and society.

It was therefore argued that it would be necessary to determine if any one procedure was more successful in producing a faster recovery in terms of pain, disability or range of motion, and to establish which procedure would have a superior long term benefit.

2.0 REVIEW OF THE RELATED LITERATURE

2.1 INCIDENCE, PREVALENCE, AND GENDER DISTRIBUTION OF NECK PAIN.

Neck pain with some limitation of movement affects about 40% to 50% of the general population at some time in their lives (Kelsey 1982:146). Although most patients with mechanical neck pain improve with time, as many as one third can continue to have moderate or severe pain fifteen years after the initial onset (Gore et al. 1987).

Recent epidemiological studies have reported that more than 30% of the population have experienced neck pain within the past 12 months, with approximately 30% of these having experienced symptoms of more than 6 months' duration. Symptomatology increases with age in both men and women (Jordan et al. 1996).

Waalen and Waalen (1993), in a study of 15 174 chiropractic patients seen at the CMCC outpatient clinics over a five year period, found that 39% of all female patients were identified as having cervical conditions compared to 26% of male patients. The influence of age on cervical complaints was also examined, and it was revealed that the average age was 31.3 years for male cervical patients and 31.7 years for female cervical patients.

In a study done by Bovim et al. (1994), a randomized cross-sectional questionnaire was used to determine the prevalence of neck pain in 10 000 Norwegian adults. Overall, 34.4% of the respondents had experienced neck pain within the year preceeding the study. The frequency of complaints lasting 1 month or longer was higher in women than in men. A total of 13.8% of the study group reported neck pain that lasted for more than 6 months.

As mentioned in Chapter one, there is a 25% to 30% incidence of one or more attacks of neck pain in working individuals between 25 and 29 years of age (Bland 1994:6). For those over 45 years of age this figure rises to 50%, and 45% of working men have had at least one attack.

In a study conducted at the Technikon Natal Chiropractic Day Clinic comparing the types of conditions seen at a teaching clinic and in private chiropractic clinics in South Africa, it was found that 14.8% of private practice patients and 16.7% of clinic patients had neck pain only (Drews 1995). It was also found that 54.4% of patients presenting to the clinic and 57.4% of patients presenting to private practitioners complained of neck pain with associated headaches or arm pain.

Patients with neck pain make up a considerable percentage of chiropractic patients (Jordan et al. 1996), and there is a growing awareness among health professionals worldwide of the large burden of illnesses associated with musculoskeletal disorders of the neck (Stock 1991).

2.2 MECHANICAL NECK PAIN

2.2.1 AETIOLOGICAL CONSIDERATIONS

In the majority of patients suffering from neck pain, the pathoanatomical source of pain cannot be diagnosed with a high degree of certainty. Symptoms arising from rupture of the cervical discs are not as common as in the lumbar spine (Jordan et al. 1996). A study done by Jordan et al. (1996) involving patients with post-traumatic neck pain, showed that the zygapophyseal joints were more often implicated as being pain producing than the discs. There are, however, a host of other tissues capable of producing pain.

Any condition which results in alteration of joint function or structure is capable of causing mechanical neck pain. Mechanical joint dysfunction and derangement of the articular soft tissues may be produced from acute injury, repetitive use injury, faulty posture or co-ordination, aging, immobilization, static overstress, and congenital or developmental defects (Bergmann et al. 1993:55).

Spinal fixation can result from working in confined, awkward spaces, faulty posture due to bad habits or unco-ordinated movements during sleep (Grieve 1988:177). Considerable research has focused on the debilitative effects of static work on the musculature of the neck region. The deleterious effects of stress, pace and repetitiveness were recognized as early as the 18th century (Jordan et al. 1996).

Mennel (1990) states that there are three constant aetiological factors associated with the onset of mechanical joint dysfunction in the cervical spine. These are :

1) intrinsic trauma (poor posture);

2) immobilization (including disuse and aging);

3) remaining symptoms from the healing of a more serious pathological condition.

2.3 MODELS OF SPINAL DYSFUNCTION

Korr (1975) attributes the intersegmental muscle spasms and fixation of joints to aberrant muscle-spindle activity. He concludes that the muscle spindle as the co-ordinator of muscle activity may increase or decrease muscle contraction. Accordingly, if the vertebral attachments of the spinal muscles are approximated by unguarded movement and silent annulospiral receptor activity, the lack of input to the central nervous system then results in the turning up of the gamma-motorneuron 'gain', increasing the intensity of the muscle contraction which produces the muscle spasm. Due to this contraction, the vertebral attachments cannot resume their normal position, and the muscle spasm is perpetuated.

Disorders of the cervical zygapophyseal joints are attracting attention as the possible source of neck pain (Aprill et al. 1990). There is evidence of pain relief in patients suffering from neck pain after intra-atricular blocks of certain cervical facet joints or the nerves supplying them. Dwyer et al. (1990) conducted a study on five normal volunteers, involving the pain patterns evoked by stimulation of the cervical zygapophyseal joints by distending the joint capsules with injections of contrast medium. Each joint produced a clinically distinguishable pattern of pain, demonstrating that the cervical facet joints can be a primary source of neck pain.

Halderman (1992:206) states that there are two mechanisms by which cervical spine pain may arise due to synovial fold pinching:

1) traction on pain sensitive tissues such as the synovial fold and fibrous joint

capsule; and

2) synovial fold traumatic synovitis with associated tissue damage and cell rupture, resulting in the release of pain producing substances such as histamine, bradykinin, potassium ions and substance P, all of which cause nociceptive nerve impulses and ischemia.

Giles and Harvey (1987) demonstrated the presence of substance P in the capsule and synovial folds of the zygapophyseal joints in patients suffering from intervertebral disc prolapse, thus providing support for Halderman's findings.

According to Gillet (1963), there are three stages of joint fixation:

1) it begins with muscular hypertonicity,

2) progresses to ligamentous shortening, and

3) results in articular adhesions.

Gatterman (1990:40-47) describes a subluxation as being the result of kinesiopathologic, neuropathophysiologic, myopathologic, and histopathologic changes relating to joints and muscles. The kinesiopathologic and myopathologic changes include: hypomobility as a result of muscle spasm caused by a joint sprain or increased muscle spindle activity; ligamentous shortening; intra-articular adhesions; intra-articular jamming due to meniscoid entrapment or disc displacement and hypermobility as a result of disc degeneration or ligamentous sprain. The neuropathophysiologic changes include: nerve irritation resulting in either increased motor, sensory or autonomic changes and nerve compression which may manifest as weakness, atrophy or loss of sensation (Gatterman 1990:40-47).

Gillet and Liekens (1969), Schafer and Faye (1989:12-17) and Bergmann (1993:58) hypothesized that mechanical joint dysfunction follows three phases of development, namely: muscular, ligamentous and articular phases. This model involves segmental muscle spasm and such contraction causes muscular fixations which with time will cause the ligaments to adapt to the limited range of motion. This adaptation involves contracture formation and shortening of the joint capsule and surrounding ligaments producing ligamentous fixations. Finally, as a result of fibrous adhesions developing between the joint surfaces and as a result of the degeneration of the inter-articular soft tissues, articular fixations may develop. The end result is possible bony ankylosis and irreversible fixation.

According to Greenman (1989:61), joint hypomobility occurs as a result of a lack of congruency between the joint surfaces, leading to an incorrect tracking mechanism causing a movement restriction. Another explanation to clarify movement restriction is that the physical and chemical properties of the synovial fluid and surfaces have changed, causing the opposing surfaces to become " sticky ".

Spinal degeneration is often initiated by local mechanical derangement, and often apparent changes in structure are absent. The development of individual motion segment dysfunction, secondary to changes in segmental muscle tone and function, is often the causative factor. Joint hypomobility is then thought to start the degenerative process due to changes in the biomechanics in the area, and this results in joint instability and finally restabilization through soft tissue fibrosis and bony exostosis (Kirkaldy-Willis 1992:105-109).

Unfortunately there is no single, conclusive theory to explain the phenomenon of the fixation complex, which manifests as joint dysfunction and pain.

2.4 CLINICAL CONSIDERATIONS

Schafer and Faye (1989:349) describe the signs and symptoms of cervical motion unit dysfunction as: articular grating, tenderness, stiffness, occipital headaches, hypertonic or flaccid muscles, numbess, pain (especially on motion), possible visceral and somatic effects, altered reflexes, weakness, fibrosis, hyperaemia, boggy tissue fibrosis, segmental atrophy, visual postural imbalance, trigger point development, palpable malalignment and functional spinal unit motion alterations.

Grieve (1988:378-380) outlines the presentation of chronic mechanical neck pain as follows :

1) Local chronic cervical pain with or without arm pain.
2) Juxtaposition of hyper- and hypomobility of the cevical spine as a result of spondolytic changes.
3) Asymmetrical neck pain worsens during the day and is aggravated by driving, reading, etc.
4) Unilateral occipital and neck pain.
5) Restricted and painful cervical rotation and lateral flexion to the painful side.
6) Prominent upper and middle trapezius and levator scapulae muscles.

Bergmann <u>et al.</u> (1993:63) have modified the acronym PARTS from Bourdillon and Day, which is used in the indentification of joint dysfunction. These are :

1) <u>Pain and Tenderness</u> - Pain perception and tenderness on palpation of the bony and soft tissue structures with regards to location, quality and intensity are evaluated. This is achieved by observation, percussion and palpation.
2) <u>Asymmetry</u> - Either localized to one level, or at multiple levels. Asymmetry is assessed by using bony landmarks of the vertebrae as reference points and relating them to other positive findings. This is achieved by observation, static palpation or Roentgenographic analysis.
3) <u>Range of Motion Abnormality</u> - Active, passive and accessory joint motion changes due to increased, decreased or abnormal movements, are identified

using motion palpation and if required stress radiography.

4) Tone, Texture and Temperature Abnormality - Changes in the soft tissues such as the skin, fascia, muscles and ligaments around an area of joint dysfunction are known to occur. These are identified by means of observation, palpation and sometimes instrumentation.

5) Special Tests - Procedures relating to certain technique systems may be necessary for a final diagnosis.

2.5 ADJUSTMENTS

Sandoz (1976) defines an adjustment as a passive manual maneouvre involving the application of a brief, sudden, small amplitude impulse which is delivered at the end of the normal passive range of motion of a joint (termed the elastic barrier of resistance), taking the joint into the paraphysiological range of motion without exceeding the anatomical integrity of the joint. It is usually accompanied by a cracking sound (cavitation) which is caused by a release of gases (primarily carbon-dioxide) within the synovial fluid of the joint.

Haldeman (1992:448) states that there are three characteristics that most aptly describe a chiropractic adjustment. These are:

1) a high velocity, carefully delivered force,

2) a specific direction or line of drive (direction of planes of articulation), and

3) a controlled depth and magnitude thrust applied through a specific contact point employing body weight, muscle power and sometimes mechanical devices.

Bergmann (1993:124) describes the characteristics of an adjustment as a direct or indirect dynamic thrust of controlled depth and speed delivered within the boundaries of the joint's anatomic integrity. This process is usually associated with an audible clicking sound.

Basmajian (1985:28-29) states that chiropractic techniques can range from general to specific manipulation, direct or indirect manipulation, contact or non-contact techniques or thrust and non-thrust techniques. He concludes that an adjustment has different characteristics for different health practitioners. Basmajian divides thrust techniques into three categories and chiropractic adjustments would fall under the first category. These are:

1) Specific thrust techniques which employ three specific criteria:

- spinal locking,
- high velocity movement,
- overpressure;

2) General thrust techniques which employ high velocity stretching procedures;

3) Surgical thrust manipulation under anaesthesia.

2.5.1 EFFECTS OF ADJUSTMENTS

Chiropractic adjustments are employed to relieve pain arising from joint dysfunction and to restore the range of motion to a joint whose function is impaired (Mennell 1960:110). The specific mechanical and physiological changes that take place to relieve the signs and symptoms of joint dysfunction have not been accurately determined. However, there are many theories relating to the possible mechanisms by which manipulation works (Bergmann et al. 1993:139).

An adjustment separates the articular surfaces which may release entrapped intra-articular structures such as synovial folds, menisci, or part of the capsule. It also stretches the segmental muscles, initiating spindle mediated reflexes that relieve the state of hypertonicity. In more chronic cases, manipulation might break intra-articular adhesions that have been observed in posterior joints (Kikaldy-Willis 1988:289).

Wyke (1973) postulates that the reduction in pain following a manipulative thrust could be that afferent input from the nociceptors (Type IV receptors) is inhibited by static and dynamic mechanoreceptors (Type 1 and 2 receptors). This inhibition may be a form of presynaptic inhibition. If stimulation of Type 1 and/or Type 2 receptors inhibits Type IV nociceptors, stretching of the apophyseal joint (as would occur in an adjustment) would reduce the nociceptive input at the anterolateral spinothalamic tract, thereby reducing pain.

Sandoz (1976) states that after a joint ' crack ' (which is associated with an adjustment), there is an increase in the passive range of motion of the joint in all directions and to a lesser extent, in the active range of motion. He postulates that this is as a result of the addition of the paraphysiological range of motion to the available active and passive ranges of motion. It is brought on by the meniscoids no longer being aspirated towards the centre of the joint. As a result of the separation of the joint surfaces, articular derangements may be reduced and proprioceptive elements may be stimulated.

According to Basmajian (1985:37), the possible role of an adjustment in restoring normal function to a joint is to restore normal flexibility of the joint capsule and surrounding ligaments and muscles by preventing contractures from forming.

Although there are many theories as to how manipulation achieves its effects, the general consensus is that the effect of manipulation at the appropriate level is to diminish pain, stiffness, and muscle spasm (Kenna and Murtagh 1989:47).

2.5.2 STUDIES INVOLVING ADJUSTMENTS

Sloop et al. (1982) conducted a double blind, randomized, controlled study on the effect of a single manipulation on patients suffering from chronic neck pain. Thirty-seven of the patients also complained of arm pain. Twenty-one patients were assigned to the manipulation group and received an amnesic dose of diazepam, while 18 patients were assigned to a control group and also received an amnesic dose of diazepam intravenously.

Results indicated no significant difference between the two groups as a result of the treatment. However, 57% of the manipulated group compared to 28% of the control group, remarked that the treatment had helped them. After the twelve week period, it was found that 7 of the 9 patients in the manipulation group felt that the treatment had helped them, compared to only 2 out of the 6 patients in the control group. However, this was not statistically significant. Improvement with regards to their severity of pain was also shown in both groups after three weeks of treatment, but there was no significant difference between the two groups. No improvement was found with regards to ranges of motion or visual analogue scales related to activities. It was concluded that although a larger percentage of patients in the manipulated group had improved compared to the control group, these improvements were not statistically significant. Therefore the value of a single adjustment in patients with chronic neck pain had not been established.

Howe et al. (1983), in a randomized, controlled study involving 52 patients, studied the effects of manipulation on acute neck pain (< 4 weeks) and / or stiffness with pain referred to the head, shoulder or arm, compared to treatment with azapropazone (an anti-inflammatory drug).

Seventeen patients received one manipulation, 4 received two manipulations, 2 received three manipulations, 1 received manipulation of the neck and lumbar spine while only 2 patients received manipulation and injection. No mention was made of the number of injections the control group received or how many times the 2 patients who received manipulation and injection were treated.

Immediately after the initial treatment, significant improvements in neck pain and stiffness and shoulder pain and stiffness were found in the manipulated group, whereas the control group showed no significant improvement. This significant difference between the two groups' symptoms was no longer evident after the first or third weeks. Significant improvements of the cervical ranges of motion were found in the manipulated group, particularly rotation (average of 5 degrees) and to a smaller degree lateral flexion (average of 2 degrees). These improvements were still evident for rotation after 1 and 3 weeks, but not for lateral flexion after the first week. The control group did not exhibit any improvement in cervical ranges of motion during the course of the study.

Nansel et al. (1990) studied the effects of a single, unilateral, lower cervical adjustment on the relief of passive end - range, lateral flexion cervical range of motion differences of more than ten degrees in asymptomatic patients. The responses of the two groups were compared:

1) those exhibiting end-range asymmetries of greater than ten degrees who, in addition, had previous neck trauma, (n=16); and
2) those who happened to exhibit end-range asymmetries of greater than ten degrees, but who had no prior history of trauma, (n=16).

All subjects underwent goniometric (Cybex EDI 320 Electronic Goniometer) re-assessment 30 minutes, 4 hours, 24 hours and 48 hours following the adjustment. A statistically significant amelioration of asymmetries was observed in both groups 30 minutes and 4 hours after manipulation. At 4 hours post manipulation there was no statistically significant difference in end-range amelioration between the two groups (Group 1: 15.2 degrees to 2.7 degrees average decrease in asymmetry; and Group 2: 13.7 degrees to 1.6 degrees average decrease in asymmetry).

After 24 hours a significant difference apppeared between the two groups (Group 1: increased from 3.5 to 8.4 degrees; Group 2: from 1.7 degrees to 2.5

degrees). By 48 hours the difference was even more striking; whereas 14 patients in Group B continued to exhibit asymmetries of less than ten degrees, 12 patients in Group A regained asymmetries of greater than ten degrees. These results indicated that among pain-free individuals, the mere presence of passive-end range asymmetry as well as the magnitude of the short term relief of cervical manipulation does not distinguish these two categories of subjects.

On the other hand, over long periods of time following manipulation, there appeared to be a tendency in individuals who had previously suffered neck trauma to re-establish their aberrant cervical motion characteristics.

A tentative hypothesis offered by the authors as explanation for the observed results was that facilitation of certain spinal reflex pathways via affferent nociceptor input from injured articular joints, caused increased gamma- and /or alpha motor efferent activity, which resulted in increased paraspinal muscle spasm causing a decrease in movement in the affected joints. This is to protect the joint from any further injury. After a few days, the pain and muscle stiffness levels decreased to the extent that 'pain' no longer reached conscious levels in the subject. But when movement to the previuosly painful area was attempted, reinforcement of these aberrant spinal reflexes caused asymmetric movement to avoid pain. (Nansel et al. 1990).

Nansel et al. (1992) compared the effects of cervical spinal adjustments, delivered bilaterally either to the upper cervical region (C2-C3) or to the lower cervical region (C6-C7), in groups of asymptomatic subjects exhibiting goniometrically verified left-right rotational or left-right lateral-flexion passive end- range asymmetries of greater than 10 degrees. Of the 350 subjects screened, 83 exhibited lateral-flexion or rotational passive end-range asymmetries of greater than 10 degrees while only 15 were found to possess asymmetries in both ranges of motion.

Goniometric evaluation both prior to, and again within 30 minutes following manipulation, revealed that lower cervical adjustments were more effective for the amelioration of lateral-flexion asymmetries than with the upper cervical adjustments, whereas upper cervical adjustments were found to be more effective for the amelioration of rotational asymmetries than those delivered to the lower cervical region. These results are consistent with the view that passive movement restriction exhibited along the rotational axis is attributable to factors related primarily to the upper cervical region, whereas restrictions of passive movement along the lateral axis are more attributable to factors related to the lower cervical region (Nansel et al. 1992).

Vernon et al. (1990) conducted a study on patients suffering from chronic mechanical neck pain (majority < 3 months) to determine the effect that an adjustment would have on the pressure pain thresholds in the paraspinal areas of joint dysfunction. A control group (4 patients) received an oscillating, rotatory mobilisation, while the manipulation group (5 patients) received a rotatory adjustment to the involved level. Pressure pain thresholds were measured by blinded examiners using a pressure threshold meter.

The results indicated that a 40% to 55% increase in pressure pain thresholds was obtained in the manipulated group, which was not evident in the mobilisation group. The diffferences in the two groups were found to be highly significant statistically. This study has drawn attention to the close relationship between joint dysfunction and paraspinal soft tissue pain syndromes.

Cassidy _et al._ (1992a), in a pre-test, post-test study on 50 consecutive unilateral neck pain sufferers with no neurological deficit, examined the effect that a single adjustment would have on pain and range of motion in the cervical spine. Pain intensity was measured using the Numerical Rating Scale-101 (NRS-101), while range of motion was measured using a cervical goniometer.

Thirty-seven of the 50 patients experienced an improvement in their pain, indicated by an average improvement of over 12 points on the NRS-101 (Pre-treatment 43.7, post-treatment 31.1). Ranges of motion were also increased. The largest increases were recorded for rotation towards the painful side

(average of 5.2 degrees), and lateral-flexion to the opposite side (average of 4.5 degrees). A significant relationship between a decrease in pain and an increase in rotation to the same side was found ($p<0.05$), (Cassidy et al. 1992a). This study was neither randomized, nor controlled, therefore the reliability of the results are questionable.

In a randomized, controlled study, Cassidy et al. (1992b) compared the immediate efffects of an adjustment to mobilization on 100 consecutive patients sufffering from unilateral neck pain of mechanical origin with referral into the trapezius muscle. Sixteen patients had neck pain for less than 1 week, 34 had neck pain for between 1 week and 6 months, and the other 50 had neck pain for longer than six months.

Prior to treatment, subjects had to fill out a pain disability index, pain intensity questionnaire (NRS-101) and their cervical ranges of motion in all three planes were measured using a rangiometer. Fifty-two patients were adjusted using a single rotatory adjustment and 48 were mobilized on the involved side.

The results indicated that the pain intensity decreased in both groups and that the range of motion increased within the 5 minute post-treatment period. It was found that 85% (44 out of 52) of the manipulated group experienced a decrease in their neck pain (NRS-101 decreased by 3 points), while patients in the mobilized group (33 out of 48) experienced a similar response (NRS-101 decreased by 10.5 points). It was also found that 6% of the manipulated group experienced an increase in pain. The range of motion was increased, particularly ipsilateral rotation, in the manipulation group. This increase was, however, not statistically significant.

The authors therefore concluded that a single adjustment was more effective than mobilization in decreasing mechanical neck pain because the manipulated group experienced nearly one and half times greater improvement in their NRS-101 scores.

2.5.3 COMPLICATIONS ARISING FROM MANIPULATION

Kleynhans and Terrett (1985) classify complications arising from spinal manipulative therapy as follows :

1) Accidents - serious impairment either permanent or fatal.
2) Incidents - consequences of spinal manipulative therapy which are noticeable by their seriousness or their long duration.
3) Reactions - consequences which are slight or short lived.
4) Indirect Complications - consequences of using spinal manipulative therapy where it cannot benefit the condition and delays diagnosis and rational treatment.

Adjusting in the upper cervical region can cause a vertebrobasilar artery accident, which could be fatal, or at least debilitating. Some patients have recovered with no residual side-effects (Halderman 1992:552). Halderman (1992:585-586) reports that pathological processes such as atherosclerosis, osteophytosis and abnormal flow patterns within one or both arteries can result in ischaemia to the brain and surrounding areas. Trauma to the arterial wall resulting in vasospasm or direct damage due to unduly forceful combined rotation and extension type adjustments thereby causing emboli to be formed, has been known to cause complications in some instances. These complications are usually synonymous with those of vertebro-basilar insufficiency syndrome.

Michaeli (1993) who analyzed the occurrence and nature of complications arising from manipulative physiotherapy in South Africa, found that between 1971 and 1989, approximately 228 050 manipulations were performed by 153 physiotherapists.

It was found that during this period 25 patients reported complications arising from manipulation ranging from dizziness, nausea, vomiting, nystagmus, headaches, blurred vision, loss of consciousness to brachialgia with and without neurological symptoms. Of these, 72% were as a result of general rotatory type adjustments, and 28% were due to localised adjustments. All these patients had full recovery from their complications within an average of 6.3 days. No such study involving chiropractors has been performed in South Africa to date.

According to Halderman (1992:554,572), contra-indications to adjustive therapy include : inflammation/infection; neoplasms; intoxication; osteoporosis; certain congenital malformations; trauma; and psychogenic disturbances. Complications occurring due to failure of recognition of contra-indications are more common than those due to poor application of an adjustment.

Although cerebrovascular accidents and other complications have been reported after cervical manipulation, the incidence of such occurrences is very low (Vernon 1988:194-206). At least 123 cases of cerebrovascular accidents after neck manipulation have been cited in the literature (Thiel 1991). Although the exact incidence of this complication is unknown, it has been estimated to occur in less than one per million treatments (Vernon 1988:194-206). Despite this, manipulation is probably safer than most other medical treatments for neck pain (Cassidy et al. 1992a).

2.6 ULTRASOUND

One of the earliest applications of therapeutic ultrasound was reported in 1947 as an attempt to relieve ' violinspielerkramp ', (violin player's cramp). Although this may no longer be a common referral for ultrasound in a modern physical therapy department, the proliferation of the number of soft tissue ailments for which ultrasound has become an accepted treatment has led ultrasound therapy to form an indispensable part of modern physical therapy practice (Burns 1987).

2.6.1 DEFINITION

Ultrasound is arbitrarily defined as sound at frequencies above the limits of human hearing, that is more than 17 000 hertz. It is indistinguishable from sound in general; it consists of alternating compressions and refractions, it requires a medium for transmission, it transmits energy, and it can be focused, refracted and reflected (De Lisa and Gans 1993:408).

Therapeutic ultrasound is a deep heating modality that produces a sound wave of 0.8 to 1.0 mega-hertz. The sound is produced by applying a high-frequency, alternating electrical current to a natural quartz or synthetic crystal. This converts the electrical current to a mechanical vibration, a reversal of the piezoelectric effect (Andrews and Harrelson 1991:105).

2.6.2 PHYSICS

In the United States, therapeutic ultrasound is limited to the frequency of approximately 1 mega-hertz. This frequency is reached by the transformation of household current of 110 volts alternating current to 500 volts or more by electronic components in the ultrasound apparatus. The higher voltage is then applied to oscillators or vibrators that boost the household frequency to the desired level of 1 mega-hertz. The higher frequency is then imposed on a crystal with piezoelectrical qualities (Kahn 1994:53).

Piezoelectricity is a natural phenomenon found in certain mineral crystals, such as quartz, but it may also be synthesized commercially, for example, lead-zirconium-titanate (PZT). This crystal transforms mechanical energy to electrical energy and its reverse, electrical into mechanical. The high frequency current of 1 mega-hertz alternating current is imposed on the PZT crystal of the transducer or soundhead, thereby transforming the energy in the crystal to a vibration. This vibratory sound wave is known as ultrasound and is beyond the normal range of audible sound waves (Kahn 1994:53-54).

2.6.3 ULTRASONIC EQUIPMENT AND APPLICATION

An ultrasonic therapy machine of the kind currently available commercially

consists of a high-frequency generator linked, typically, to a transducer housed in a submersible hand-held applicator. The transducer is usually a flat disc of piezoelectric ceramic material such as lead zirconate titanate. Although many machines operate at only one frequency, 1 mega-hertz, the more versatile operate at a range of frequencies, for example,1.5 and 3 mega-hertz.
(Nyborg and Ziskin 1985:121).

Some machines can produce only a continuous beam of ultrasound, while others allow the beam to be emitted in either continuous or pulsed mode. The effective radiating area of the transducer is generally about 5 centimetres squared. The power output of the machines can be varied generally in the range of 0.1 to 3 watts per centimetre squared. Most machines are equipped with timers and give an audible signal on completion of the set treatment time. An additional refinement on some machines is a warning light or an audible signal which operates if acoustic coupling to the target is inadequate.
(Nyborg and Ziskin 1985:122).

Utlrasound machines use ceramics and quartz piezoelectric crystals to convert electrical signals to ultrasonic energy. These piezoelectric materials are bound to metal and this combination serves as the applicator. Each machine is designed to indicate when the applicator is energized, the nominal output power, and, when appropiate, the waveform and frequency. Machines have timers that turn off the machine at the end of treatment. Ultrasound frequency is relatively invariant and is usually within 5% of the manufacturer's specifications. Output power, however, may change with the age of the unit as well as during a treatment period. As a result, output energies vary by 20% or more from specifications. Intensities are also often incorrect and therefore machines should be recalibrated on a routine basis. (De Lisa and Gans 1993:409).

In order for the sound wave to be propagated forward, it must pass through a medium that can be compressed. It cannot move through air, so a coupling agent is used to make a connection between the sound head and the patient's skin. The most commonly used coupling agents are commercially prepared gels, water, and mineral oil. Studies conducted have shown that commercially prepared gels have consistently been found to be the most efficient in transmitting sound waves. Water is less efficient, but is advocated for body surfaces too irregular to ensure transmission when using gel, for example, at the hand and ankle. The body part is immersed in a water bath. For small areas or body parts where gel would be unpleasant, such as the face, transmission can be accomplished by using a water-filled balloon. A balloon is filled with water until all the air is removed, and the neck of the balloon is placed over the sound head. A thin layer of gel is placed between the balloon and the skin. (Andrews and Harrelson 1991:107).

Customary use of ultrasound for target tissues at a depth of 3 to 5 centimetres requires a sound head no smaller than 5 centimetres squared. Usual dosages range from 0.5 to 3.0 watts per centimetre squared with the specific dosage for each individual being determined by the depth of the target tissue, the degree of heating desired, and the patient's response. If an even lower level of heating or nonthermal effects are desired, the sound can be pulsed. Using an adequate layer of coupling medium, the clinician moves the sound head in circular, overlapping strokes. Recommended field size of sonation is a 3 to 4 inch square. Periosteal pain occurs when tissue temperatures exceed tolerance levels and the clinician should immediately reduce the intensity by 10 to 15% or expand the field size. Stationary application of ultrasound is discouraged because of the rapid temperature rise creating " hot spots" and increasing the possibility of blood clot formation. To ensure temperature elevation to therapeutic levels, sonation needs to last at least 5 to 10 minutes. (Andrews and Harrelson 1991:108).

2.6.4 PHYSIOLOGIC EFFECTS

According to Kahn (1994:55-57), ultrasound has four basic physiologic effects :

1) Chemical Reactions - Ultrasound vibrations stimulate tissues to enhance chemical reactions and processes therein and ensure circulation of necessary elements and radicals for recombination.

2) Biologic Responses - The permeability of membranes is increased by ultrasound, which enhances transfer of fluids and nutrients to tissues.

3) Mechanical Responses - a) Cavitation: The high frequency vibration of ultrasound deforms the molecular structure of loosely bonded substances. This phenomenon is therapeutically useful for the sclerolytic effects in the attempt to reduce spasm, increase ranges of motion, break up calicific depositions and mobilizing of adhesions and scar tissue. If used to extremes of power or duration, this deforming mechanism can collapse the molecules and cause destruction of substances, a phenomenon called 'cavitation'.

b) Tendon Extensibilty: The sclerolytic action of ultrasound apparently increases the extensibility of tendons, crucial to those that have been shortened by disease, inflammation or strain.

4) Thermal Effects - a) Heating Benefits: It is the most important of the four physiologic effects. Rapid oscillations of molecules causes a buildup of heat. The heat buildup with ultrasound is localized to the tissues directly under the transducer head.

b) Interface Heat Buildup: Heat produced by ultrasound is found at an interface where two diffferent tissues abut with a common space intervening. The most common sites for heat buildup are the periosteal bones between the hard surface of the bone and the periosteum. When the soundwave front enters the tissue and approaches this boundary layer, the change in media from moist tissue to periosteum, to air , and then to bone leads to refraction of the ultrasound wave.

c) Shearing Effect: The transformation of the longitudinal waveform to the transverse waveform is called the 'shearing effect', and is to be avoided because this produces considerable heat and periosteal burn can result.

2.6.5 THERAPEUTIC ACTIONS

Nyborg and Ziskin (1985:123-124) classify these actions into those where there is evidence that their primary cause is the increase in temperature induced by ultrasound, and those in which nonthermal mechanisms play a significant role.

1) Thermally Induced Therapeutic Effects:

Many of the therapeutic effects of ultrasound fall into this category. They include increase in the extensibility of collagen rich structures such as tendons and joint capsules, decrease in joint stiffness, reduction of pain and muscle spasms, and production of a mild inflammatory reaction including a marked increase in blood flow. The temperature must remain within the range of 40-45 degrees celsius for at least 5 minutes to produce the effects listed above. (Nyborg and

Ziskin1985:123).

Ultrasound allows collagen rich tissues to be heated preferentially. Scar tissue, joint capsules and tendons lying deep within the body can therefore be heated to the therapeutically effective range without producing damaging temperature elevations in the skin and subcutaneous adipose tissue. Other anatomic structures that can be heated with ultrasound include the periosteum, superficial corticol bone, joint menisci, fibrotic muscle, tendon sheaths, and the major nerve roots (Nyborg and Ziskin 1985:124).

2) Nonthermally Induced Therapeutic Effects:

The use of ultrasound at levels below those inducing the physiologically significant temperature increases, can be of therapeutic advantage in the treatment of injured tissues. Therapeutically significant effects of ultrasound include the stimulation of tissue regeneration, soft tissue repair, protein synthesis, blood flow in chronically ischemic tissues, bone repair, induction of repair of ununited bone fractures, and the relief of postherpetic pain. These therapeutic effects can be obtained by using lower intensities than those necessary to ensure physiologically significant levels of heating, that is 0.1 and 0.2 watts per centimetre squared (Nyborg and Ziskin 1985:124).

In the human body, ultrasound has several pronounced effects on biological tissues. It is attenuated by certain tissues and reflected by bone. Because of the increased extensibility ultrasound produces in tissues of high collagen content, combined with the close proximity of joint capsules, tendons, and ligaments to cortical bone where they receive a more intense irradiation, it is an ideal modality for increasing mobility in those tissues with restricted range of motion. Ultrasound also increases blood flow to an area as the body attempts to cool overheated tissue. This is thought to be useful in the resolution of inflammatory exudates and calcium deposits in bursae and tendon sheaths. (Andrew and Harrelson 1991:106).

A final effect of ultrasound is the stirring and streaming of molecules in the path of the sound wave. This nonthermal effect is believed to be partly responsible for the positive effect of ultrasound on chronic wounds and is the basis for phonophoresis, where it is believed that drug molecules are propelled forward into the body. (Andrew and Harrelson 1991:106).

2.6.6 INDICATIONS

Ultrasound is indicated with spasm in neuromuscular and musculoskeletal conditions such as athletic injuries, scar tissue problems, warts, ganglia, podiatric conditions, breast engorgement pain during postpartum nursing and postimplant sclerosis in breast augmentation surgery (Kahn 1994:57).

Ultrasound is an extremely useful clinical tool, especially when stretching tight ligaments, tendons, and capsular tissues. It effectively induces therapeutic temperatures in deep tissues to speed healing (Andrew and Harrelson 1991:108).

De Lisa and Gans (1993:410-411) outline the following indications:

1) Tendinitis and Bursitis - Clinical studies claim good to fair improvement in terms of decreased pain and increased motion, in 88% to 90% of patients.

2) Musculoskeletal Pain - This is probably the most common indication for ultrasound treatment, but even here, controversy about its effectiveness persists because of lack of controlled studies.

3) Degenerative Arthritis - The goals of ultrasound treatment are reduced pain, increased range of motion, speeded healing, and reduction of muscle spasm.

4) Contractures - Contracture treatment approaches vary but all include heat and vigorous stretching.

5) Herpes Zoster - A few clinical studies show marked improvement with low

intensity pulsed and continuous ultrasound at frequencies of 1 to 1.5 megahertz.

6) Plantar Warts and Keloids - claims have been made that these have been successfully treated with ultrasound.

7) Trauma - There are limited reports of speeded resolution of injection indurations and hematomas after ultrasound treatment.

8) Skin Ulcers - Ultrasound is reported to promote protein synthesis and to accelerate the healing of skin ulcers.

9) Inflammation - Inflammation and swelling are frequently promoted as indications for ultrasound therapy, even though aggravation might be expected on the basis of heating efforts.

2.6.7 STUDIES INVOLVING ULTRASOUND

Gam and Johannsen (1995) from the Department of Rheumatology in Denmark, conducted a meta-analysis to assess the evidence of the effect of ultrasound in the treatment of musculoskeletal disorders. They reviewed 293 papers published on therapeutic ultrasound since 1950, through the Index Medicus and

Medline. The selection criteria used were the following: published studies of therapeutic ultrasound, conducted on human subjects with musculoskeletal disorders, compared with alternative treatment or control group.

Of the 293 papers found, 22 fulfilled the inclusion criteria set. Appropriate data were lacking in many cases and many studies were described by the authors as randomized, but no method was described, which was unacceptable. In 16 of these trials, ultrasound treatments were compared with sham ultrasound and in 13 cases data were presented in a way that made pooling possible. Most of the variables used in the trials to assess the effect of ultrasound were related to the subjects pain, muscle strength, walking distance and range of motion. Two standardized effect sizes were applied to the results to enable evaluation of the effect of ultrasound treatment on pain. None of the methods gave evidence that pain relief could be achieved by ultrasound treatment. Hence, the authors concluded that the use of ultrasound in the treatment of musculoskeletal disorders is based on empirical experience, but is lacking firm evidence from well-designed controlled studies. (Gam and Johannsen 1995).

Shields et al. (1996) conducted a study to determine the efficacy of ultrasound and phonophoresis in relieving pain in individuals with various types of musculoskeletal pain. One hundred and seventy-four individuals with musculoskeletal pain participated in this study. Their mean age was 41.2 years.

Patients were randomly assigned to one of the following groups: ultrasound, ultrasound with hydrocortisone, pure control (no treatment), and sham ultrasound. Both subjects and therapists were blinded to the treatment. No differences existed among the groups for age, duration of symptoms, or body part involved.

Ten daily treatments were completed using a 10 centimetre squared transducer set at 1 mega-hertz frequency and continuous mode. The duration of sonation and quantity of coupling medium was set at 0.045 minutes per centimetre squared and 1 capacity per centimetre squared, respectively. Sonation intensity was adjusted to 0.8 to 1.0 watts per centimetre squared. Sham groups received sonation via an identical unit with an inactive transducer. Pain intensity was the primary outcome assessed using a visual analog scale (VAS). All patients completed the VAS immediately prior to each treatment. The results showed that the profile among the treatment groups was significantly different and there was a significant change in pain over the 10 day treatment period. The self reported pain level in all treatment groups was significantly lower when compared to the control and sham ultrasound groups. No significant difference was present between the ultrasound with hydrocortisone and ultrasound without hydrocortisone. The major finding from this study was that ultrasound with or without hydrocortisone significantly reduced the patients' perceived pain over the ten day treatment period, which was less than that of a pure control group not receiving ultrasound.(Shields et al.1996).

Nwuga (1983) studied the efficacy of ultrasound therapy in the treatment of back pain resulting from rupture of the intervertebral disc. The subjects chosen for the study were 73 men, aged 35 to 45 years old. Criteria for inclusion in the study included symptoms so severe at the time of referral that the patients were unable to work; pain reference or numbness distributed unilaterally; no prior treatment for the condition; the onset of pain within 2 weeks of the time of entry into the study; and the ability to perform straight-leg raising on the affected side of less than 40 degrees. Three groups were studied: 1.) a treatment group, 2.) a placebo group, and 3.) a control group. Subjects were assigned as they became available to these groups in the order described, provided they met with the set criteria.

The treatment group was not only on bed rest at home but also received ultrasound therapy 3 times a week for 4 weeks. This was administered with the transducer head making contact with the affected area, using an Aquasonic gel as a coupling medium, with wattage of 1 to 2 watts per centimetre squared determined by patient tolerance. Each subject received treatment for 10 minutes.

The placebo group received the same therapy as the treatment group, but with the ultrasound machine turned off. The control group received only bed rest and analgesics. Treatment was terminated if, during the 4 week experimental period, pain was no longer present. This happened in the case of 4 subjects in the treatment group and 1 in the placebo group. Lumbar ranges of motion were measured and recorded before and after the 4 week therapy period for each subject and subjects were also questioned by a neutral assessor. Group comparisons showed statistical significance in favour of the treatment group, leading to the conclusion that ultrasound therapy is significantly effective in the treatment of back pain resulting from prolapse of the lumbar intervertebral disc. (Nwuga 1983).

Two of the most common adverse side-effects resulting from physical training and rehabilitation are muscular pain and soreness. Hasson et al. (1990) conducted a study to compare the analgesic effect of pulsating ultrasound treatment and placebo on delayed onset of muscle soreness produced by an eccentric exercise bout and the effect of pulsed ultrasound on muscular performance following an eccentric exercise bout. Eighteen untrained subjects were randomly assigned to: 1.) ultrasound (n=6) over the areas of concentrated muscle soreness, that is vastus lateralis and medialis; 2.) placebo ultrasound (n=6); 3.) no therapeutic intervention (n=6).

The muscle soreness exercise bout consisted of stepping up on a bench with the right leg (concentric) and lowering the body weight down (eccentric) with the left leg. The exercise bout lasted 10 minutes at a stepping frequency of 15 cycles per minute. For the second visit, subjects reported post exercise, and muscle performance and soreness perception (SP) were re-evaluated. Each of the three groups then received their respective treatment. Group 1 received ultrasound at an intensity of 0.8 watts per centimetre squared, at a frequency of 1.0 megahertz and for a duration of 20 minutes. Group 2 underwent the exact same procedure, but with the ultrasound unit turned off. On the third visit, 48 hours post exercise, muscle performance and muscle SP were again evaluated. There was no significant difference between the groups at 24 hours. However, following therapeutic intervention, the muscular performance of the group 1 at 48 hours was significantly greater than that of groups 2 or 3. (Hasson et al. 1990).

Rush and Shore (1994) from the Department of Rehabilitation Medicine in Toronto, randomly surveyed 100 specialists in rehabilitation medicine and 100 rheumatologists concerning their perceptions of the value of 11 different physical modalities including ultrasound in the treatment of seven different musculoskeletal conditions: neck pain, back pain, acute arthritis, joint contracture, tendinitis, reflex sympathetic dystrophy and frozen shoulder. Sixty-three percent of all physicians were in academic and 31% in private practice. Almost half of the physicians in each group had been in practice for at least 10 years and there was more rheumatologists than specialists in rehabilitation medicine (82% vs 62%).

There were differences in the perceived benefits of modalities amongst the 200 physicians as a whole, which varied by modality and by condition. This survey revealed that 80% of physicians regarded ultrasound to be useful in the treatment of neck pain and 20% did not. Overall, specialists in rehabilitation medicine valued modalities significantly more than rheumatologists. Significant differences between specialists in rehabilitation medicine and rheumatologists by specific modality for specific disease were not found. This survey demonstrated that further physician education in modalities is essential to ensure that the patient receives the best available and most cost-effective treatment in order to improve the quality of care for patients with musculoskeletal disease. (Rush and Shore1994:566-568).

2.6.8 STUDIES INVOLVING ULTRASOUND AND MANIPULATION

Koes et al. (1991b, 1992a, 1993) conducted a randomized clinical trial on the effectiveness of manual therapy, physiotherapy, treatment by the general practitioner, and placebo therapy on chronic non-specific back and neck complaints of not less than 6 weeks duration. One hundred patients suffering with neck pain were treated in the four groups and their mean duration of complaint was 1 year. Treatments consisted of exercises, massage and physical therapeutic modalities (ultrasound, heat, shortwave diathermy, electrotherapy) for the physiotherapy group. The manual therapy group received manipulation or mobilization. The patients treated by their general practitioners received medication and advice related to posture and exercise, while a fourth group acted as a control group and received detuned ultrasound or shortwave diathermy. The treatments were performed for a maximum period of 3 months and follow-up measurements were taken at 3, 6 and 12 weeks.

Results for patients with chronic neck and low back pain indicated that at 3 and 6 weeks the manual therapy group and the physiotherapy group had a much greater improvement in their main complaints and global perceived effect compared to the general practitioner and control groups. At 12 weeks however, the difference between the groups was minimal. No statistically significant difference was found between any of the groups with regards to pain severity or daily functioning, and all groups tended to improve equally. The manual therapy group had a greater improvement in physical functioning at all three measurements compared to the other groups.

This was statistically significant at 3 weeks but not at 12 weeks. Spinal mobility did not seem to change significantly in any of the groups, and its suitability for measuring progress in patients with chronic neck and low back pain was questioned. It is of interest to note that the manual therapy group received the least number of treatments (5.4) as compared to the physiotherapy group (14.7), but no other significant differences were noted between the manual therapy or physiotherapy groups at any of the follow-up measurements.

The authors also performed a 1 year follow-up on the above study (Koes et al. 1992b, 1993), but due to drop outs and change over, only analyses with regards to the manual therapy and physiotherapy groups were made. After the 12 month follow-up period manual therapy appeared to be slightly more effective than physiotherapy. This was evident by a greater mean improvement of the manual therapy patients' neck pain as compared to the physiotherapy group. Unfortunately, not a clear enough distinction was made between neck pain and low back pain patients. It is also unclear what the role of ultrasound played in the overall effectiveness of the physiotherapy treatment.

2.6.9 CONTRAINDICATIONS AND PRECAUTIONS

According to Kahn (1994:57), contraindications in the use of ultrasound are as follows:

1) Growing epiphyses, in the pregnant uterus, on bony prominences, in ailments of the eye, testicular tissues,and in the presence of pacemakers.

2) Special concern must be given to patients with sensory loss. (i.e. they cannot feel their tissues being burned.)

3) Metallic implants or surgical fixation materials. The interface of metal / tissue may be an ideal site for heat build-up and possible burn.

4) The possible disruption of osteogenic processes in healing fractures.

Ultrasound has a number of specific limitations, according to De Lisa and Gans (1993:411). These are:

1) Fluid-filled cavaties such as the eyes and gravid uterus should be avoided owing to the risks of cavitation and heat damage.

2) Sonification of the heart, brain, cervical ganglia, tumors, areas of hemorrhage or stasis, or ischemia, pacemakers, and infection sites should be avoided for obvious heat, neurophysiological, and mechanical reasons.

3) The spine should not be exposed to high intensities, and laminectomy sites in particular should be avoided.

4) The presence of metal in muscle or next to bone produces no more of a temperature elevation than would be expected if no metal was present. However, studies related to such treatments were carried out with a limited number of subjects.

2.7 CONCLUSION

The literature review presented here is designed to give an overall understanding of the clinical enigma of mechanical neck pain and the role of manipulation or ultrasound as a mode of therapy. As can be seen from numerous studies, chiropractic or spinal manipulative therapy has been shown to be effective in the treatment of neck pain (Howe et al. 1983; Johnson et al. 1989; Cassidy et al. 1992a; Koes et al. 1993). There appears to be consensus that spinal manipulative therapy is a therapeutic approach that in many cases offers more immediate pain relief to patients with spinal related disorders than other forms of conservative therapy.

The literature itself is fairly abundant in studies of ultrasonic therapy, but deals very scarcely with ultrasound therapy for the treatment of neck pain. It is evident that study design is particularly difficult. It appears from the above studies (Nwuga 1983; Koes et al. 1993; Shields et al.1996) that ultrasound does indeed have an effect on pain producing structures. It is therefore important to establish what long term effects both therapies may have on mechanical neck pain.

Neck pain with some limitation of movement seems to be a common complaint (Kelsey 1982:146). The neck is the most mobile section of the spine and is, therefore, very vulnerable to injury as stability is compromised for the sake of mobility (Bland 1994:3). There is little evidence of any research concerning the relative effectiveness of different conservative therapeutic approaches, especially in the treatment of neck pain.

3.0 RESEARCH METHODOLOGY

This was an randomized, consecutive, comparative group study involving a sample group of 30 patients. Advertisements were placed in local Natal newspapers and on radio, and all patients who responded were screened to determine if they suffered from mechanical neck pain. Only patients between the ages of 16 and 60 years without hard neurological signs were considered for the study. Once the case history (Appendix F), general physical examination (Appendix G), and regional examination of the cervical spine (Appendix H) had been completed, the patients were randomly placed in one of the two groups, either the adjustment or ultrasound group.

This was accomplished by placing 30 possibilities into a hat; 15 for adjustment and fifteen for ultrasound treatment. Before the first patient was treated, all 30 cards were drawn consecutively to determine the order as to which group each patient was assigned to upon acceptance into the study. The position of any patient that dropped out was then filled by the next new patient joining the study.

A radiological study of the cervical spine was conducted at the Technikon Natal Radiography Department when clinically indicated and was reported on by a radiologist before any treatment was performed. The prescribed views were: an

A-P, a Lateral, a right and left Oblique and an Open Mouth View. This was to ensure that no contra-indication to manipulation existed.

Once the patients had given written consent for their participation in the study, the initial part of the study began. This entailed the completion of the disability (Appendix A), pain intensity (Appendix B) and pain quality (Appendix C) questionnaires by the patients. These questionnaires were chosen as they had been previously demonstrated to exhibit good reliability and validity in measuring neck pain (Melzack 1975, Jensen et al. 1986, Vernon and Mior 1991).

Ranges of motion of the cervical spine were measured using the cervical range of motion goniometer (CROM), (Performance Attainment Associates, St. Paul, MN). The CROM goniometer was chosen, because it had been demonstrated to produce good to excellent intra-tester and inter-tester reliability in measuring cervical ranges of motion (Rheault et al. 1992). Goniometric reliability in a clinical setting had been shown to be high (Rothstein et al. 1983), and the CROM goniometer is highly reliable when compared to cervical range of motion measurements using different techniques such as universal or visual estimation (Youdas et al. 1991).

Cervical ranges of motion were measured in all six degrees with the patient sitting in a straight-backed chair with their arms resting at their sides and their feet flat on the ground. The CROM goniometer was placed on the patient as if he/she were putting on a pair of glasses and the velcro straps were fastened behind the head. Measurements were made in the following manner:

1) Cervical Flexion and Extension - The patient was instructed to firstly tuck in his/her chin to include sub-occipital flexion, and then attempt to put his/her chin on his/her chest. Cervical extension was measured by first getting the patient to tilt his/her head back (sub-occipital extension) and then to try and get his/her forehead parallel to the ceiling. These readings were taken off the sagittal plane meter and recorded on Appendix D. Only one reading for each direction was taken.

2) Lateral Flexion - The patient was instructed to laterally flex his/her neck as far as possible to the left and right without elevating the shoulders or rotating the head. The two measurements were then read off the lateral flexion meter and recorded on Appendix D.

3) Rotation - For rotation, the magnetic yoke and rotation arm was used. The sagittal plane and lateral flexion meters were checked to ensure that they were at zero, while the rotation meter was set at zero by turning the dial. The patient was instructed to turn his/her head as far as he/she could to the right and then to the left, keeping their eyes moving along a horizontal line and avoiding any shoulder rotation. The patient's shoulders were stabilized during this process by the observer. The two readings were read off the rotation meter and recorded on Appendix D. (Modified from CROM Procedure Manual, 1988:4-6).

The affected joint/s were identified using motion palpation and other signs such as muscle hypertonicity, local tenderness, the texture and tone of the underlying tissues, any anatomical asymmetry, " subluxation " or any lasting soreness (Bergmann et al. 1993:63).

Immediately thereafter, a single pressure threshold meter reading (algometer) was obtained from each patient. Before the procedure was carried out the patient was instructed to respond with " yes " when the pressure applied was felt to cause tenderness. With the patient lying prone (head in the neutral position), the most tender spinous process of the cervical vertebra was then identified by the observer with the left index finger. The pressure pad was then placed directly over the articular pillars of the cervical facet joint and a force directly posterior to anterior was applied through the vertebra. The force was applied at a rate of one kilogram per second until the patient reported discomfort. At this stage the algometer was removed and the reading was recorded (Appendix E).

The algometer has received variable reports of reliability. Jansen et al. (1990) found that in a pre-post context to evaluate treatment effects, 26% of the sites selected for testing were significantly different after ten minutes in asymptomatic subjects. On the other hand, Fischer (1986), in a larger group (n=50), studied the use of the algometer in the quantification of tender spots in asymptomatic subjects and concluded a high reproducibility and an excellent validity of measurements obtained. In the light of these findings, the algometer was used in the present study.

Once the affected area/s had been identified, the patients were treated according to the group to which they had been assigned. Patients in both groups received soft tissue therapy to the upper back and cervical musculature for a duration of 5 minutes, before manipulation or ultrasound was performed.

The adjustment group:

Patients in this group who presented with a fixation/s of the cervical spine motion unit received adjustments, using " Diversified " cervical rotatory break and/or lateral break techniques (Szaraz 1990:51,57), at each consultation. Patients received adjustments involving minimal rotation, whereby skin slack was removed in the direction of thrust until the contact was firmly secure over the posterior articular pillar of the cervical spine. The indifferent hand was then placed over the contra-lateral temporal area of the skull, cupping the patient's ear and was used to laterally flex the patient's head and neck towards the contact hand, while at the same time, rotating the patient's head and neck slightly away from the contact hand until all the joint slack under the contact finger had been removed. Once this had been achieved, a high velocity, short amplitude thrust was applied in the direction of the planes of articulation of the posterior facet joints. This procedure was repeated at any other levels where fixations were found.

The ultrasound group:

Patients in this group received therapeutic ultrasound over the affected area/s of the cervical musculature. This procedure had the patient placed in a prone position and the affected area/s were then isolated. Ultrasound gel was then applied over the sound head and on the skin over the affected area/s of the neck. The ultrasound machine was then switched on and set on a pulsed mode, at an intensity ranging from 0.5 watts per square centimeter to 1.0 watts per square centimeter, for a duration of 5 minutes. The sound head was then moved by the clinician, in circular, overlapping strokes, over the affected area/s of the neck. This procedure was continued until the timer on the ultrasound machine elicited an audible signal, indicating the end of treatment.

Patients received 2 adjustments per week for a maximum of 8 treatments. During the first, fourth, eighth and follow-up consultations, patients were required to complete the questionnaires. Pain thresholds and cervical ranges of motion were again measured. At the end of the 4 week treatment period, the second phase of the study began.

The second phase entailed completion of the questionnaires, measurements of the cervical ranges of motion and pain thresholds for a third time.

After a further 4 weeks of no treatment the third phase of the study was completed. The questionnaires, pressure pain thresholds and cervical ranges of motion were once again completed and the patients were then released from the study.

After the completion of the study the data that had been collected were scored. The neck disability index (Appendix A) was scored from 0 to 5 for each of the ten categories. The first option received a score of 0, while the sixth option received a score of 5. These individual scores were then summed and divided into the maximum possible total of 50 to arrive at a percentage disability for each patient at each measuring time. The score for each patient at each measuring time was then recorded in spreadsheet format.

Responses for the ' worst' and the ' least ' pain in the numerical pain rating scale (Appendix B) for each patient at each measuring time were recorded separately as raw data in spreadsheet format.

Responses for the quality of pain questionnaire (Appendix C) were scored with a

0 for none, 1 point for mild, 2 points for moderate and 3 points for severe pain. The individual scores were then tallied and divided into a maximum of 45 to obtain a percentage. Each percentage for each patient at the various measuring times was then recorded in spreadsheet format.

Data collected by the algometer and the goniometer did not get scored and were entered into spreadsheet format in their raw form.

The data contained in the spreadsheets then underwent non-parametric statistical analyses. The specific tests employed in this procedure were the Wilcoxon Signed-Ranks test for comparing the data within the two groups and the Mann-Whitney test for comparison of data between the groups (DeGroot 1989:571-584). The results obtained from these analyses were used to discuss the role of adjustments and ultrasound in treating mechanical neck pain and to draw up any conclusions and recommendations related to their effectiveness.

4.0 THE RESULTS

4.1 Introduction

The results discussed in this chapter deal with the subjective and objective findings of both treatment groups. The subjective data were obtained from the questionnaires discussed in Chapter Three. Cervical range of motion and pain threshold measurements were used to obtain the objective data.

Both the intra-treatment as well as the inter-treatment data were considered, and have been statistically analysed. The null and alternate hypotheses were either rejected or accepted, based on the statistical criteria for each measurement parameter.

Furthermore, demographic data obtained from the patients has also been obtained by analysing the age and gender distribution of both treatment groups.

4.2 The Hypotheses

The null hypothesis used for Sub-problems One and Two (stated in chapter 1) is the same for both treatment groups and is defined as follows:

Ho: There would be no statistical difference in the subjective and objective clinical findings on analysis of the data, showing that this treatment protocol was ineffective.

The hypothesis used for these sub-problems is again the same for both treatment groups and is defined as follows:

Ha: There would be a statistical difference in the subjective and objective clinical findings on analysis of the data, showing that this treatment protocol was effective.

In order to integrate the two sub-problems, a third hypothesis and a null hypothesis are required, and these are defined as given below:

Ho: There would be no stastistical difference in the subjective and objective clinical findings on analysis of the inter-group data, showing that the two treatment protocols are equally effective.

Ha: There would be a statistical difference in the subjective and objective clinical findings on analysis of the inter-group data, showing that the two treatment protocols were not equally effective.

4.3 The Analysed Data

The data were statistically analysed at a 95 % confidence interval.

As a reminder: Treatment group 1: received adjustments plus soft tissue therapy and Treatment group 2: received ultrasound plus soft tissue therapy.

4.3.1 Non - Parametric Paired Hypothesis Tests

4.3.1.1 Objective Data - Range of Motion

FORWARD FLEXION

TABLE 4.1 One sample analysis of flexion comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	1	1
P value (sig)	0.5 (ns)	0.5 (ns)

The null hypothesis is accepted for Group1, as there was no statistically significant difference between the first, final and follow - up consultations, indicating that there was no significant improvement as a result of the treatment.

TABLE 4.2 One sample analysis of flexion comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.015861	0.422676
P value (sig)	0.007930 (s)	0.211338 (ns)

The null hypothesis is rejected for the first and final consultation, as there was a statistically significant difference, indicating that there was improvement as a result of the treatment. The null hypothesis was accepted for the first and follow - up consultation as there was no statistically significant difference, indicating no long term improvement as a result of the treatment.

EXTENSION

TABLE 4.3 One sample analysis of extension comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.267256	0.096092
P value (sig)	0.133628 (ns)	0.048046 (s)

The null hypothesis is accepted for the first and final consultation, as there was no significant difference, indicating no significant improvement. The null hypothesis is rejected for the first and month follow - up consultation as there was a statistically significant difference in the measurements taken. This indicated that there was long - term improvement as a result of the treatment.

TABLE 4.4 One sample analysis of extension comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.227799	0.301698
P value (sig)	0.113899 (ns)	0.150849 (ns)

There was no statistically significant difference between the first, final, and follow - up consultations and thus the null hypothesis is accepted for Group 2, indicating that there was no significant improvement as a result of the treatment at a 95 % confidence level.

RIGHT ROTATION

TABLE 4.5 One sample analysis of right rotation comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.148914	0.579097
P value (sig)	0.07445 (ns)	0.289548 (ns)

In Group 1 the null hypothesis is accepted for right rotation, as there was no statistically significant difference between the first, final, and follow - up consultations, indicating that there was no significant improvement due to the treatment.

TABLE 4.6 One sample analysis of right rotation comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.789264	0.038866
P value (sig)	0.394632 (ns)	0.019433 (s)

For Group 2 the null hypothesis is accepted for the first and final consultation because of no statistically significant differences, indicating that the treatment resulted in no significant improvement. The null hypothesis is rejected for the first and month follow - up consultation as there was a statistically significant difference showing a long term improvement.

LEFT ROTATION

TABLE 4.7 One sample analysis of left rotation comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.579097	0.148914
P value (sig)	0.289548 (ns)	0.074457 (ns)

There was no statistically significant difference between the first, final, and follow - up consultations. The null hypothesis is therefore accepted for Group 1, indicating that there was no significant improvement as a result of the treatment.

TABLE 4.8 One sample analysis of left rotation comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.121335	0.096092
P value (sig)	0.060667 (ns)	0.048046 (s)

For left rotation the null hypothesis is accepted for the first and final consultaion, as there was no significant difference, indicating no significant improvement. The null hypothesis is rejected for the first and month follow - up consultation, as there was a statistically significant difference, indicating that there was long term improvement as a result of the treatment.

LEFT LATERAL FLEXION

TABLE 4.9 One sample analysis of left lateral flexion comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.181449	0.422676
P value (sig)	0.090724 (ns)	0.211338 (ns)

Table 4.9 shows that the null hypothesis is accepted for this group, as there was no statistically significant difference in the left lateral flexion measurements between the first, final, and follow - up consultations, indicating that there was no significant improvement as a result of the treatment.

TABLE 4.10 One sample analysis of left lateral flexion comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.061368	0.009823
P value (sig)	0.030684 (s)	0.004911 (s)

The statistical analysis of the second treatment protocol resulted in the null hypothesis being rejected, as there was a significant difference between the consultations considered, indicating that there was improvement as a result of this approach.

RIGHT LATERAL FLEXION

TABLE 4.11 One sample analysis of right lateral flexion comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.422676	0.038866
P value (sig)	0.211338 (ns)	0.019433 (s)

The null hypothesis was accepted for the first and final consultation as a result of no statistically significant differences, indicating no significant improvement. However, the null hypothesis is rejected for the first and month follow - up consultation, as there was a statistically significant difference in the measurements taken. This indicated that there was long term improvement as a result of the treatment.

TABLE 4.12 One sample analysis of right lateral flexion comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.181449	0.009823
P value (sig)	0.090724 (ns)	0.004911 (s)

For Group 2 the null hypothesis is accepted for the first and final consultation because of no statistically significant differences observed. The null hypothesis is rejected for the first and month follow - up consultation as there was a statistically significant difference, showing a long term improvement.

ALGOMETER

TABLE 4.13 One sample analysis of algometer readings comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.0181449	0.009374
P value (sig)	0.0090724 (s)	0.004687 (s)

The null hypothesis is rejected for Group 1, as there was a statistically significant difference between the first, final, and follow - up consultations, indicating that there was improvement as a result of the treatment.

TABLE 4.14 One sample analysis of algometer readings comparing tx1, tx3 and and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.038866	0.009823
P value (sig)	0.019433 (s)	0.004911 (s)

As with Group 1 the null hypothesis is rejected, as there was a significant difference between the consultations, indicating an improvement as a result of the treatment.

4.3.1.2 Subjective Data - Questionnaires

CMCC NECK DISABILITY INDEX

TABLE 4.15 One sample analysis of CMCC Neck Disability Index comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.061368	0.422676
P value (sig)	0.030684 (s)	0.211338 (ns)

The null hypothesis is rejected for Group 1, as there was a statistically significant difference between the first and final consultaions, indicating an improvement as a result of the treatment. The null hypothesis was accepted for the first and month follow - up consultation as a result of no statistically significant difference, indicating only short term improvement as a result of the treatment protocol used.

TABLE 4.16 One sample analysis of CMCC Neck Disability Index comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.301698	0.181449
P value (sig)	0.150849 (ns)	0.090724 (ns)

The null hypothesis is accepted for Group 2, as there was no statistically significant difference between the consultations considered, indicating there was no improvement as a result of the treatment.

McGILL SHORT - FORM QUESTIONNAIRE

TABLE 4.17 One sample analysis of McGill Short - Form Questionnaire comparing tx1, tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.148914	0.0265
P value (sig)	0.074457 (ns)	0.01325 (s)

The null hypothesis is accepted for the first and final consultation because of no statistically significant difference, indicating that the treatment resulted in no significant improvement. The null hypothesis is rejected for the first and month follow - up consultatiion as there was a statistically significant difference, showing a long term improvement.

TABLE 4.18 One sample analysis of McGill Short - Form Questionnaire comparing tx1, tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.016156	0.000512
P value (sig)	0.008078 (s)	0.000256 (s)

In Table 4.18 the null hypothesis is rejected for the second group, because of a statistically significant difference between the first, final, and follow - up consultations, indicating that the treatment was effective.

NUMERICAL PAIN RATING SCALE - 101

Worst Pain Experienced

TABLE 4.19 One sample analysis of Numerical Pain Rating Scale comparing tx1,tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.0265	0.096092
P value (sig)	0.01325 (s)	0.048046 (s)

In the statistical analysis of the NRS 101 questionnaire the null hypothesis is rejected for this group, as there was a significant difference between the consultations considered, indicating that there was improvement as a result of this treatment protocol.

TABLE 4.20 One sample analysis of Numerical Pain Rating Scale comparing tx1,tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.181449	0.096092
P value (sig)	0.090724 (ns)	0.048046 (s)

In Group 2 the null hypothesis is accepted, as there was no statistically significant difference between the first and final consultation, indicating no significant improvement. The null hypothesis is rejected for the first and month follow - up consultation, as there was a statistically significant difference. This indicated that there was long term improvement as a result of the treatment.

NUMERICAL PAIN RATING SCALE - 101

Least Pain Experienced

TABLE 4.21 One sample analysis of Numerical Pain Rating Scale comparing tx1,tx3 and tx4 of Group 1

	tx1 - tx3	tx1 - tx4
Z value	0.096092	0.0704401
P value (sig)	0.048046 (s)	0.03522 (s)

In the statistical analysis of this questionnaire for Group 1 the null hypothesis is rejected, because of a significant difference between the consultations, indicating an improvement.

TABLE 4.22 One sample analysis of Numerical Pain Rating Scale comparing tx1,tx3 and tx4 of Group 2

	tx1 - tx3	tx1 - tx4
Z value	0.182422	0.772826
P value (sig)	0.091211 (ns)	0.386413 (ns)

There was no statistically significant difference between the first, final, and follow - up consultations and the thus the null hypothesis is accepted for Group 2 indicating that there was no significant improvement.

4.3.2 Non - Parametric Unpaired Hypothesis Tests

4.3.2.1 Objective Data - Range of Motion

FORWARD FLEXION

TABLE 4.23 Two sample analyses of flexion measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.404897	0.933541	0.616819	0.707613
P value	0.202448 (ns)	0.466770 (ns)	0.308409 (ns)	0.353806 (ns)

The null hypothesis is accepted for the first, fourth, eighth, and follow - up consultations, as there was no significant difference in the efficacy of the two treatment protocols.

EXTENSION

TABLE 4.24 Two sample analyses of extension measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.662087	0.327692	1	0.818446
P value	0.331043 (ns)	0.163846 (ns)	0.5 (ns)	0.409223 (ns)

In this comparison of the two treatment groups the null hypothesis is accepted, as there was no statistically significant differences between the consultations considered for both groups. This indicated that both treatment protocols were equally effective.

RIGHT ROTATION

TABLE 4.25 Two sample analyses of right rotation measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.317667	0.087254	0.145406	0.491697
P value	0.158833 (ns)	0.043627 (s)	0.072703 (ns)	0.245848 (ns)

Table 4.25 indicates that the null hypothesis is accepted for right rotation measurements, as there was no significant difference between the first, eight and follow - up consultations of both groups. This indicates that there was no statistically significant difference in the efficacy of the two treatment protocols However, the null hypothesis is rejected for the fourth consultation, as there was a significant difference between the groups, indicating a difference in the efficacy of the two treatment protocols. Ultrasound, proving to be the more effective method of treatment.

LEFT ROTATION

TABLE 4.26 Two sample analyses of left rotation measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.440783	0.083313	0.517424	0.47688
P value	0.220391 (ns)	0.041656 (s)	0.258712 (ns)	0.23844 (ns)

Once again, the null hypothesis is accepted for the first, final, and follow - up consultations, as there was no significant differences between the groups, indicating that there was no significant difference in the efficacy of the two treatment protocols. The null hypothesis is rejected for the fourth consultation as there was a significant difference between the groups. This indicates that there was a statistically significant difference in the efficacy of the two treatment protocols, with adjustments being the superior method of treatment.

LEFT LATERAL FLEXION

TABLE 4.27 Two sample analyses of left lateral flexion measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.326495	0.786013	0.313326	1
P value	0.163247 (ns)	0.393006 (ns)	0.156663 (ns)	0.5 (ns)

The null hypothesis is accepted for left lateral flexion, as there was no significant difference between the consultations of both groups. This result indicated that there was no difference in the efficacy of the two treatment protocols studied.

RIGHT LATERAL FLEXION

TABLE 4.28 Two sample analyses of right lateral flexion measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.064968	0.0549957	0.049254	0.024755
P value	0.032484 (s)	0.027497 (s)	0.024627 (s)	0.012377 (s)

The null hypothesis is rejected, as there was a statistically significant difference between the first, fourth, final, and month follow - up consultations of both groups. This fact indicated that there was a significant difference in the efficacy of the two treatment methods employed. Adjustments, proving to be the more effective treatment protocol.

ALGOMETER

TABLE 4.29 Two sample analyses of algometer measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.933127	0.344659	1	0.702503
P value	0.466563 (ns)	0.172329 (ns)	0.5 (ns)	0.351251 (ns)

In Table 4.29 the null hypothesis is accepted for the results of the algometer readings, as there was no significant difference between the first, fourth, and month follow - up consultations of both groups, thus indicating that both treatment protocols were equally effective.

4.3.2.2 Subjective Data - Questionnaires

CMCC NECK DISABILITY INDEX

TABLE 4.30 Two sample analyses of CMCC Neck Disability measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.279446	0.479012	0.111951	0.28831
P value	0.139723 (ns)	0.239506 (ns)	0.055975 (s)	0.144155 (ns)

When considering the first set of subjective data, the null hypothesis is accepted for the first, fourth and follow-up consultations. This can be concluded as there was no significant difference between the consultations of the two treatment groups, thus indicating no significant difference in the efficacy of both treatment protocols. However, the null hypothesis is rejected for the final consultation, as there was a significant difference between the groups, indicating a difference in the efficacy of the two treatment protocols. Adjustments, proving to be the more effective method of treatment, with regards to improving disability.

McGILL SHORT FORM QUESTIONNAIRE

TABLE 4.31 Two sample analyses of McGill Short Form Questionnaire measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.405108	0.589363	0.176148	0.66198
P value	0.202554 (ns)	0.294681 (ns)	0.088074 (ns)	0.33099 (ns)

In Table 4.31 the null hypothesis is accepted for the results of the McGill Short Form Questionnaire, as there was no statistically significant differences between the consultations of the two groups, thus indicating that both treatment protocols were equally effective.

NUMERICAL PAIN RATING SCALE - 101

A. Worst Pain Experienced

TABLE 4.32 Two sample analyses of Numerical Pain Rating Scale measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.389939	0.587441	0.89992	0.502846
P value	0.194969 (ns)	0.293720 (ns)	0.44996 (ns)	0.251423 (ns)

The null hypothesis is accepted because of no statistically significant differences between the first, fourth, final, and month follow - up consultation of both groups. Thus indicating no differences in the efficacy of the two treatment methods employed.

B. Least Pain Experienced

TABLE 4.33 Two sample analyses of Numerical Pain Rating Scale measurements comparing both treatment groups

	tx 1	tx 2	tx 3	tx 4
Z value	0.781293	0.883391	0.335034	0.848909
P value	0.390646 (ns)	0.441695 (ns)	0.167517 (ns)	0.424454 (ns)

Once again, the null hypothesis is accepted as there was no significant differences between the consultations considered for both groups. This indicates that both treatment protocols were equally effective.

4.6 DEMOGRAPHIC DATA

TABLE 4.34 Demographic data related to the adjustment group. (n=15)

PATIENTS	AGE	SEX	CHRONICITY	TRAUMA	NECK	NECK +	NECK +
ADJ.					ONLY	HEAD	SHOUL
GROUP						ACHE	DER
1	36	M	1 year	N	Y		
2	39	M	5 years	Y-MVA	Y		
3	26	F	4 years	N			Y
4	32	F	4 years	N			Y
5	33	F	3 years	N			Y
6	49	M	1 year	N			Y
7	59	F	6 years	Y-MVA		Y	
8	55	F	1 year	N			Y
9	19	F	2 years	Y-MVA		Y	
10	26	M	1 year	N			Y
11	26	F	2 years	Y-MVA			Y
12	29	F	4 years	N		Y	
13	42	M	10 years	Y-MVA		Y	
14	39	F	1 year	N		Y	
15	25	F	5 years	N			Y
TOTAL	MEAN	M:F	MEAN	Y:N	TOTAL	TOTAL	TOTAL
	AGE		CHRONICITY				
15	35.67	5:10	3.33 years	5:10	2	5	8

TABLE 4.35 Demographic data related to the ultrasound group. (n=15)

PATIENTS	AGE	SEX	CHRONICITY	TRAUMA	NECK	NECK +	NECK +
U/S					ONLY	HEAD	SHOUL
GROUP						ACHE	DER
1	44	M	2 years	N		Y	
2	32	F	5 years	Y-MVA		Y	
3	29	F	1 year	Y-MVA			Y
4	46	F	1 year	N			Y
5	38	M	1 year	Y-MVA	Y		
6	25	M	2 years	N		Y	
7	56	M	10 years	N			Y
8	39	F	3 years	N			Y
9	58	F	8 years	Y-MVA			Y
10	30	M	3 years	N		Y	
11	38	F	1 year	Y-MVA		Y	
12	44	M	4 years	N		Y	
13	35	M	6 years	Y-MVA	Y		
14	24	F	13 years	N			Y
15	48	M	7 years	N			Y
TOTAL	MEAN	M:F	MEAN	Y:N	TOTAL	TOTAL	TOTAL
	AGE		CHRONICITY				
15	39.1	8:7	4.47 years	6:9	2	6	7

5.0 DISCUSSION

5.1 INTRODUCTION

This chapter involves the discussion of the results obtained from the range of motion readings and the questionnaires.

Firstly, the objective and subjective intra-treatment results are discussed to assess the efficacy of each treatment protocol in the management of mechanical neck pain.

Secondly, the discussion studies the objective and subjective inter-treatment results. The findings were used to assess whether there was a significant difference in the two treatment protocols, thereby indicating which treatment protocol was more effective for the treatment of mechanical cervical spine pain.

5.2 INTRA - TREATMENT COMPARISON

5.2.1 The Objective Data

5.2.1.1 Cervical Range of Motion

The first treatment group (adjustments), demonstrated no statistically significant differences in forward flexion, right rotation, left rotation, and left lateral flexion. However, a statistically significant difference was found for extension (Table 4.3) and right lateral flexion (Table 4.11) at the 1 month follow-up consultation, suggesting that there was a clinically significant improvement in these ranges of motion.

The second treatment group (ultrasound), demonstrated a significant improvement in forward flexion (Table 4.2), right rotation (Table 4.6), left rotation (Table 4.8), left lateral flexion (Table 4.10), and right lateral flexion (Table 4.12), indicating a clinically significant increase in almost all the ranges of motion. The significant improvement in left lateral flexion was at the final treatment and 1 month follow-up consultation. Forward flexion was only significantly improved at the final treatment, and left and right rotation only at the 1 month follow-up consultation.

The CROM goniometer used to measure range of motion in this study has been shown by Rheault et al. (1992) and Youdas et al. (1991) to have a high intra-examiner and inter-examiner reliability.

From the above results it was found that the second treatment group had a greater improvement in the range of motion than the first treatment group.

As no studies had previously involved both adjustments and ultrasound in the treatment of mechanical neck pain, the results obtained in this study were compared to related studies which involved either adjustments or ultrasound.

Howe et al. (1983) and Hviid (1971) both found significant increases in the cervical ranges of motion following adjustments to the cervical spine over treatment periods of between 3 and 5 weeks. This was especially evident in rotation. This was not found in this study, despite the general overall increase in range of motion in the adjustment group. However, extension and right lateral flexion showed significant improvement only at the 1 month follow-up consultation.

These differences may have been influenced by the larger sample sizes used in the above two studies, or the questionable reliability of the goniometers employed in the previous studies. Both were designed by the authors who performed the studies, and no reliability studies had been performed on them by independent individuals. In a double-blind study involving the use of adjustments on chronic neck pain sufferers, Sloop et al. (1982) found no significant improvement with regards to range of motion over a 3 week treatment period. It is therefore evident that different authors found conflicting results when measuring the effect of adjustments on increasing range of motion, especially related to chronic complaints.

The trend towards regaining limited mobility after the final treatment is supported by authors Hviid (1971) and Nansel et al. (1990). They found decreases in the increased mobility during the follow-up periods. In this study it was evident that the adjustment group had maintained their increased mobility after the 4 week follow-up period.

The study by Nansel et al. (1990) was confined to asymptomatic patients with regards to pain. It was found that in the group with a previous history of trauma to the cervical spine, 12 out of the 16 patients returned to their limited lateral flexion ranges within 48 hours after a single adjustment. In each case the restricted movement was found to return to the same side as before the adjustment. This was not found in the group with no history of previous trauma to the cervical spines.

When the demographic data of the patients in the adjustment group of this study were analyzed (Table 4.34), it was evident that 67% of the adjustment group had no previous history of trauma to the cervical spine. Therefore the trend towards maintaining their increased mobility was supported by the findings of Nansel et al. (1990). The patients without a history of previous trauma maintained their increased mobility to a greater degree post treatment.

The chronicity of the patients' complaints may have played a role in the relative differences in results occurring between the adjustment and ultrasound groups. The majority of both groups' complaints was of a chronic nature (Tables 4.34 and 4.35). If one considers the type of joint dysfunction or pathology most likely occurring in and around the joint at that stage, it is possible that many patients may have presented with ligamentous fixations (Gillet and Liekens 1969; Schafer and Faye 1989). This involves shortening of the ligaments and contracture formation of the joint capsules.

Gillet and Liekens (1969) reported that although the increase in range of motion after an adjustment to muscular fixations was quite apparent, this increase was not as dramatic in adjustments to ligament fixations.

Ultrasound is a deep heating modality that produces many therapeutic effects. These include increase in the extensibility of collagen rich structures such as tendons and joint capsules, decrease in joint stiffness, reduction of pain and muscle spasms. Ultrasound allows collagen rich structures to be heated preferentially. Scar tissue, joint capsules and tendons lying deep within the body can therefore be therapeutically heated (Nyborg and Ziskin 1985:123,124).

This may be the reason why ultrasound, in the form of Therapeutic Heat Energy, may have had a more dramatic effect on increasing the range of motion in the cervical spine in patients with more fibrosis due to trauma or chronicity.

Nwuga (1983) studied the efficacy of ultrasound therapy in the treatment of low back pain resulting from rupture of the lumbar intervertebral disc. Three groups were studied: 1.) a treatment group, 2.) a placebo group, 3.) a control group. The treatment group was not only on bed rest but also received ultrasound therapy 3 times a week for 4 weeks. Lumbar ranges of motion were measured before and after the 4 week therapy period. Group analysis showed statistically significance differences in the lumbar ranges of motion, in favour of the treatment group, leading to the conclusion that ultrasound therapy is significantly effective in the treatment of low back pain. Even though this study cannot be directly compared with Nwuga's (1983) findings because it is a study of the lumbosacral spine and there was no manipulation group, both Nwuga's group, that received ultrasound, and Group 2 , which received ultrasound therapy to the cervical spine, showed significant range of motion increases. Group 2 in this study showed increased ranges of motion in all planes except extension, as a result of the treatment.

5.2.1.2 Algometer

Both groups reached statistically significant levels of improvement at the stage of the final treatment and after the 4 week follow-up period (Table 4.13 and Table 4.14). The ultrasound group showed superior improvement. Findings reported in the literature reviewed support this result. Ultrasound has been shown to significantly reduce pain in individuals with various types of musculoskeletal complaints (Shields et al. 1996). Manipulation has also been shown, over the short term, to significantly reduce the paraspinal pain tolerance levels of paraspinal muscle and cutaneous tissue (as measured by the algometer) in symptomatic as well as asymptomatic subjects (Vernon 1988, Vernon et al. 1990). It was possible that the significant differences noted in the pain threshold levels in the adjustment group may have been due to the stiffer spinal joints resulting in decreased algometer readings. It may have also been possible that the resulting increased range of motion and decreased pain in the ultrasound group could allow for the increased paraspinal pain tolerance levels seen in the second treatment group.

5.2.2 The Subjective Data : Questionnaires

5.2.2.1 Disability

The CMCC Neck Disability Index Questionnaire, a revised form of the Oswestry Low Back Pain Index (Vernon and Mior 1991), has been shown to demonstrate a degree of test-retest reliability and validity (Vernon and Mior 1991).

After the 4 weeks of treatment the adjustment group experienced a significant improvement with regards to their levels of disability (Table 4.15). At the 1 month follow-up consultation the adjustment group experienced a slight deterioration with regards to disability and was no longer statistically significant. No statistically significant improvements were found in the ultrasound group, despite an overall improvement in their levels of disability, which nevertheless failed to reach levels of statistical significance (Table 4.16).

The results suggest support for the hypothesis that adjustments would improve the patients' perceptions of disability related to mechanical neck pain.

5.2.2.2 Pain

The McGill Pain Questionnaire was utilized to analyze the patients' severity of

neck pain, but not the " type" of neck pain they were suffering from.
Within the ultrasound group a significant decrease in pain was experienced at the stage of the final treatment and again at the 1 month follow-up consultation (Table 4.18). Statistically significant decreases in pain severity were observed within the adjustment group after the 4 week follow-up period (Table 4.17). No previous studies appear to have used the McGill Pain Questionnaire as a subjective measure for evaluating mechanical neck pain.

The adjustment group showed statistically significant improvements in their "least" pain and "worst" pain experienced as revealed by the NRS-101 Pain Questionnaire at both the final treatment and 1 month follow-up consultation (Table 4.21 and Table 4.19). The "least" and "worst" pain scores showed only a significant improvement within the ultrasound group only after the 4 week follow-up period (Table 4.22 and Table 4.20). The adjustment group appeared to have responded better with a greater reduction in pain at all stages of the study compared to the ultrasound group.

This may be explained by the rapid separation of the joint surfaces, that has been shown to occur during an adjustment, and the freeing of trapped pain-sensitive tissues i.e. meniscoid (Lewit 1978) or synovial fold (Haldeman 1992). The ultrasound group tended to respond more slowly and had a greater decrease in pain at the 1 month follow-up consultation, but it must be noted that the two groups did not have similar pain levels before the treatment started.

Over the whole study the adjustment group had a greater decrease in pain with regards to the "least" pain and "worst" pain perceived, but they had began the study with much higher levels of pain as compared to the ultrasound group (Table 4.19, Table 4.20, Table 4.21 and Table 4.22).

The different biomechanical effects that adjustments and ultrasound exert on the joints and surrounding soft tissues may account for this. The high velocity thrusts employed in adjustments may exert a greater and quicker effect on the joint mechanoreceptors and nociceptors, which in turn affects reflex responses on pain inhibition. Many of the mechanoreceptors and nociceptors involved with pain inhibition are high threshold receptors (Wyke 1985). The levels of stimulation produced from a slow and gentle procedure, such as Ultrasound, may not have a dramatic effect initially. With a series of treatments, however, sufficient afferent input may be achieved to stimulate these pain inhibiting pathways. This is an area which needs further research.

Howe et al. (1983) and Sloop et al. (1982) both found significant improvements with regards to neck pain in patients treated with adjustments over a period of 3 weeks. Howe et al. (1983) also mention that the greatest decrease in pain in the adjustment group appeared after the first treatment, and that with further treatments the pain levels did not change dramatically. These results do not support Howe et al's. observations since the findings of this study were that the greatest decrease in pain intensity occurred at the final and 1 month follow-up consultations.

Shields et al. (1996) conducted a study to determine the efficacy of ultrasound and phonophoresis in relieving pain in individuals with various types of musculoskeletal pain. Pain intensity was measured using the visual analog scale, which was completed prior to each treatment. The results showed that there was a significant change in the pain levels over the 10 day period in the treatment group when compared to the control and sham ultrasound groups. When compared to this study, it must be noted that the ultrasound group also showed an overall significant improvement in the levels of perceived pain.

5.3 INTER - TREATMENT COMPARISON

5.3.1 The Objective Data

5.3.1.1 Cervical Range of Motion

With flexion (Table 4.23), extension (Table 4.24), and left lateral flexion (Table 4.27), there were no statistically significant diffferences between the two treatment groups. This indicates that both treatments were equally effective. However, it was found that with right lateral flexion (Table 4.28, Fig 5.1) there was a statistically significant difference between the two treatment groups at all four stages of the study. Right and left rotation (Table 4.25, Fig 5.2 and Table 4.26, Fig 5.3) showed statistically significant differences only at the fourth consultation. This indicates that the two treatment protocols were not equally effective as far as increasing right lateral flexion, right rotation and left rotation ranges of motion was concerned. Adjustments proved to be the more effective treatment protocol as far increasing right lateral flexion and left rotation. Therapeutic ultrasound proved to be the more effective treatment protocol as far as increasing right rotation.

5.3.1.2 Algometer

No statistically significant differences in the mean improvements in pressure pain threshold levels were noted between the two groups at any of the four measurement stages of the study (Table 4.29). This indicates that the two treatment protocols were equally effective as far as reducing pain threshold levels was concerned.

5.3.2 The Subjective Data

5.3.2.1 Questionnaires

The statistical comparison of the initial, fourth, final, and one month follow-up measurements revealed no significant differences between the two treatment groups, for the McGill Short Form Questionnaire (Appendix C), and the NRS 101 Pain Questionnaire (Appendix B).

The fact that there were still no statistically significant differences at the fourth, final, as well as the one month follow-up consultations, indicates that both treatment protocols were equally effective according to the above subjective data.

Analysis of the CMCC Neck Disability Index (Appendix A), revealed a statistically significant improvement in disability between the two treatment groups at the stage of the final treatment (Table 4.30, Fig 5.4). The results showed that there was a difference in the efficacy of the two treatment protocols, with adjustments being the superior treatment approach in improving disability.

Graphs depicting significant differences between the two treatment groups :

Fig. 5.1 Comparison of mean improvement in right rotation

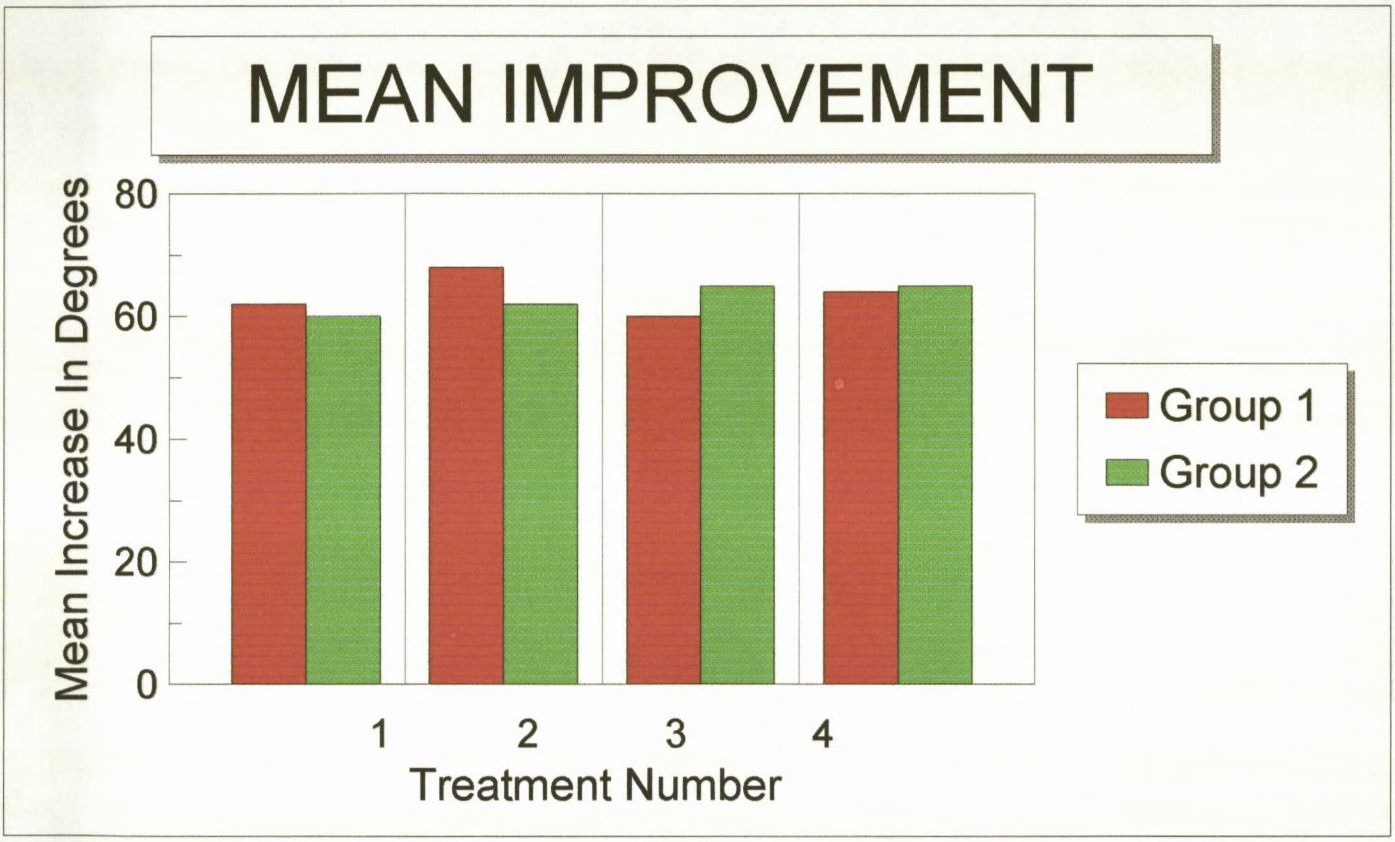


Fig. 5.2 Comparison of mean improvement in left rotation

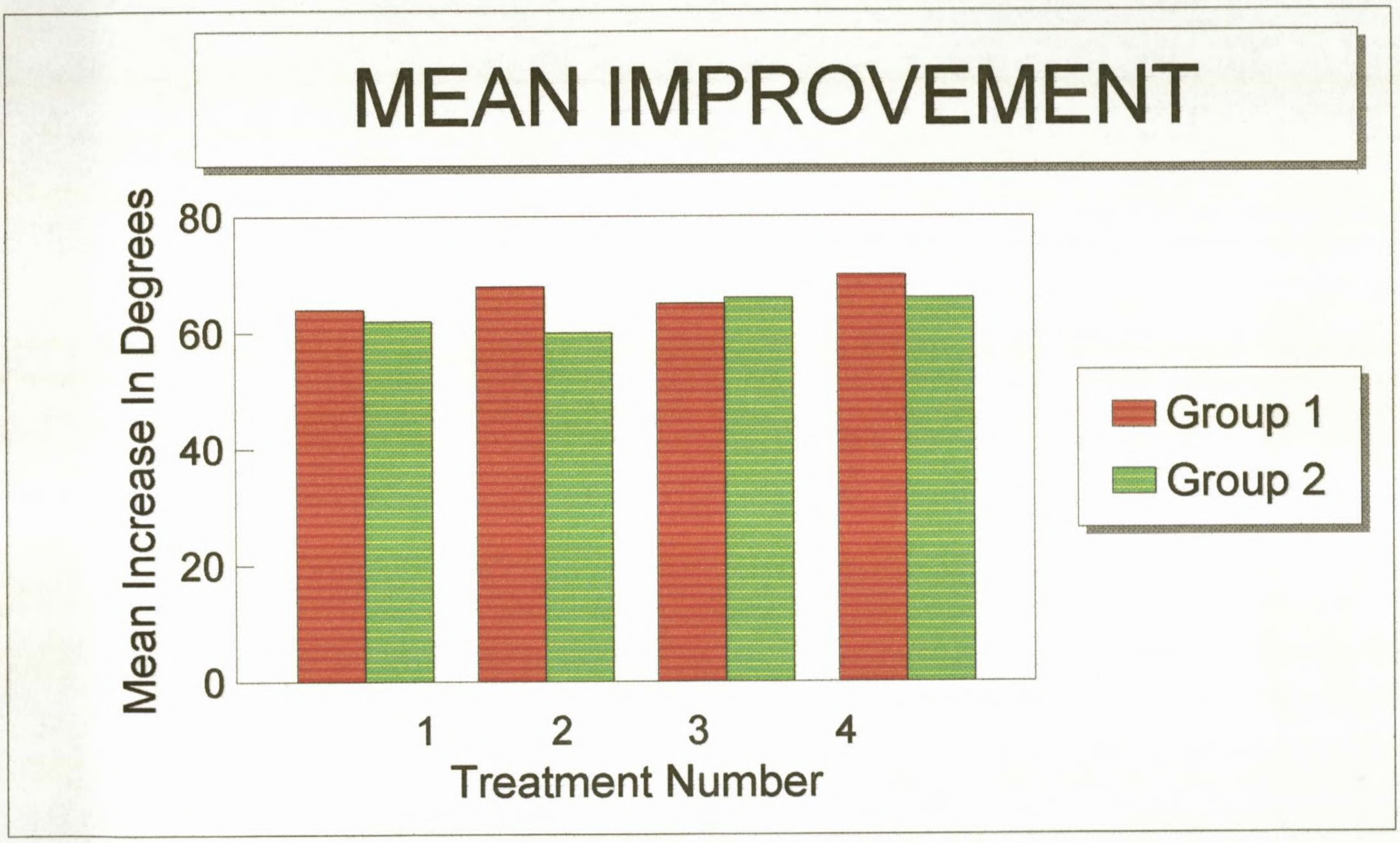


Fig. 5.3 Comparison of mean improvement in right lateral flexion

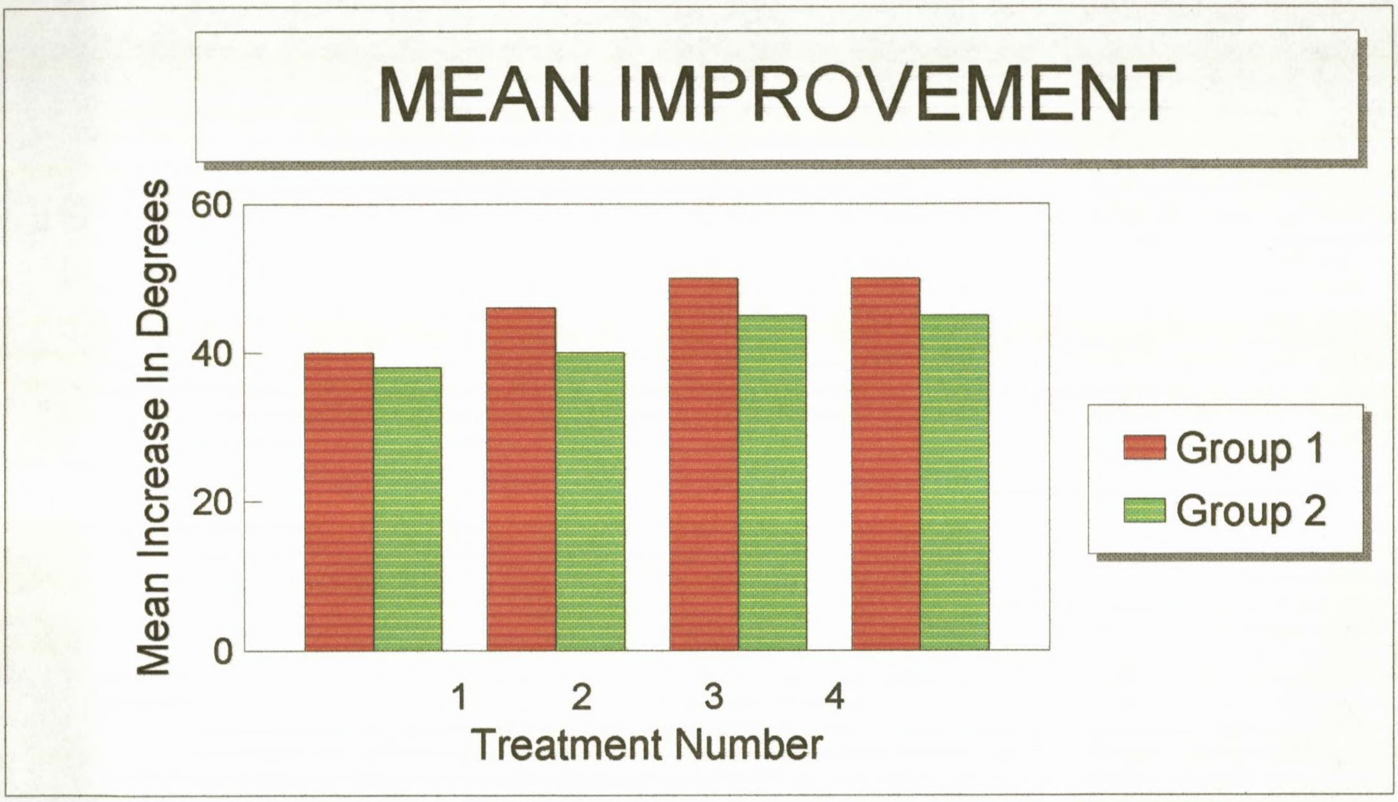
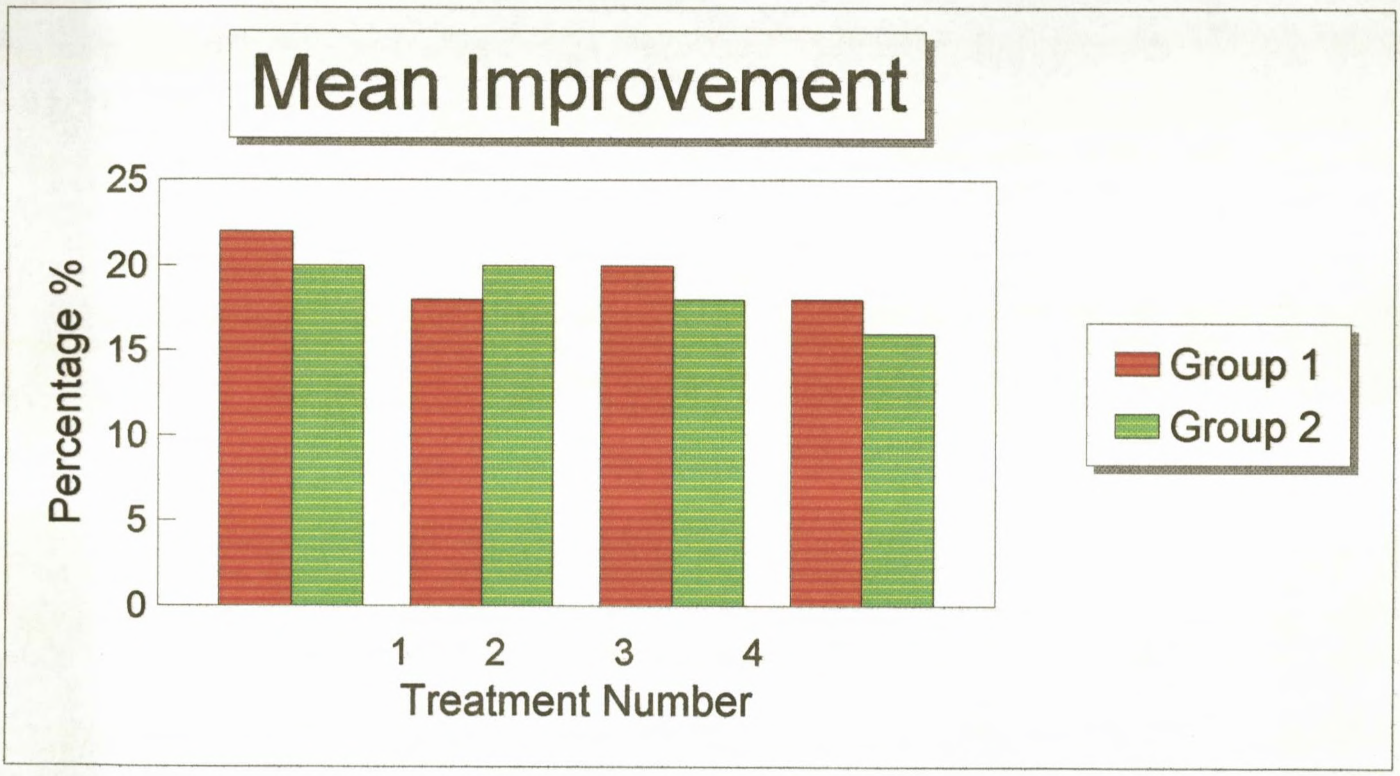


Fig. 5.4 Comparison of mean improvement in CMCC Neck Disability Index Scores



5.4 Discussion

It was hypothesized that both treatment groups would show favourable results in terms of the subjective and objective findings.

The results indicate that both treatment groups responded favourably to their respective treatment protocols, that each treatment method acted with equivalent efficacy and that the rate of patient improvement was similar.

The first two hypotheses, which stated that there would be an improvement as a result of each respective treatment protocol, were accepted. The third hypothesis, stating that there would be a difference in efficacy between the two treatment groups, was rejected for all the data, except for right lateral flexion, right and left rotation ranges of motion measurements, and disability measurements, for which the hypothesis was accepted. This would indicate that the first treatment protocol (adjustments) was more effective than the second, in terms of increasing right lateral flexion and left rotation ranges of motion, and improving disability. This would also indicate that the second method of treatment was more effective as far as increasing right rotation ranges of motion.

5.5 Limitations of this Study

The objective measurements, in the form of the goniometer readings, may have been subject to human error. This could have been as a result of the fact that the calibrations were only in increments of 2 degrees, which may have made the instrument insensitive to subtle changes in cervical motions. Added to this is the possible risk of incorrect user methods.

The subjective measurements, in the form of the three questionnaires, may also have had some limitations. The patient may have felt the need to please the researcher and record an improvement which was beyond that which was actually felt.

The gender distribution between the two treatment groups, particularly of male patients, could have been closer, which would have given more representative results.

Another weakness of this study was the small sample size, which could have resulted in a Type 2 error (Bajpai et al. 1978 : 212). This is when the null hypothesis is accepted as true when it is actually false.

5.6 Comparison of the Results with Other Research

Koes et al. (1991b, 1992a, 1993) conducted a blinded randomized clinical trial comparing the effectiveness of manual therapy (adjusting and mobilizing the spine), physiotherapy (exercises, massage, and physical therapy modalities which included ultrasound), treatment by the general practitioner (medication and postural advice), and a placebo therapy (de-tuned ultrasound and shortwave diathermy). This was performed on patients with non-specific back and neck complaints. Treatments were performed for a maximum period of three months and follow-up measurements were taken at 3, 6 and 12 weeks. Results indicated that the manual therapy and physiotherapy groups had a much greater improvement in their main complaints at 3 and 6 weeks compared to the other two therapies. However, the manual therapy group had a greater improvement in physical functioning at all measurements compared to the other groups.

Koes et al. (1993) used sub-group analysis to assess the relative efficacy of manual therapy and physiotherapy in treating chronic patients with non-specific back and neck complaints, who had not received physiotherapy or manual therapy during the preceeding two years. The results suggested that manual therapy was more effective than physiotherapy in treating these conditions.

The results of this study cannot be compared directly with this research project because in the cited study not a clear enough distinction was made between neck pain and low back pain patients.

What can be correlated is the fact that both treatment (the manual therapy and physiotherapy) groups of this study, showed a significant improvement in cervical range of motion as a result of the treatment, with the adjustment group showing superior improvement. The patients from both treatment groups also reported a significant improvement in pain intensity and quality of life, with the adjustment or manual therapy group again showing superior improvement. These findings support spinal manipulative therapy, and to a slightly lesser degree physiotherapy (which in some cases included ultrasound), as effective treatment protocols for neck pain.

6.0 RECOMMENDATIONS AND CONCLUSION

The results of this study over the 4 week treatment period and 4 week follow-up period indicated that adjustments appeared to be more beneficial than ultrasound in the treatment of mechanical neck pain. Statistically significant differences were noted between the two treatment groups for right and left rotation measurements at the fourth consultation, and right lateral flexion range of motion measurements at all four stages of the study. Adjustments proved to be the more effective treatment protocol as far as increasing right lateral flexion and left rotation, and ultrsound for right rotation. However, the CMCC Neck Disability Questionnaire measurements showed statistically significant differences at the final treatment stage indicating that adjustment was the more effective treatment protocol with regards to improving disability. No statistically significant difference was noted between the two treatment groups for any of the other outcome measures after the 4 weeks of treatment or after the follow-up period.

Several outcome measures within each group showed significant improvements at certain stages of the study when compared to pre-treatment values. The ultrasound group appeared to have more improvement with regards to mobility especially after the 4 weeks treatment period and follow-up period. The adjustment group showed an overall improvement in all cervical ranges of motion compared to pre-treatment values. The adjustment group tended to have more improvement with regards to disability and a much slower response with regards to pain reduction, particularly after the first treatment. The ultrasound group experienced a much quicker response with regards to pain reduction.

Future studies in which a comparison is to be made should use a random sampling technique which takes into account the patient's gender, age and, possibly, physique. In order to make this study more valid, other factors could be more congruent. This would include factors such as the levels of dysfunction, the duration of the complaint, and the dismissal of subjects with other co-existing complaints.

An important factor to consider would be the sample size. With treatment groups of only 15, this study could merely be considered as a pilot study. For further studies in this regard, a sample size of at least 30 is recommended so that paired and unpaired t-tests can be performed. This would make a trend in results more apparent and sensitive to the subtle changes in data. With samples of this size a statistical quality control test could be performed.

Both treatment groups received a 5-minute massage, with oil, by hand. A suggestion for future research purposes in this field is that massage either be eliminated or done using a mechanical device for a fixed period of time, to ensure equal preparation of all patients to minimize this added variable influencing the results.

Relating to the great differences in anatomy and biomechanics in the upper and lower cervical spine, a study specific to each of these regions is also recommended. Other factors to consider would be to use only one form of adjustment, as there may be subtle differences in the rotatory techniques which have not yet been revealed. With regards to ultrasound it is suggested that one specific intensity be used instead of a range to possibly attain a more accurate result.

Due to the limited experience of any undergraduate researcher in the field of manual therapy, it is suggested that more experienced manual therapists repeat this study in order to further substantiate the role of adjustments and ultrasound in the treatment of mechanical neck pain.

It is recommended that passive ranges of motion be analyzed instead of active ranges of motion. Wong and Nansel (1992) have shown that measuring passive ranges of motion demonstrates range of motion asymmetries to a greater extent than active ranges of motion. In measuring passive ranges of motion 'corticol influences' (Wong and Nansel 1992) are absent and the effects of a certain treatment on the ranges of motion of the joint may, therefore, become apparent. The use of passive movement would also exclude the influence that muscle can have on reducing mobility and would, hence possibly, be a more reliable indicator of pure joint movement.

The Short Form McGill Pain Questionnaire used in the study was less reliable than the NRS-101, because it is more difficult to analyze. This is supported by the findings of Jensen et al. (1986), and it is therefore suggested that it be excluded in future studies.

As the majority of patients in this study suffered from chronic neck pain, it is suggested that the study be repeated on a population suffering from acute neck pain to establish whether the duration of the complaint plays any role in the effectiveness of the treatment. In acute neck pain severe limitation of movement is common, normally in rotation and to a lesser extent lateral flexion. In chronic neck pain a more generalized reduction in mobility is evident. The mechanisms and pathological processes producing acute and chronic neck pain are not the same. In acute neck pain inflammation causing pain and reduced mobility is hypothesized to be from entrapped soft tissues and muscle spasm (Lewit 1978 and Haldeman 1992:205), while chronic neck problems, causing low grade pain and reduced mobility, are hypothesized to be from adhesions, ligament shortening or capsular contracture (Gillet and Liekens 1969). The different physical and biomechanical effects of adjustments and ultrasound on the joints and surrounding tissues, therefore needs to be analyzed in chronic as well as acute patients.

It is the author's opinion, by considering the results produced in this study, that both forms of treatment are effective in treating mechanical neck pain. In order to decide which treatment is of greater benefit the primary objective of the treatment must be established. If it is to restore mobility and improve disability, then adjustments appear to be more beneficial. If it is to decrease pain, it appears that ultrasound would be more suitable. Further research is required to refute or validate these findings.

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CMCC NECK DISABILITY INDEX

PATIENT NAME:______________________________________ FILE #:_______ DATE:_________

This questionnaire has been designed to give the doctor information as to how your neck 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 realise 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 - Reading

☐ I can read as much as I want to with no pain in my neck.
☐ I can read as much as I want to with slight pain in my neck.
☐ I can read as much as I want with moderate pain in my neck.
☐ I can't read as much as I want because of moderate pain in my neck.
☐ I can hardly read at all because of severe pain in my neck.
☐ I cannot read at all.

Section 5 - Headaches

☐ I have no headaches at all.
☐ I have slight headaches which come in-frequently.
☐ I have moderate headaches which come in-frequently.
☐ I have moderate headaches which come frequently.
☐ I have severe headaches which come frequently.
☐ I have headaches almost all the time.

Section 6 - Concentration

☐ I can concentrate fully when I want to with no difficulty.
☐ I can concentrate fully when I want to with slight difficulty.
☐ I have a fair degree of difficulty in concentrating when I want to.
☐ I have a lot of difficulty in concentrating when I want to.
☐ I have a great deal of difficulty in concentrating when I want to.
☐ I cannot concentrate at all.

Section 7 - Work

☐ I can do as much work as I want to.
☐ I can only do my usual work, but no more.
☐ I can do most of my usual work, but no more.
☐ I cannot do my usual work.
☐ I can hardly do any work at all.
☐ I can't do any work at all.

Section 8 - Driving

☐ I can drive my car without any neck pain.
☐ I can drive my car as long as I want with slight pain in my neck.
☐ I can drive my car as long as I want with moderate pain in my neck.
☐ I can't drive my car as long as I want because of moderate pain in my neck.
☐ I can hardly drive at all because of severe pain in my neck.
☐ I can't drive my car at all.

Section 9 - Sleeping

☐ I have no trouble sleeping.
☐ My sleep is slightly disturbed (less than 1 hr. sleepless).
☐ My sleep is mildly disturbed (1-2 hrs. sleepless).
☐ My sleep is moderately disturbed (2-3 hrs. sleepless).
☐ My sleep is greatly disturbed (3-5 hrs. sleepless).
☐ My sleep is completely disturbed (5-7 hrs. sleepless).

Section 10 - Recreation

☐ I am able to engage in all my recreation activities with no neck pain at all.
☐ I am able to engage in all my recreation activities, with some pain in my neck.
☐ I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.
☐ I am able to engage in a few of my usual recreation activities because of pain in my neck.
☐ I can hardly do any recreation activities because of pain in my neck.
☐ I can't do any recreation activities at all.

APPENDIX B

NUMERICAL RATING SCALE - 101

Name: 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 a hundred (100) would mean "pain as bad as it could be." Please write only one number.

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 a hundred (100) would mean "pain as bad as it could be". Please write only one number.

APPENDIX C

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

APPENDIX D

RANGE OF MOTION RESULT SHEET

PATIENT: ______________________ FILE NO: ________ DATE: _________

FLEXION ______________________________

EXTENSION ______________________________

RIGHT ROTATION ___________________________

LEFT ROTATION ___________________________

RIGHT LATERAL FLEXION ___________________

LEFT LATERAL FLEXION ___________________

APPENDIX E

ALGOMETER RESULT SHEET

PATIENT: ______________________ FILE NO: ________ DATE: _________

PRE- TREATMENT _________________________________

FOURTH TREATMENT _____________________________

FINAL TREATMENT _______________________________

ONE MONTH FOLLOW-UP ___________________________

APPENDIX F

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:	TN	Current:	TN
	Other		Other

X-ray Studies:

Previous:	TN	Current:	TN
	Other		Other

Clinical path. lab.:

Previous:	TN	Current:	TN
	Other		Other

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 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. Family history:
   - Immediate family:
     - Age
     - Health
     - Cause of death
     - DM
     - Heart disease
     - TB
     - HBP
     - Stroke
     - Kidney disease
     - CA
     - Arthritis
     - Anaemia
     - Headaches
     - Thyroid disease
     - Epilepsy
     - Mental illness
     - Alcoholism
     - Drug addiction
     - Other

8. Psychosocial history:

Home situation

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.

APPENDIX G

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Underline abnormal findings in RED and elaborate on back of relevant page, if necessary.
Mark "NAD" if normal.

Patient:________________________________ File #______

Last name First name

Clinician:__________________ Signature:______________

Intern:____________________ Signature:______________

Date:________________

Height:____________ Weight:__________ Temp:__________

Rates: Heart:_______ Pulse:_______ Respiration:__________

Blood pressure: Arms: L / R /

Legs: L / R /

General appearance:

STANDING EXAMINATION.

Minor's sign
Skin changes
Posture
erect
Adam's
"Ranges of motion:

T/L spine: Flexion: 90 Fingers to floor
Extension: 30
R.lat.flex.: 30 Fingers down leg
L.lat.flex.: 30 Fingers down leg
Rot.to R.: 35
Rot.to L.: 35

Flex.

L.Rot. R.Rot.

L.lat flex. R.lat. flex.

Ext.

/ = pain-free limitation; // = painful limitation.

Romberg's sign.
Premotor drift.
Trendelenburg's sign.
Gait.
rhythm
balance
pendulousness
on toes
on heels
tandem
Half squat.
Scapular winging.
Muscle tone.
Spasticity/Rigidity.

Shoulder:

- skin
- symmetry
- ROM - glenohumeral
  - scapulo-thoracic
  - acromioclavicular
  - elbow
  - wrist

Chest measurement

- inspiration
- expiration

Visual acuity

Breast examination:

- Inspection:
  - skin
  - size
  - contour
  - nipples
  - arms overhead
  - hands against hips
  - leaning forward.
- Palpation:
  - axillary lymph nodes.

<u>SEATED EXAMINATION.</u>

- Spinal posture
- Head
  - scalp
  - skull
  - face
  - skin
- Eyes
  - conjunctiva
  - sclera
  - eyebrows
  - eyelids
  - lacrimal gland
  - nasolacrimal duct
  - alignment
  - corneal reflex
  - ocular movement

L			R		
III	IV	VI	III	IV	VI

  - visual fields
  - accommodation
  - iris
  - pupils
  - red reflex
  - optic disc

- vessels
- general background
- macula
- vitreous
- lens

Ears:
- auricle
- ear canal
- drum
- auditory acuity
- Weber test
- Rinne test

Nose:
- external
- internal
  - septum
  - turbinates
  - olfaction
- Sinuses (frontal & maxillary):
  - tenderness
  - transillumination
- Mouth and pharynx:
  - lips
  - buccal mucosa
  - gums and teeth
  - roof
  - tongue
    - inspection
    - movement
    - taste
    - palpation
  - pharynx
    - inspection
    - [illegible] X

Neck:
- posture
- size
- swelling
- scars
- discoloration
- hair line

ROM:

Flexion: 45 chin to larynx
chin to sternum

Extension: 55 forehead parallel
to floor

L.lat.flex: 40

R.lat.flex: 40

L.rot.: 70

R.rot.: 70

Flex.

L.Rot. R.Rot.

L.Lat. flex. R.lat. flex.

Ext.

lymph nodes
trachea
thyroid
carotid arteries (thrills, bruit)
CN V
CN VII
CN VIII (nystagmus)
CN IX
CN XI
CS —
Inspection
ROM
deviation
Palpation
crepitus
tenderness

- Neurological:
  - Dermatomes
    - C5
    - C6
    - C7
    - C8
    - T1
  - Tendon reflexes
    - biceps
    - triceps
    - brachioradialis
  - Muscle strength
    - C5
    - C6
    - C7
    - C8
    - T1
  - Coordination:
    - point-to-point
    - dysdiadochokinesia
- Thorax:
  - Chest:
    - Inspection:
      - skin
      - shape
      - respiratory distress
      - rhythm (respiratory)
      - depth
      - effort
      - intercostal/supraclavicular retraction
    - Palpation:
      - tenderness
      - masses
      - respiratory expansion
      - tactile fremitus
    - Percussion:
      - lungs (posterior)
      - diaphragmatic excursion
      - kidney punch
    - Auscultation:
      - breath sounds
        - vesicular
        - bronchial
      - adventitious sounds
        - crackles (rales)
        - wheezes (rhonchi)
      - voice sounds
        - bronchophony
        - whispered pectoriloquy
        - egophony

Cardiovascular:
auscultation (aortic [illegible])
Allen's test

SUPINE EXAMINATION

JVP
[illegible]
auscultation heart (L.lat.[illegible] beat)
respiratory excursion
percussion chest (anterior)
breast palpation

The abdomen:

Inspection:
- skin
- umbilicus
- contour
- peristalsis
- pulsations
- hernias (umbilical/incisional)

Auscultation:
- bowel sounds
- bruit

Percussion:
- general
- liver
- spleen

Palpation:
- superficial reflexes
- cough
- light
- rebound tenderness
- deep
- liver
- spleen
- kidneys
- aorta
- intra-/extra-abdominal wall mass
- shifting dullness
- fluid wave

Acute abdomen:
- where pain began and now
- cough
- tenderness
- guarding/rigidity
- rebound tenderness
- Rovsing's sign
- psoas sign
- obturator sign
- cutaneous hyperaesthesia
- rectal exam
- Murphy's sign.

Male genitals and hernias.

- Inspection:
  - skin
  - prepuce
  - glans
  - meatus
  - size/lies
  - scrotum
  - inguinal/femoral bulges
- Palpation:
  - penis (tenderness/induration)
  - testes
  - epididymis
  - inguinal canal
  - femoral canal
  - cremasteric reflex
- Auscultation:
  - scrotal mass.

Peripheral vasculature:

- Inspection:
  - skin
  - nail beds
  - pigmentation
  - hair loss
- Palpation:
  - pulses - radial, brachial, femoral, popliteal, post.tibial, dorsalis pedis
  - lymph nodes - epitrochlear, femoral (horizontal & vertical)
  - temperature (feet & legs)
- Manual compression test
- Retrograde filling (Trendelenburg) test
- Arterial insufficiency test

Musculoskeletal:

- ROM
  - hip
    - flex. 90/120
    - ext. 15
    - abd. 45
    - add. 30
    - int rot 40
    - ext rot 45
  - knee
    - flex. 130
    - ext. 0/15
  - ankle
    - plantar flex 45
    - dorsiflex 20
    - inversion 30
    - eversion 20
  - leg length

- Neurological:
  - dermatomes
    - L1
    - L2
    - L3
    - L4
    - L5
    - S1
  - muscle strength
    - hip flexion
    - knee extension
    - ankle dorsiflexion
    - plantar flexion
  - tendon reflexes
    - patellar
    - Achilles
  - plantar reflex
- Rectal examination:
  - Inspection
    - sacrococcygeal & perianal areas
  - Palpation
    - sphincter tone
    - tenderness
    - induration
    - nodules
    - prostate
    - seminal vesicles

Mental status

- Appearance and behaviour:
  - level of consciousness
  - posture and motor behaviour
  - dress, grooming, personal hygiene
  - facial expression
  - affect
- Speech and language:
  - quantity
  - rate
  - volume
  - fluency
  - aphasia (prn)
- Mood
- Thought processes (logical, relevant, organised)
- Memory and attention:
  - orientation (time, place, person)
  - remote memory
  - recent memory
  - new learning ability
- Higher cognitive functions:
  - information and vocabulary (general & specialised knowledge)
  - abstract thinking.

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC.

REGIONAL EXAMINATION -- CERVICAL SPINE.

PATIENT:____

FILE # :____________________ DATE:____________________

INTERN/RESIDENT:______________________________________

SUPERVISING CLINICIAN :________________________________

OBSERVATION :

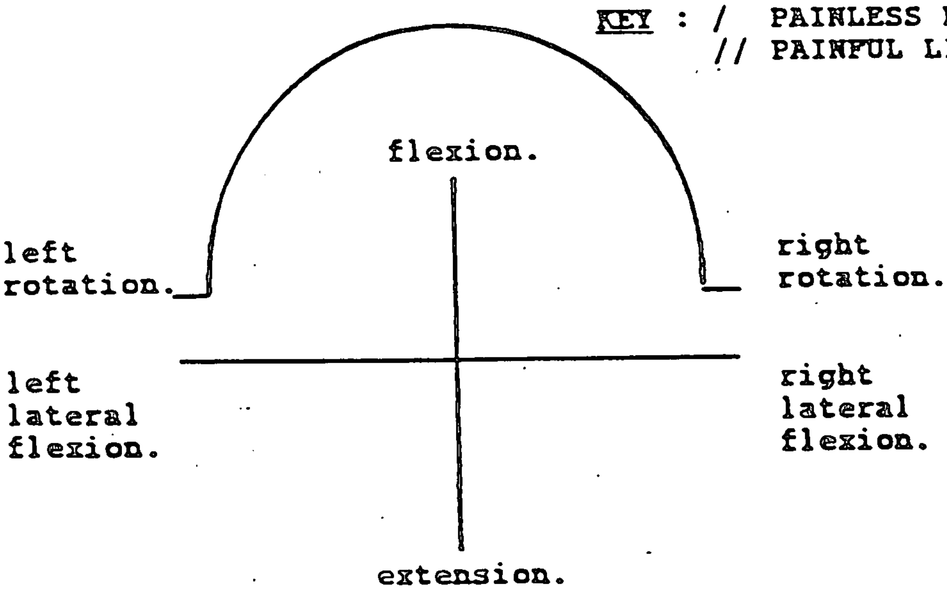
Posture
Swellings
Scars
Discoloration
Hair Line
Bony and soft tissue contours

Shoulder position:
Left =
Right =
Muscle spasm
Facial expression

RANGE OF MOTION:

Flexion = 45 degrees.
Extension = 70 degrees.
L/R Rotation = 70 degrees.
L/R Lateral flexion = 45 degrees.

KEY : / PAINLESS LIMITATION.
// PAINFUL LIMITATION.



PALPATION : lymph nodes.
trachea.
thyroid gland.

ORTHOPAEDIC EXAMINATION :

Tenderness
Active MP Trigger Points :
SCM.
Trapezius.
Scaleni.
Levator Scapulae.
Posterior Cervical musculature.

Doorbell Sign
Kemp's Test
Cervical Distraction
Halstead's Test
Hyperabduction Test (Wright's)
Shoulder abduction Test
Dizziness rotation Test
Brachial Plexus Tension

Cervical Compression
Lateral Compression
Adson's Test
Costoclavicular Test
Eden's (traction) Test
Shoulder depression Test.
Lhermitte's Sign
O'Donoghue Manoeuvre

Remarks : ____

____

____

____

NEUROLOGICAL EXAMINATION :

DERMATOMES: Left	Right.
C2	
C3	
C4	
C5	
C6	
C7	
C8	
T1	

MYOTOMES: Left	Right.
C1	
C2	
C3	
C4	
C5	
C6	
C7	
C8	
T1	

REFLEXES: Left	Right.
C5	
C6	
C7	

VASCULAR :

	LEFT.	RIGHT.
BLOOD PRESSURE.		
CAROTIDS.		
SUBCLAVIAN ARTERIES.		
WALLENBERG'S TEST.		

COMMENTS:

MOTION PALPATION :

Jt.play		Left						Right					Jt.play	
P/A	Lat	Fle	Ext	LF	AR	PR		Fle	Ext	LF	AR	PR	P/A	Lat
							C0							
							C1							
							C2							
							C3							
							C4							
							C5							
							C6							
							C7							
							T1							
							T2							
							T3							
							T4							

INFORMED CONSENT FORM **APPENDIX I**

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

TITLE OF RESEARCH PROJECT

____

____

NAME OF SUPERVISOR

____

NAME OF RESEARCH STUDENT

____

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)