# THE RELATIVE EFFECTIVENESS OF MANIPULATION VERSUS A COMBINATION OF MANIPULATION AND ORAL TRAUMEEL S IN THE TREATMENT OF MECHANICAL NECK PAIN.

Mini-dissertation in partial compliance with the requirements for the Masters Degree in Technology: Chiropractic, in the Department of Chiropractic at the Durban Institute of Technology.

By

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I, Graeme John Harpham, declare that this dissertation represents my own work, both in conception and execution.

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**This dissertation is dedicated to my parents Anne and John for getting me started on this road as well as the rest of my many family and friends who stood by me and supported me through the long years of study.**
**The fruits of labour are finally ripe.**

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## ABSTRACT

According to the recent literature the application of non-steroidal anti-inflammatory drugs (NSAIDS) is the mainstay and first line of conventional treatment for many types of pain, including that of spinal origin (DiPalma and DiGregorio 1994; Dabbs and Lauretti 1995; Koes et al. 1997). NSAID therapy has inherent side effects (Goodman and Simon 1994), however, given the risks involved, they are still of value as an adjunct to spinal manipulation (Crawford 1988), which has been shown to have less side effects and be more effective than conventional NSAIDS (Dabbs and Lauretti 1995; Giles and Müller 1999).

A homeopathic alternative to NSAIDS is Traumeel S, it fulfils all the criteria for a locally acting therapeutic medication, with promotion of the natural healing process, and minimum side effects (Zell et al. 1989). A study by Hepburn (2000) compared the relative efficacy of Traumeel S against NSAIDS in the treatment of cervical facet syndrome. Hepburn concluded that there was statistically no difference between the two therapies. It could therefore be inferred that Traumeel S may be a valid alternative to NSAID therapy in the treatment of cervical facet syndrome. This study tested this hypothesis by comparing the effectiveness of spinal manipulation with the concurrent administration of oral Traumeel S against spinal manipulation alone in order to assess the potential benefit of combining Traumeel S with manipulation.

This double-blinded randomised clinical controlled trial incorporated 38 volunteers that met the inclusion criteria. Each subject was assigned randomly to either the control group (manipulation + placebo) or the experimental group (manipulation +Traumeel S) while maintaining the integrity of the double-blinding. The normal clinical procedure of the DIT Chiropractic Day Clinic was observed. Both subjective and objective measures were taken before treatment at each visit. The subjects were given a total of 4 treatments within a maximum of 3 weeks.

Evaluation of the intra-group statistical results showed that both groups improved in a statistically significant manner ($p<0.001$) in both the NRS pain rating scale and CMCC neck disability index, the CROM (Cervical Range of Motion Instrument) values showed that only flexion and left lateral flexion displayed improvement ($p=0.005$ and $p=0.003$) in both groups. The algometer readings showed no improvement over time in both groups, raising the question of appropriateness of the measurement tool.

Evaluation of the inter-group statistical results showed that the NRS results indicated no treatment effect. The CMCC values showed no interaction between the two groups, however there was evidence that showed that the placebo group was decreasing at a faster rate than the active group, implying that if the study had continued for longer the placebo group could have improved to a greater extent than the active group. The CROM values were mixed, with some directions improving, some staying the same, and some worsening. These results were therefore inconsistent and so are unable to produce any valid conclusions from them. The algometer once again showed no change over time or interaction between time and group implying the apparent inappropriateness the measurement tool.

According to this study, there is no statistical benefit to the addition of Traumeel S oral tablets in the Chiropractic treatment of acute and/or sub-acute mechanical neck pain (or facet syndrome) in terms of objective and subjective findings for a protocol of 4 treatments over a 3 week period.

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# CHAPTER 1 INTRODUCTION

## 1.1 Introduction

According to the recent literature, the application of non-steroidal anti-inflammatory drugs (NSAIDS) is the mainstay and first line of conventional treatment for many types of pain, including that of spinal origin (DiPalma and DiGregorio 1994; Dabbs and Lauretti 1995; Koes et al. 1997).

There is growing concern about the safety of the application of NSAIDS, especially in patients who are not on prescription NSAIDS but on large doses of over-the-counter NSAIDS, which have mostly gastrointestinal side effects (Goodman and Simon 1994). Serious complications occur fairly infrequently as a result of NSAID therapy, however, this being said, it can be shown that an alternative treatment, such as spinal manipulation, has less side effects and is more effective than conventional NSAIDS (Dabbs and Lauretti 1995; Giles and Müller 1999). However, given the risks involved with NSAID therapy they are still of value as an adjunct to spinal manipulation (Crawford 1988).

A homeopathic alternative to NSAIDS is Traumeel S, as it fulfils all the criteria for a locally acting therapeutic medication, which are:

- good analgesic action,
- fast resorption of oedema and haematomas,
- enhancement of microcirculation

with promotion of the natural healing process, and minimum side effects (Zell et al. 1989). Studies using Traumeel S show that it is highly effective for a wide variety of conditions and considered by physicians as necessary in daily practice (Ludwig and Weiser 2001; Zenner and Metelmann 1992; Heel 1986).

A study by Hepburn (2000) compared the relative efficacy of Traumeel S against NSAIDS in the treatment of cervical facet syndrome. Hepburn concluded that

there was statistically no difference between the two therapies, it could therefore be inferred that Traumeel S may be a valid alternative to NSAID therapy in the treatment of cervical facet syndrome.

Giles and Müller (1999) show that spinal manipulation is the most effective method of treating spinal pain on its own. However, the literature suggests that there is benefit in combining manipulation with an “anti-inflammatory type” drug (Serrentino 2003; Oberbaum 1998; Crawford 1988).

This study tested this hypothesis by comparing the effectiveness of spinal manipulation with the concurrent administration of oral Traumeel S against spinal manipulation alone in order to assess the potential benefit of combining Traumeel S with manipulation.

## 1.2 Aim and Objectives

The aim of this study is to investigate the efficacy of spinal manipulation alone versus spinal manipulation with the concurrent administration of oral Traumeel S in patients with mechanical neck pain in terms of objective and subjective clinical findings.

The first objective is to determine the relative effectiveness of spinal manipulation and Traumeel S in terms of subjective pain perception and in terms of objective clinical findings.

The second objective is to determine the relative effectiveness of spinal manipulation and placebo in terms of subjective pain perception and as compared to a spinal manipulation alone in terms of objective clinical findings.

# CHAPTER 2 REVIEW OF THE RELATED LITERATURE

## 2.1 Epidemiology

An epidemiological study was conducted by Drews (1995) on patients with pain of cervical origin, using information from 162 new patents at the Durban Institute of Technology Chiropractic Clinic over a three month period. The results showed that 16.7% presented with neck pain, 21.6 % with neck pain and headache, and 16.1% presented with neck pain and arm pain. Grieve (1988) reported that the prevalence of neck pain among 2500 randomly selected men and women was 16% and 20% respectively. Neck pain is costly in terms of treatment, individual suffering and time lost from work (Jordan et al 1998). One particular study showed that 5% of industrial workers were unable to work due to neck pain (Grieve 1988). Lawrence (1969) found that at any one time 12% of adult females and 9% of adult males were suffering from neck pain and that 35% of the general population can remember having had neck pain at some time.

## 2.2 Functional Anatomy of the Cervical Spine

The cervical spine can be divided into two anatomically and biomechanically distinct sections, the lower cervical spine incorporating C3 to C7 and the upper cervical spine comprising C1 and C2 (Haldeman 1992; Reid 1992).

### 2.2.1 Lower Cervical Spine

The region from C3 to C7 basically resembles the architecture of the rest of the spinal column. These vertebrae are small, with broad bodies that are slightly raised laterally, forming uncinate processes on the upper surfaces. As in other regions of the spine, the vertebral bodies gradually increase in size down to C7 which is in response to the increase in weight-bearing load. The posterior arches are sloped backward and enclose a relatively large triangular shaped vertebral

foramen. Perforating each transverse process is a transverse foramen, through which pass the vertebral artery (except at C7), the vertebral veins, and the sympathetic nerves. The articular processes are stacked laterally on the bodies in the form of pillars, on which the facet joints (or zygapophyseal joints) are located. These facet joints are almost flat, and orientated in a plane at about 45 degrees to the horizontal and 90 degrees to the midline, the angle of inclination to the horizontal plane however increases from the lower to the upper cervical spine. Although the facet joints are relatively large in area compared to the intervertebral disc, they are not primarily weight-bearing joints. The joint capsules are lax and richly innervated which is associated with a greater degree of kinaesthetic sense for the cervical region. (Windsor 2004; Porterfield and DeRosa 1995; Haldeman 1992)

### 2.2.2 Upper Cervical Spine

The upper cervical spine (or occipitoatlantoaxial complex) consists of the occiput, the atlas (C1), and the axis (C2) and the unique architecture of the complex is directly related to its biomechanical function. The axis has a vertically orientated peg-like projection called the dens (or odontoid process), onto which the ring-like atlas is eccentrically mounted via a midline synovial articulation between the anterior arch of the atlas and the dens and re-enforced by the transverse ligament. The rotation of the atlas around the dens is responsible for the exceptional axial range of motion of the cervical spine. Bony masses on the lateral aspects of the atlas form the articulations between the occiput and the axis. The superior facets of the atlas are ellipsoid in shape and are cupped congruently to the occipital condyles and produce a predominately biaxial direction of movement, the inferior facets tend to be mildly convex in the anteroposterior direction and mildly concave in the mediolateral direction and face inferior and medially to the corresponding facets of C2. The inferior aspect of C2 resembles a typical cervical vertebra in appearance and articulation. (Windsor 2004; Porterfield and DeRosa 1995; Haldeman 1992)

### 2.2.3 Innervation

The fibrous capsules of the synovial facet joints contain more mechanoreceptors (type I, II, and III) than in the lumbar spine as well as free nerve endings. This neural input from the facet joints may be important for proprioception and pain sensation and may modulate protective muscular reflexes. The facet joints are innervated by both the anterior and ventral dorsal rami. C0-C1 and C1-C2 joints are innervated by the ventral rami of the 1st and 2nd cervical spinal nerves, two branches of the 3rd cervical spinal nerve dorsal ramus innervate C2-C3 facet joint, while the remaining cervical facet joints (C3-C4 to C7-T1) are supplied by the dorsal rami medial branches one level above and below the joint. These medial branches send off articular branches to the facet joints as they wrap around the waists of the articular pillars. Any pain sensations that one might experience are sent to the brain via the spinal cord by unmyelinated C fibres, and to a lesser extent by myelinated A-delta fibres, these fibres are mainly present in the medial branch of the posterior primary rami of the spinal nerves. (Windsor 2004; Haldeman 1992)

### 2.2.4 Ligamentous Stability

The anterior longitudinal ligament (ALL) and the posterior longitudinal ligament (PLL) are the major stabilisers of the intervertebral joints. Both ligaments are found throughout the length of the spine, however, the ALL is closely adhered to the intervertebral discs while the PLL is not well developed in the cervical spine. The ALL becomes the anterior atlantooccipital membrane at the level of the axis, while the PLL merges with the tectorial membrane. Both ligaments continue onto the occiput. (Windsor 2004; Porterfield and DeRosa 1995)

The supraspinous ligament, interspinous ligament, and ligamentum flavum maintain the stability between the vertebral arches. The supraspinous ligament runs along the tips of the spinous processes, the interspinous ligament runs between the spinous processes, and the ligamentum flavum runs from the anterior surface of the cephalad lamina to the posterior surface of the caudad

lamina. The interspinous ligament and especially the ligamentum flavum control excessive flexion and anterior translation. The ligamentum flavum also connects to and re-enforces the facet joint capsules on the ventral aspect. The ligamentum nuchae is the cephalad continuation of the supraspinous ligament and has a prominent role in stabilising the cervical spine. (Windsor 2004; Porterfeild and DeRosa 1995)

### 2.2.5 Cervical Range of Motion

The types of motion present in the cervical spine are flexion, extension, lateral flexion (lateral bending), and rotation. The cervical spine is most flexible in flexion and rotation, which occur most freely in the upper cervical area and get progressively more restricted towards the lower levels. Cervical motion, however, hardly ever happens in isolation, it is always coupled with another motion. Rotation around the Y axis is coupled to rotation around the Z axis and vice versa (i.e. lateral flexion is coupled to rotation) (Schafer and Faye 1990).

Haldeman (1992), states that, for the cervical spine, the approximate normal values for extension are between 30° and 40°, 45° of flexion, between 30° and 45° of lateral flexion to the left and right, and 60° - 90° of rotation to each side.

## 2.3 Mechanical Neck Pain

Patients that present with mechanical neck pain complain of neck pain, headaches, and limited range of motion. The pain is described as a dull aching discomfort in the posterior neck that sometimes radiates to the shoulder or mid back regions (Windsor 2004; Reid 1992).

Clinical features that often are associated with cervical facet pain include tenderness to palpation over the facets or paraspinal muscles, pain with extension and/or rotation, and absent neurological abnormalities (Windsor 2004). Schafer and Faye (1990) also include the presence of asymmetries or mis-alignments that are observed or palpated statically, abnormalities in range of

motion detected through motion palpation, and special orthopaedic tests. Signs of cervical spondylosis, narrowing of the intervertebral foramina, osteophytes, and other degenerative changes are present equally in people with and without neck pain (Windsor 2004).

A study by Bogduk and Marsland (1988) attempted to determine if the facet joints in patients without objective neurological signs were the primary source of their neck pain. Those with lower cervical spine pain underwent C5 and C6 medial branch blocks first (using bupivacaine), if they did not find relief then the adjacent levels were blocked until the pain was relieved. Those that had upper neck pain underwent third occipital nerve blocks, and C3 and C4 if necessary. Fifteen out of twenty four patients had complete relief of their neck pain, and repeat blocks had the same effect. No clinical or radiological features corresponded with the positive responses. This finding suggests that facet joints in the cervical spine can be a significant source of neck pain.

According to Strasser (2004) the causes of mechanical neck pain include activities and events that influence cervical biomechanics such as extended sitting, repetitive movement, accidents, falls and blows to the body or head, normal aging and everyday wear and tear.

## 2.4 Chiropractic Treatment of Mechanical Neck Pain

### 2.4.1 Spinal manipulation

Haldeman (1992) defines spinal manipulative therapy as “all procedures where the hands are used to mobilise, adjust, stimulate or otherwise influence the spinal and paraspinal tissues with the aim of influencing the patient’s health”. Chiropractors seek out areas in the cervical spine that have decreased movement that are associated with neck pain using palpation. Once found, the affected joint/s are treated via manipulation to release the joint and restore movement. The Chiropractic adjustment is an effective way of providing the force necessary to facilitate the restoration of this movement (Schafer and Faye 1990). Cassidy et al. (1992) describes the adjustment as a high velocity, low

amplitude thrust directed beyond the passive range of motion of the spine and associated with an audible ‘crack’ caused by the cavitation of the underlying facet joint.

Sandoz (1976) states that a Chiropractic adjustment is a passive manual manoeuvre during which the three-joint-complex (intervertebral disc and facet joints) is suddenly carried beyond the normal physiological range of movement without exceeding the boundaries of anatomical integrity.

### 2.4.2 Effectiveness of Spinal Manipulation in the Management of Neck Pain

Cassidy et al. (1992) produced a study in which 100 patients were either given a spinal manipulation or mobilisation technique to treat mechanical neck pain. It was determined that a single manipulation is more effective than mobilisation in decreasing pain in patients with mechanical neck pain, although both treatments did increase range of motion in the neck to similar degrees.

A study by Vernon et al. (1990) examined the effect of cervical manipulation versus mobilisation on pressure pain threshold in the cervical spine measured 5 minutes after the intervention. Of the two methods used, manipulation produced significantly higher increases in the pressure pain threshold.

Yeomans (1992) assessed the cervical intersegmental mobility before and after manipulative therapy. Two systems of mensuration were utilised in 58 case studies. The results revealed that the post-manipulative mobility is significantly greater than the pre-manipulative data with the exception of the C1 segment of both male and female treatment groups.

### 2.4.3 Risks of Spinal Manipulation

The most significant risk to spinal manipulation that has caught the media's attention is the risk of stroke following manipulation. The literature, however, agrees that the risk of stoke is 1 to 3 incidents per 100,000 treatments in patients receiving a course of treatments per year, or 0.001% (Dabbs and Lauretti 1995). The estimated risk of death following spinal manipulation is 1 death per 400,000 patients receiving a course of treatments per year, or 0.00025% (Dabbs and Lauretti 1995).

Manipulation is well tolerated in the healthy spine, however pathological conditions already present in the spine can lead to a risk of complication. Such conditions include infective processes, inflammatory processes such as Rheumatoid arthritis, metabolic disturbances such as osteoporosis, congenital defects or malformations, severe trauma, and neoplasia (Haldeman 1992).

## 2.5 Treatment Alternatives

According to the recent literature the application of non-steroidal anti-inflammatory drugs (NSAIDS) is the mainstay and first line of conventional treatment for many types of pain, including that of spinal origin (DiPalma and DiGregorio 1994; Dabbs and Lauretti 1995; Koes et al. 1997). A meta-analysis of 26 published randomised clinical trials evaluating NSAIDS for low back pain showed that they are effective in providing short-term relief from uncomplicated low back pain, however are less effective in patients with sciatica and/or nerve root symptoms (Koes et al. 1997). This treatment is also used to treat neck pain (DiPalma and DiGregorio 1994; Dabbs and Lauretti 1995). Other treatment alternatives include other forms of physical therapy including mobilisation, soft tissue therapy, stretching, and ultra-sound therapy; inter-articular facet joint injection; medial branch blocks; percutaneous radiofrequency neurotomy; and surgical intervention such as fusion (Windsor 2004).

## 2.6 Safety

There is growing concern about the safety of the application of NSAIDS, especially in patients who are not on prescription NSAIDS but on large doses of over-the-counter NSAIDS possibly on the recommendation (but not prescription) of their chiropractor, physiotherapist, or other therapist (Goodman and Simon 1994). The side effects of NSAIDS are documented as being particularly harsh on the gastrointestinal tract, predisposing to ulceration and bleeding from the GIT possibly leading to abdominal pain, diarrhoea and possibly death (Goodman and Simon 1994). Other side effects include renal injury and possible renal failure, interference with anti-hypertensive drugs, CNS effects such as aseptic meningitis, psychosis, cognitive dysfunction, dizziness and headache, effects on the foetus during pregnancy, anti-platelet activity, oedema, dry mouth, rash and tiredness (Goodman and Simon 1994; Koes et al. 1997).

It however, must be noted that the risks of serious complications following NSAID therapy are only minimal, but alternative treatment such as chiropractic spinal manipulation still has less side effects (Dabbs and Lauretti 1995) and is more effective (Giles and Müller 1999) than NSAID therapy.

Given the risks involved, NSAID therapy is still of value as an adjunct to spinal manipulation due to its anti-inflammatory effects. The value of NSAID's was established by inducing inflammatory reactions and controls in laboratory rabbits and then treating the lesions with NSAID's, it demonstrated the value of applying NSAID's topically when conservatively managing an acute patient (Crawford 1988). Studies by the Medical Scientific Department at Biologische Heilmittel Heel GmbH in Germany (1986) on Traumeel S however, display a side effect rate of only 130 out of 3,651,580 cases (0.0035%), all of which could be classified as allergic reactions.

## 2.7 Basic Principles of Homeopathy

Homeopathy is a self-consistent scientific system of medical therapy, which was founded by Christian Friedrich Samuel Hahnemann in 1796. It is based on the observed biological fact that if a disease process disturbs an organism's bio-energetic state, it can be predictably restored to normal by specially prepared medicinal stimuli that need only be administered in small doses, or more often in sub-physiological deconstructions to which the body has an altered receptivity to (Gaier 1991). This receptivity occurs provided that, in a healthy organism the medical agents chosen would produce symptoms and clinical features like those of the disease, and that obstacles to cure have been removed (Gaier 1991).

There are three main principles that feature in Homeopathy, the first is "Like Cures Like" which is also known as the Law of Similars which implies a match between the primary symptoms of the remedy and the symptoms of the patient. An example of this would be the remedy for stings and histamine reactions being derived from bees (Apis), or the remedy for insomnia being derived from the green coffee bean (Coffea) (Kayne 1997).

The principle of "Minimal Dose" is quite unique to homeopathy, remedies are diluted down to various degrees of dilution depending on the condition being treated, acute conditions are treated using dilutions right down to 1 in $10^{60}$ and even further, due to the fact that the potency of the remedies are increased, this dilution process is called 'potentisation'. However, different conditions require different potencies to be effective, therefore only the minimal amount of the remedy that is effective is used in treatment (Kayne 1997).

The 'Single Remedy' principle comes from the belief that Hahnemann had that the body could not suffer from more than one disease at a time, and that any and all diverse symptoms were linked to a single cause or disease process, Hahnemann therefore believed that only one simple remedy was all the treatment necessary to provide relief (Kayne 1997).

It has been found through clinical experience that some homeopathic remedies can be mixed together and administered successfully as a complex, breaking away from the 'Single Remedy' philosophy. Traumeel S is such a complex. Complex remedies can be administered if the prescriber is unsure of which remedy is the most appropriate, thereby increasing the chance of a correct prescription. Complexes are also used to address multiple symptoms of a single condition at the same time which saves time and is more convenient (Kayne 1997).

## 2.8 Traumeel S

### 2.8.1 Therapeutic Criteria

A homeopathic alternative to NSAIDS is Traumeel S, it fulfils all the criteria for a locally acting therapeutic medication, which are:

- ❖ good analgesic action,
- ❖ fast resorption of oedema and haematomas,
- ❖ enhancement of microcirculation

with promotion of the natural healing process, and a minimum of side effects (Zell et al. 1989), but uses a completely different method of action (Conforti et al. 1997).

### 2.8.2 Method of Action

Research by Conforti et al (1997) suggests that the anti-inflammatory effects of Traumeel S are not due to its action on a specific cell-type of immunomodulation cell (e.g. on granulocytes) or due to a biochemical mechanism (e.g. platelet activity) associated with conventional anti-inflammatory drugs. Instead, Traumeel S appears to inhibit the acute neurogenic mechanisms of inflammation at a local level, regulated by the release of neuropeptides by sensitive nerve endings.

### 2.8.3 Components of Traumeel S

Traumeel S is a homeopathic complex that is available in various dosage forms (such as drops, tablets, injection solution, and ointment), with the function of each of the ingredients of Traumeel S being:

- Enhancement of wound healing following blows, falls and contusions – *Arnica montana*, *Calendula officinalis* and *Symphytum officinale*.
- Analgesic effects – *Aconitum napellus*, *Arnica montana*, *Matricaria Chamomilla*, *Hamamelis virginiana*, *Hypericum perforatum*, and *Bellis perennis*.
- Haemostatic effects – *Aconitum napellus*, *Arnica montana*, *Hamamelis virginiana* (venous bleeding), and *Achillea Millefolium* (arterial bleeding) and *Hepar sulfuris calcareum* ("sealing" of blood vessels).
- Anti-inflammation and anti-viral – *Mercurius solubilis Hahnemanni*.
- Stimulation of body defence mechanisms – *Echinacea purpurea* and *Echinacea angustifolia*.
- All rubor (redness), tumor (swelling), calor (temperature changes), and dolor (pain) symptoms which are the features of inflammation – *Atropa Belladonna*.

(Stock 1988)

### 2.8.4 Indications and Side Effects

The main indications for the application of Traumeel S are trauma and injury, inflammation and soft tissue swelling, to increase the non-specific defence mechanism, as well as degenerative processes and arthroses (Oberbaum 1998; Heel 1986). The preparation has no known toxic side effects because its ingredients are diluted by several orders of magnitude below toxic levels (Oberbaum 1998). It should, however, be noted that an increased flow of saliva may occur after taking this medication and hypersensitivity reactions may occur in individual cases (Biotherapeutic Index 2003). There is substantial anecdotal evidence that the administration of *Arnica montana* in low homeopathic potencies (e.g. 6CH or lower) may induce the extravasation of blood instead of producing

the required effect of reducing the extravasation (Hopkins 2003). The following reactions have been recorded as potential side-effects in patients taking preparations containing *Rudbeckia* (*Echinacea*): rashes, itching, facial swelling (rare), acute respiratory distress, vertigo, and acute hypotension (Biotherapeutic Index 2003).

## 2.9 Efficacy

A study by Hepburn (2000) compared the relative efficacy of Traumeel S against NSAIDS in the treatment of cervical facet syndrome, the study involved a double-blind, comparative, clinical trial using 50 consecutive patients at the Durban Institute of Technology Chiropractic Clinic divided into two groups, and concluded that there was statistically no difference between the two therapies. However both groups did improve significantly. It could therefore be inferred that Traumeel S is a reasonable substitute to NSAID therapy in the treatment of cervical facet syndrome according to his research.

Treatment using Traumeel S for such conditions as arthosis, myogelosis, sprains, periarthropathia humeroscapularis, epicondylitis, tendovaginitis, and others, showed that 78.6% of patients had complete and long-term relief from complaints or definite long-term improvement, 17.8% improved for a limited amount of time, 3.5% showed no change, and 0.1% worstened (Zenner and Metelmann 1992). Similarly, pediatric (0-12 year old children) injuries treated with Traumeel S ointment rated 97% of patients as “good” or “very good” results, regardless of age or symptoms (Ludwig and Weiser 2001). Heel (1986) conducted a survey of 3030 physicians of various disciplines of whom 2859 (94.3%) considered Traumeel S to be necessary in their daily practice.

Giles and Müller (1999) showed that spinal manipulation on its own is the most effective method of treating spinal pain. The literature also seems to indicate Traumeel S as the drug of choice over (or in conjuction with) NSAIDS as an adjunct to spinal manipulation for neck pain due to its lack of side effects and comparable anti-inflammatory action (Serrentino 2003; Oberbaum 1998).

## 2.10 Hypothesis

Therefore, this study aims to test this hypothesis by comparing the effectiveness of spinal manipulation with the concurrent administration of oral Traumeel S in patients with mechanical neck pain and spinal manipulation along with placebo. This would distinguish how much spinal manipulation would be enhanced as an intervention by the addition of Traumeel S.

# CHAPTER 3 MATERIALS AND METHODS

## 3.1 Research Design

The study design chosen was that of a double-blind, comparative, clinical trial that involved two treatment groups, both groups received spinal manipulation with each group receiving either a homeopathic remedy (Traumeel S) or placebo remedy respectively.

## 3.2 Advertising

This study was limited to patients from the province of Kwa-Zulu Natal who were informed of the research by advertisements at the Durban Institute of Technology Chiropractic Clinic as well as other regional meeting places and newspapers.

## 3.3 Sampling

Convenience sampling was utilized for the first 44 subjects who met the inclusion criteria, there were however 6 drop-outs during the course of the study which therefore reduced the sample size to 38.

## 3.4 Double blinding and randomisation

To ensure double-blinding during the study, the boxes containing the active / placebo tablets were identical except for a unique identification number which eventually indicated whether the contents were active (Experimental group) or placebo (Control group). The list that highlighted which number corresponded to which group was held in the offices of Heel SA. The boxes were stored at the Durban Institute of Technology Chiropractic Clinic mixed together in one large container. As the subjects presented themselves, they were assigned one of the treatment boxes in no particular order.

## 3.5 Clinical procedure

All patients were required to read and sign a letter of information **(Appendix A)** and an informed consent **(Appendix B)** form to protect their interests and to make sure they understood the research completely. All potential patients underwent a medical history **(Appendix C)**, physical examination **(Appendix D)**, and a cervical spine regional orthopaedic examination **(Appendix E)**.

### 3.5.1 Inclusion criteria

- Only patients between the age of 18 and 55 were accepted.
- Only acute or sub-acute cases were accepted, defined as the onset being no longer than two weeks before the start of the trial (acute exacerbations of chronic conditions were also accepted).
- Patients were accepted displaying signs and symptoms of mechanical neck pain / cervical facet syndrome being:
    1. Pain / tenderness over the osseous and soft tissue area.
    2. Asymmetry / misalignment qualities identified through observation and static palpation.
    3. Abnormal range of motion detected actively and through motion palpation.
    4. Tissue tone difference over the area of dysfunction detected through palpation.
    5. Special orthopaedic tests (see cervical regional)

(Schafer and Faye 1990)

### 3.5.2 Exclusion criteria

- Patients were excluded showing any contraindications to spinal manipulation being:
    1. Presence of vertebral basilar artery insufficiency syndrome (positive Wallenberg's test).

2. History of positional vertigo, arteriosclerosis, transient ischemic attacks, hyper- or hypotension, cardiovascular disease, diabetes, and medications such as anticoagulants that would predispose to vascular insult.
3. Presence of spinal tumours.
4. Presence of bone infections.
5. Presence of recent traumatic injuries (i.e. Whiplash)
6. History of Rheumatoid Arthritis or other arthritides.
7. Presence of neurological symptoms such as headaches, visual disturbances, drop attacks, transient weakness in the legs, and family history of stroke.

(Gatterman 1990; Bergmann 1993)

- Patients were excluded showing any contraindications to Traumeel S.
    1. Hypersensitivity or anaphylactic reaction to one of the active ingredients of Traumeel S.
    2. Presence of progressive systemic disease such as…

        Tuberculosis
        Leukoses
        Collagen disorders
        Multiple sclerosis
        AIDS / HIV infection, and other autoimmune disorders.

        (Biotherapeutic Index 2003)
- Patients were also excluded that were suffering from gastritis or any other gastric related illness.
- Patients were not to have any other form of treatment for their neck pain during the trial period.

### 3.5.3 Interventions

The Control group received spinal manipulation with the addition of placebo oral tablets, while the Experiment group received spinal manipulation with the addition of Traumeel S oral tablets. To ensure double blinding, the researcher

was kept unaware of which numbers were correlated with which group (as explained above).

The spinal manipulation was administered to which ever level, in which ever direction was indicated via motion palpation (Haldeman 1992) of the subject's cervical spine during the regional orthopaedic examination. The manipulation technique applied to the subjects of this study was according to the Diversified Technique, as described by Haldeman (1992).

Each subject received three (3) treatments over a period of two weeks with a follow up visit after a further week to collect the final data (i.e. four appointments were made).

### 3.5.4 Measurement Instrumentation

Subjective data collection tools were:

- The CMCC Neck Disability Index, which has been shown to have a high degree of validity and test-retest reliability (Vernon and Mior 1991).
- The Numerical Pain Rating Scale – 101. The validity and practicality has been demonstrated by Jensen et al. (1986).

Objective data collection tools were:

- (CROM) Cervical Range of Motion Instrument (Performance Attainment Associates; Patient no. 4,777,965 & 4,928,709) - . This device has been shown to display good intra and inter examiner reliability in measuring cervical ranges of motion (Youdas 1991).
- Pressure algometer - Wagner FDK20 Force Dial (Wagner Instuments, P.O. Box 1217, Greenwich, CT, 06836, U.S.A.). The device was placed over the area of greatest perceived tenderness to the patient. Fischer (1987) showed that the algometer demonstrated good reliability.

### 3.5.5 Data collection

The data was collected before treatment on each visit. The subjective data that was collected was the CMCC Neck Disability Index and the Numerical Pain Rating Scale – 101. The objective data that was collected was the cervical range of motion, and pressure algometer readings.

## 3.6 Statistical procedure

Data was captured in MS Excel and exported into SPSS version 11.5 (SPSS Inc. Chicago, Ill) for analysis.

Intra-group analysis involved description of the outcome measurements over the four time points in each group graphically by means of box and whisker plots. Statistical testing for a time change within each group was achieved with the Friedman test.

Quantitative variables were checked for departure from normality using the skewness statistic. Inter-group analysis was performed with repeated measures ANOVA (analysis of variance) to test three hypotheses simultaneously on each outcome measurement between the within-subjects effects of time and the between-subjects effects of treatment group:

1.) the effect of time
2.) the effect of group and
3.) the time by group interaction (the treatment effect).

Profile plots of estimated marginal means were done for each outcome showing group by time to assist in interpretation of the ANOVA results. There was no missing data.

Hypothesis testing decision rule: a two tailed p value of $<0.05$ was considered statistically significant.

# CHAPTER 4 THE RESULTS

## 4.1 Intra-group Analysis

### 4.1.1 Active Group

**Subjective measurements:**

Figure 1 and Table 1 show the distributions of NRS and CMCC measurements in the active group over the four time points. NRS measurements decreased over time until the 3rd visit, where after the measurements increased slightly. CMCC measurements showed a steady decrease over the 4 time points. Table 2 shows the results of the Friedman test to assess whether the change over time was significant. For both NRS and CMCC there was a highly significant change over time ($p<0.001$) (Tables 2 and 3).

**Table 1: Distribution of subjective measurement scores over time in the active treatment group**

| | TIME | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | |
| | Median | Range | Median | Range | Median | Range | Median | Range |
| NRS | 45 | 59 | 23 | 74 | 10 | 68 | 18 | 58 |
| CMCC | 20 | 50 | 10 | 46 | 8 | 22 | 6 | 24 |

**Table 2: Friedman Test Statistics for NRS in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 30.737 |
| df | 3 |
| Asymp. Sig. | <0.001 |

a Friedman Test

**Table 3: Friedman Test Statistics for CMCC in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 31.246 |
| df | 3 |
| Asymp. Sig. | <0.001 |

a Friedman Test

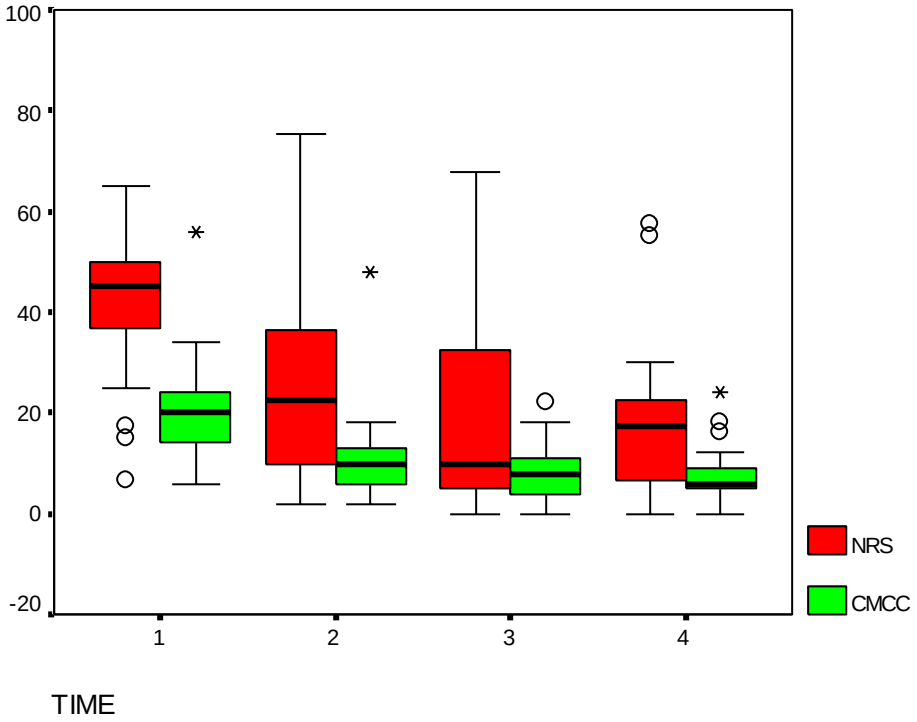


**Figure 1: box and whisker plot of subjective measurements over time in active treatment group**

**Objective measurements:**

Flexion increased significantly over time in the active group (p = 0.005) as did left lateral flexion (p =0.003), while extension, right lateral flexion, right and left rotation and algometer readings did not show a significant change over time. This is reflected in Figures 2 and 3.

**Table 4: Distribution of objective measurement scores over time in the active treatment group**

| | TIME | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | |
| | Median | Range | Median | Range | Median | Range | Median | Range |
| FLEX | 50 | 56 | 56 | 50 | 56 | 44 | 60 | 50 |
| EXT | 50 | 36 | 50 | 46 | 52 | 46 | 52 | 52 |
| RIGHT LAT | 36 | 34 | 34 | 36 | 36 | 34 | 38 | 34 |
| LEFT LAT | 36 | 36 | 40 | 34 | 38 | 52 | 38 | 32 |
| RIGHT ROT | 66 | 42 | 62 | 42 | 62 | 30 | 68 | 40 |
| LEFT ROT | 60 | 38 | 62 | 44 | 64 | 28 | 68 | 36 |
| ALGOMETER | 1.6 | 3.6 | 1.4 | 3.7 | 1.4 | 2.0 | 1.4 | 2.2 |

**Table 5: Friedman Test Statistics for Flexion in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 12.898 |
| df | 3 |
| Asymp. Sig. | .005 |

a Friedman Test

**Table 6: Friedman Test Statistics for Extension in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 5.029 |
| df | 3 |
| Asymp. Sig. | .170 |

a Friedman Test

**Table 7: Friedman Test Statistics for Right Lateral flexion in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 1.044 |
| df | 3 |
| Asymp. Sig. | .791 |

a Friedman Test

**Table 8: Friedman Test Statistics for Left Lateral flexion in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 13.776 |
| df | 3 |
| Asymp. Sig. | .003 |

a Friedman Test

**Table 9: Friedman Test Statistics for Right Rotation in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 7.400 |
| df | 3 |
| Asymp. Sig. | .060 |

a Friedman Test

**Table 10: Friedman Test Statistics for Left Rotation in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 3.317 |
| df | 3 |
| Asymp. Sig. | .345 |

a Friedman Test

**Table 11: Friedman Test Statistics for Algometer in the active group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 3.309 |
| df | 3 |
| Asymp. Sig. | .346 |

a Friedman Test

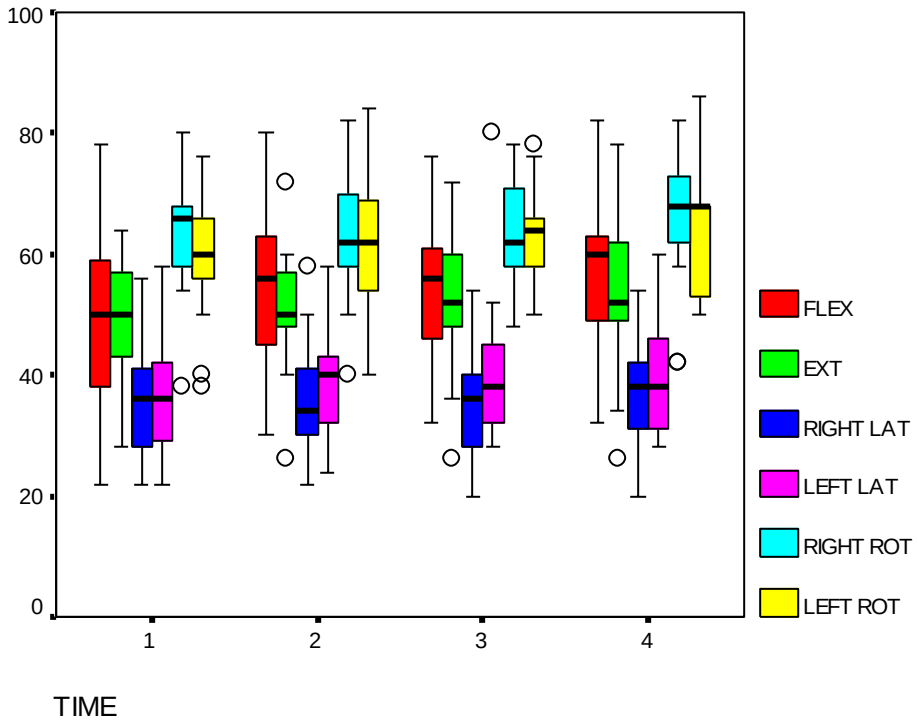


**Figure 2: box and whisker plot of objective CROM measurements over time in active treatment group**

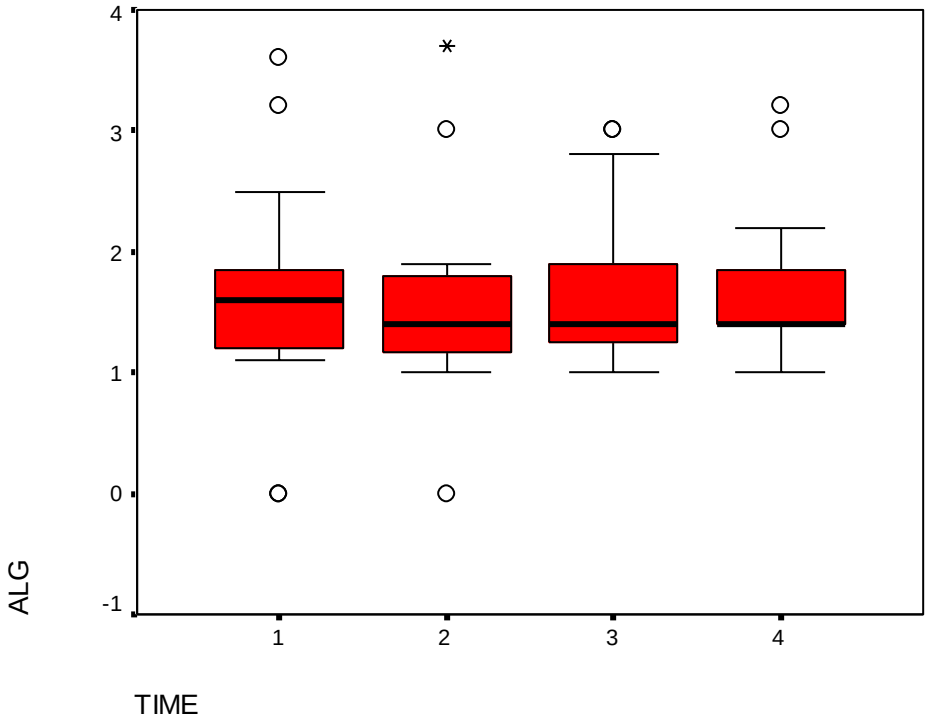


**Figure 3: box and whisker plot of algometer measurements over time in the active treatment group**

### 4.1.2 Placebo Group

**Subjective measurements:**

There was a highly significant decrease over time in the placebo group for NRS ($p<0.001$) and CMCC ($p<0.001$) (see Tables 12-14). This is also shown graphically in Figure 4.

**Table 12: Distribution of subjective measurement scores over time in the placebo treatment group**

| | TIME | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | |
| | Median | Range | Median | Range | Median | Range | Median | Range |
| NRS | 50 | 63 | 30 | 78 | 35 | 58 | 25 | 48 |
| CMCC | 24 | 46 | 14 | 42 | 12 | 26 | 6 | 24 |

**Table 13: Friedman test statistics for NRS in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 34.110 |
| df | 3 |
| Asymp. Sig. | <0.001 |

a Friedman Test

**Table 14: Friedman test statistics for CMCC in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 41.221 |
| df | 3 |
| Asymp. Sig. | <0.001 |

a Friedman Test

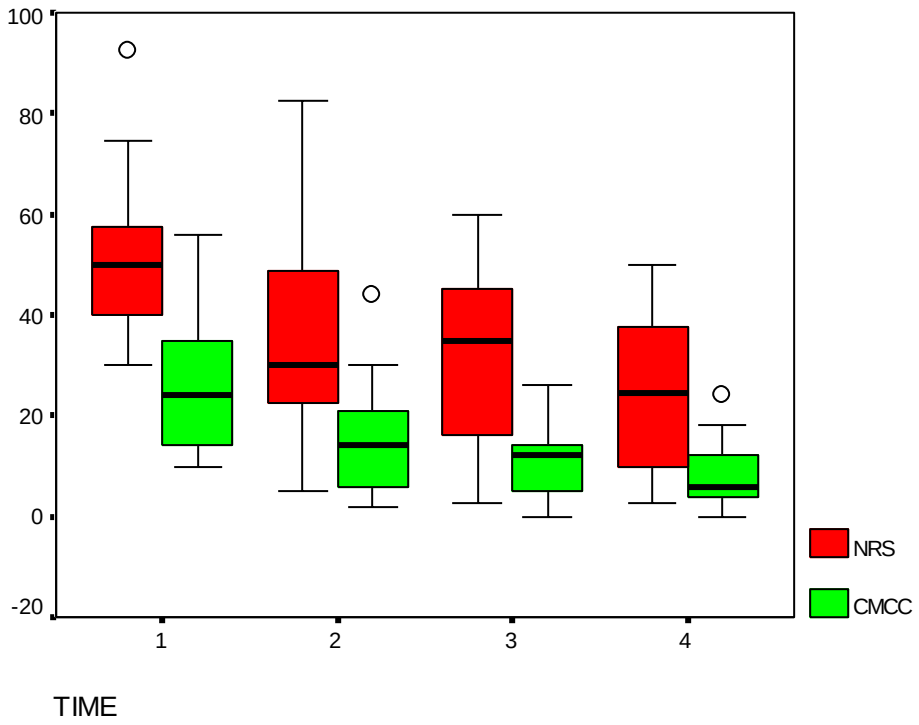


**Figure 4: box and whisker plot of subjective measurements over time in the placebo group**

### Objective measurements:

Flexion and left lateral flexion increased significantly over time in the placebo group. The other measurements did not show a significant change over time. This is reflected in Figures 5 and 6.

**Table 15: Distribution of objective measurement scores over time in the placebo treatment group**

| | TIME | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | |
| | Median | Range | Median | Range | Median | Range | Median | Range |
| FLEX | 54 | 42 | 50 | 50 | 58 | 46 | 60 | 30 |
| EXT | 58 | 54 | 58 | 50 | 62 | 64 | 62 | 54 |
| RIGHT LAT | 36 | 46 | 40 | 38 | 40 | 50 | 40 | 54 |
| LEFT LAT | 36 | 48 | 40 | 30 | 44 | 34 | 42 | 36 |
| RIGHT ROT | 64 | 44 | 70 | 64 | 68 | 52 | 68 | 38 |
| LEFT ROT | 66 | 38 | 68 | 36 | 68 | 44 | 70 | 40 |
| ALGOMETER | 1.6 | 5.2 | 1.5 | 6.5 | 1.5 | 4.5 | 1.5 | 4.0 |

**Table 16: Friedman test statistics for Flex in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 7.950 |
| df | 3 |
| Asymp. Sig. | .047 |

a Friedman Test

**Table 17: Friedman test statistics for Ext in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 6.348 |
| df | 3 |
| Asymp. Sig. | .096 |

a Friedman Test

**Table 18: Friedman test statistics for Right Lat in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 3.972 |
| df | 3 |
| Asymp. Sig. | .265 |

a Friedman Test

**Table 19: Friedman test statistics for Left Lat in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 8.380 |
| df | 3 |
| Asymp. Sig. | .039 |

a Friedman Test

**Table 20: Friedman test statistics for Right Rot in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 2.809 |
| df | 3 |
| Asymp. Sig. | .422 |

a Friedman Test

**Table 21: Friedman test statistics for Left Rot in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | 5.434 |
| df | 3 |
| Asymp. Sig. | .143 |

a Friedman Test

**Table 22: Friedman test statistics for Algometer in the placebo group**

| | |
|---|---|
| N | 19 |
| Chi-Square | .711 |
| df | 3 |
| Asymp. Sig. | .871 |

a Friedman Test

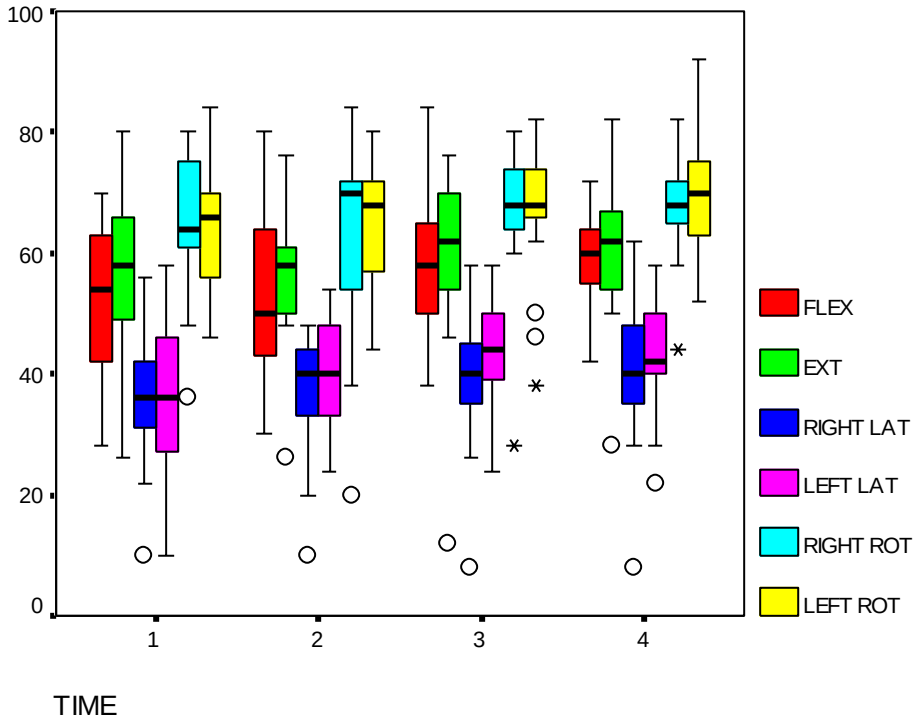


**Figure 5: box and whisker plot of objective CROM measurements over time in placebo treatment group**

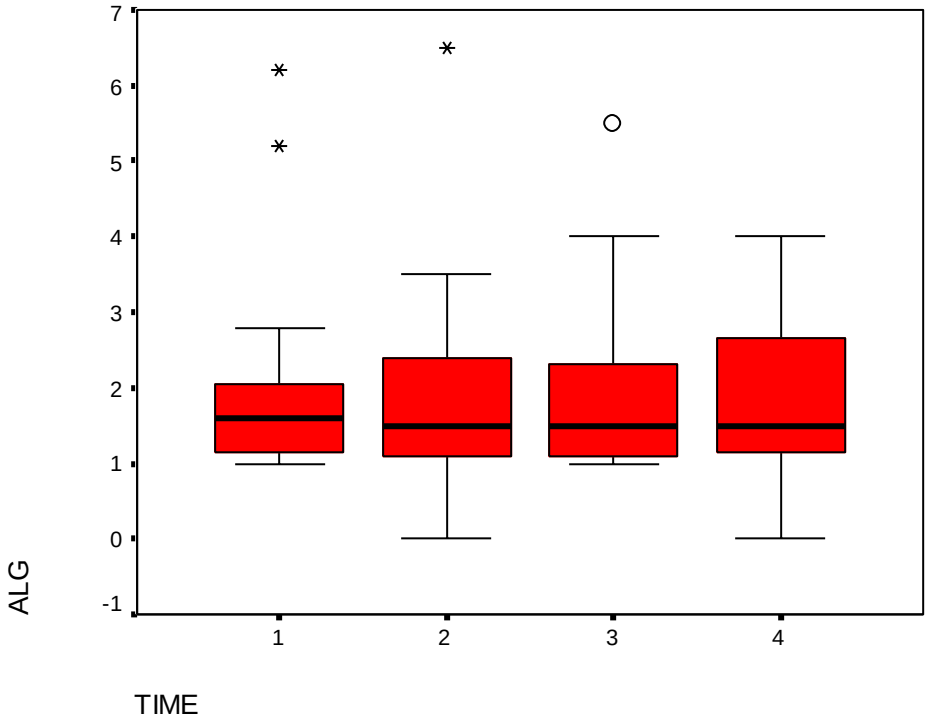


**Figure 6: box and whisker plot of algometer measurements over time in the placebo treatment group**

## 4.2 Inter-group Analysis

### 4.2.1 Objective Measurements

**Flexion:**

There was a significant effect of time overall (p = 0.003) in both groups. There was no difference between the groups nor interaction between time and group. Thus the treatment had no different effect on flexion than the placebo. This is better explained by the profile plot in Figure 7, which shows that both groups increased at a similar rate over time.

**Table 23: Hypothesis tests for repeated measures ANOVA for Flexion**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.667 | 0.003 |
| Group | F=0.193 | 0.663 |
| Time*group | Wilk's lambda 0.939 | 0.539 |

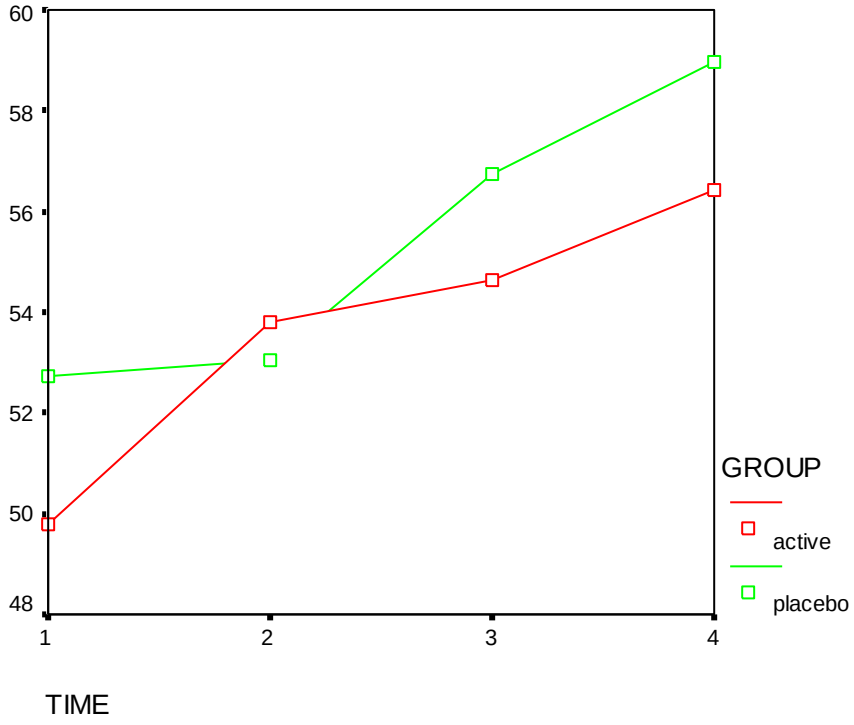


**Figure 7: profile plot of mean flex over time by group**

**Extension:**

Extension showed a significant change over time in both groups and there was a marginally significant difference between the two groups at each time point. This is not an indication of treatment effect, since the interaction was non significant, and Figure 8 shows that the slopes of the lines of the two groups were almost parallel.

**Table 24: Hypothesis tests for repeated measures ANOVA for Extension**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.781 | 0.036 |
| Group | F=3.419 | 0.073 |
| Time*group | Wilk's lambda 0.957 | 0.676 |

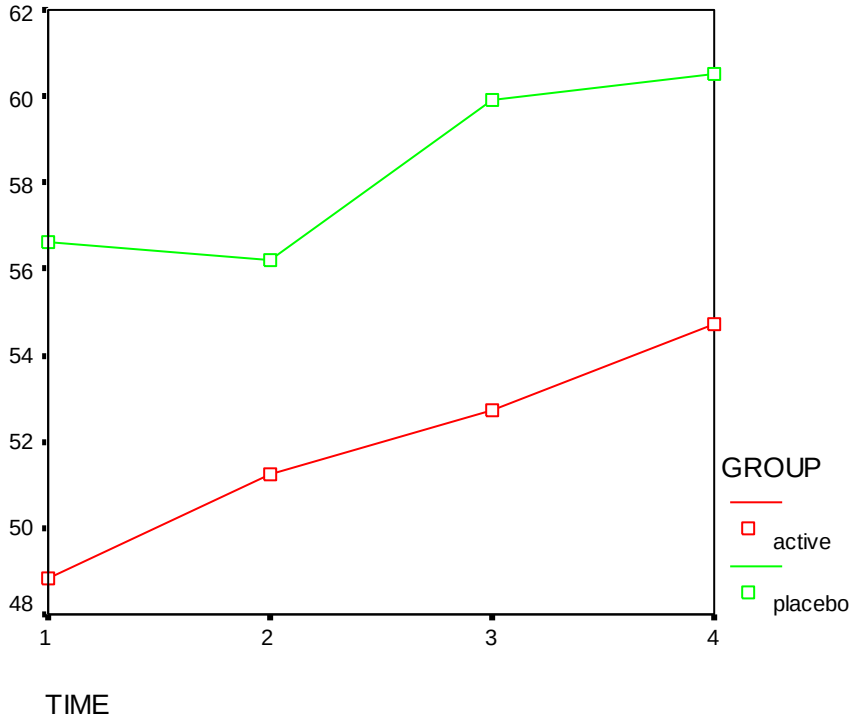


**Figure 8: profile plot of mean extension over time by group**

### Right lateral flexion:

There was a significant time effect overall for right lateral flexion (p = 0.029), but no significant group effect or time by group interaction (treatment effect). This means that the two groups changed significantly over time to the same extent. However, when one examined Figure 9 it is evident that the placebo group (especially from visit 2 onwards) increased at a faster rate than the treated group. There was no statistical evidence of this, however.

**Table 25: Hypothesis tests for repeated measures ANOVA for Right lateral flexion**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.771 | 0.029 |
| Group | F=0.521 | 0.475 |
| Time*group | Wilk's lambda 0.893 | 0.273 |

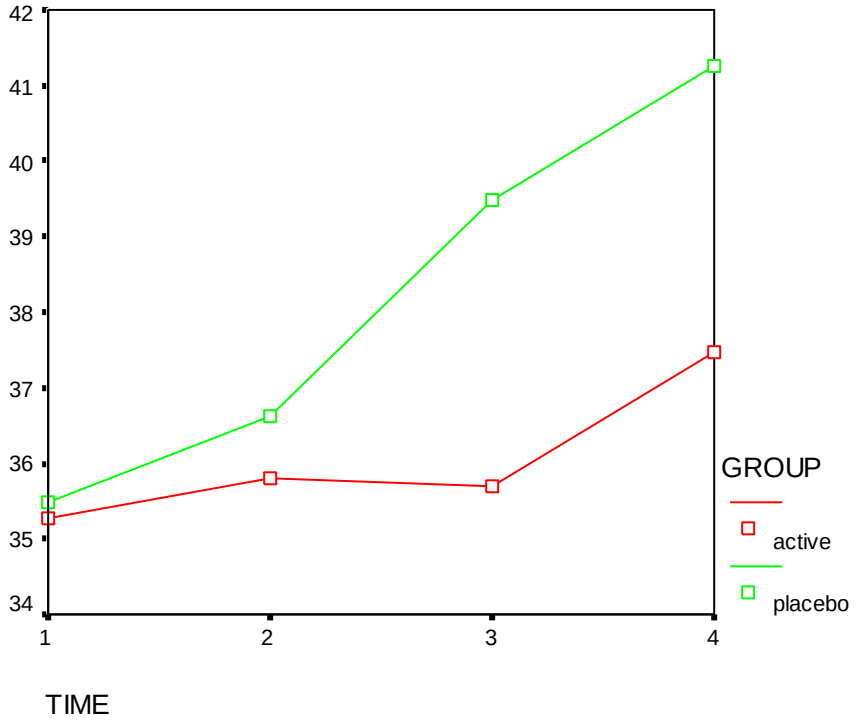


**Figure 9: profile plot of mean right lateral flexion over time by group**

### Left Lateral flexion:

Left lateral flexion also showed a significant increase over time in both groups (p = 0.003) and no evidence of treatment effect. Figure 10 confirms the trend that the placebo group increased at a faster rate than the active treated group.

**Table 26: Hypothesis tests for repeated measures ANOVA for Left lateral flexion**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.672 | 0.003 |
| Group | F=0.432 | 0.515 |
| Time*group | Wilk's lambda 0.967 | 0.766 |

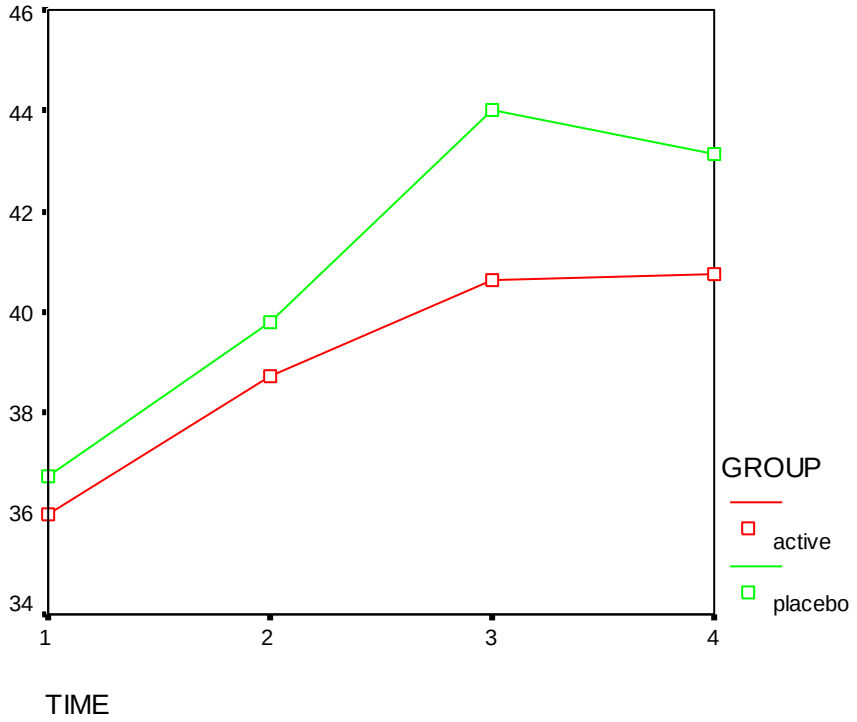


**Figure 10: Profile plot of mean left lateral flexion over time by group**

### Right Rotation:

There was a marginally significant increase over time in both groups (p = 0.053) but no difference between the treatment groups and no treatment effect. This is shown in Figure 11 where the active group shows a slow increase until visit 3 and thereafter a steep increase, while the placebo group shows a drop in mean right rotation between visit 1 and 2, followed by a very steep increase to end up at a higher mean than the active treated group. Thus there is a trend of the placebo group showing better results than the active treated group.

**Table 27: Hypothesis tests for repeated measures ANOVA for Right rotation**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.800 | 0.053 |
| Group | F=0.366 | 0.549 |
| Time*group | Wilk's lambda 0.916 | 0.389 |

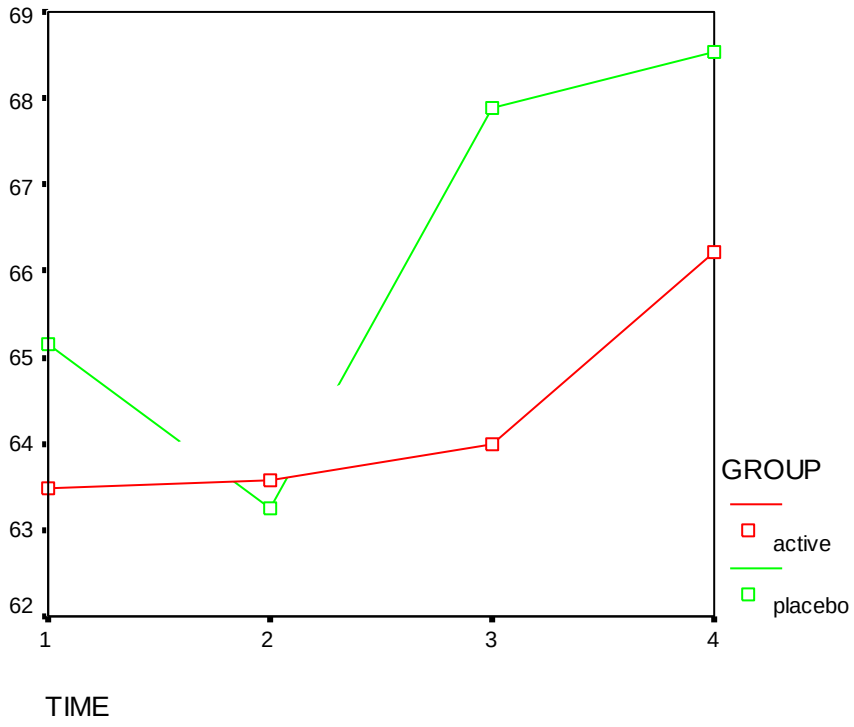


**Figure 11: Profile plot for mean right rotation by group over time**

**Left Rotation:**

There was a significant change (increase) over time in both group and there was no evidence of a treatment effect (p = 0.800). Figure 12 shows that both groups increased at the same rate over time.

**Table 28: Hypothesis tests for repeated measures ANOVA for left rotation**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.761 | 0.024 |
| Group | F=1.821 | 0.186 |
| Time*group | Wilk's lambda 0.971 | 0.800 |

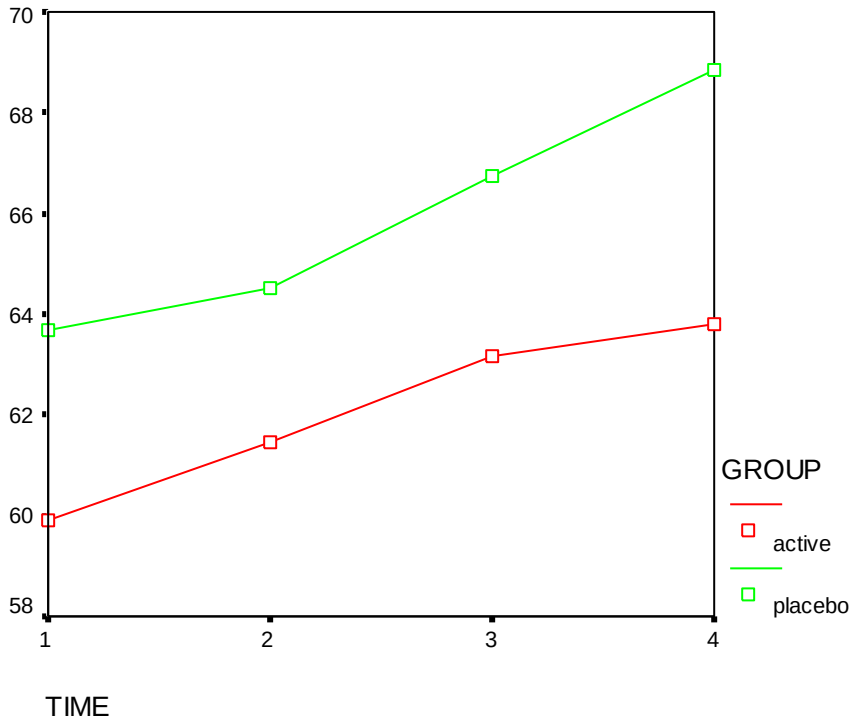


**Figure 12: profile plot of mean left rotation by group over time**

**Algometer:**

There was no change over time nor treatment effect for algometer readings. Thus neither of the groups improved or got worse over time. This is shown in Figure 13 where it can be seen that the placebo group showed a very slight decrease in scores while the active group showed a slight increase in scores, but this change over time and interaction between time and group was not significant.

**Table 29: Hypothesis tests for repeated measures ANOVA for algometer readings**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.968 | 0.771 |
| Group | F=1.116 | 0.298 |
| Time*group | Wilk's lambda 0.978 | 0.861 |

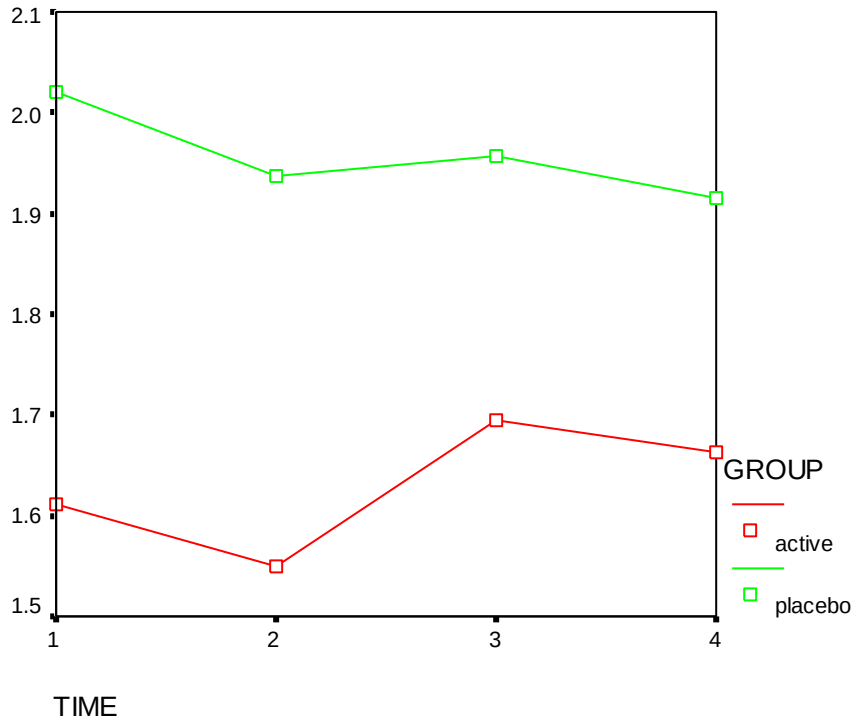


**Figure 13: Profile plot of mean algometer reading over time by group**

### 4.2.2 Subjective Measurements

**NRS:**

There was a significant decrease over time of NRS scores in both groups. The rate of decrease was the same in both groups (p = 0.167) and there was a marginally significant difference between the scores of both groups at each time point. Figure 14 shows that the placebo group had higher scores at all time points than the active treatment group. This is not an indication of a treatment effect, rather of different baselines in the two groups.

**Table 30: Hypothesis tests for repeated measures ANOVA for NRS scores**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.295 | <0.001 |
| Group | F=3.385 | 0.074 |
| Time*group | Wilk's lambda 0.863 | 0.167 |

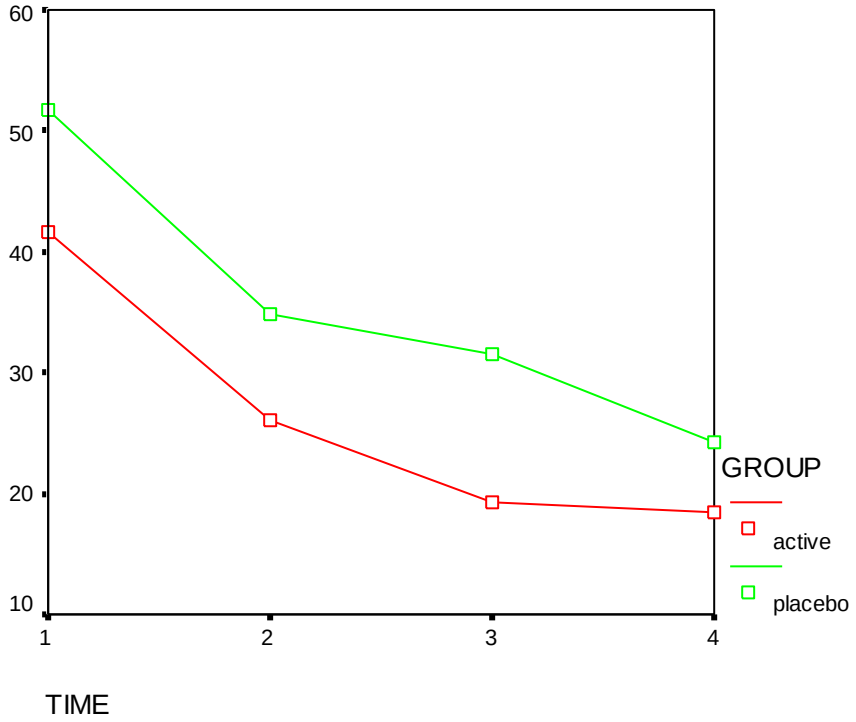


**Figure 14: Profile plot of mean NRS score over time by group**

**CMCC:**

There was a significant decrease over time for both groups (p<0.001). The interaction between time and group was marginally significant (p = 0.079). This means a slight effect of the treatment. Figure 15 shows that the slopes of the two lines were not parallel, the placebo group was decreasing at a faster rate than the active treated group. Had this been significant it would have indicated a detrimental effect of the treatment.

**Table 31: Hypothesis tests for repeated measures ANOVA for CMCC scores**

| Effect | Statistic | p value |
|---|---|---|
| Time | Wilk's lambda 0.323 | <0.001 |
| Group | F=1.681 | 0.203 |
| Time*group | Wilk's lambda 0.821 | 0.079 |

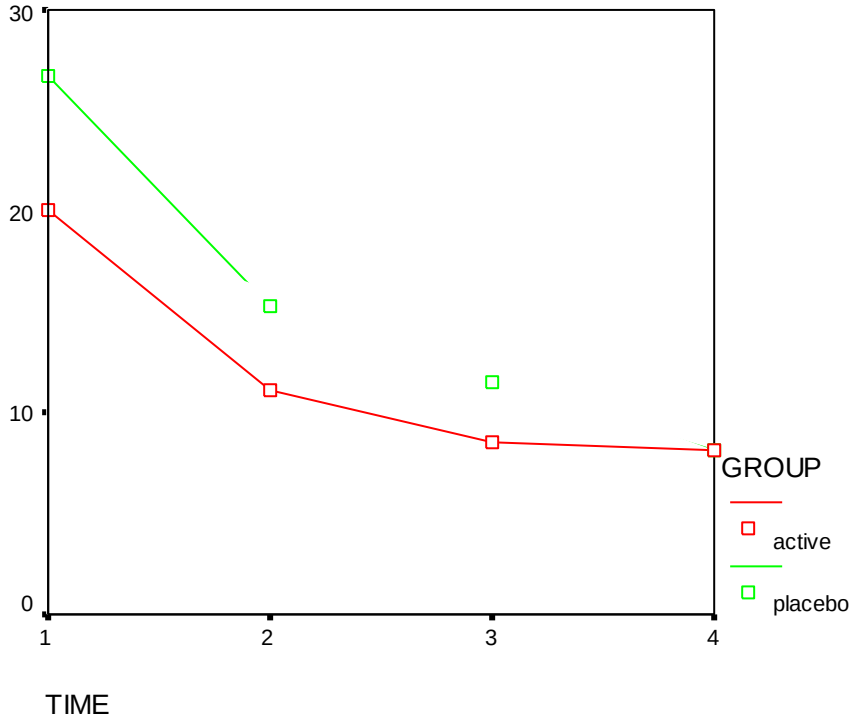


**Figure 15: Profile plot of mean CMCC by group over time**

## 4.3 Demographics

Out of the 38 patient sample size, 14 were male (36.8%) and 24 were female (63.2%), this indicates a predominance in the number of female subjects that took part, this could possibly be due to the predominance office workers/secretaries that suffered from neck pain.

The age range of the sample population extended from 18 to 55 years, with a mean occurrence of 37.2 years.

# CHAPTER 5 DISCUSSION

## 5.1 Intra-group Analysis

### 5.1.1 Subjective measures

The subjective measures used for this study were the NRS pain rating scale and the CMCC neck disability index. The literature suggests that Chiropractic treatment in the form of spinal manipulation is effective in reducing pain in patients suffering from neck pain (Strasser 2004; Giles and Muller 1999; Cassidy et al. 1992; Vernon et al. 1990). Traumeel S is also effective in treating painful syndromes (Ludwig and Weiser 2001; Oberbaum 1998; Zenner and Metelmann 1992; Heel 1986). In the active and placebo groups individually, a strongly statistically significant improvement in NRS and CMCC findings ($p<0.001$) was found which is represented graphically in Figures 1 and 4. The results obtained confirm the current literature, however there was no significant difference between the active and placebo groups in terms of the NRS pain rating scale and the CMCC neck disability index. This is possibly due to the strong effect of the manipulation which may have over-shadowed the effect of the Traumeel S. It is also possible that the sample population did not have enough inflammation for the Traumeel S to act on and therefore seemed to have no effect, to combat this effect. As a future recommendation, a more sensitive objective measure of inflammation and pain could be used.

### 5.1.2 Objective Measures

According to Cassidy et al. (1992) and Yeomans (1992) , spinal manipulation has the effect of increasing mobility to the treated area. It was found in this study that in fact range of motion did not increase in all directions, only flexion ($p=0.005$) and left lateral flexion ($p=0.003$) showed significant improvement in both the active and placebo groups (Fig. 2 and 5). Extension, right lateral flexion, and right and left rotation showed no significant improvement over time. This lack of improvement in these directions could be due to infrequency of treatment, as

many of the sample population had office jobs, certain ergonomic factors could have played a role such as computer mouse use and holding the telephone between the ear and shoulder. Viewed separately, there was no significant difference between the active or placebo groups in terms of CROM readings, possibly due to the small sample size or that the subjects were not severe enough to show a measurable difference in mobility. There is literature, however, that maintains that range of motion did not correlate well with symptomatic improvement in neck pain patterns, and high levels of cervical mobility have not demonstrated any predictive values regarding the development of neck symptoms in pain free individuals (Jordan et al. 1998)

The pressure algometer instrument was used as an objective measure of pain as used by Vernon et al. (1990). In this study it was seen that in both the placebo and active groups there was no statistically significant improvement over time (Fig. 3 and 6), therefore there was no improvement in pressure pain threshold. It is likely that the algometer was not sensitive enough to detect any treatment effect that might have been present

## 5.2 Inter-group Analysis

### 5.2.1 Subjective Measurements

Examination of the NRS scores showed that the placebo group had constantly higher values at each treatment (time point) as compared to the active group (Fig. 14), possibly due to poor sampling and the small group size. It can also be noted from Figure 14 that the rate of decrease was also the same in both groups ($p=0.167$). This is not an indication of a treatment effect (i.e. one treatment working better than the other); rather it is more likely to be a difference of baselines, or starting points, of the two groups. The evident difference in baselines is unexpected in so far as the researcher was not able bias one group or the other in terms of NRS scores, due to the double blinding and randomisation procedure; each individual subject was free to choose whatever NRS and CMCC values that were most appropriate to them during the course of the treatment. It is possible that, due to the small sample size, the effect of

chance and incomplete randomisation of the population also lead to the apparent discrepancy in baseline readings. Both the active and placebo groups showed a significant decrease over time, this could possibly be due to the strong effect of the spinal manipulation that was administered to each group (Giles and Muller 1999; Casidy et al. 1992; Yeomans 1992; Vernon et al. 1990; Turk and Ratkolb 1987) rather than the treatment effect of the Traumeel S. A further reason could be dissimilarity in clinical severity between the two groups at the outset, if the placebo group was clinically worse at the start, one could expect their improvement to be more dramatic.

Examination of the CMCC scores showed a significant decrease over time for both the active and placebo groups ($p<0.001$), however the interaction between time and group (i.e. treatment effect) was only marginally significant ($p=0.079$). It can be seen in Figure 15 that the gradient of the two lines were not parallel, the placebo group was decreasing at a faster rate than the active group, this means that the active treatment group had a mildly detrimental effect on the research subjects. Such results could possibly also be due to the strong effect of the spinal manipulation that was administered to each group (Giles and Muller 1999; Casidy et al. 1992; Yeomans 1992; Vernon et al. 1990; Turk and Ratkolb 1987) that "over-powered" the treatment effect of the Traumeel S.

### 5.2.2 Objective Measurements

According to the literature (Jordan et al. 1998; Cassidy et al. 1992; Yeomans 1992), spinal manipulation increases spinal mobility. It was found in this study that there was a significant increase over time in both groups, however there was no treatment effect that was demonstrated, in fact in some instances a detrimental effect could be inferred in the active group. Flexion ($p=0.539$), left rotation ($p = 0.800$), and right lateral flexion ($p=0.273$) showed no difference between the active and placebo groups over time and therefore no treatment effect. Extension displayed a marginally significant difference between the two groups however this is not a result of a treatment effect as Figure 8 shows that the gradients of the two graphs are almost parallel. Left lateral flexion showed no

evidence of a treatment effect (p=0.776), however the placebo group did increase at a faster rate than the active group (Fig. 10). Right rotation also showed no evidence of a treatment effect (p=0.389), however it is shown in Figure 11 that the active group shows a slow increase until visit 3 and thereafter a steep increase, while the placebo group shows a drop in mean right rotation between visit 1 and 2, followed by a very steep increase to end up at a higher mean than the active treated group. Thus there is a trend of the placebo group showing better results than the active treated group, the logical conclusion from these results is that the Traumeel S had a detrimental effect on the subject's range of motion. As homeopathic preparations have been known to aggravate symptoms before relief may be experienced, the apparent worsening of the active group could be due to a treatment aggravation of the Traumeel S, however such aggravations are not usually a feature of complex remedies like Traumeel S but rather of deep-acting constitutional remedies, they usually occur after 10 to 14 days and can last 2 to 8 days (Gaier 1991). Another possible reason for the discrepancy is that during the treatment process, the manipulation was not restricted to any one specific direction and was applied to any direction in which fixations were discovered according to motion palpation findings. It is therefore possible for one or two directions to have been manipulated more often than others, this and the small sample size of the study may have diluted the overall effect of the treatment. Furthermore these results could be due to clinical disparity between the two groups or indeed a co-intervention in the placebo group beyond the researcher's knowledge.

Unlike the findings of Vernon et al. (1990), this study found that the algometer readings showed that neither of the groups improved or got worse over time (p=0.861). In Figure 13 it can be seen that the placebo group showed a very slight decrease in scores while the active group showed a slight increase in scores, but this change over time and interaction between time and group was not significant. This result could be due to the algometer not being the correct data collection instrument or that there was a misuse of the instrument (every precaution was taken by the researcher to make sure that the instrument was properly used) or that the instrument was not sensitive enough.

## 5.3 Summary of Results

There was no statistical evidence of an effect of the treatment relative to the placebo over the four visits. This may be due to lack of power of the multivariate tests due to small sample size. However, certain trends are visible. For most subjective and objective outcome measurements, the placebo group tended to improve at a faster rate than the treated group. If this study were to be regarded as a pilot study, the statistical analysis undertaken shows that if the sample size was increased it might have indicated a detrimental effect of the active treatment relative to the placebo. Thus, these results would not indicate that further larger studies should be undertaken.

# CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

## 6.1 Conclusion

Evaluation of the intra-group statistical results showed that both groups improved in a statistically significant manor ($p<0.001$) in both the NRS and CMCC measures, the CROM values showed that only flexion and left lateral flexion displayed improvement ($p=0.005$ and $p=0.003$) in both groups, possibly due to those directions being manipulated more than the others, or that the effect of manipulation on range of motion is short lived. A reason for those particular directions being most improved is that during this study, many subjects that suffered from mechanical neck pain worked in the office environment, thus factors such as computer mouse use, holding the telephone between the ear and shoulder, and monitor placement would impact only certain ranges of motion rather than others. The algometer readings showed no improvement over time in both groups, raising the question of appropriateness of the measurement tool.

Evaluation of the inter-group statistical results showed that the NRS results indicated no treatment effect. The CMCC values showed no interaction between the two groups, however there was evidence that showed that the placebo group was decreasing at a faster rate than the active group, implying that if the study had continued for longer the placebo group could have improved to a greater extent than the active group, i.e. the Traumeel S had a detrimental effect on the subjects. The CROM values were erratic, with some directions improving, some staying the same, and some worsening. These results were therefore inconsistent and so are unable to produce any valid conclusions from them, the reason for these inconsistencies could be attributed to the small sample size and that one direction of manipulation may have been treated more than another and was not kept as standard. The algometer once again showed no change over time or interaction between time and group implying the apparent inappropriateness and/or insensitivity of the measurement tool.

A flaw in the research procedure could have been the combination of manipulation with Traumeel S to determine its efficacy, the spinal manipulation is such a strong treatment tool that it appears to have overwhelmed the effect of the Traumeel S and so may have resulted in misleading results and statistics. The aggravation effect of homeopathic preparations could also have influenced the results, a longer time-frame might have shown the active group "bouncing back" but there was no statistical evidence of this, and studies have shown Traumeel S to work much faster (Ludwig and Weiser 2001). The condition treated may also have been incorrect, either Traumeel S is just not effective in treating mechanical neck pain, or that the level of inflammation present in the subjects was too low for the Traumeel S to have had a significant measurable effect over and above the spinal manipulation. There was also no trauma or definitive injury as such on which the Traumeel S could have an action. A more accurate objective measure of pain and inflammation is needed.

It is therefore the researcher's conclusion that, according to this study, there is no statistical benefit to the addition of Traumeel S oral tablets in the Chiropractic treatment of acute and/or sub-acute mechanical neck pain (or facet syndrome) in terms of objective and subjective findings for a protocol of 4 treatments over a 3 week period.

## 6.2 Recommendations

In the opinion of the researcher, a large draw-back to this study was the small sample size, a larger sample group would allow for a more representative slice of the population. A larger sample size would have made the measurement of range of motion more representative, and a type II error would have been avoided. The small sample size also allowed chance to have a larger impact (e.g. people with less symptoms could have been predominantly in one group), and the chance of incomplete randomisation would be greater, therefore greater numbers would increase the power of the study. However, if this study were to be regarded as a pilot study, the statistical analysis undertaken shows that if the sample size was increased it might have indicated a detrimental effect of the

active treatment relative to the placebo. Thus, these results would not indicate that further larger studies should be undertaken.

In order to remove the inconsistencies that occurred in the CROM readings, a more focused approached would have proved more successful, this would mean limiting treatment to only one direction or pair of directions. The CROM inconsistencies could also have been as a result of the many office workers that were incorporated into the study due to the fact they had neck pain, office ergonomics could predispose these subjects to certain fixations rather than others. To avoid this effect, the sample population should be more homogenised, either including exclusively office workers or removing them from the subject pool.

Each subject was responsible for taking the research tablets at home, away from the researcher, patient compliance might have been an issue as some subjects might forget to take them, or some people may have forgotten more often than others. Even though the research subjects were instructed not to take any other pain medication during the study, it is possible that they may have done so without notifying the researcher. Homeopathic remedies are also sensitive to the presence of strong flavours such as coffee or peppermint (even toothpaste), if the Traumeel tablets were taken near such things the effect of the Traumeel S may be diminished. As far as possible, verification of compliance was undertaken at the end of each treatment session verbally.

The lack of statistical significance of the algometer leads the researcher to question the appropriateness of the measurement tool. A more significant effect of the Traumeel S tablets might have been observed if the anti-inflammatory effects were more readily observable and appropriately measured, thus a better and/or more sensitive objective measurement instrument is needed to measure inflammation and pain. Different results may have been observed if the measurements were taken immediately or shortly after the treatment, showing a more pronounced effect.

In retrospect, this study should have incorporated in the statistical analysis a mention of whether the lesion was on the left or right sides and a note of occupational influence on the subject group. The sample size should have been larger (60 subjects instead of 38), and the population group should have been more homogenous. A more accurate (or sensitive) measure of inflammation should be found to measure the effect of the Traumeel S, such as a blood test (ESR or CRP). Perhaps more of an effect could be visualised if the subject population was more symptomatic (i.e. post traumatic syndromes, whiplash, or arthritis). Traumeel S has different application methods, in future studies, using a different treatment regime may show different results, changes such as different potencies, different dosages, and different application forms such as treatment via an injectable solution, may prove more appropriate to this condition.

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# APPENDIX H

# THE RELATIVE EFFECTIVENESS OF MANIPULATION VERSUS A COMBINATION OF MANIPULATION AND ORAL TRAUMEEL S IN THE TREATMENT OF MECHANICAL NECK PAIN.

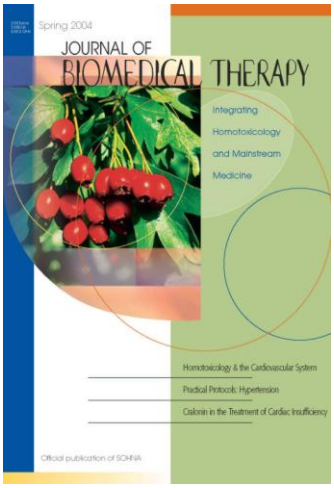
**Journal article written in the format of the**
**JOURNAL OF BIOMEDICAL THERAPY**

By

**Graeme Harpham**

Heel Canada Inc.

# JOURNAL OF BIOMEDICAL THERAPY

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# Journal Article

## Introduction

According to the recent literature the application of non-steroidal anti-inflammatory drugs (NSAIDS) is the mainstay and first line of conventional treatment for many types of pain, including that of spinal origin [1, 2, 3]. NSAID therapy has inherent side effects [4], however, given the risks involved, they are still of value as an adjunct to spinal manipulation [5], which has been shown to have less side effects and be more effective than conventional NSAIDS [2; 6; 7].

A homeopathic alternative to NSAIDS is Traumeel S, it fulfils all the criteria for a locally acting therapeutic medication, with promotion of the natural healing process, and minimum side effects [8]. A recent study compared the relative efficacy of Traumeel S against NSAIDS in the treatment of cervical facet syndrome. The researcher concluded that there was statistically no difference between the two therapies, it could therefore be inferred that Traumeel S may be a valid alternative to NSAID therapy in the treatment of cervical facet syndrome [9]. This study tested this hypothesis by comparing the effectiveness of spinal manipulation with the concurrent administration of oral Traumeel S against spinal manipulation alone in order to assess the potential benefit of combining Traumeel S with manipulation.

## Materials & Methods

This double-blinded randomised clinical controlled trial incorporated the first 38 volunteers that met the inclusion criteria; which were the presence of acute or sub/acute mechanical neck pain according to orthopaedic examination [10] and aged between 18 & 55. Exclusion criteria were any contraindication to cervical manipulation [11, 12] or any sensitivity to the components of Traumeel S [13]. Each subject was assigned randomly to either the control group (manipulation + placebo) or the experiment group (manipulation +Traumeel S) while maintaining the integrity of the double-blinding. Each subject received cervical manipulation

according to the Diversified Technique [14]. The normal clinical procedure of the DIT Chiropractic Day Clinic was observed. Both subjective (CMCC Neck Disability index [15] and NRS – 101 pain rating scale [16]) and objective measures (CROM instrument [17] and Pressure Algometer [18]) were taken before treatment at each visit. The subjects were given a total of 4 treatments within a maximum of 3 weeks.

Data was captured in MS Excel and exported into SPSS version 11.5 (SPSS inc. Chicago, Ill) for analysis. Intra-group analysis involved description of the outcome measurements over the four time points in each group graphically by means of box and whisker plots. Statistical testing for a time change within each group was achieved with the Friedman test. . Inter-group analysis was performed with repeated measures ANOVA (analysis of variance) to test three hypotheses simultaneously on each outcome measurement between the within-subjects effects of time and the between-subjects effects of treatment group: 1.) the effect of time; 2.) the effect of group and; 3.) the time by group interaction (the treatment effect). A two tailed p value of $<0.05$ was considered statistically significant.

## Results

Evaluation of the intra-group statistical results showed that both groups improved in a statistically significant manor ($p<0.001$) in both the NRS and CMCC measures individually, the CROM values showed that only flexion and left lateral flexion displayed improvement ($p=0.005$ and $p=0.003$) in both groups. The algometer readings showed no improvement over time in both groups, raising the question of appropriateness of the measurement tool.

Evaluation of the inter-group statistical results showed that the NRS results indicated no treatment effect. The CMCC values showed no interaction between the two groups, however there was evidence that showed that the placebo group was decreasing at a faster rate than the active group, implying that if the study

had continued for longer the placebo group could have improved to a greater extent than the active group. The CROM values were mixed, with some directions improving, some staying the same, and some worsening. These results were therefore inconsistent and so are unable to produce any valid conclusions from them. The algometer once again showed no change over time or interaction between time and group implying the apparent inappropriateness the measurement tool.

There was no statistical evidence of an effect of the treatment relative to the placebo over the four visits. This may have been due to lack of power of the multivariate tests due to small sample size. However, certain trends were visible. For most subjects and objective outcome measurements, the placebo group tended to improve at a faster rate than the treated group. If the sample size was increased this might have indicated a detrimental effect of the active treatment relative to the placebo. The results do not indicate that further larger studies should be undertaken.

**Discussion & Conclusion**

According to this study, there is no statistical benefit to the addition of Traumeel S oral tablets in the Chiropractic treatment of acute and/or sub-acute mechanical neck pain (or facet syndrome) in terms of objective and subjective findings for a protocol of 4 treatments over a 3 week period.

There was a lack of statistical power to this study due to the small sample size used and a high chance of a type two error.

The erratic CROM readings could have been due to the effect of the small sample size, and the influence of a chance incomplete randomisation effect.

The lack of statistical significance of the algometer leads the researcher to question the appropriateness of the measurement tool. A more significant effect of the Traumeel S tablets might have been observed if the anti-inflammatory

effects were more readily observable and appropriately measured, thus a better and/or more sensitive measurement instrument was needed.

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17. (CROM) Cervical Range of Motion Instrument (Performance Attainment Associates; Patient no. 4,777,965 & 4,928,709)

18. Pressure algometer - Wagner FDK20 Force Dial (Wagner Instuments, P.O. Box 1217, Greenwich, CT, 06836, U.S.A.)