

**An investigation into the relative effectiveness of
Transeva and Spinal manipulative therapy for
mechanical low back pain.**

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

By

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DEDICATION

This work is dedicated to my wonderful parents, Bev and Ian, whose love, support and encouragement throughout my Chiropractic Journey and throughout my life have allowed me to get to where I am today. I love you.

A special thank you to my husband, Murray who has been at my rescue and has supported me through these final moments helping me to achieve my dreams.
You've been fantastic, thanks my love.

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ABSTRACT

AN INVESTIGATION INTO THE RELATIVE EFFECTIVENESS OF TRANSEVA AND SPINAL MANIPULATIVE THERAPY FOR MECHANICAL LOW BACK PAIN.

Objective:

The aim of this study was to investigate the relative effectiveness of Transeva and spinal manipulative therapy for mechanical low back pain.

The objectives evaluated the effectiveness of only administering Transeva therapy alone, or Spinal manipulative therapy alone as well as Transeva therapy with Spinal manipulative therapy on mechanical low back pain with respect to the patients' subjective and objective responses to the respective treatment group. The final objective was to correlate the subjective and objective data collected to determine the effectiveness of each of the therapies in comparison with another.

Design:

A sample of thirty patients diagnosed with mechanical low back pain were accepted into the study. These patients were randomly divided into three groups of 10, which received different treatment protocols for mechanical low back pain.

Outcome Measure:

The following outcomes were measured; a decrease in pain (measured with the Numerical Pain Rating Scale (NRS), a decrease in disability (measured with the Roland-Morris Questionnaire), a decrease in local tenderness (measured with the pressure Algometer) and an increase in lumbar range of motion (measured with the Inclinator). The data was collected prior to treatment one, prior to treatment four and at the sixth follow-up visit.

Results and Conclusion:

All groups improved with the treatments they received; however, no single treatment was statistically better than any other treatment intervention tested.

However, the Spinal manipulative therapy group had a statistically significant faster reduction in pain on the NRS readings with $p=0.048$.

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DEFINITIONS:

Low Back Pain:

Low back pain is defined as pain that extends from the thoracic diaphragm to the pelvic diaphragm (noted as the area on the body surface being between the twelfth ribs bilaterally and the gluteal folds bilaterally) (Nyland et al., 2003).

Mechanical Low Back Pain:

Mechanical low back pain is defined as pain resulting from the susceptibility of the spine to static loads due to kinetic deviation from normal function and gravity and muscle forces (Gatterman, 1990: 129). According to Kirkaldy-Willis and Cassidy, (1988: 133-135), mechanical low back pain refers to low back pain within the dysfunction stage, and thus specifically to the posterior facet syndrome and sacroiliac syndrome.

Myofascial Trigger Points:

Myofascial trigger points are defined as a hyper-irritable location within a taut band of skeletal muscle that is painful when compressed and can give rise to characteristic referred pain, tenderness and tightness. Cumulatively they result in myofascial pain syndrome (Esenyel et al., 2000, Chaitow and DeLany, 2002).

Joint Dysfunction:

For the purposes of this research this is defined as a joint (facet / sacro-iliac) presenting with decreased end feel or joint play (as per motion palpation), muscle hypertonicity (as evidenced by myofascial trigger points) and local tenderness to pressure over the facet joints (Gatterman, 1990).

Modalities:

For purposes of this research this refers to any form of electrotherapy that a patient may receive whilst being treated for low back pain in a standard clinical setting.

Incidence:

Incidence is defined as the frequency with which something, such as a disease, appears in a particular population or area. The incidence is distinct from the prevalence which refers to the number of cases on a certain date. (Longmore et al., 2001)

Faradic Current:

A faradic current is a short duration interrupted direct current. Faradism was used to describe the type of the current produced by a faradic coil, which is a type of induction coil was termed Faradism and is used for pain control and neuromuscular syndromes (Forster and Palastanga, 1990).

CHAPTER ONE

INTRODUCTION.

1.1 THE PROBLEM AND ITS SETTING.

Mechanical low back pain is a common health problem which can be costly and disabling (Morris, 2006; Hills, 2005; Manga, 1993; Burton and Cassidy, 1992 and Cox, 1998). In this respect Kirkaldy-Willis and Cassidy, (1988), principally refer to mechanical low back pain as caused by posterior facet syndrome and sacroiliac syndrome. The most common treatment modalities for mechanical low back pain include but are not limited to manipulation (Smith, 2003; Bergmann and Peterson, 2002; Whelan et al., 2002; Cooperstein et al., 2001; Kruger, 1999; Bronfort, 1992; Di Fabio, 1992;), electromodality application (Haldeman, 2005; Forster and Palastanga, 1990) and exercise (Van Tulder et al., 2000), with the former two interventions being utilized singularly or in combination with other therapies (Haldeman, 2005). Although there is evidence to show that there is a direct benefit for the patient when these therapies are used singularly, there is little evidence available to indicate whether a direct benefit exists for the patient when these therapies are used in combination. Theoretically a combination with other manual therapies should allow for the best in clinical outcomes.

As is indicated above, one of the therapies used in the treatment of mechanical low back pain are electromodalities (Haldeman, 2005; Forster and Palastanga, 1990). Within this category lies faradism (which is widely used in the treatment of muscular-, tendon-, joint- and neuro-pathologies) and causes a sustained involuntary wavelike muscular contraction to affect the patients presenting complaint (Greene, 2003).

The Transeva has a similar waveform in relation to the faradic wave pattern (Sanya, 2000; Defranca, 1988 and Graham, 1893), it could therefore be

assumed that the effects of faradism apply to the Transeva. This along with the increased use of the Transeva (Bedell-Sivright, 2005; Greene, 2003; Lewis, 2003; Rawlens, 2003; White, 2003), indicates that this electromodality should be researched further to identify its potential uses. In addition as the review of current literature does not show any studies that have established the efficacy of the Transeva in the treatment of mechanical low back pain, this study aimed to develop the clinical science related to the management of mechanical low back pain with this relatively untested intervention as well as in combination with Spinal manipulative therapy.

1.2 OBJECTIVES OF THE STUDY.

The objective of this study was to investigate the relative effectiveness of Transeva and Spinal manipulative therapy for mechanical low back pain.

Objective one was to determine the effectiveness of the following therapies: a) Spinal manipulative therapy, b) Transeva and c) Transeva followed by Spinal manipulative therapy for mechanical low back pain in terms of subjective clinical findings using the Numerical Pain Rating Scale (NRS) and the Roland- Morris Questionnaire:

Hypothesis 1.

It was hypothesized that Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva or combined Transeva and Spinal manipulative therapy, in terms of subjective clinical findings.

Hypothesis 2.

It was hypothesized that Transeva therapy would be more effective in the management of mechanical low back pain when compared to Spinal

manipulative therapy or combined Transeva and Spinal manipulative therapy, in terms of subjective clinical findings.

Hypothesis 3.

It was hypothesized that Transeva followed by Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or Transeva, in terms of subjective clinical findings.

Objective two was to determine the effectiveness of the following therapies: a) Spinal manipulative therapy, b) Transeva and c) Transeva followed by Spinal manipulative therapy for mechanical low back pain in terms of objective clinical findings using the pressure Algometer and Inclinator.

Hypothesis 4.

It was hypothesized that Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva or combined Transeva and Spinal manipulative therapy, in terms of objective clinical findings.

Hypothesis 5.

It was hypothesized that Transeva therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or combined Transeva and Spinal manipulative therapy, in terms of objective clinical findings.

Hypothesis 6.

It was hypothesized that Transeva followed by Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or Transeva, in terms of objective clinical findings.

1.3 RATIONALE.

Chiropractic treatments vary according to the chiropractor, where some practitioners incorporate electrotherapy modalities in conjunction with manipulation (Cooperstein, 2004), while others use manipulation alone (Bergmann, 2002). However, only a small number of studies have been researched comparing combined therapy to single intervention therapy.

Spinal manipulative therapy aims to decrease the hypertonicity in the muscles by neural pathways (Herzog et al., 1999; Korr (Leach, 1994); Nansel et al., 1993 and Rebechini-Zasadny et al., 1981). Herzog et al., (1999) stated that much has been written about reflex responses caused by Spinal manipulative therapy, but there are no experimental reports showing responses in clinically relevant situations.

The Transeva aims to decrease the hypertonicity in the muscles by increasing blood flow to the area (Shekida Industries, 1993; Foster and Palastanga, 1990).

This research aimed to establish, whether treating with either Spinal manipulative therapy or Transeva therapy is more or less effective than combining these two interventions in the treatment of mechanical low back pain. It is assumed that this may result in a synergistic affect resulting in decreasing hypertonicity of the muscle; however this has yet to be established.

1.4 ASSUMPTIONS OF THIS STUDY.

Due to the similarity in the waveform of the Transeva in relation to the faradic wave pattern (Graham, 1893; DeFranca 1988 and Sanya 2000), it was assumed that the effects of faradism hold true for the Transeva (Greene, 1993).

1.5 POTENTIAL BENEFITS OF THIS STUDY.

The Transeva causes a contraction-relaxation action in the muscle which increases arterial circulation, and aids venous and lymphatic return which prevents stagnation of inflammatory products in the tissues that restricts adhesion formation (Greene, 1993). Graham (1893) concluded that the faradism achieves the quickest means of relief after stretching or tearing injuries to muscles. As there is a reduction in adhesions, there is increased range of motion (Vernon and Mrozek, 2005; Leach, 1994) and possibly a decrease in pain due to the increased mobility of the muscle within its sheath (Bedell-Sivright, 2005).

This study would provide important information with regards to the efficacy of Transeva compared to Spinal manipulative therapy and combined Transeva and Spinal manipulative therapy for the treatment of mechanical low back pain. Once published, it would provide the chiropractor or any other manual therapist with more knowledge of simple, effective, non-invasive treatment for mechanical low back pain in terms of pain relief and an increase in muscle range of motion.

In view of the fact that there is only a small number of research studies available on the effects of treatment with Transeva on mechanical low back pain, it is hoped that further studies will be conducted into the use of the Transeva on other joint, muscular and soft tissue conditions.

1.6 CONCLUSION.

The aim of this study was to investigate the relative effectiveness of Transeva and Spinal manipulative therapy for mechanical low back pain. In the remaining chapters the researcher will outline the pertinent literature around this topic, (Chapter 2). Chapter 3 will describe the methodology of the study in detail. Chapter 4 will present the statistics and discussion of the results and Chapter 5 will conclude this study and offer recommendations.

CHAPTER TWO

LITERATURE REVIEW.

2.1 MECHANICAL LOW BACK PAIN.

Low back pain (LBP) is a major international problem and there are many epidemiological and statistical studies documenting the high incidence and prevalence of low back pain (Morris, 2006; Hills, 2005; Manga *et al.*, 1993). Surveys suggest that the lifetime incidence of LBP ranges from 60-90% with a 5% annual incidence. For persons younger than 45 years, mechanical LBP represents the most common cause of disability, and it is the third most common cause of disability in persons aged older than 45 years (Hills, 2005). While Hills, (2005) states there is no mortality associated with mechanical LBP, morbidity in terms of lost productivity, use of medical services, and cost to society is staggering. Similarly the lifetime incidence of low back pain in Indian and Coloured communities in South Africa was found to be 78.2% and 76.6% respectively (Docrat, 1999). And in Black South Africans it was found to be 57.6% (Van der Meulen, 1997).

2.2 ANATOMY AND BIOMECHANICS OF THE LUMBAR SPINE AND SACRO-ILIAC JOINTS.

The facet joints in the lumbar spine consist of the articular processes which arise from the vertebrae above and below. The superior articular processes have a slight concave articular surface and face posteromedially, while the inferior articular processes have a convex articular surface and face anterolaterally. The facet joints are typically synovial joints with hyaline cartilage covering their articular surfaces and a capsule surrounding the joint (Kirkaldy-Willis, 1992). This capsule is composed of three layers (Leach, 1994), the outer layer is thick and fibrous over the dorsal aspect of the joint while the anterior aspect of the capsule

is made from the ligamentum flavum (Kirkaldy-Willis, 1992). The synovial membrane is made up of middle and inner layers. The middle layer, called the subintima, adjoins the fibrous capsule. It is formed of adipose and areolar tissue in varying proportions. Blood vessels and lymphatics course through the subintima. The inner layer, the synovial intima, lines the joint space (Leach, 1994). Rudimentary invaginations of the capsule known as menisci, project into the joint space (Borenstein et al., 1995).

The sacro-iliac joint is made up of the sacrum and the adjacent iliac bones. The articular surface is broad ear shaped and points posterolaterally. The articular surface of the sacrum is covered by hyaline cartilage, while the articulating surface of the iliac bones are covered by fibrocartilage (Haldeman, 2005). The surfaces of the sacro-iliac joint have ridges and depressions which restrict movement and contribute to the strength of the joint as weight is transmitted from the vertebral column to the lower extremities (Giles and Singer, 1997).

The joints of the lumbar spine are innervated by three types of joint mechanoreceptors. Type I and II are myelinated and have an influence on muscle tone when stimulated. The type IV mechanoreceptor is an unmyelinated free nociceptive nerve ending (Haldeman, 2005).

The ligaments surrounding the sacro-iliac joint also contribute to the stability of the joint. These consist of the thin, anterior sacro-iliac ligament, the thick strong posterior sacro-iliac ligament and the interosseous sacro-iliac ligaments. The iliolumbar ligament is thick and is a major stabilizer of L5 on the sacrum. Proximally it attaches to the anterior part of L5 transverse process, distally it divides into two bands, one which attaches to the iliac crest anterior to the sacro-iliac joint and second band blends in with the ventral sacro-iliac ligaments (Kirkaldy-Willis, 1992).

The lumbosacral spine musculature consists of three layers of extensor muscles, flexors, lateral flexors, and rotators. The superficial layer of the extensor muscles consists of the sacrospinalis which originates from the dorsal part of the iliac crest, medial and lateral sacral crests and spinous processes of the sacrum and lumbar spine, it then divides into the iliocostalis, longissimus and spinalis muscles. The intermediate layer of the extensor muscles consists of the multifidus which has two origins one from the laminar area of the sacrum and the medial surface of the posterior and superior sacro-iliac spines and one from the mamillary processes in the lumbar spine. It then inserts on the inferior and medial margin of the lamina and adjacent spinous processes. The deep layer of the extensor muscles consists of the interspinalis which runs between spinous processes and intertransversarius muscle which bridges adjacent transverse processes, accessory process to transverse process and accessory process to mamillary process. The flexors of the lumbar spine consist of the rectus abdominus, external oblique, internal oblique, intertransversus, psoas major and iliacus. The lateral flexion of the lumbar spine is possible through co-contraction of the abdominal obliques, intertransversarius and quadratus lumborum, pure lateral flexion can be produced by a single contraction of the quadratus lumborum. The lumbar spine rotation is produced by unilateral oblique muscle contraction as well as the fact that most extensors and lateral flexors follow an oblique course and produce rotation (Kirkaldy-Willis, 1992).

2.3 AETIOLOGY OF MECHANICAL LOW BACK PAIN.

No consensus exists among physicians, physiotherapists, or chiropractors concerning the most appropriate treatment and management of mechanical LBP (Manga *et al.*, 1993). Nevertheless there is agreement that pain arising from the intervertebral disc or any synovial joint (e.g. facet joint or sacro-iliac joint), from within either or around them, results in reflex hypertonic muscle spasm in an attempt to prevent painful movement of the joint (Herzog *et al.*, 1999). Thus another contributing factor to the presenting pain is that of myofascial trigger

points (hypertonic muscles) in addition to contributing to the joint dysfunction. Gatterman and Goe (1990) proposed that traumatic or postural strain of a muscle could generate a trigger point, hypertonic muscle bands and restricted spinal joint motion resulting in mechanical low back pain. The trauma or postural strain results in tissue pathology resulting in disruption of small blood vessels, release of platelets and serotonin which together with the histamine, released from the mast cells as a result of connective tissue damage, sensitizes the nerve endings resulting in pain. During chronic postural strain there is sustained local contraction resulting in hypertonic bands and myofascial trigger points which have uncontrolled metabolism, accumulating metabolites such as prostaglandin which further sensitize pain endings. There is also local vasoconstriction, resulting in local ischemia and edema which organizes to form fibrous adhesions. This may also result in ligamentous shortening and articular adhesions that occur restricting movement further (Gatterman, 1990).

These pain syndromes are referred to as mechanical low back pain which is characterized by posterior facet syndrome and sacro-iliac syndrome (Gatterman, 2005 and Kirkaldy-Willis et al., 1988). Thus as seen from the above the syndromes are composed of myofascial and joint dysfunction components.

Schafer and Faye, (1989) suggest these syndromes may be caused by:

1. sprain/strain.
2. poor posture.
3. disuse.
4. overuse.
5. developmental abnormalities.
6. joint dysfunction (fixation/hypermobility).
7. degenerative changes.
8. combination of any of the above.

According to Kirkaldy-Willis (1988) three further aspects must be considered when looking at the origins of low back pain. These include:

1. Emotional factors – anxiety, depression, fear, tension.
2. Changes in muscle – impaired local circulation, sustained muscle contraction, vasoconstriction, structural muscle changes and abnormal contraction.
3. Changes in the three joint complex – strains, synovitis, facet joint syndrome, degeneration and disc degeneration.

The intervertebral disc and the posterior facet joints make up a three joint complex. Any changes that may affect the posterior facet joints could possibly affect the disc and vice versa. The pathogenesis of mechanical low back pain can be divided into three stages of degeneration (Kirkaldy-Willis and Burton, 1992):

1. Dysfunction.
2. Instability.
3. Stabilization.

The symptoms associated with the dysfunction stage are as follows:

1. Facet joint inflammation.
2. Muscle hypertonicity.
3. Joint dysfunction.
4. Disc pathology.

The posterior facet syndrome and sacro-iliac syndrome demonstrate these degenerative changes of the three joint complex in the dysfunctional phase and predispose the patient to disc herniation, degeneration and strains of the low back leading to mechanical low back pain (Gatterman, 1990).

2.4 TREATMENT OF MECHANICAL LOW BACK PAIN.

Treatment approaches to these mechanical low back pain syndromes have included electrotherapy, manipulation, exercise, traction, contrast therapy as well

as medication including non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants to benefit patients to a greater or lesser extent.

Rosen (1994), Hutchings (1998) and Chettiar (2001) addressed myofascial trigger points through the use of modalities and found that the results were varied. According to Rosen (1994) modalities are beneficial in the treatment of myofascial trigger points in terms of achieving muscle relaxation, improved circulation, pain relief and relief of muscle hypertonicity. This was supported by Hutchings (1998) and Chettiar (2001) with respect to the effectiveness of soft tissue modalities in the treatment of myofascial trigger points. In addition Hutchings (1998) showed that electrode placement of the transcutaneous electrical nerve stimulation over the pain referral zone as opposed to directly over the trigger points showed no difference, patients in both groups improved equally. However none of the above addressed the joint dysfunction component.

With particular reference to electrical (faradic) stimulation, Sanya (2000) found that comparing faradic stimulation to active mobilization exercise in patients with post-surgical temporomandibular joint dysfunction (TMJD) hypomobility that both interventions were effective in relieving pain and increasing intercuspal openings. However electrical stimulation was observed to be more effective than mobilization in joint hypermobility. This is in contrast to Tsolakis (2001), who compared Spinal manipulative therapy to interferential current, where all measurements improved to the same degree with the exception of the Oswestry Back Pain Disability Index Questionnaire which showed that manipulation was more effective in restoring the patient's function and decreasing their disability by the end of the clinical trial than interferential current therapy.

The above literature illustrates well the dichotomy emphasized by Schneider (1995) who states that Chiropractors who use only manipulative techniques will have limited success in the treatment of patients with joint dysfunction as they are excluding the muscular component of treatment and vice versa.

This limited research is particularly applicable to the Transeva which is said to treat patients with myofascial pain syndrome and is said to restore normal muscle tone, increase blood flow to the area resulting in tissue waste products rapidly cleared away, large supply of oxygen and nutrients delivered to the part and prevention of stagnation of lymph (Shekida Industries, 1993; Forster and Palastanga, 1990). The Transeva is also said to increase the absorption of fluid and extravasated blood and lymph flow is promoted minimizing adhesion formation. In addition to this, in chronic pain syndromes the Transeva is thought to decrease adhesions that have already formed allowing normal muscle function to return.

2.4.1 TRANSEVA THERAPY.

Faradism is a treatment using a current produced from a faradic coil (Forster and Palastanga, 1990). Faradic treatment was painful and therefore lost its appeal. The Transeva is a modern advancement on the faradic treatment, which is not painful and has numerous therapeutic abilities.

According to Forster and Palastanga (1990), and Greene (2003), the Transeva produces an attenuated faradic current which is a short duration interrupted direct current and has a frequency of 50-100 Hz and pulse duration of 0.1-1.0 m/s. When a muscle contraction is stimulated electrically, it is similar to a voluntary contraction and has similar changes in the muscle. The contraction results in increased metabolism, this results in an increase in output of waste products and an increased need for oxygen and food stuffs. The waste products or metabolites produced result in capillary and arteriole dilation and this in turn results in increased blood supply to the muscle. When the muscles contract they exert a pumping action on the surrounding veins and lymphatic drainage thus increasing venous and lymphatic return to the heart.

This increase in venous and lymphatic return produced by the contractions caused by the Transeva prevent products of inflammation collecting in the tissues which thereby prevents adhesion formation. This results in pain relief as decreased adhesion formation allows for increased range of motion (Vernon and Mrozek, 2005; Leach, 1994).

This is supported by Graham (1893) who concluded that the faradism affords the quickest means of relief after stretching or tearing injuries to muscles.

The effects of treatment by rhythmic muscular contractions of the Transeva can thus be summarized as follows (Greene, 1993):

1. Muscle elasticity, irritability and contractility (i.e. hypertonicity), are rapidly restored to normal.
2. An increase in blood is brought to the muscles and to neighboring tissues with all the attendant beneficial physio-chemical consequences.
3. Waste tissue products are rapidly cleared away and stagnation of lymph, with its serious sequelae, is prevented.
4. A large supply of oxygen and nourishment is brought to the injured part.
5. Rapid absorption of fluid and extravasated blood and lymph is actively promoted.
6. Beneficial chemical and physical changes after muscle activity take place.
7. The movements of muscle do not allow organization of lymph to take place between their surfaces and thus the danger of adhesions is minimized.
8. As the movements do much to prevent stagnation of lymph in areolar tissue in the joint interspaces, the danger of the areolar tissue losing the suppleness and flexibility necessary for efficient joint action is diminished.
9. If adhesions have formed in the muscles and peri-articular tissues, the adherent surfaces are gently and gradually torn apart by causing increasingly powerful contractions of the muscles.

10. Muscles are prevented from wasting, particularly if treatment is given soon after the injury. Muscles already wasted increase in bulk.
11. No attempt is made to cut short the process of inflammation, but to guide and control the process.

Thus many manual therapy practitioners have resorted to utilizing the Transeva in practice, to augment their manipulative or other manual therapy techniques (Greene, 2007; White, 2007; Sidley, 1994). This is however supported by Schneider (1995) who indicates that a more holistic approach is of greater benefit. This is further supported by Bedell-Sivright (2005), who found that treating the myofascial trigger points only, patients with joint dysfunctions had a lesser clinical improvement than those that did not. Thus it is recommended on a small amount of evidence that the Transeva should form part of a multilevel treatment protocol.

2.4.2 SPINAL MANIPULATIVE THERAPY.

Spinal manipulative therapy consists of specific contacts, either long or short lever techniques. The articular manipulation is one which is of a high velocity and low amplitude and has a specific direction or vector (Bergmann et al., 2002).

Koes et al., (1991) suggest that manual therapy has demonstrated to be one of the most successful treatment protocols for mechanical low back pain. This is supported by Bronfort (1992) that after twenty four trials assessing the efficacy of Spinal manipulative therapy for the treatment of low back pain, stated that Spinal manipulative therapy is a safe therapeutic approach and that in many cases offers the patient more relief than any other form of conservative treatment. This is further supported by Cooperstein et al., (2001) who suggests that Spinal manipulative therapy has been validated as a safe and effective treatment for certain types of back pain of mechanical origin. Gatterman, (1990) supports this further as it results in improved flexibility, reduced pain and increased joint mobility.

Meade et al., (1995) conducted a study with 741 patients aged 18-64 comparing chiropractic treatment to hospital outpatient management for low back pain over an extended period of time. At the end of a 3 year follow-up period, those patients receiving chiropractic treatment reported a 29% higher level of improvement in pain and disability compared to the hospital outpatients. This study suggested that chiropractic treatment of low back pain was better than standard hospital outpatient management in terms of the relief of the symptoms.

Homewood (1979) described that joint dysfunction may interfere with the nerve supply and result in a decrease in muscular activity. He hypothesized that removal of the joint dysfunction could restore normal physiological processes, increase muscle activity, improve functional ability and normalize torque ratios. This hypothesis is supported by Nansel et al., (1993), Rebechini-Zasadny et al., (1981), Korr (Leach, 1994) and Herzog et al., (1999). Leach (1994) proposed that manipulation of the spine could relax muscle hypertonicity by affecting the central nervous system input into a muscle spindle. This is further supported by Herzog (1999) who suggested that spinal manipulation resulted in reflex responses which resulted in increased functional ability of a patient, pain reduction and inhibition of a hypertonic muscle.

Leach's (1994) adhesion hypothesis states that joint dysfunction causes a restriction in movement as well as a period of inflammation. This immobilization and inflammation results in adhesion formation within and between the connective tissues as a result of fibrin deposits which are produced during the inflammatory phase.

Kirkaldy-Willis and Burton (1992) explain the effects of Spinal manipulative therapy on the grounds of mechanical and reflex mechanisms. The central transmission of pain can be blocked by increased proprioceptive input. The articular capsules of the spinal facet joints are densely populated by

mechanoreceptors. These encapsulated nerve endings relay proprioceptive information on joint position and mobility through large myelinated fibers to the substantia gelatinosa of the dorsal horn of the spinal cord. These impulses then compete for central transmission with impulses from smaller unmyelinated fibres from adjacent tissues. Thus increased proprioceptive input in the form of spinal mobility tends to decrease the central transmission of pain from adjacent spinal structures.

Restricted joint movement is increased by Spinal manipulative therapy and therefore induces motion into articular structures that helps to inhibit pain transmission by means of closing the spinal gating mechanism within the substantia gelatinosa, i.e. manipulation causes an increase in proprioceptive input, which has a reflex inhibition on the transmission of pain (Kirkaldy-Willis and Burton, 1992).

Articular mechanoreceptor stimulation has also a reflexogenic effect on motor unit activity in the muscles over the joint being stimulated. Stretching the apophyseal joint capsules can cause a reflex inhibition of facilitated motor neuron pools that are responsible for the increased excitability, which results in muscular hypertonicity that is commonly associated with low back pain (Kirkaldy-Willis and Burton, 1992).

Contra-indications to Spinal manipulative therapy (Bergmann and Peterson, 2002).

1. Absolute contraindications:

- vertebrobasilar insufficiency.
- aneurysm.
- disc prolapse with neurological deficit.
- fracture or dislocation.
- bone tumors.
- bone infections (tuberculosis).

2. Relative contraindications:

- atherosclerosis.
- anticoagulant therapy.
- arthropathies.
- hypermobility.
- severe sprains and strains.
- osteomyelitis, osteoporosis, osteomalacia.
- severe sacral nerve root compression.

2.4.3 COMBINATION THERAPY.

Thus from the literature presented, the effect of a single modality may only achieve a limited clinical response in mechanical low back pain, where a synergistic effect of combination therapies may actually benefit the patient more.

However little research has been done comparing a combined therapy to single intervention therapy especially with respect to those modalities that could augment manipulation. As a result Rosen (1994), notes that modalities should be used as an adjunct to other treatments rather than as the primary treatment. This is further supported by Haldeman (2005) who states that physical modalities should not be relied upon as primary treatment procedures. Instead, they should be used as a supplement to other treatment methods such as manipulation or rehabilitation.

2.5 CONCLUSION.

This research endeavors to ascertain the outcomes of patients receiving single intervention treatment as opposed to combined intervention treatment. This proposed study could provide the chiropractor with a simple, effective, non-invasive modality to add to the choice of myofascial treatments currently available for use in the clinical environment.

CHAPTER THREE

MATERIALS AND METHODS.

3.1 INTRODUCTION.

The general procedure which was carried out in the research study is outlined in this chapter. This includes a description of the design, the subjects and interventions, primary and secondary data, as well as statistical procedures used to assess the data.

3.2 THE STUDY DESIGN.

This study was designed as a randomized quantitative comparative clinical trial. This project received approval from the Institutional Review Board of Durban University of Technology (DUT) and was compliant with the ethical standards of the Helsinki Declaration of 1975. All participants gave informed consent before entering the trial (Appendix K).

3.2.1 Objectives of the study.

The aim was to compare three different treatment groups (Spinal manipulative therapy versus Transeva versus combined Spinal manipulative therapy and Transeva) and to identify the effectiveness of each treatment protocol in terms of objective and subjective measurements.

3.2.2 Selection of subjects.

Thirty patients were obtained from the greater Durban area by convenience sampling, using advertisements (Appendix A) posted around Durban University of Technology Campus, local gymnasiums, sporting clubs and local post boxes.

The advertisements offered free treatment for people between the ages of 20 and 45 years suffering from low back pain. No restrictions were placed on the patients' gender, racial group or occupation.

Patients responding to the advert were telephonically questioned for their age, whether or not they had a history of trauma or surgery, where their area of pain was and whether they would rate their pain on a scale of 0-10 between 4 and 8. An appointment was made for the initial consultation with the eligible candidates at the D.U.T. Chiropractic Day Clinic. At the initial consultation inclusion and exclusion criteria were assessed using a case history (Appendix B), physical examination (Appendix C) and a lumbar regional examination (Appendix D) to assess whether the patient qualified for the study.

3.2.3 Inclusion and exclusion criteria.

Although unconventional the inclusion and exclusion criteria have been classified according to posterior facet and sacro-iliac syndrome:

1. Patients had to be at least 20 years of age to ensure that participants were skeletally mature. To avoid and reduce the chance of sacroiliac and / or spinal ankylosis participants were not admitted into the study if they were over the age of 45 years (Kirkaldy-Willis and Burton, 1992).
2. The patient had to pass a full sensory neurological examination which included a sharp-blunt and light-crude touch test with their eyes closed to test the dorsal columns and spinothalamic tracts (Guyton and Hall, 2000) and to ensure the patient was able to feel the stimulus of the Transeva and the pressure Algometer. Patients were also not allowed to have had leg pain that was radicular in origin and they may not have suffered from neurological deficits, otherwise they were excluded from the study (Haslett, 1995).

3. Patients had to have a chief complaint of mechanical low back pain that could have been attributable to posterior lumbar facet syndrome and or sacro-iliac syndrome and were diagnosed by the criteria below. For the purpose of this research patients must have had the pain for at least six weeks or more, which was denoted as a chronic condition (Haldeman, 2005) and thereby ensured homogeneity and standardized the sample group (Mouton, 1996).

The following synopsis outlines the signs and symptoms of posterior facet syndrome to assist diagnosis of the syndrome.

For a diagnosis of posterior facet syndrome the patient had to have majority (5/9) of the following signs and symptoms:

Symptoms:

- Pain is localized but may radiate to hip and buttock (Morris, 2006; Vizniak and Carnes, 2004; Travell and Simons, 1999; Kanner, 1994; Plaugher, 1993).
- Pain in the proximal thigh but does not extend below the knee (Morris, 2006; Vizniak and Carnes, 2004; Travell and Simons, 1999; McCulloch and Transfeldt, 1997; Kanner, 1994; Plaugher, 1993).
- Low back stiffness is felt with inactivity and in the mornings (Morris, 2006; McCulloch and Transfeldt, 1997; Seaman, 1997; Plaugher, 1993).
- No neurological deficits (Morris, 2006; Vizniak and Carnes, 2004; Plaugher, 1993).
- No root tension signs (Morris, 2006; Vizniak and Carnes, 2004; Plaugher, 1993).
- Muscles splinting and guarded motions (Morris, 2006; Vizniak and Carnes, 2004; Plaugher, 1993).

- Pain increases with extension (Morris, 2006; Vizniak and Carnes, 2004; Adams and Dolan, 1995; Plaughner, 1993;).
- On straight leg raising at around approximately 90 degrees pain is felt in the proximal sacro-iliac joints, back and buttock (Morris, 2006; McCulloch and Transfeldt, 1997).

The following synopsis outlines the signs and symptoms of sacro-iliac syndrome: For a diagnosis of sacro-iliac syndrome the patient had to have majority (3/5) of the following signs and symptoms.

- Localized pain over the sacro-iliac joints and possible lower back and buttock radiation (Morris, 2006; Vizniak and Carnes, 2004; McCulloch and Transfeldt, 1997).
 - Focal sacro-iliac tenderness on examination (Morris, 2006; Vizniak and Carnes, 2004; McCulloch and Transfeldt, 1997; Vleeming et al., 1997).
 - There may be possible radiation to the buttocks and posterior thigh and groin (Morris, 2006; Vizniak and Carnes, 2004; McCulloch and Transfeldt, 1997).
 - The pain is aggravated by the following orthopaedic tests which usually have positive results, Patrick FABER and Gaenslens (Morris, 2006; Vizniak and Carnes, 2004; McCulloch and Transfeldt, 1997).
 - Palpatory and postural signs of misalignment as well as altered joint play (Morris, 2006; Vizniak and Carnes, 2004; McCulloch and Transfeldt, 1997; Dreyfuss et al., 1994).
 - The sacro-iliac pain is not caused by pathological processes such as infection, crystal deposition disease, inflammatory spondyloarthropathies and malignancy (Morris, 2006; Dreyfuss et al., 1994).
4. To be included patients had to have a dysfunction in the lumbar spine region as Gillet-Liekens method of motion detection within the sacro-iliac joint as discussed by Leach (1994) and Bergmann et al., (2002).

5. To be included in the study the patient had to have trigger points found in at least one of the following muscles: quadratus lumborum, erector spinae, rectus abdominus, multifidus, iliopsoas, piriformis, gluteus maximus, gluteus medius, gluteus minimus, sartorius and hamstrings, as trigger points in these muscles could have referred pain to the lower back (Travell and Simons, 1999).

As stated by Travell, Simons and Simons (1983) myofascial trigger points can be identified clinically by the following common characteristics:

- A palpable taut band.
 - A localized spot of tenderness.
 - Restricted stretch range of motion.
 - Increased pain on passive or active.
 - Weakness of the involved muscle.
 - Local twitch response.
 - A jump sign.
 - Referred pain on manual compression of the myofascial trigger point.
6. Patients initial scores on the Numerical Pain Rating Scale (Jenson et al., 1986) had to be between 4 and 8 to be included in the study which ensured homogeneity (Mouton, 1996).
 7. Patients had to have read the Letter of Information (appendix F) and signed the Informed Consent Form (appendix G) before they were included in the study.
 8. Patients were excluded if they took any analgesics (Seth, 1999) or received any other form of treatment for their pain in the last 6 weeks.

9. Any patient who had the following contraindications to Spinal manipulation were excluded (Bergmann and Peterson, 2002).

Absolute contraindications: vertebrobasilar insufficiency, aneurysm, disc prolapse with neurological deficit, fracture, dislocation, bone tumours, bone infections (tuberculosis). Relative contraindications: atherosclerosis, anticoagulant therapy, arthropathies, hypermobility, severe sprains and strains, osteomyelitis, osteoporosis, osteomalacia, severe sacral nerve root compression.

10. Any patient who required special tests or clinical tests for example radiographs or blood tests that would refute or confirm a diagnosis was excluded so as to maintain a homogenous sample population (Mouton, 1996).
11. Any patient for whom electrical current and faradic current was contraindicated as per Kahn (1994) was excluded. These included pace makers and new fractures. This was to avoid unwanted motion, active haemorrhage and development of phlebitis.
12. Patients who had received low-back surgery were excluded from this study as the source of their pain may have been related to the surgery (Kirkaldy-Willis et al., 1992).
13. Patients who had a diagnosis of any systemic manifestation of arthritides which may have been contributing to or have been a cause of the low back pain were excluded from this study (Haslett, 1995).
14. Patients who were or possibly were pregnant were excluded from the study due to hormone induced ligament laxity and possible resultant instability thereby causing low back pain (Vleeming et al., 1990).

3.2.4 Allocation of subjects.

Once the patient was deemed suitable for the study, the patient was informed about the study and given a Letter of Information (Appendix F) which described the study in detail. If they agreed to participate in the study they were asked to sign an Informed Consent Form (Appendix G) before the treatment commenced.

Once included, patients were randomly allocated (Mouton, 1996). This was achieved by using 30 pieces of small paper, 10 which had an A on them, the next 10 had a B on them, and the remaining had a C on them. These were placed in a box, shaken and the patients drew out one at a time. This indicated which group the patient was allocated to.

Patients who chose group A received Spinal manipulative therapy, patients who chose group B received Transeva and patients who chose group C received Transeva followed immediately by Spinal manipulative therapy.

The patient was then scheduled for treatments according to the following protocol; the patients had to come for three treatments in the first week, two treatments in the second week and a follow up reading no more than one week from treatment four, i.e. within 7 days of the penultimate treatment. See Table 3.1.

Table 3.1 Treatment protocols.

	Week 1			Week 2		Follow up
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6 ¹
	Rx ² 1:			Rx 2:		Rx: 3
Group A	SMT ³	SMT	SMT	SMT	SMT	
Group B	T ⁴	T	T	T	T	
Group C	SMT & T	SMT & T	SMT & T	SMT & T	SMT & T	

And this treatment protocol was chosen because of its favorable responses to manipulation which studies showed as normally occurring between 7-10 days (Gatterman, 1990). The treatment protocol for previous treatment with the Transeva for neck pain with associated myofasciitis was two treatments (Bedell – Sivright, 2005), however this was limited to myofascial trigger points only and therefore an increase in treatments was considered optimal for this research.

3.3 INTERVENTIONS.

According to Forster and Palastanga (1990), the faradic current is a short duration interrupted direct current with a pulse duration of 0.1-1ms and a frequency of 50-100 Hz. Transeva has a similar waveform in relation to the faradic wave pattern, it could therefore be assumed that the effects of faradism hold true for the Transeva (Greene, 1993).

¹ No more than 1 week after visit 4

² Rx – Data readings (included pressure Algometer, Inclinator, Numerical Pain Rating Scale and Roland-Morris Questionnaire),

³ SMT – Spinal manipulative therapy

⁴ T – Transeva

Transeva (Shekida Industries, 1993; Bedell – Sivright, 2005):

- The patient, after passing a full sensory neurological examination including a sharp-blunt and light-crude touch test with their eyes closed, was then positioned with their eyes open, lying prone with the saline-soaked negative pad placed under their thighs.
- Ultrasound gel was applied to the low back area to be treated as a transmission medium for the faradic current.
- The faradic treatment was applied for a duration of 20 minutes with a pulse of 0.1-1ms and a frequency of 50-100HZ (Forster and Palastanga, 1990).
- The mobile electrode was moved over the lubricated treatment area until the researcher's hand holding the mobile electrode felt a muscular contraction.
- Bony prominences were avoided and the surge control was adjusted to give about 90-100 contractions per minute.
- As the patient became accustomed to which degree of muscular contraction, which was usually after one to two minutes, the intensity was increased slowly to induce muscular contraction.
- Because of its full contact with the skin, it could not be strapped in one place as this would have aggravated the myofascial trigger points in the area to which it was strapped.
- At the final stage of the treatment, the intensity was reduced gradually to zero. The machine was then switched off.

Manipulation:

The motion palpation was used as described by the Gillet-Liekens method (Leach, 1994). In this context, motion palpation was defined as palpatory diagnosis of passive and active segmental joint range of motion. (Bergmann et

al., 1993). This is where there is an application of variable manual pressure through the surface of the body for the purpose of determining the shape, size, consistency, position, inherent mobility, and health of the tissues beneath.

A lumbar or sacro-iliac dysfunction had to be found in one or more directions for inclusion of the subject into the study. The Researcher placed one thumb over the second sacral tubercle and the other thumb on the posterior superior iliac spine (PSIS) on the side of the joint.

Manipulations were applied as described in Bergmann et al., (1993) to the relevant dysfunctions found in the direction where there was reduced range of motion found on motion palpation as per Schafer and Faye (1989).

Manipulations of the Lumbar Spine (Bergmann et al., 1993):

Pisiform – Spinous.

Indication: Flexion joint dysfunction.

Patient Position: Patient was in lateral recumbent with either side up, with both knees and hips flexed, with headrest in the elevated position.

Researcher position: Square stance.

Indifferent Hand: Stabilized the shoulder and upper body.

Segmental Contact Point: Pisiform contact.

Contact point: Spinous process of the fixated segment.

Vector: Inferior to superior and posterior to anterior.

Procedure: Patient was positioned in flexion, contact was on the spinous process of the fixated vertebra, joint slack was taken out till resistance was felt and a body drop thrust was applied.

Pisiform-Facet.

Indication: Extension joint dysfunction.

Patient Position: Patient was lateral recumbent with joint dysfunction side up, in good side posture position and headrest in the elevated position.

Researcher Position: Square stance.

Indifferent Hand: Stabilized the shoulder and upper body.

Segmental contact point: Pisiform contact.

Contact point: Facet joint of the fixated segment.

Vector: Posterior to anterior.

Procedure: Patient was positioned and contact was on the facet of the fixated vertebrae, joint slack was taken out till resistance was felt (the patient was asked to arch their back and stick their stomach out) and a body drop thrust was applied.

Pisiform Facet (lumbar roll).

Indication: Posterior-Anterior (PA) rotation joint dysfunction.

Patient Position: Patient was lateral recumbent with the joint dysfunction side up, in side posture position with headrest in the elevated position.

Researcher position: Was initially square stance and then moved to fencer stance.

Indifferent hand: Stabilized, with some counter-rotation, the shoulder and upper body by using the patient's hand to contact over the shoulder (or lower down if it was necessary).

Segmental Contact Point: Pisiform contact.

Contact Point: Facet joint of the fixated segment.

Vector: Posterior to anterior and inferior to superior.

Procedure: Patient was positioned in side posture, knee was flexed until movement was felt at involved level, skin slack was removed, contact was on the facet of the fixated vertebrae, then moving to fencer stance rolling the patient over so that the Researcher's lateral thigh was against the patients lateral thigh, joint slack was taken out till resistance was felt and a body drop with pectoral thrust was applied.

Pisiform Spinous.

Indication: Lateral flexion joint dysfunction.

Patient Prone: Patient lateral recumbent with joint dysfunction side up, in good side posture position and headrest in the elevated position.

Researchers Position: Square stance.

Indifferent Hand: Stabilized the shoulder and upper body.

Segmental Contact Point: Pisiform contact.

Contact Point: Lateral aspect of the spinous process of the fixated segment.

Vector: Lateral to medial and slight posterior to anterior.

Procedure: Patient was positioned in normal side posture, contact was on the lateral aspect of the spinous process of the fixated vertebra, joint slack was taken out till resistance was felt and a body drop thrust was applied.

Manipulations of the sacro-iliac joints (Bergmann et al., 1993):

Side Posture.

Indication: Upper and lower sacro-iliac joint flexion dysfunction.

Patient Position: Proper side posture position with the lesion side sacro-iliac joint up toward the Researcher.

Doctor position: Square stance.

Contact Point: Sacro-iliac joint with the Researcher's caudad hand.

Segmental Contact Point: Upper aspect of the upper sacro-iliac joint at the point of joint dysfunction.

Indifferent Hand: Stabilized the upper body at the patient's shoulder.

Vector: Was into the joint dysfunction in relation to the sacro-iliac joint.

Procedure: Patient was positioned in good side posture, stress was initiated into the sacro-iliac joints and pelvis, contact was made and stress was applied to the joint dysfunction, a body drop thrust was applied when the elastic barrier was met.

Pisiform – sacro-iliac– genu.

Indication: Upper sacro-iliac joint extension dysfunction.

Patient position: Prone.

Doctor position: Lunge position in opposite side of fixated sacro-iliac joint.

Contact point: Sacro-iliac joint with the Researcher's cephalad hand.

Segmental Contact Point: Upper aspect of the down sacro-iliac joint at the point of joint dysfunction.

Indifferent Hand: Contact the anterior aspect of the flexed knee in the same side of the fixated sacro-iliac joint.

Vector: Into the joint dysfunction in relation to the sacro-iliac joint.

Procedure: Patient was positioned with the sacro-iliac joint in extension with the hip extended, stress was initiated into the sacro-iliac joints and pelvis, contact is made and stress was applied to the joint dysfunction, thrust was applied when the elastic barrier was met.

Pisiform-sacro-iliac-genu.

Indication: Lower sacro-iliac joint extension dysfunction.

Patient Position: Prone.

Researcher position: Lunge position on same side of fixated sacro-iliac joint.

Contact point: Sacro-iliac joint with the Researcher's cephalad hand.

Segmental Contact Point: Lower aspect of the down sacro-iliac joint at the point of joint dysfunction.

Indifferent hand: Contact the anterior aspect of the flexed knee in the same side of the fixated sacro-iliac joint.

Vector: Into the joint dysfunction in relation to the sacro-iliac joint.

Procedure: Patient is positioned with the sacro-iliac joint in extension with the hip extended, stress is initiated into the sacro-iliac joints and pelvis, contact was made and stress was applied to the joint dysfunction, thrust was applied when the elastic barrier was met.

Group A was treated with Spinal manipulative therapy only for each of their treatments.

Group B was treated with the Transeva only for each of their treatments.

Group C was treated with the Transeva first followed immediately by Spinal manipulative therapy for each of their treatments.

Intervention Frequency:

Each patient received:

3 treatments (treatment 1,2, and 3) in the first week.

2 treatments (treatment 4 and 5) in the second week.

And one follow-up reading no more than one week after treatment 4.

3.4 METHOD OF MEASUREMENTS.

3.4.1 Subjective measurements.

3.4.1.1 Numerical Pain Rating Scale.

Subjective pain is still considered one of the most important measurements available to researchers and clinicians (Jenson et al., 1986).

The patient's perception of pain intensity is marked on a numerical scale from 0 – 100, with 0 being no pain and 100 representing the worst pain. The patient indicates by means of a percentage on a 10cm line, when the pain was at its worst and again on another 10cm line when it was at its least. The average of these two figures indicates the average pain experienced by the patient as a percentage.

Jenson et al., (1986) conducted a study that concluded that the Numerical Pain Rating Scale was superior to the other measures due to its simple and practical method of administering and scoring, which may be in written or verbal form and its results did not seem to be dependant on age.

A study on seventy-nine chiropractic patients by Bolton and Wilkinson (1998) compared three pain scales, including the Visual Analogue Scale, the Verbal Rating Scale and the Numerical Pain Rating Scale. It was found that the Numerical Pain Rating Scale was the most responsive and was recommended for most types of outcome studies.

3.4.1.2 Roland-Morris Questionnaire.

The Roland-Morris Questionnaire (RMQ) (Roland and Morris, 1983) was used for its simplicity which according to Stratford et al., (1998) reduces ambiguity of the questions.

The RMQ was derived from Bergner et al., (1981) Sickness Index Profile (SIP). The SIP is a lengthy questionnaire from which Roland and Morris, in an attempt to improve its utility and practicality, extracted 24 items (from 136 items) that they believed would be most relevant for low back pain.

In a study by Deyo (1986) it was concluded that the RMQ appears at least as valid as the lengthier scales.

The advantages of the RMQ over the SIP were discussed in Deyo's (1986) study of conservatively treated mechanical low back pain patients. The advantages included:

- (1) a shorter instrument (24 versus 136 questions).
- (2) similar correlation to the Physical Dimension portion of the SIP; and
- (3) psychosocial function that was less susceptible to change than

physical function.

- (4) Another advantage of the RMQ in the low back pain population is that it is condition specific for low back pain, unlike the generic or general health SIP.

The study completed by Roland and Morris (Yeomans, 2000) was referred to as the best single study of assessing short term outcomes of primary care patients with low back pain (Von Korff and Saunders, 1996).

3.4.2 Objective Measurements.

3.4.2.1 The Inclinator.

The digital dual-Inclinometer was used to measure each patients' active lumbar ranges of motion in flexion, extension, bilateral lateral flexion, and bilateral rotation. Previous research indicates that these measurements appear to be reliable when taken by the same examiner (Witvrouw et al., 2001).

A study was conducted by Newton and Waddell (1991) to test the validity and reliability of three methods of measuring lumbar spine mobility: digital Inclinator, kyphometer and finger to floor. The authors concluded that inter-test reliability for the Inclinator method was good, with an intra-class correlation value of 0.76, and validity was confirmed by X-ray measurements. It was noted that the Inclinator was quick and easy to use, and had the advantage of being able to measure a comprehensive group of tests of lumbar mobility.

A more recent study conducted by Saur et al., (1996) on 54 patients measured the reliability and validity of measuring lumbar range of motion with an Inclinator. By correlating measurements based on anatomic reference points

determined by radiographs and those taken using the Inclinator alone, the noninvasive Inclinator technique was concluded to be highly reliable and valid ($p < 0.001$), and a useful clinical tool for measuring lumbar range of motion.

Prior to measurements being taken, the patient was educated on the use of the Inclinator and demonstrated the various movements required during measurement of active range of motion, by the researcher. All measurements were taken with the patient standing on a firm surface. The patient's maximum active range of motions from an erect neutral spine position in flexion, extension, bilateral lateral flexion and bilateral rotation were then measured in degrees, according to the protocol laid out in the manufacturer's procedure manual and instructional video, and recorded on the patient's data capture form (Appendix H). The Dual Inclinator used was: The Dualer Lite. Manufacturer: JTech Medical Industries, 357 West 910 South, Heber City, Utah, USA.

3.4.2.2 The Pressure Algometer.

The Algometer used in this trial was the Wagner FDK20 Force Dial (Wagner Instruments, P.O. Box 1217, Greenwich, CT, 06836, USA).

Fischer (1987) described the Algometer pressure/pain threshold readings as the minimum pressure or force that induces pain or discomfort.

The Algometer is a force gauge fitted with a rubber disc which has a surface area of 1cm². Pressure is applied to a defined surface on the body through the rubber disc. The gauge is calibrated in kg/cm². The device consists of a dial attached to a metal rod with a tread on the end. Pressure exerted on the rod moves the indicator in a clockwise direction. Pressing the knob returns the indicator to zero after each measurement. The achieved force value is held until the knob is

pressed (maximum hold function), allowing a reading even after the meter is removed from the body (Fischer, 1987).

The patients were educated as to how the gauge worked and that it would be placed on two of the most tender myofascial trigger points identified. The two most tender trigger points were measured as according to Korr (cited in Leach, 1994) a decrease in muscle hypertonicity results in increased joint motion. The pressure would be increased until the pressure sensation changed to pain (pain threshold point) at which stage the patient must verbalize that such a change has taken place by saying 'now'.

The higher the reading the less tenderness was felt, indicating a higher tolerance to pain.

According to Fischer (1987), the effects of treatments as injections, physiotherapy modalities or manipulation can be quantified and the reproducibility of the Algometer measurement also indicates that the records of pain intensity are reliable.

3.5 THE LOCATION OF THE DATA.

The primary data was obtained from the Roland-Morris Questionnaire, the Numerical Pain Rating Scale, the pressure Algometer and Inclinator readings. The data was collected prior to treatment one, prior to treatment four and at the sixth follow-up visit.

3.6 STATISTICAL ANALYSIS.

SPSS version 15.0 (SPSS Inc, Chicago, Ill, USA) was used to analyse the data. A p value of <0.05 was considered as statistically significant.

Demographics and baseline outcomes were compared between the three treatment groups using one way ANOVA with Bonferroni post hoc tests or Pearson's chi square tests for categorical variables. The treatment effect was analysed by repeated measures ANOVA since repeated data are collected over three time points. Since there were three treatment groups, all three possible 2 way combinations of treatment groups were analysed separately. A significant time by treatment group interaction was taken as a significant treatment effect. Profile plots by group over time will be generated to graphically compare the treatments and to examine for a trend if the effect was non significant. Pearson's correlations were compiled intra-group to assess correlations between changes in outcome measurements over time.

CHAPTER FOUR

RESULTS AND DISCUSSION.

4.1 Introduction.

This chapter contains the statistical analysis of the subjective and objective data obtained from the patients over the 2 week treatment period. The patients in group A received Spinal manipulative therapy, group B received Transeva and group C received Transeva followed by Spinal manipulative therapy.

Data for this study was obtained from a case history, lumbar regional examination, Roland-Morris Questionnaire, as well as from a Numerical Pain Rating Scale, Inclinator and Algometer readings. The questionnaire was explained fully to the patients before they completed it. The researcher took all the Algometer and Inclinator readings and all the treatments were done by the Researcher.

4.2 Review of the Objectives.

The objective of the study was to investigate the relative effectiveness of Transeva and Spinal manipulative therapy for mechanical low back pain.

Objective one was to determine the effectiveness of the following therapies for mechanical low back pain in terms of subjective clinical findings using the NRS and the RMQ.

- A) Spinal manipulative therapy.
- B) Transeva.
- C) Transeva followed by Spinal manipulative therapy.

Hypothesis 1.

It was hypothesized that Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva or combined Transeva and Spinal manipulative therapy, in terms of subjective clinical findings.

Hypothesis 2.

It was hypothesized that Transeva therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or combined Transeva and Spinal manipulative therapy, in terms of subjective clinical findings.

Hypothesis 3.

It was hypothesized that Transeva followed by Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or Transeva, in terms of subjective clinical findings.

Objective two was to determine the effectiveness of the following therapies for mechanical low back pain in terms of objective clinical findings using the pressure Algometer and Inclinator.

- A) Spinal manipulative therapy.
- B) Transeva.
- C) Transeva followed by Spinal manipulative therapy.

Hypothesis 4.

It was hypothesized that Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva or combined Transeva and Spinal manipulative therapy, in terms of objective clinical findings.

Hypothesis 5.

It was hypothesized that Transeva therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or combined Transeva and Spinal manipulative therapy, in terms of objective clinical findings.

Hypothesis 6.

It was hypothesized that Transeva followed by Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or Transeva, in terms of objective clinical findings.

4.3 THE DATA:

The data was in two forms, primary and secondary data:

4.3.1 The Primary data:

There were four types of primary data:

- ❖ The patient's response to the Numerical Pain Rating Scale (Appendix I).
- ❖ The patient's response to the Inclinator (Appendix H).
- ❖ The patient's response to the Roland-Morris Questionnaire (Appendix J).
- ❖ The patient's response to the Algometer (Appendix I).

4.3.2 The Secondary Data:

The published documentation as referenced in the attached reference list on mechanical low back pain, Spinal manipulative therapy and Transeva.

4.3.3 Abbreviations:

Δ - Change in.

Alg Tp1 -	Algometer trigger point one.
Alg Tp2 -	Algometer trigger point two.
Ext -	Extension.
Flex -	Flexion.
Llf -	Left lateral flexion.
Lrot -	Left rotation.
NRS -	Numerical Pain Rating Scale.
Rlf -	Right lateral flexion.
RMQ -	Roland-Morris Questionnaire.
Rrot -	Right rotation.
Sig -	Significance.
SMT -	Spinal manipulative therapy.
T -	Transeva.
T&SMT -	Transeva and Spinal manipulative therapy.

4.4 RESULTS:

4.4.1 Patient inclusion and drop out:

In total 33 patients were enrolled into the study, however only 30 completed the study. Three patients dropped out of the study. One patient was from the Spinal manipulative therapy group and dropped out of the study after treatment two due to interruptions by strikes and the DUT Chiropractic Day Clinic closing for a week. The second patient was from the Transeva and Spinal manipulative therapy combination group, this patient did not return after treatment one as he reported he felt his condition had resolved. The third patient was also from the Transeva and Spinal manipulative therapy group, who did not return after treatment four due to difficulties with transport. It is important to know how many patients dropped out from each group and their reasons because studies indicated that if they dropped out from the same group, then the results of that group could be

incorrect as possibly only the people who improved remained in the study (Mouton, 1996).

4.4.2. Demographics.

4.4.2.1 Age.

Table 4.1 and 4.2 show that there was no significant difference between the mean age of the three groups ($p=0.284$), although the mean age of group A tended to be lower than that of group B and group C.

Table 4.1: Descriptive statistics for comparison of age between treatment groups.

Treatment group	Mean	N	Std. Deviation
T	28.90	10	4.701
SMT	33.10	10	8.582
T&SMT	33.40	10	6.931
Total	31.80	30	7.000

Table 4.2: ANOVA comparison of mean age between the treatment groups.

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	126.600	2	63.300	1.321	.284
Within Groups	1294.200	27	47.933		
Total	1420.800	29			

4.4.2.2 Gender.

Overall the patients mean age was 31.8 years and 53.3% were male. Although there tended to be a predominance of females in Group B, the difference was not statistically significant ($p=0.585$) (Table 4.3).

Table 4.3: Cross tabulation of treatment group and gender.

			Treatment group			Total
			T	SMT	T&SMT	
Gender	Male	Count	6	4	6	16
		% within gender	37.5%	25.0%	37.5%	100.0%
	Female	Count	4	6	4	14
		% within gender	28.6%	42.9%	28.6%	100.0%
Total		Count	10	10	10	30
		% within gender	33.3%	33.3%	33.3%	100.0%

Pearson's chi square = 1.071, $p=0.585$

4.4.2.3 Ethnic Group.

The patients' demographic breakdown was 90% White, 6.7% Black and 3.3% Asian. Table 4.4 shows that there was little difference in terms of ethnic group between the three treatment groups ($p=0.521$). There tended to be a predominance of white patients in Group C the combined Transeva and Spinal manipulative therapy group.

Table 4.4: Cross tabulation of treatment group and ethnic group.

			Treatment group			Total
			T	SMT	T&SMT	
Ethnic	White	Count	9	8	10	27
		% within ethnic	33.4%	29.6%	37.0%	100.0%
	Black	Count	1	1	0	2
		% within ethnic	50.0%	50.0%	.0%	100.0%
	Asian	Count	0	1	0	1
		% within ethnic	.0%	100.0%	.0%	100.0%
Total		Count	10	10	10	30
		% within ethnic	33.3%	33.4%	33.3%	100.0%

Pearson's chi square = 3.222, p=0.521

Summary:

There was no significant age difference between the treatment groups ($p=0.284$), or gender difference ($p=0.585$) or Ethnic group difference ($p=0.521$). This is important and ensures a homogenous sample group (Mouton, 1996) and no statistical corrections need to be done on the results to effectively compare the outcomes of the groups.

Baseline Outcomes comparisons:**Table 4.5: ANOVA Comparison of baseline (pre treatment) outcomes between treatment groups:**

Treatment group		NRS	Alg Tp1	Alg Tp2	Flex	Ext	Rrot	Lrot	Rlf	Llf	RMQ
T	Mean	4.30	2.7033	2.6050	116.6000	18.0667	55.4667	57.1333	23.0667	23.2000	4.80
	N	10	10	10	10	10	10	10	10	10	10
	Std. Deviation	.53	1.13556	1.03697	40.49197	11.92135	17.68741	18.80189	9.03874	7.65652	2.860
SMT	Mean	4.52	2.6967	2.7833	93.0667	11.9333	52.3000	48.1333	19.0333	19.3000	4.50
	N	10	10	10	10	10	10	10	10	10	10
	Std. Deviation	1.60	.74890	.64007	37.11204	2.79682	22.13508	22.50333	5.70780	6.71915	4.767
T&SMT	Mean	4.66	2.9000	2.8567	114.4333	12.7333	71.0000	69.8667	23.7333	22.9000	4.60
	N	10	10	10	10	10	10	10	10	10	10
	Std. Deviation	.75	.39876	.65018	34.47062	3.05020	23.03460	20.66918	4.70828	7.15447	3.502
Total	Mean	4.49	2.7667	2.7483	108.0333	14.2444	59.5889	58.3778	21.9444	21.8000	4.63
	N	30	30	30	30	30	30	30	30	30	30
	Std. Deviation	1.04	.79549	.77692	37.70559	7.55563	21.97485	21.94747	6.84144	7.16505	3.662
P value		0.75	0.821	0.770	0.315	0.143	0.124	0.080	0.259	0.414	0.984

As expected, there were no significant differences between the three treatment groups in terms of baseline outcome measurements. This indicated that randomization process was considered as complete. The importance of the baseline outcome measures having no significant difference, is that it ensures that all three groups were similar at the start so that true conclusions from the results produced after the treatments can be made. However if the baseline measures had significant differences then a statistical correction would have to be done on all the results before any conclusions could be made.

4.4.3 Inter and Intra-group analysis:

4.4.3.1 Subjective findings:

With respect to this study, objective one was to determine the effectiveness of the following therapies: a) Spinal manipulative therapy, b) Transeva and c) Transeva followed by Spinal manipulative therapy for mechanical low back pain in terms of subjective clinical findings using the Numerical Pain Rating Scale (NRS) and the Roland- Morris Questionnaire:

4.4.3.1.1 Subjective findings: NRS:

Table 4.6: Within-and between-subjects effects for NRS:

Effect	Statistic	p value
Time	Wilk's lambda=0.477	<0.001
Group	F=1.740	0.195
Time*group overall	Wilk's lambda = 0.696	0.048
Time*group Transeva and Spinal manipulation groups	Wilk's lambda = 0.831	0.207
Time*group Transeva and both	Wilk's lambda = 0.806	0.161
Time*group Spinal manipulation and both	Wilk's lambda = 0.669	0.033

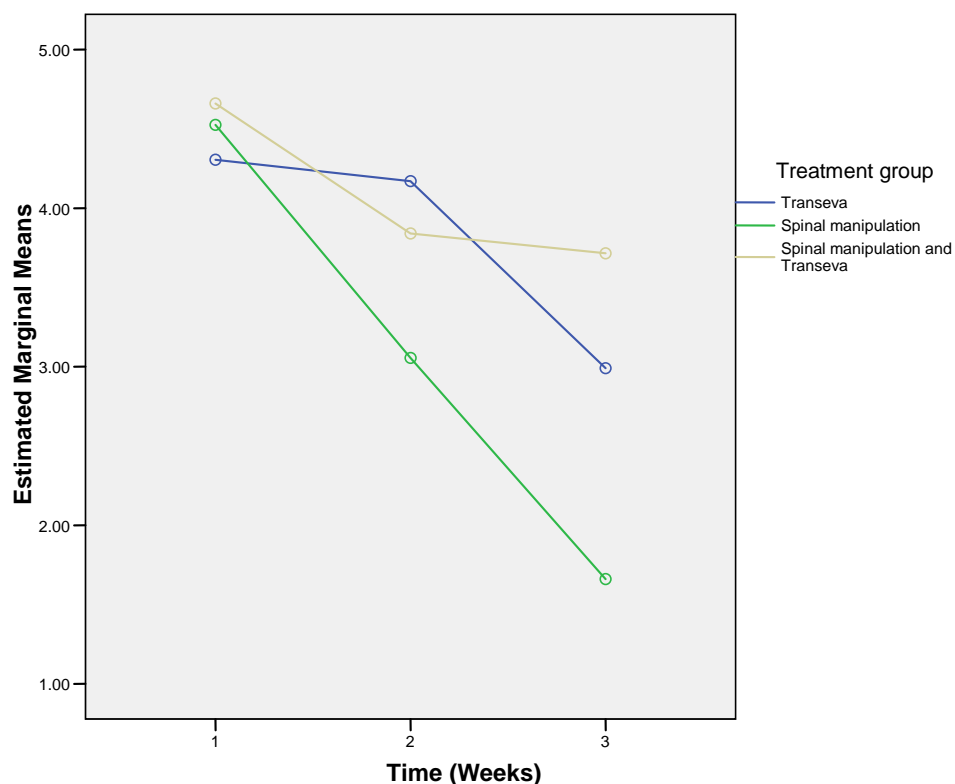


Figure 4.1: Profile plot of mean NRS by time and group

NRS:

There was a statistically significant time*group interaction effect for NRS overall when comparing the three treatment groups ($p=0.048$). However, when comparing each treatment to the other, it appeared that the significance was between the Spinal manipulation group and the group which received both treatments ($p=0.033$). Figure 4.1 shows that pain decreased at a faster rate in the Spinal manipulation group than any other group. This indicated that the Spinal manipulation group showed a significantly faster rate of pain reduction than the group which received both treatments but not significantly faster than the Transeva group.

Discussion:

It seemed that the Spinal manipulation group showed that pain decreased at a faster rate in comparison to the Transeva and Spinal manipulation and Transeva groups, this could be due to the fact that Spinal manipulation works on all four joint mechanoreceptors, stimulating the type I and II mechanoreceptors which has an influence on muscle tone, as well as having an inhibitory effect on the unmyelinated free nociceptive nerve endings, thereby blocking the pain sensation (Freeman and Wyke, 1967 in Haldeman, 2005; Roberts et al., 1995).

The group which received both Transeva and Spinal manipulative therapy seemed to improve initially in terms of their pain rating but then the rate of reduction in pain slowed down between reading 2 and 3. It seems that this could be due to the patients' perception of receiving both treatments thereby expecting to do better which is an example of an observer effect (Mouton, 1996). A study by Hurwitz (2002) showed in a large trial that combining physical modalities with Spinal manipulation did not result in any better outcomes when compared to using Spinal manipulation alone for the treatment of low back pain. However the perceived treatment effectiveness was greater in the group which received both physical modalities and Spinal manipulation.

It could also be possible that the Transeva aggravates the joint dysfunction which was present so that the lesion is worse than it was at baseline before the Spinal manipulative therapy was applied. This is possible through muscle contraction on an already contracted muscle pulling on the joint capsule causing further inflammation. According to Korr's theory of gamma gain (Leach, 2004), muscle hypertonicity is as a result of the central nervous system (CNS) ordering the muscle to contract which carries with it low-gain gamma motor-neuron activity. At the same time there is approximation of the joint attachments which dampens annulospiral signals to CNS, so the CNS orders further contraction and turns up the gamma gain to take up the slack. Increasing the gamma motor activity likewise results in increased fusimotor activity and the muscle is contracted

further resulting in hypertonicity. A manipulation is thought to stretch this muscle hypertonicity to such a degree that it causes the CNS to turn down the contraction. So if the Transeva was applied to the muscle first and relieved the muscle hypertonicity, and then a manipulation was applied, a major stretch would be applied to normal muscle tone resulting in the CNS to order contraction and possibly resulting in reflex muscle hypertonicity which would explain the initial improvement in pain and then the rate of improvement dropping.

The group which received Transeva only, seemed to have a slow rate of reduction in pain initially, but then the rate of pain reduction improved. This could be due to the patients being unfamiliar with the Transeva and therefore were more skeptical and had a slower rate of improvement initially. The initial delay in improvement may also be as a result of delayed onset muscle soreness (DOMS) caused by the contractions produced by the Transeva. DOMS is soreness which appears 24 to 48 hours after exercise (Abraham, 1977) involving eccentric contraction and results in tenderness on palpation, increased muscle stiffness, painful contraction and stretching (Smith, 1991). Another possibility is that the patients in the Transeva group had both muscle and joint dysfunction and that the muscle dysfunction was being addressed by the Transeva but the joint restrictions remained. The treatment effect of the Transeva is pain reduction, reduction in muscle tension, reduction in fibrous tissue and adhesions and an increase in circulation (Greene, 1993), however it does not directly increase joint motion. Haldeman (2005) states that physical modalities should not be relied upon as primary treatment procedures. Instead, they should be used as a supplement to other treatment methods such as manipulation or rehabilitation.

Null hypothesis: There is no difference in the treatment effect of the three groups in terms of NRS measurements.

The null hypothesis is rejected for this outcome and therefore concluded that there was a significant treatment effect for NRS.

4.4.3.1.2 Subjective Findings: RMQ:

Table 4.7: Within-and between-subjects effects for RMQ:

Effect	Statistic	p value
Time	Wilk's lambda=0.543	<0.001
Group	F=0.565	0.575
Time*group overall	Wilk's lambda = 0.919	0.692
Time*group T and SMT	Wilk's lambda = 0.920	0.492
Time*group T and T&SMT	Wilk's lambda = 0.931	0.497
Time*group SMT and T&SMT	Wilk's lambda =0.999	0.989

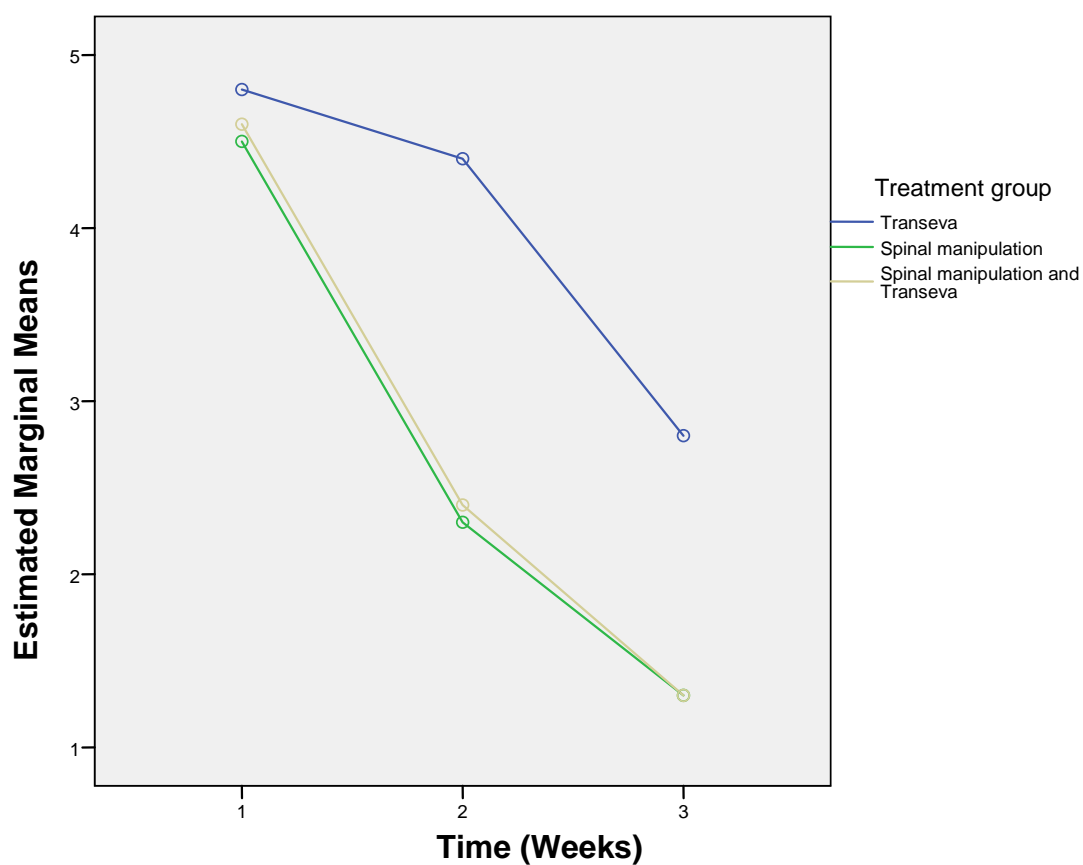


Figure 4.2: Profile plot of mean RMQ by time and group

RMQ:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was highly significant overall ($p < 0.001$) meaning regardless of which treatment group they were in, RMQ measurements changed highly significantly over the three time points. Figure 4.2 shows that the change was a decrease in RMQ score over time and that the profiles of the groups were almost parallel over time.

Discussion:

The Spinal manipulative therapy group and the group which received both Transeva and Spinal manipulative therapy fared best with reduction in disability and almost equally so.

It seems that a reasonable reduction in pain in the Spinal manipulative therapy group, resulted in an equal reduction in disability. This could be explained through the effects of manipulation increasing range of motion, decreasing pain, and improvement of function. This is supported by Homewood (1979) as well as Herzog et al., (1999) who said that certain reflex responses following manipulation have been attributed to having an increasing effect on functional ability of the patient, pain reduction and inhibition of hypertonic muscle.

The Transeva and Spinal manipulative therapy group however had a greater reduction in disability than in pain; this could possibly be an indication that the Roland-Morris Questionnaire was not as sensitive as the Numerical Pain Rating Scale (Yeomans, 2000). Roland and Fairbank (2000) suggest that while RMQ can be used in chronic back pain patients, often it is preferred as a measurement for acute low back pain sufferers because its questions appear to be more applicable to those with recent pain.

It seems that the Transeva group fared the same in their reduction in disability as they did with their reduction in pain, again with an initial lag time, possibly due to

the unknown machine or DOMS and then showing a faster rate of improvement after reading two.

It is a possibility that the Transeva group and the Spinal manipulative therapy group had both muscle and joint dysfunction components to their low back pain where as it is possible that the Transeva and Spinal manipulative therapy combination group had mainly joint dysfunction. Therefore a recommendation for future studies would be to try homogenize the groups ensuring they had equal amounts of muscle and joint dysfunction.

Null hypothesis: There is no difference in the treatment effect of the three groups in terms of RMQ scores.

The null hypothesis is accepted.

4.4.3.2 Objective Findings:

4.4.3.2.1 Objective Findings: Algometer trigger point 1:

Table 4.8:

Within-and between-subjects effects for Algometer Trigger point 1

Effect	Statistic	p value
Time	Wilk's lambda=0.572	0.001
Group	F=0.164	0.849
Time*group overall	Wilk's lambda = 0.883	0.508
Time*group T and SMT	Wilk's lambda = 0.872	0.313
Time*group T and T&SMT	Wilk's lambda = 0.919	0.488
Time*group SMT and T&SMT	Wilk's lambda = 0.964	0.734

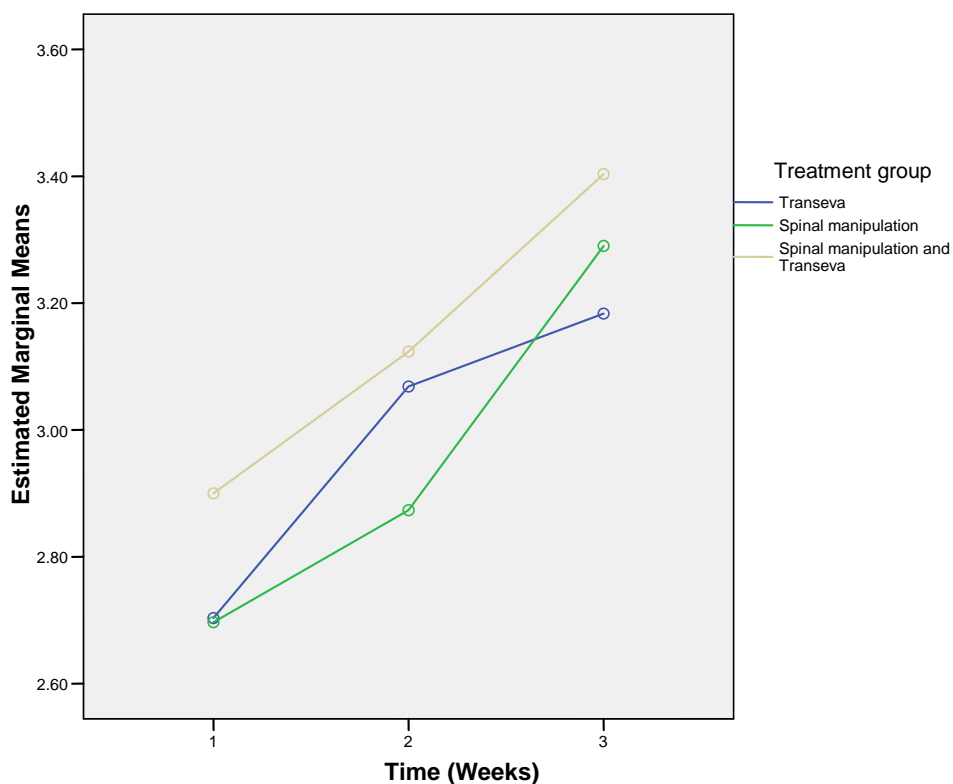


Figure 4.3: Profile plot of mean Algometer trigger point 1 by time and group

Algometer trigger point 1:

There was no significant treatment effect for this outcome overall or when each group was compared to each other group. The time effect was significant overall ($p=0.001$), meaning regardless of which treatment group they were in, Algometer measurements improved significantly over the three time points.

4..4.3.2.2 Objective Findings: Algometer trigger point 2

Table 4.9:

Within-and between-subjects effects for Algometer Trigger point 2

Effect	Statistic	p value
Time	Wilk's lambda=0.399	<0.001
Group	F=0.549	0.584
Time*group overall	Wilk's lambda = 0.965	0.919
Time*group T and SMT	Wilk's lambda = 0.994	0.951

Time*group T and T&SMT	Wilk's lambda = 0.956	0.683
Time*group SMT and T&SMT	Wilk's lambda = 0.955	0.675

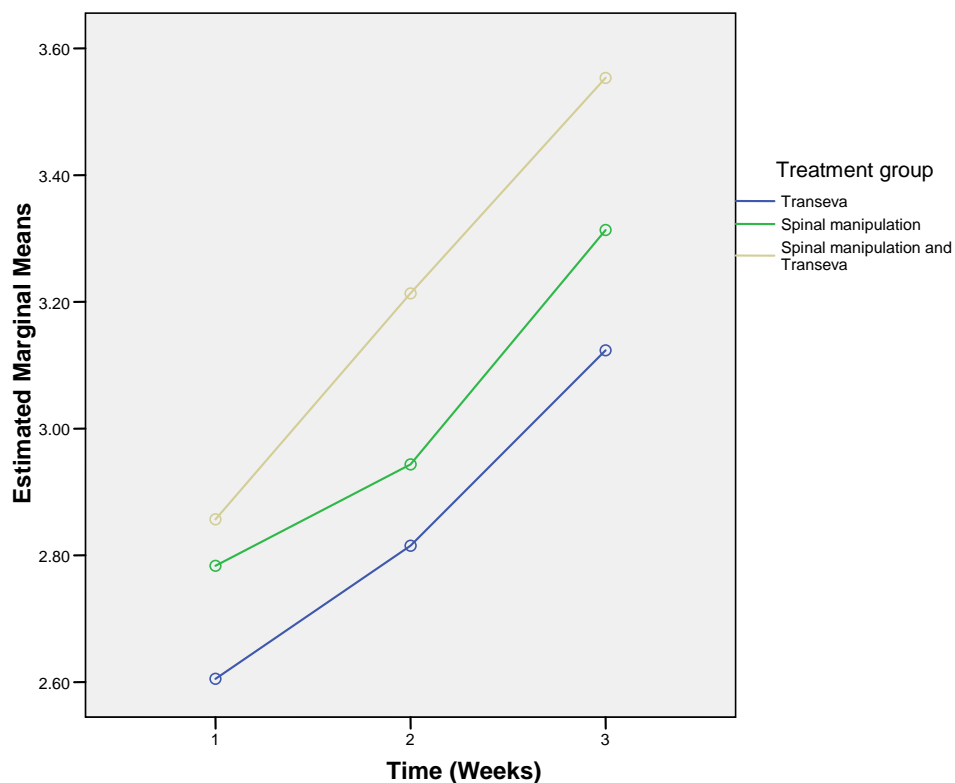


Figure 4.4: Profile plot of mean Algometer trigger point 2 by time and group

Algometer trigger point 2:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was significant overall ($p < 0.001$), meaning regardless of which treatment group they were in, Algometer measurements improved significantly over the three time points. Figure 4.4 shows parallel profiles over time of the three treatment groups.

Discussion:

The Spinal manipulative therapy group seemed to show a delay in improvement in terms of the Algometer measurements. This could be due to the fact that the

Spinal manipulative therapy addresses the joint dysfunction directly, resulting in increased motion and function, with an eventual resultant decrease in muscle hypertonicity, this could explain the lag time and then the faster rate of improvement between reading 2 and 3. Clinical investigations on the effects of Spinal manipulation on muscle activity are limited. In a study done by Triano (1997), Triano was unable to record any significant myoelectric activity or muscle responses with the application of high velocity low amplitude side-posture lumbar-adjusting procedures.

The Transeva group seemed to improve at a faster rate initially and then slowed down. This contrast against the possibility that DOMS is a symptom of this condition which is pain on palpation and the pressure applied from the Algometer would induce this pain. However, this supports the argument that the Transeva was addressing the muscle hypertonicity and so started to improve but the joint dysfunction remained and so the muscle hypertonicity started to return. Trigger point one improves less between readings 2 and 3 than trigger point 2, this difference seems to be due to the fact that trigger point one was the worst of the two trigger points and most often the closest to the joint dysfunction which again supports the suggestion that the joint dysfunction present caused the slower improvement in the Transeva between readings 2 and 3.

The Transeva and Spinal manipulative therapy combination group fared the best of the three groups in terms of both trigger point 1 and 2. This is supported by the suggestion that the muscle and joint dysfunction was addressed in the treatment and so the muscle hypertonicity decreased over time and did not return (Leach, 2004). Reading one of both trigger point 1 and 2 was higher in this group than the other two groups indicating there was less muscle hypertonicity to start with, which could support the suggestion that this group had more of a joint dysfunction than muscle component in their low back pain. This argues against the hypothesis that the Spinal manipulative therapy being applied after the Transeva resulted in reflex muscle hypertonicity as mentioned above.

Null hypothesis: There is no difference in the treatment effect of the three groups in terms of Algometer measurements of Tp1 and Tp2.

The null hypothesis was accepted.

4.4.3.2.3 Objective Findings: Inclinator: Flexion:

Table 4.10: Within-and between-subjects effects for Flexion.

Effect	Statistic	p value
Time	Wilk's lambda=0.989	0.861
Group	F=0.145	0.251
Time*group overall	Wilk's lambda = 0.788	0.178
Time*group T and SMT	Wilk's lambda = 0.912	0.458
Time*group T and T&SMT	Wilk's lambda = 0.755	0.092
Time*group SMT and T&SMT	Wilk's lambda =0.841	0.231

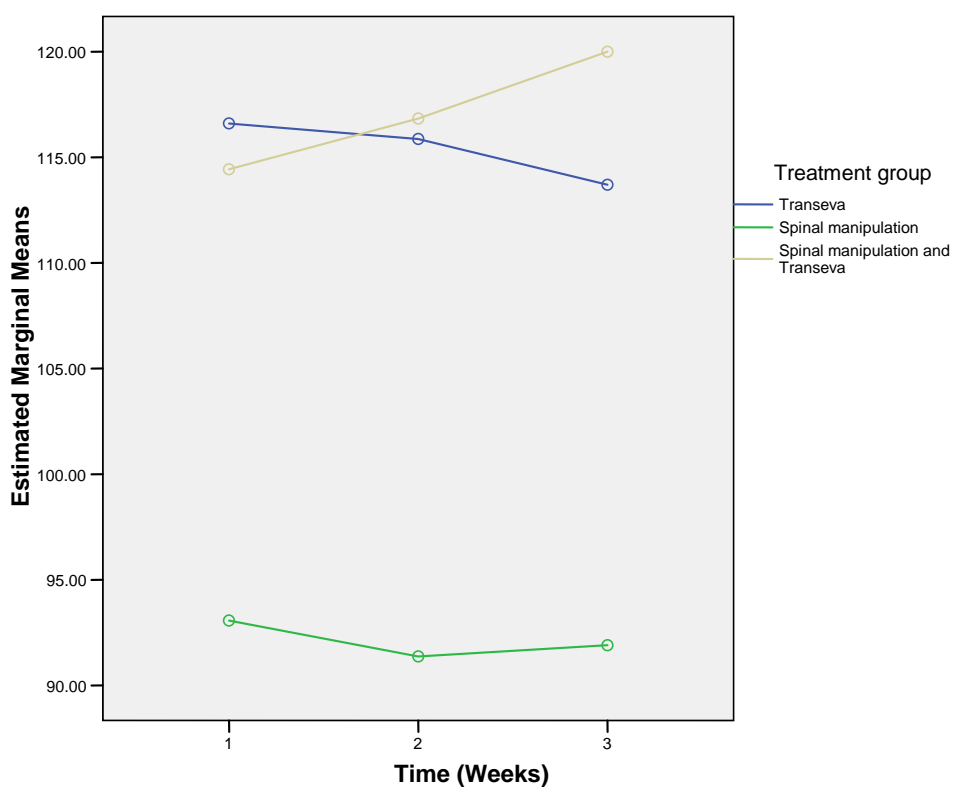


Figure 4.5: Profile plot of mean Flexion by time and group.

Flexion:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was not significant overall ($p=0.861$) meaning regardless of which treatment group they were in, flexion measurements did not change significantly over the three time points. Figure 4.5 shows that the Transeva group and the group which received both treatments interacted over time (crossing over of profiles) which meant that there was a non significant trend ($p=0.092$) that the group which received both treatments performed better than the Transeva group.

4..4.3.2.4 Objective Findings: Inclinator: Extension.

Table 4.11: Within-and between-subjects effects for Extension.

Effect	Statistic	p value
Time	Wilk's lambda=0.949	0.507
Group	F=2.726	0.084
Time*group overall	Wilk's lambda = 0.916	0.677
Time*group T and SMT	Wilk's lambda = 0.962	0.720
Time*group T and T&SMT	Wilk's lambda =0.974	0.797
Time*group SMT and T&SMT	Wilk's lambda = 0.817	0.179

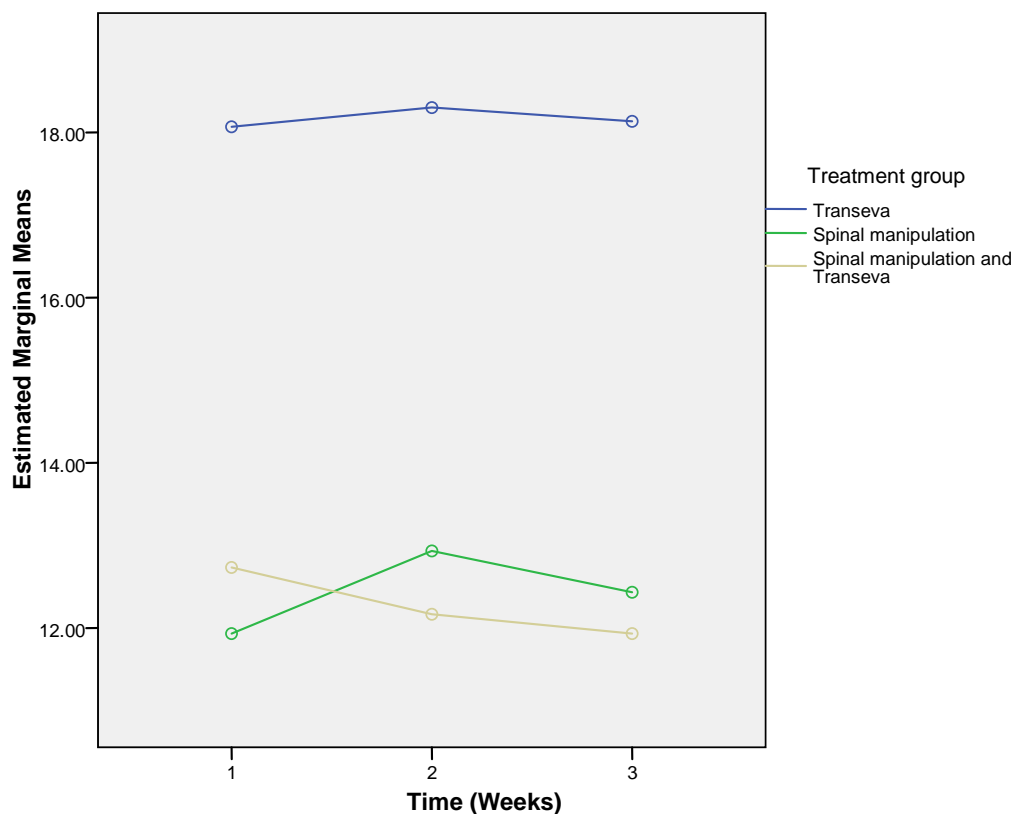


Figure 4.6: Profile plot of mean Extension by time and group.

Extension:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was not significant overall ($p=0.507$) meaning regardless of which treatment group they were in, extension measurements did not change significantly over the three time points. Figure 4.6 shows that the profiles of all groups were almost parallel.

Discussion:

In all groups it seems that flexion readings did not change much over time.

The combination group seems to improve the most in terms of flexion over the period of time, this could be supported by the suggestion that both the muscle component was addressed by the Transeva and the joint dysfunction was addressed by the Spinal manipulative therapy resulting in increased range of motion. It seems though that the combination groups' range of motion got marginally worse over time with regards to extension. This could possibly be due to the fact that extension originally produced the pain and therefore the person was reluctant to move into this position as they perceived it as the painful position. The pain on extension could also be supported by the previous argument that the Transeva aggravated the joint lesion before the Spinal manipulative therapy was applied possibly resulting in inflammation of the facet joints which would be aggravated on extension (Morris, 2006; Vizniak and Carnes, 2004).

The Transeva group decreased in flexion over time. This is supported by the hypothesis that the joint dysfunction had not been addressed and therefore the restriction in movement remained. In time a restricted facet results in disc degeneration (Gatterman 1990, Kirkaldy-Willis, 1988). If the Transeva removed the muscle splint that was protecting the disc, the person would be reluctant to move into flexion over time. This also supports the argument of DOMS, as the muscle stiffness of the involved muscles mainly the quadratus lumborum and gluteal muscles would be resistant to stretch into flexion as these muscles normally produce extension (Kirkaldy-Willis, 1992) The Transeva group was almost static over time with regards to extension and again this could be explained due to the joint dysfunction not being addressed by the Transeva and therefore the restriction in movement remained. This pattern also supports the hypothesis of DOMS as extension is produced by contraction of the involved muscles and the symptoms of DOMS is normally precipitated on stretch of the relevant muscle.

With regards to the Spinal manipulative therapy group, flexion decreased marginally over time. This supports the argument that perhaps there is little effect on the muscle (Triano, 1997). This pattern could be explained by the hypothesis that a restricted facet joint eventually over time results in disc degeneration (Gatterman 1990, Kirkaldy-Willis, 1988). Flexion movements place pressure on the disc which could explain the low flexion reading in this group at baseline, reading 2 and 3. The Spinal manipulation group improved the best with regards to extension over time although not a large amount. This supports the hypothesis that the joint dysfunction was addressed and that the motion and function was restored and the inflammation of the facet joints decreased enabling extension movements.

Null hypothesis: There is no difference in the treatment effect of the three groups in terms of Inclinator measurements of flexion and extension.

The null hypothesis is accepted.

4.4.3.2.5 Objective Findings: Inclinator: Right rotation.

Table 4.12: Within-and between-subjects effects for Right rotation.

Effect	Statistic	p value
Time	Wilk's lambda=0.682	0.007
Group	F=4.044	0.029
Time*group overall	Wilk's lambda = 0.941	0.809
Time*group T and SMT	Wilk's lambda = 0.996	0.970
Time*group T and T&SMT	Wilk's lambda = 0.906	0.443
Time*group SMT and T&SMT	Wilk's lambda =0.945	0.620

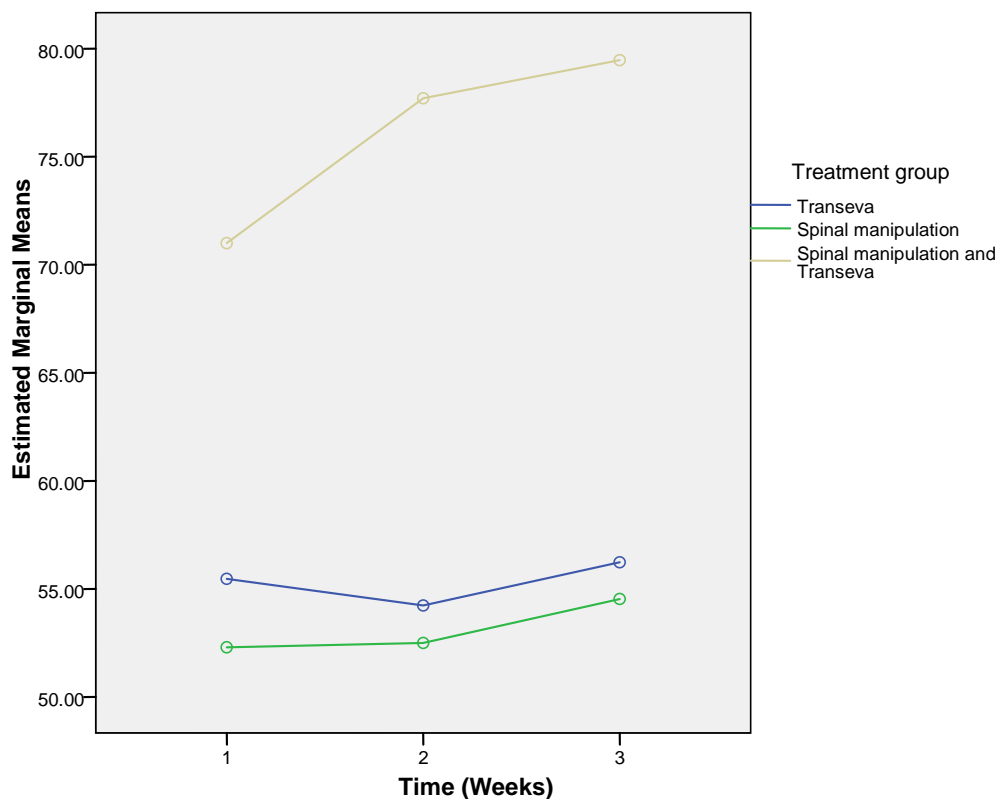


Figure 4.7: Profile plot of mean Right rotation by time and group.

Right rotation:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was significant overall ($p=0.007$) meaning regardless of which treatment group they were in, right rotation measurements changed significantly over the three time points. Figure 4.7 shows that the profiles of the group which received both interventions increased more than the other two but the difference was not statistically significant.

4.4.3.2.6 Objective Findings: Inclinator: Left rotation.

Table 4.13: Within-and between-subjects effects for Left rotation.

Effect	Statistic	p value
Time	Wilk's lambda=0.948	0.501
Group	F=4.163	0.027
Time*group overall	Wilk's lambda = 0.902	0.605
Time*group T and SMT	Wilk's lambda=0.940	0.593
Time*group T and T&SMT	Wilk's lambda = 0.904	0.424
Time*group SMT and T&SMT	Wilk's lambda = 0.944	0.611

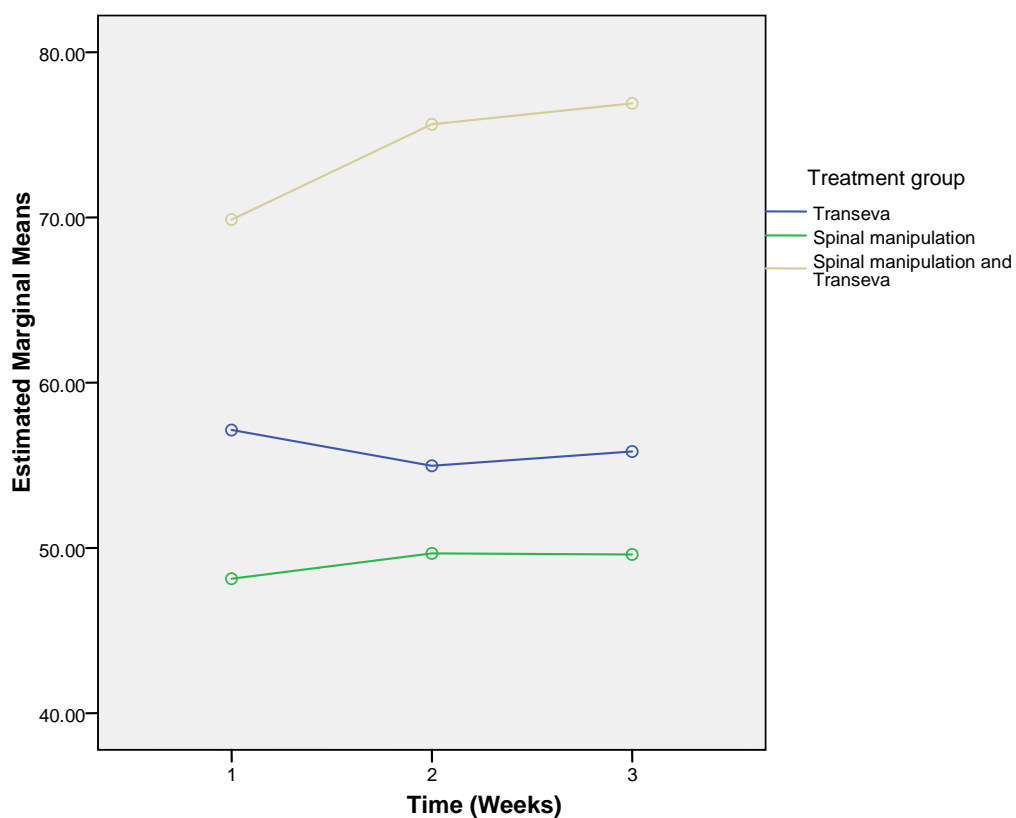


Figure 4.8: Profile plot of mean Left rotation by time and group.

Left rotation:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was not significant overall ($p=0.501$) meaning regardless of which treatment group they were in, left rotation measurements did not change significantly over the three time points. Figure 4.8 shows that the profiles of the group which received both interventions increased more than the other two but the difference was not statistically significant.

Discussion:

The Transeva and Spinal manipulative therapy combination group seemed to improve the most over time. This supports the hypothesis that the treatments addressed both the muscle and joint dysfunction components of the low back pain resulting in increased range of motion in both left and right rotation.

The Transeva group barely improved over time on right rotation and was almost static on left rotation, which would support the hypothesis that the joint dysfunction was not addressed and therefore the restriction remained and the range of motion did not improve. This also supports the hypothesis of the DOMS with increased stiffness and therefore a small to no increase in range of motion.

The Spinal manipulative therapy group improved marginally over the period of the study but this is normal as there is not a great degree of rotation in the lumbar spine normally (Bergmann, 2002; White and Punjabi, 1990) as well as the fact that it possibly had little effect on the muscle activity.

Null hypothesis: There is no difference in the treatment effect of the three groups in terms of Inclinator measurements of right rotation or left rotation.

The null hypothesis is accepted.

4.4.3.2.7 Objective Findings: Inclinator: Right Lateral Flexion.

Table 4.14: Within-and between-subjects effects for Right Lateral Flexion.

Effect	Statistic	p value
Time	Wilk's lambda=0.655	0.004
Group	F=1.580	0.224
Time*group overall	Wilk's lambda = 0.833	0.305
Time*group T and SMT	Wilk's lambda = 0.834	0.213
Time*group T and T&SMT	Wilk's lambda = 0.909	0.444
Time*group SMT and T&SMT	Wilk's lambda = 0.873	0.316

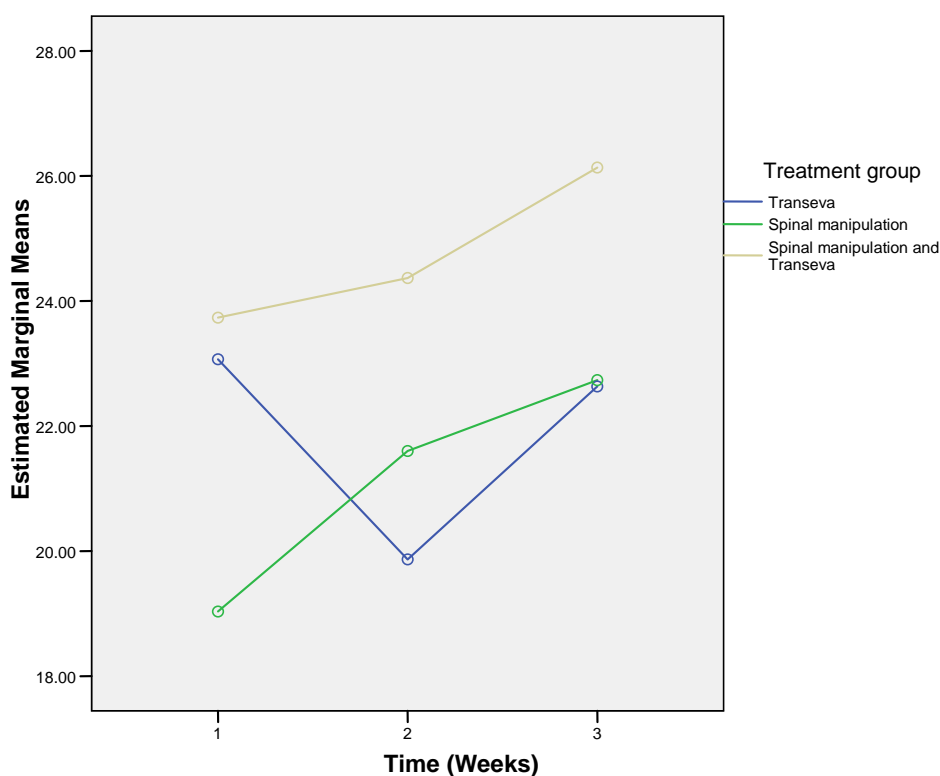


Figure 4.9: Profile plot of mean Right Lateral Flexion by time and group.

Right Lateral Flexion:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was significant overall

($p=0.004$) meaning regardless of which treatment group they were in, right lateral flexion measurements changed significantly over the three time points.

4.4.3.2.8 Objective Findings: Inclinator: Left Lateral Flexion.

Table 4.15: Within-and between-subjects effects for Left Lateral Flexion.

Effect	Statistic	p value
Time	Wilk's lambda=0.802	0.057
Group	F=0.723	0.494
Time*group overall	Wilk's lambda = 0.830	0.294
Time*group T and SMT	Wilk's lambda = 0.757	0.094
Time*group T and T&SMT	Wilk's lambda = 0.982	0.377
Time*group SMT and T&SMT	Wilk's lambda = 0.974	0.798

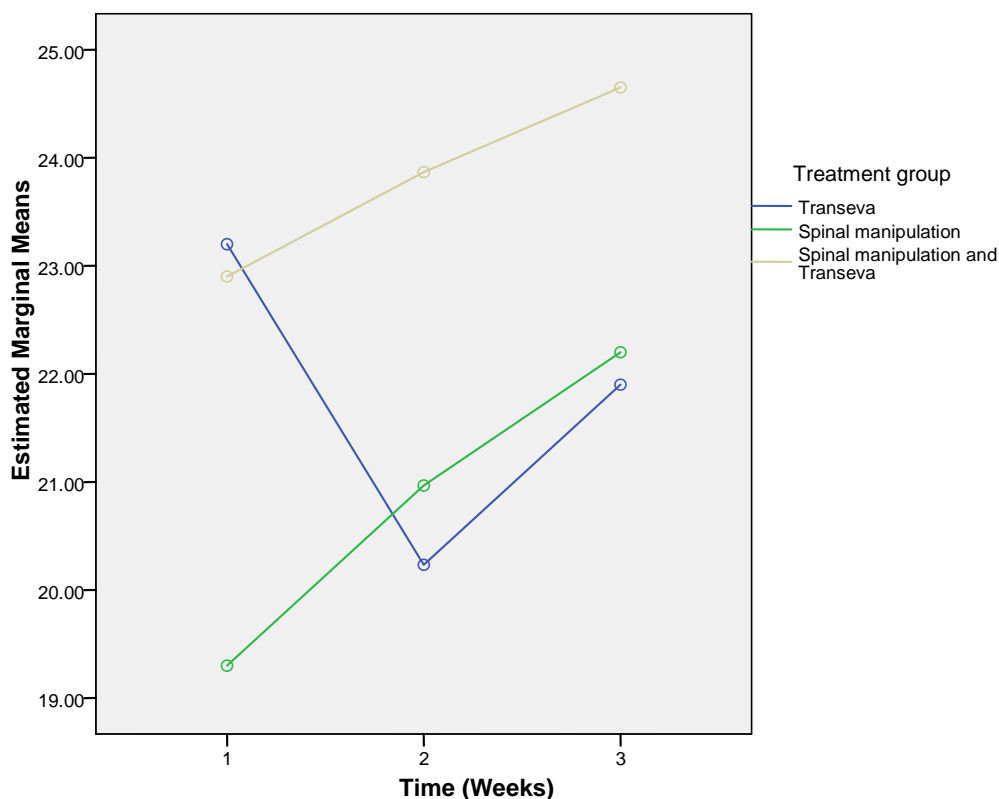


Figure 4.10: Profile plot of mean Left Lateral Flexion by time and group.

Left Lateral Flexion:

There was no overall significant treatment effect for this outcome or when each group was compared to each other group. The time effect was borderline non significant overall ($p=0.057$) meaning regardless of which treatment group they were in, left lateral flexion measurements changed not quite significantly over the three time points.

Discussion:

The Transeva and Spinal manipulative therapy group combination improved the most in terms of right and left lateral flexion over time. This supports the hypothesis that both the muscle and joint dysfunction components were addressed through the treatment.

The Spinal manipulative therapy group also improved over time, as the joint dysfunction was addressed, the range of motion increased. There is naturally a greater degree of lateral flexion in the spine than rotation which could explain the greater degree of improvement.

In the Transeva group lateral flexion decreased between reading 1 and 2 and then improved between reading 2 and 3. This could be explained as, the removal of the muscle hypertonicity and splinting through the use of Transeva, the restriction and joint dysfunction was then aggravated which then resulted in reactive muscle hypertonicity.

4.4.4 Intra-group correlation between changes in outcomes over time.

In the Transeva group there was a significant negative correlation between change in NRS and flexion ($r = - 0.798$), NRS and extension ($r = - 0.632$), NRS and right rotation ($r = - 0.804$), NRS and left rotation ($r = - 0.676$) and a strong

positive correlation with NRS and RMQ ($r = 0.959$). Change in flexion was positively correlated with change in right rotation ($r = 0.892$), change in left rotation ($r = 0.725$) and negatively with RMQ ($r = -0.869$). Change in right rotation was positively correlated with change in left rotation ($r = 0.861$) and negative with RMQ ($r = -0.892$). Change in left rotation was negatively correlated with RMQ ($r = -0.702$) and change in left lateral flexion was positively correlated with change in right lateral flexion ($r = 0.827$).

In the Spinal manipulation group change in NRS was significantly positively correlated with RMQ change ($r = 0.860$). Change in Algometer TP1 was positively correlated with change in Algometer TP2, and negatively with change in right lateral flexion ($r = -0.772$). Change in Algometer TP2 was also negatively correlated with change in right lateral flexion ($r = -0.760$). Change in flexion was very strongly positively correlated with change in right and left rotation ($r = 0.900$ and $r = 0.918$ respectively). Right and left rotation were also highly correlated ($r = -0.965$).

The change in Algometer TP2 was negatively correlated with RMQ ($r = -0.720$) for group which received both manipulation and Transeva. Flexion and left lateral flexion ($r = 0.662$), and extension and left rotation ($r = 0.717$), as well as right and left rotation ($r = 0.947$) were all positively correlated.

Δ Llf	Pearson Correlation	-.550	.108	.416	.517	.605	.354	.062	1	.827(**)	-.493
	Sig. (2-tailed)	.100	.767	.232	.126	.064	.315	.865		.003	.148
	N	10	10	10	10	10	10	10	10	10	10
Δ Rlf	Pearson Correlation	-.443	.284	.511	.369	.321	.216	.069	.827(**)	1	-.345
	Sig. (2-tailed)	.200	.426	.131	.295	.366	.548	.849	.003		.329
	N	10	10	10	10	10	10	10	10	10	10
Δ RMQ	Pearson Correlation	.959(**)	-.210	.045	-.869(**)	-.593	-.892(**)	-.702(*)	-.493	-.345	1
	Sig. (2-tailed)	.000	.560	.902	.001	.071	.001	.023	.148	.329	
	N	10	10	10	10	10	10	10	10	10	10

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Table 4.17: Correlation between changes in outcomes in group 2 (Spinal manipulative therapy).

		Δ NRS	Δ Alg Tp1	Δ Alg Tp2	Δ Flex	Δ Ext	Δ Rrot	Δ Lrot	Δ Llf	Δ Rlf	Δ RMQ
Δ NRS	Pearson Correlation	1	-.382	.131	.074	-.125	.003	.048	.290	.311	.860(**)
	Sig. (2-tailed)		.276	.718	.839	.730	.994	.895	.416	.382	.001
	N	10	10	10	10	10	10	10	10	10	10
Δ Alg Tp1	Pearson Correlation	-.382	1	.720(*)	-.098	-.006	-.248	-.240	.080	-.772(**)	-.502
	Sig. (2-tailed)	.276		.019	.788	.988	.490	.504	.826	.009	.139
	N	10	10	10	10	10	10	10	10	10	10
Δ Alg Tp2	Pearson Correlation	.131	.720(*)	1	-.111	-.098	-.387	-.280	-.039	-.760(*)	-.219
	Sig. (2-tailed)	.718	.019		.761	.787	.270	.433	.915	.011	.543
	N	10	10	10	10	10	10	10	10	10	10
Δ Flex	Pearson Correlation	.074	-.098	-.111	1	.272	.900(**)	.918(**)	.614	.404	.053
	Sig. (2-tailed)	.839	.788	.761		.448	.000	.000	.059	.247	.883
	N	10	10	10	10	10	10	10	10	10	10
Δ Ext	Pearson Correlation	-.125	-.006	-.098	.272	1	.424	.443	.419	.269	.113
	Sig. (2-tailed)	.730	.988	.787	.448		.222	.200	.228	.453	.757
	N	10	10	10	10	10	10	10	10	10	10
Δ Rrot	Pearson Correlation	.003	-.248	-.387	.900(**)	.424	1	.965(**)	.603	.545	.102
	Sig. (2-tailed)	.994	.490	.270	.000	.222		.000	.065	.103	.780
	N	10	10	10	10	10	10	10	10	10	10
Δ Lrot	Pearson Correlation	.048	-.240	-.280	.918(**)	.443	.965(**)	1	.597	.525	.100

	Sig. (2-tailed)	.895	.504	.433	.000	.200	.000		.068	.119	.783
	N	10	10	10	10	10	10	10	10	10	10
Δ Llf	Pearson Correlation	.290	.080	-.039	.614	.419	.603	.597	1	.351	.299
	Sig. (2-tailed)	.416	.826	.915	.059	.228	.065	.068		.321	.401
	N	10	10	10	10	10	10	10	10	10	10
Δ Rlf	Pearson Correlation	.311	-.772(**)	-.760(*)	.404	.269	.545	.525	.351	1	.600
	Sig. (2-tailed)	.382	.009	.011	.247	.453	.103	.119	.321		.067
	N	10	10	10	10	10	10	10	10	10	10
Δ RMQ	Pearson Correlation	.860(**)	-.502	-.219	.053	.113	.102	.100	.299	.600	1
	Sig. (2-tailed)	.001	.139	.543	.883	.757	.780	.783	.401	.067	
	N	10	10	10	10	10	10	10	10	10	10

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Δ Llf	Pearson Correlation	.062	.422	.228	.662(*)	-.470	.047	-.170	1	-.315	.258
	Sig. (2-tailed)	.865	.225	.526	.037	.171	.897	.639		.376	.471
	N	10	10	10	10	10	10	10	10	10	10
Δ Rlf	Pearson Correlation	-.506	-.176	-.553	-.038	-.001	-.287	-.032	-.315	1	.291
	Sig. (2-tailed)	.136	.626	.097	.917	.998	.421	.931	.376		.415
	N	10	10	10	10	10	10	10	10	10	10
Δ RMQ	Pearson Correlation	.067	.060	-.720(*)	.446	.358	.326	.362	.258	.291	1
	Sig. (2-tailed)	.854	.869	.019	.197	.310	.358	.304	.471	.415	
	N	10	10	10	10	10	10	10	10	10	10

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

Table 4.19 Discussion.

T	Significant positive 0.959 (**)	Δ NRS and RMQ.	This would be expected because as pain decreases so should functional disability decrease.
	Significant positive 0.892 (**)	Δ Flex and Rrot.	This is expected as if the one range of motion increases so should the other.
	Significant positive 0.725 (*)	Δ Flex and Lrot.	This is expected as if the one range of motion increases so should the other.
	Significant positive 0.861(**)	Δ Rrot and Lrot.	This is expected as if the one range of motion increases so should the other.
	Significant positive 0.827(**)	Δ Rlf and Llf.	This is expected as if the one range of motion increases so should the other.
	Significant negative - 0.632(*)	Δ NRS and Ext.	This would be expected because as pain decreases range of motion should increase.
	Significant negative - 0.804(**)	Δ NRS and Rrot.	This would be expected because as pain decreases range of motion should increase.
	Significant negative - 0.676(*)	Δ NRS and Lrot.	This would be expected because as pain decreases range of motion should increase.
	Significant negative - 0.798(**)	Δ NRS and Flex.	This would be expected because as pain decreases range of motion should increase.
	Significant negative - 0.892(**)	Δ RMQ and Rrot.	As functional disability decreases range of motion should increase.
	Significant negative - 0.702(*)	Δ RMQ and Lrot.	As functional disability decreases range of motion should increase.
	Significant negative - 0.869(**)	Δ RMQ and Flex.	As functional disability decreases range of motion should increase.
SMT	Significant positive 0.860(**)	Δ NRS and RMQ.	As pain is reduced functional ability improves.
	Significant positive 0.720(*)	Δ Alg Tp1 and Alg Tp2.	Treatment effect on both trigger points.
	Significant positive 0.900(**)	Δ Rrot and Flex.	This is expected as if the one range of motion increases so should the other.
	Significant positive 0.918(**)	Δ Lrot and Flex.	This is expected as if the one range of motion increases so should the other.
	Significant positive 0.965(**)	Δ Rrot and Lrot.	This is expected as if the one range of motion increases so should the other.
	Significant negative - 0.772(**)	Δ Alg Tp1 and Rlf.	The only manner to attempt an explanation in terms of this relationship would be to assume that the cumulative Tps for all patients were worse on the left, thereby decreasing initial Llf readings and increasing Rlf readings. With resolution of the Tps (increased Algometer reading), there would have been an increase in the Llf readings and a concomitant decrease in the Rlf readings, thus resulting in the significant negative result achieved here. This is however speculative (in that it is assumed that measures are always taken from the neutral position – especially at

			the outset of clinical trials, however the question that arises alludes to this not necessarily being the case) and it is suggested that future research look into this phenomenon.
	Significant negative - 0.760(*)	Δ Rlf and Llf.	Irrespective of the presence of dysfunction, the relationship between Rlf and Llf will always be negative as these movements occur around one axis and in one plane. As a result an increase in one has to result in a decrease in the other irrespective of the original starting position for the measures.
T&SMT	Significant positive 0.662 (*)	Δ Llf and Flex.	There is a positive correlation as these movements stress/stretch the muscle so if one improves it is likely the other would also improve.
	Significant positive 0.717(*)	Δ Lrot and Ext.	This is explained as both these movements stress one or both facet joints and if one movement increases then the other movement is likely to increase.
	Significant positive 0.947(**)	Δ Lrot and Rrot.	This is expected as if the one range of motion increases so should the other.
	Significant negative - 0.720(*)	Δ RMQ and Alg Tp2.	Reduction in trigger point increase in functional ability.

4.5 Results in context of objectives and hypothesis.

Objective one was to determine the effectiveness of the following therapies for mechanical low back pain in terms of subjective clinical findings using the Numerical Pain Rating Scale (NRS) and the Roland-Morris Questionnaire

- A) Spinal manipulative therapy.
- B) Transeva.
- C) Transeva followed by Spinal manipulative therapy.

Hypothesis 1.

It was hypothesized that Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva or combined Transeva and Spinal manipulative therapy, in terms of Numerical Pain Rating Scale and Roland-Morris Questionnaire.

Hypothesis 1 rejected for RMQ

Hypothesis 1 accepted for NRS

Hypothesis 2.

It was hypothesized that Transeva therapy in comparison to Spinal manipulative therapy or combined Transeva and Spinal manipulative therapy would be more effective in the management of mechanical low back pain, in terms of subjective clinical findings

Hypothesis 2 rejected for RMQ and NRS.

Hypothesis 3.

It was hypothesized that Transeva followed by Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or Transeva, in terms of subjective clinical findings.

Hypothesis 3 rejected for RMQ and NRS

Objective two was to determine the effectiveness of the following therapies for mechanical low back pain in terms of objective clinical findings using the pressure Algometer and Inclinator.

- A) Spinal manipulative therapy.
- B) Transeva.
- C) Transeva followed by Spinal manipulative therapy.

Hypothesis 4.

It was hypothesized that Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva or combined Transeva and Spinal manipulative therapy, in terms of objective clinical findings.

Hypothesis 4 rejected for Inclinator and Algometer.

Hypothesis 5.

It was hypothesized that Transeva therapy in comparison to Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Transeva and Spinal manipulative therapy, in terms of objective clinical findings.

Hypothesis 5 rejected for Inclinator and Algoneter.

Hypothesis 6.

It was hypothesized that Transeva followed by Spinal manipulative therapy would be more effective in the management of mechanical low back pain when compared to Spinal manipulative therapy or Transeva, in terms of objective clinical findings.

Hypothesis 6 rejected for Inclinator and Algoneter.

4.6 Conclusion:

According to the objective measurements, the treatment effect was not statistically significant for Algoneter or Inclinator readings. The time effect was statistically significant for the Algoneter readings and Right rotation and Right lateral flexion in terms of the Inclinator readings. This means that regardless of the treatment group, these readings changed significantly over three time points. In terms of the Algoneter readings and the Extension Inclinator readings there was a trend that neither treatment group was better than the other as the profiles were parallel. In terms of Flexion, Right rotation, Left rotation and Right and Left lateral flexion Inclinator readings, there was a trend that the combined Spinal manipulative therapy and Transeva group improved the most over time but not statistically significantly so.

In terms of subjective outcomes, the treatment effect and time effect was statistically significant for NRS readings in terms of the Spinal manipulative therapy group and the combined Spinal manipulative therapy and Transeva.

In terms of NRS readings there was a trend that the Spinal manipulative therapy improved at a faster rate than the other groups but not statistically significantly so. The treatment effect was not statistically significant for the RMQ readings, however the time effect was highly significant, meaning regardless of the treatment group, these readings changed significantly over time.

Chapter Five

Conclusion and Recommendations.

5.1 Conclusion

This study consisted of 30 patients, divided into 3 groups of 10 each. Every patient underwent a full case history, physical, and lumbar regional examination to determine their applicability for the study with respect to mechanical low back pain.

Thereafter each patient was placed into either the Transeva, Spinal manipulative therapy, or combined Transeva and Spinal manipulative therapy groups at random. Those patients that were in group A were in the Transeva group, those in group B were in the Spinal manipulative therapy group and those in C were in the combined Transeva and Spinal manipulative therapy group. All patients then received 5 treatments plus 1 follow up consultation.

At set intervals (prior to treatments 1 and 4, and at the follow up consultation) measurements were taken with the NRS, and Roland-Morris questionnaire (subjective readings), Inclinator and Algometer (objective readings).

The evaluation of these recordings showed that treatments showed a statistical improvement in terms of subjective and objective clinical findings to conclude that:

The Spinal manipulation group showed the best improvement in terms of pain reduction over all three visits.

The Spinal manipulative therapy group and the group which received Transeva and Spinal manipulative therapy showed the greatest improvement in the patient's ability to manage everyday life.

The Transeva and Spinal manipulative therapy combination group improves consistently and significantly for all readings when comparing Algometer trigger points and majority of the movements measured with the Inclinator.

Thus it would seem that the Transeva and Spinal manipulative therapy group is able to achieve greater clinical efficacy than the Spinal manipulative therapy group or the Transeva group.

Schneider (1995) states that Chiropractors who use only manipulative techniques will have limited success in the treatment of patients with joint dysfunction as they are excluding the muscular component of treatment and vice versa.

This is further supported by Haldeman (2005) who states that physical modalities should not be relied upon as primary treatment procedures. Instead, they should be used as a supplement to other treatment methods such as manipulation or rehabilitation.

Thus from the research presented, the effect of a single modality may only achieve a limited clinical response in mechanical low back pain, where a synergistic effect of combination therapies may actually benefit the patient more.

5.2 Recommendations for future studies.

Methodological

It is recommended for patients to have one-month follow-up to assess continued results.

It would be recommended to do another baseline reading after the Transeva was applied but before the Spinal manipulative therapy in the combination group as this might give more information as to whether the Transeva should be administered first or if the Spinal manipulative therapy should be administered before the Transeva.

Results based recommendations

It is recommended that the patients' disability be analyzed with a more appropriate questionnaire than the Roland-Morris Questionnaire. Perhaps a new questionnaire should be devised as many patients reporting chronic low back pain with many symptoms reported that the questions on the Roland-Morris Questionnaire were too extreme and that they would have to be suffering from severe back pain for the questions to be true.

It would be recommended that future research looks into the phenomenon of whether or not it is possible to take Inclinator readings from the true neutral position. If a trigger point is present on the left, it is assumed the patient is not able to attain true neutral. This could give further information on the significant negative found in the Spinal manipulation group between changes in Algometer trigger point one and Right lateral flexion and Right lateral flexion and Left lateral flexion.

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Are you between the ages of **20** and **45** and suffering
from:

Low Back Pain

Research is currently being carried out at the Durban
University of Technology Chiropractic Day Clinic

Free Treatment

available to those who qualify to take part in this study.

Contact **Caryn Marshall** on 031 3732205/
031 3732512 for more information.

APPENDIX B: CASE HISTORY

DURBAN INSTITUTE OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: Date:

File # : Age :

Sex : Occupation:

Intern :Signature:

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: _____ Signature : _____

Case History:

Case History:

Examination:

Previous:

Current:

X-Ray Studies:

Previous:

Current:

Clinical Path. lab:

Previous:

Current:

Case Status:

PTT: _____ Signature: _____ Date: _____

CONDITIONAL: Reason for Conditional:	
Signature:	Date:

Conditions met in Visit No:	Signed into PTT:	Date:
-----------------------------	------------------	-------

Signed off: _____ Date: _____

Intern's Case History:

1. **Source of History:**
2. **Chief Complaint : (patient's own words):**
3. **Present Illness:**

- ▶ Location
- ▶ Onset : Initial:
Recent:
- ▶ Cause:
- ▶ Duration
- ▶ Frequency
- ▶ Pain (Character)
- ▶ Progression
- ▶ Aggravating Factors
- ▶ Relieving Factors
- ▶ Associated S & S
- ▶ Previous Occurrences
- ▶ Past Treatment
- ▶ **Outcome:**

Complaint 1	Complaint 2

4. Other Complaints:**5. Past Medical History:**

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

6. Current health status and life-style:

- ▶ Allergies
- ▶ Immunizations
- ▶ Screening Tests incl. xrays
- ▶ Environmental Hazards (Home, School, Work)
- ▶ Exercise and Leisure
- ▶ Sleep Patterns
- ▶ Diet
- ▶ Current Medication
Analgesics/week:
- ▶ Tobacco
- ▶ Alcohol
- ▶ Social Drugs

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

APPENDIX C: PHYSICAL**DURBAN INSTITUTE OF TECHNOLOGY**

22/10/2002

**PHYSICAL EXAMINATION
SENIOR & RESEARCH**

Patient: _____ File#: _____ Date: _____
_Student: _____ Signature: _____

VITALS

Pulse rate		Respiratory rate	
Blood pressure	R	L	Medication if hypertensive:
Temperature		Height	
Weight:	Any recent change Y/N	If Yes : how much gain/loss	Over what period

GENERAL EXAMINATION

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

SYSTEM SPECIFIC EXAMINATION**CARDIOVASCULAR EXAMINATION****RESPIRATORY EXAMINATION****ABDOMINAL EXAMINATION****COMMENTS****NEUROLOGICAL EXAMINATION:** See regionals**Clinician:** _____ **Signature:** _____

APPENDIX D: REGIONAL EXAMINATION - LUMBAR SPINE AND PELVIS

Patient: _____ File#: _____ Date: ____ \ ____ \ ____
Intern\Resident: _____ Clinician: _____

STANDING:

Posture– scoliosis, antalgia, kyphosis
Body Type
Skin
Scars
Discolouration

Minor's Sign
Muscle tone
Spinous Percussion
Schober's Test (6cm)
Bony and Soft Tissue Contours

GAIT:

Normal walking
Toe walking
Heel Walking
Half squat

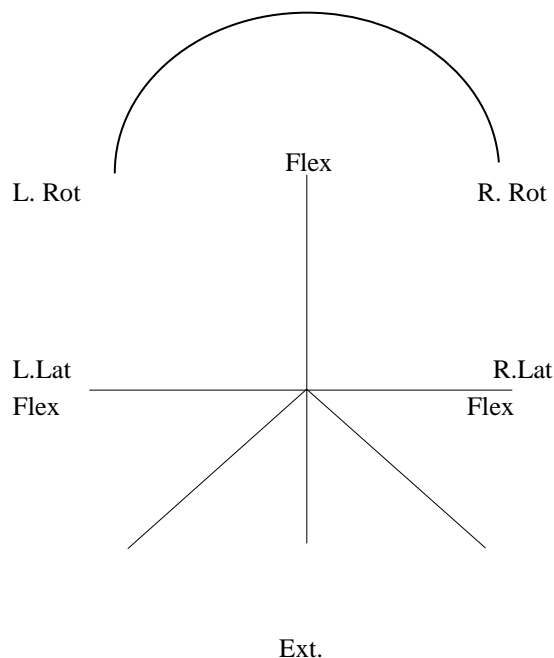
ROM:

Forward Flexion = 40-60° (15 cm from floor)

Extension = 20-35°

L/R Rotation = 3-18°

L/R Lateral Flexion = 15-20°



Which movt. reproduces the pain or is the worst?

- Location of pain
- Supported Adams: Relief? (SI)
- Aggravates? (disc, muscle strain)

SUPINE:

Observe abdomen (hair, skin, nails)

Palpate abdomen\groin

Pulses - abdominal

- lower extremity

Abdominal reflexes

S L R		Degree	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	Foot	Braggard
	L										
	R										

	L	R
Bowstring		
Sciatic notch		
Circumference (thigh and calf)		
Leg length: actual -		
apparent -		
Patrick FABERE: pos\neg – location of pain?		
Gaenslen's Test		
Gluteus max stretch		
Piriformis test (hypertonicity?)		
Thomas test: hip \ psoas? \ rectus femoris?		
Psoas Test		

SITTING:

Spinous Percussion

Valsalva

Lhermitte

TRI POD Sl, +, ++		Degree	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	Foot	Braggard
	L										
	R										

Slump 7 test	L										
	R										

LATERAL RECUMBENT:

L

R

Ober's		
Femoral n. stretch		
SI Compression		

PRONE:

L

R

Gluteal skyline		
Skin rolling		
Iliac crest compression		
Facet joint challenge		
SI tenderness		
SI compression		
Erichson's		
Pheasant's		

	Latent	Active	Radiation
<i>MF tp's</i>			
QL			
Paraspinal			
Glut Max			
Glut Med			
Glut Min			
Piriformis			
Hamstring			
TFL			
Iliopsoas			
Rectus Abdominis			
Ext/Int Oblique muscles			

NON ORGANIC SIGNS:

Pin point pain
Axial compression
Trunk rotation
Burn's Bench test

Flip Test
Hoover's test
Ankle dorsiflexion test
Repeat Pin point test

NEUROLOGICAL EXAMINATION

Fasciculations

Plantar reflex

level	Tender?	Dermatomes		DTR	L	R
		L	R			
T12				Patellar		
L1				Achilles		
L2						
L3				Proprioception		
L4						
L5						
S1						
S2						
S3						

MYOTOMES

Action	Muscles	Levels	L	R	
Lateral Flexion spine	Muscle QL				
Hip flexion	Psoas, Rectus femoris				5+ Full strength
Hip extension	Hamstring, glutes				4+ Weakness
Hip internal rotat	Glutmed, min;TFL, adductors				3+ Weak against grav
Hip external rotat	Gluteus max, Piriformis				2+ Weak w/o gravity
Hip abduction	TFL, Glut med and minimus				1+ Fascic w/o gross movt
Hip adduction	Adductors				0 No movement
Knee flexion	Hamstring,				
Knee extension	Quad				W - wasting
Ankle plantarflex	Gastroc, soleus				
Ankle dorsiflexion	Tibialis anterior				
Inversion	Tibialis anterior				
Eversion	Peroneus longus				
Great toe extens	EHL				

History
Passive ROM
Orthopedic

History
ROM: Active

MOTION PALPATION AND JOINT PLAY

R

Upper Thoracics		
Lumbar Spine		
Sacroiliac Joint		

APPENDIX E
S.O.A.P.E. NOTE

DURBAN INSTITUTE OF TECHNOLOGY

Patient Name:		File #:	Page:
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input type="text"/>	A: P: E:
Special attention to:		Next appointment:	
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input type="text"/>	A: P: E:
Special attention to:		Next appointment:	
Date:	Visit:	Intern:	Signature:
Attending Clinician:			
S: Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		Intern Rating <input type="text"/>	A: P: E:
Special attention to:		Next appointment:	

APPENDIX F:

LETTER OF INFORMATION

Dear Participant.

Welcome to my research study in mechanical low back pain.

Title of study: An investigation into the relative effectiveness of Transeva and spinal manipulative therapy for mechanical low back pain.

Principle Investigator: Caryn Marshall
Contact details: 0842071424

Supervisors: Dr. C.M. Korporeal 031 3732611
M.Tech:Chiropractic, CCFC, CCSP, ICSSD
Dr. R. White 033 3422649
M.Tech: Chiropractic

Introduction: I am investigating the effect of the Transeva for the treatment of mechanical low back pain. The Transeva is a modality originally produced by sir Charles Strong and later manufactured by Winks Shekida Industries which produces a rhythmic muscular contraction in the form of a faradic current. It has been found that faradism not only increases the arterial supply to the muscle but also improves the return circulation via the veins and lymphatics to the same degree. Trigger points are tender areas in the muscles that, when active they refer pain that mimics other painful conditions. Trigger points are very common and are often overlooked as a source of pain. Thus treatment will help in developing more clinical sound treatment protocols within the scope of Chiropractic care.

Procedures: At the initial consultation you will undergo a History, Physical, and a Regional examination, after which you will be accepted providing you fit the necessary criteria for the research. Once accepted into the study you will receive three treatments within the first week, two within the second week and a follow up no more than one week after treatment four. You will remain in the study as long as you commit to the appointment schedule.

Reasons why you may be withdrawn from the study without your consent:

The participant may not take any form of medication that will influence the results of the study or undergo any other treatment during the duration of the study (i.e. Analgesics, muscle relaxants, NSAIDS, steroids or manual therapy). The participant must not change their lifestyle and enter into any new activity. A consent form will be required to be filled out prior to the treatment.

Risks/Discomforts: You may have slight feelings of muscular stiffness after the treatment has taken place.

Benefits: All treatment will be free of charge and will be conducted at the Durban University of Technology Chiropractic Day Clinic. Please be assured that all information will be regarded as strictly confidential.

Remuneration: none

Costs of study: none

Confidentiality: All the information will be coded so identification will not be disclosed.

Persons to contact for problems/questions: Caryn Marshall
Dr Charmaine Korporaal
Dr Rowan White

Ethical or procedural questions: contact FRC- Mr Singh 031-3732701

By signing the informed consent form you agree to participate in the research study.

Name:

Yours sincerely

Caryn Marshall
(Researcher)

Dr Charmaine Korporaal
(Supervisor)

Dr Rowan White
(co-supervisor)

APPENDIX G: Informed Consent Form

INFORMED CONSENT FORM
(To be completed by patient / subject)

DATE: _____

TITLE OF RESEARCH PROJECT: An investigation into the relative effectiveness of Transeva and spinal manipulative therapy for mechanical low back pain.

NAME OF SUPERVISOR :Dr C. M.Korporaal Tel: 031 3732611

NAME OF CO-SUPERVISOR :Dr. R. White Tel: 033 3422649

NAME OF RESEARCH STUDENT :Caryn Marshall Tel: 0842071424

Please circle the appropriate answer

- | | YES | NO |
|---|-----|----|
| 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. Do you understand the implications of your involvement in this study? | Yes | No |
| 7. Do you understand that you are free to | | |
| a) withdraw from this study at any time? | Yes | No |
| b) withdraw from the study at any time, without reasons given | Yes | No |
| c) withdraw from the study at any time without affecting your future health care or relationship with the Chiropractic day clinic at the Durban University of Technology. | Yes | No |
| 8. Do you agree to voluntarily participate in this study | Yes | No |
| 9. Who have you spoken to regarding this study? | | |

If you have answered NO to any of the above, please obtain the necessary information from the researcher and / or supervisor before signing. Thank You.

Please Print in block letters:

Participant Name: _____ Signature: _____

Witness Name: _____ Signature: _____

Researcher's Name: _____ Signature: _____

Supervisor's /
Co-supervisor's Name: _____ Signature: _____

APPENDIX H:**INCLINOMETER READINGS**

PATIENT NAME: _____

FILE NUMBER: _____

FLEXION

	Visit 1			Visit 4			Visit f/u		
Date									
Reading									
Mean									

EXTENSION

	Visit 1			Visit 4			Visit f/u		
Date									
Reading									
Mean									

RIGHT ROTATION

	Visit 1			Visit 4			Visit f/u		
Date									
Reading									
Mean									

LEFT ROTATION

	Visit 1			Visit 4			Visit f/u		
Date									
Reading									
Mean									

RIGHT LATERAL FLEXION

	Visit 1			Visit 4			Visit f/u		
Date									
Reading									
Mean									

LEFT LATERAL FLEXION

	Visit 1			Visit 4			Visit f/u		
Date									
Reading									
Mean									

APPENDIX I:

Numerical Rating Scale -101 Questionnaire

Date: _____ File no: _____ Visit no: _____

Patient name: _____

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **when it's at its worst**. A zero (0) would mean “no pain at all”, and one hundred (100) would mean “pain as bad as it could be”.

Please mark on the line where would best describe your pain

0 _____ 100

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **when it's at its least**. A zero (0) would mean “ no pain at all”, and one hundred (100) would mean “ pain as bad as it could be”.

Please mark on the line where would best describe your pain

0 _____ 100

ALGOMETER READINGS:

Patient Name: _____

File number: _____

[illegible]

APPENDIX J

NAME: _____ DATE: _____ AGE: _____

SCORE:

ROLAND-MORRIS LOW BACK PAIN AND DISABILITY QUESTIONNAIRE

When your back hurts you may find it difficult to do some of the things you normally do. Mark only the sentences that describe today.

1. ☐ I stay at home most of the time because of my back.
2. ☐ I change position frequently to try and get my back comfortable.
3. ☐ I walk more slowly than usual because of my back.
4. ☐ Because of my back, I am not doing any jobs that I usually do around the house.
5. ☐ Because of my back, I use a handrail to get upstairs.
6. ☐ Because of my back, I lie down to rest more often.
7. ☐ Because of my back, I have to hold on to something to get out of an easy chair.
8. ☐ Because of my back, I try to get other people to do things for me.
9. ☐ I get dressed more slowly than usual because of my back.
10. ☐ I stand up only for short periods of time because of my back.
11. ☐ Because of my back, I try not to bend or kneel down.
12. ☐ I find it difficult to get out of a chair because of my back.
13. ☐ My back is painful almost all of the time.
14. ☐ I find it difficult to turn over in bed because of my back.
15. ☐ My appetite is not very good because of my back.
16. ☐ I have trouble putting on my socks (or stockings) because of pain in my back.
17. ☐ I walk only short distances because of my back pain.
18. ☐ I sleep less well because of my back.
19. ☐ Because of back pain, I get dressed with help from someone else.
20. ☐ I sit down for most of the day because of my back.
21. ☐ I avoid heavy jobs around the house because of my back.
22. ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
23. ☐ Because of my back, I go up stairs more slowly than usual.
24. ☐ I stay in bed most of the time because of my back.

From Roland M, Morris R. A study of the natural history of back pain: Part I: Development of a reliable and sensitive measure of disability in low-back 1983;8:141-144

The original 24 item Roland –Morris Questionnaire is displayed. The RM-18 deletes items 2, 15, 17, 19, 20, and 24 without affecting its quality

**ETHICS CLEARANCE CERTIFICATE**

Student Name	C Marshall	Student No	20200731
Ethics Reference Number	FHSEC 028/07	Date of FRC Approval	08/10/2007
Research Title:	An investigation into the relative effectiveness of Transeva and spinal manipulative therapy for mechanical low back pain.		

In terms of the ethical considerations for the conduct of research in the Faculty of Health Sciences, Durban University of Technology, this proposal meets with Institutional requirements and confirms the following ethical obligations:

1. The researcher has read and understood the research ethics policy and procedures as endorsed by the Durban University of Technology, has sufficiently answered all questions pertaining to ethics in the DUT 186 and agrees to comply with them.
2. The researcher will report any serious adverse events pertaining to the research to the Faculty of Health Sciences Research Ethics Committee.
3. The researcher will submit any major additions or changes to the research proposal after approval has been granted to the Faculty of Health Sciences Research Committee for consideration.
4. The researcher, with the supervisor and co-researchers will take full responsibility in ensuring that the protocol is adhered to.
5. **The following section must be completed if the research involves human participants:**

	YES	NO	N/A
❖ Provision has been made to obtain informed consent of the participants	✓		
❖ Potential psychological and physical risks have been considered and minimised	✓		
❖ Provision has been made to avoid undue intrusion with regard to participants and community	✓		
❖ Rights of participants will be safe-guarded in relation to:			
- Measures for the protection of anonymity and the maintenance of Confidentiality.	✓		
- Access to research information and findings.	✓		
- Termination of involvement without compromise	✓		
- Misleading promises regarding benefits of the research	✓		

C Marshall
SIGNATURE OF STUDENT/RESEARCHER

13/02/08
DATE

[Signature]
SIGNATURE OF SUPERVISOR/S

7/2/2008
DATE

Kyau
SIGNATURE OF HEAD OF DEPARTMENT

14/2/08
DATE

[Signature] (FOR S. REID)
SIGNATURE: CHAIRPERSON OF RESEARCH ETHICS COMMITTEE

4/12/2008
DATE