A Clinical Investigation into the Effect of Spinal Manipulative Therapy on Chronic Idiopathic Constipation in Adults

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic at Durban Institute of Technology.

I, Ruwaida Vadachia, do declare that this dissertation is representative of my own work in both conception and execution.

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Dedication

For
my dear parents,
whose good guidance and upbringing
has made me
all that
I
am
today!

Acknowledgements

To the Lord, Almighty, for allowing me to see this, and all that I set out to do, to completion.

To Professor Hoosen Vawda, who taught me many good principles of medicine and life.

To my dear friend, Nazneen, knowing you are there, has made my world a better place, thank you.

To Bilkees for always being a source of wise words and much needed assistance.

To the patients who participated in my study, thank you for making this possible.

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Abstract

Chronic Idiopathic Constipation (CIC) is a common patient complaint (Browning 1999) and as such is defined as : “Constipation” being the infrequent or difficult evacuation of faeces, “idiopathic”, denoting the condition occurs in the absence of any known cause and “chronic”, implying a problem that has persisted for a long time (Anderson 1989).

It has been suggested that the bony subluxation or motion segment dysfunction in the spine, could produce these symptoms (e.g. altered visceral function) in the segmentally related visceral structures (Korr 1976, Nansel and Slazak 1995, Budgell 2000).

In support of this three case reports in the literature suggest that spinal manipulative therapy to effect removal of these bony subluxations or motion segment dysfunctions, may relieve chronic idiopathic constipation (Hewitt 1993, Marko 1994, Redly 2000). However all three cases involved a single patient case analysis, where patients received spinal manipulation and a vast improvement in bowel function within three weeks of the initiation of the intervention was noted. Only one case report measured global wellbeing outcomes and was able to document a steady increase in the patient’s sense of wellbeing (Redly 2000).

As a result of the above evidence in the literature, the researcher was led to the following hypotheses regarding spinal manipulation and chronic idiopathic constipation:

- That spinal manipulation would affect a decrease in the subject’s abdominal pain intensity and level of constipation and an increase in the subject’s sense of wellbeing and spinal range of motion.

- That placebo would affect an increase in the subject's abdominal pain intensity and level of constipation and a decrease in the subject's sense of wellbeing and spinal range of motion.
- That spinal manipulation would be more effective than placebo in bringing about a decrease in the subject's abdominal pain intensity and level of constipation and an increase in the subject's sense of wellbeing and spinal range of motion.

In order to attain these outcomes, the study took the form of a simple two period cross-over structure involving a total of 30 patients, between the ages of 20 and 60, obtained by means of convenience sampling, and assigned to one of two groups, with each patient receiving either the intervention (spinal manipulation) or the control (placebo) in the first period and the alternative in the succeeding period. In this way, subjects' response to the intervention and the control, could be documented and compared (Friedman et al 1998).

Following a telephonic screening and an initial consultation to take baseline readings, patients in group one received spinal manipulation to the thoracic and lumbar spines while patients in group two received placebo (using detuned ultrasound), twice weekly for two weeks. The groups then crossed over. Five readings were taken in all over the period of the trial, these included the degree of constipation (constipation index), pain rating (numerical rating scale), sense of well being (global well being scale) and spinal range of motion (inclinometer readings).

Data analysis was done in SAS version 9.1 (SAS Institute Inc., Cary, NC). Analysis of the results revealed that spinal manipulation brought about a significant improvement in the constipation index ($p=0.0027$), pain rating ($p<0.0001$), global well being ($p<0.0001$) and spinal range of motion ($p<0.0001$). The treatment appeared to have a prolonged effect with the improvement being sustained until at least the end of the study. An increase in sense of wellbeing

was documented during control, this change may be attributable to the placebo effect.

Based on this study, it could be concluded, that spinal manipulation may play a significant role in the management of chronic idiopathic constipation, however further research into exactly which spinal levels should be manipulated and the mechanism whereby the documented effect is produced, is required in order to further substantiate the outcome of this research.

GLOSSARY

"Constipation" is defined as the infrequent or difficult evacuation of faeces, with "idiopathic", denoting that the condition occurs in the absence of any known cause and "chronic", implying a problem that has persisted for a long time (Anderson 1989). For the purposes of this study, chronic idiopathic constipation is defined as less than three bowel movements per week and one or more of straining at stools, a sensation of incomplete evacuation or the passing of pellet like stools, at least 25% of the time (Redly 2000), with abdominal discomfort/pain.

CHAPTER ONE

Introduction

1.1 INTRODUCTION

Chronic Idiopathic Constipation (chronic idiopathic constipation) is a common patient complaint. In the United States alone; it is the reason behind more than 2.5 million physician visits per year (Browning 1999). In this respect "Constipation" is defined as the infrequent or difficult evacuation of faeces, with "idiopathic", denoting that the condition occurs in the absence of any known cause and "chronic", implying a problem that has persisted for a long time (Anderson 1989).

The exact prevalence of chronic idiopathic constipation is largely unknown, but is reported to range from 2.0 – 12.8% in the general population (Browning 1999, Duowu et al 2000). This is a result of the literature definition of chronic idiopathic constipation demonstrating ambiguity, with patients showing a tendency toward defining constipation on the basis of symptoms whereas health professionals more often consider the frequency of bowel movements (Tramonte et al 1997, Redly 2000). Thus the diagnosis of chronic idiopathic constipation is often one of exclusion and depends largely on the particular patient's perception of normal bowel function (Orr et al 1997, Tramonte et al 1997).

Currently, the most widely accepted diagnostic criteria for chronic idiopathic constipation are the symptoms of less than three bowel movements per week and one or more of straining at stools, a sensation of incomplete evacuation or the passing of pellet like stools, at least 25% of the time (Redly 2000).

It has thus been suggested that the bony subluxation or motion segment dysfunction in the spine could produce symptoms (e.g. altered visceral function) in the segmentally related visceral structures (Hewitt 1993, Redly 2000). This assertion is supported by the work of Korr (1976), Nansel and Szlazak (1995)

and more recently Budgell (2000). Furthermore and in support of the above, a blinded, clinical controlled trial, identified statistically significant segmental tenderness and range of motion differences, between the groups, in the thoraco-lumbar spines of patients with and without functional abdominal pain (in the absence of organic pathology), at the same segmental levels from which the sympathetic innervation of visceral structures such as the colon is derived (Jorgensen and Fosgreen 1990, Crossman and Neary 1998, Redly 2000).

Taking the above literature based suggestion into account and with respect to treatment of chronic idiopathic constipation, there are three case reports in the literature which suggest that spinal manipulative therapy may relieve chronic idiopathic constipation (Hewitt 1993, Marko 1994, Redly 2000) by removing the bony subluxations or motion segment dysfunction. All three cases involved a single patient case analysis, where patients received manipulation to the cervical (Hewitt 1993, Marko 1994), thoracic and lumbar spines (Hewitt 1993, Marko 1994, Redly 2000). All cases reported a vast improvement in bowel function within three weeks of the initiation of the intervention. Only one case report measured global wellbeing outcomes and was able to document a steady increase in the patient's sense of wellbeing (Redly 2000).

Thus the above evidence in the literature (Korr 1976, Jorgensen and Fosgreen 1990, Nansel and Szlazak 1995, Crossman and Neary 1998, Budgell 2000, Redly 2000), led the researcher to hypothesize that spinal manipulation applied to the thoracic and lumbar spine could have an effect on the symptoms of patients suffering from chronic idiopathic constipation.

Therefore the aim of this research was to investigate the possible effect of spinal manipulation on chronic idiopathic constipation in terms of subjective and objective clinical measures.

1.2 AIM AND OBJECTIVES

This study aimed to investigate the possible effect of spinal manipulation on chronic constipation in terms of subjective and objective clinical measures.

1.2.1 The ***first objective*** was to evaluate the effect of spinal manipulation on subjects' abdominal pain intensity, sense of wellbeing, spinal range of motion and level of constipation.

Hypothesis 1:

It was hypothesized that spinal manipulation would effect a decrease in the subject's abdominal pain intensity and level of constipation and an increase in the subject's sense of wellbeing and spinal range of motion.

1.2.2 The ***second objective*** was to evaluate the effect of placebo on subjects' abdominal pain intensity, sense of wellbeing, spinal range of motion and level of constipation.

Hypothesis 2:

It was hypothesized that placebo would effect an increase in the subject's abdominal pain intensity and level of constipation and a decrease in the subject's sense of wellbeing and spinal range of motion.

1.2.3 The ***third objective*** was to compare the effects of spinal manipulation versus placebo on subject's abdominal pain intensity, sense of wellbeing, spinal range of motion and level of constipation.

Hypothesis 3:

It was hypothesized that spinal manipulation would be more effective than placebo in bringing about a decrease in the subject's abdominal pain intensity and level of constipation and an increase in the subject's sense of wellbeing and spinal range of motion.

1.3 RATIONALE

The prevalence of chronic constipation is reported to be approximately 2.0-12.8% in the general population, affecting one in fifty individuals; in the United States more than 500 million dollars is expended for prescription and non – prescription laxatives per annum (Tramonte et al 1997,Browning 1999).

In addition patients who are chronically constipated tend to have a diminished perception of their quality of life, many having to rely on laxatives, some of which have side effects. While laxatives may improve chronic idiopathic constipation in the short term, long term usage can result in undesirable side effects and evidence suggests that laxatives (bulk or fibre) do not improve the patient's sense of well being (Younoszai and Tolaymat 1989, Tramonte et al 1997, Browning 1999).

Therefore an adjunct to treatment that is not related to medicinal intervention would be of benefit to the patients.

Thus there have been three case reports, which suggest that chronic idiopathic constipation may be alleviated by spinal manipulation (Hewitt 1993, Marko 1994, Redly 2000). One case report measured global well being outcomes and was able to show a steady increase in the patient's sense of well being (Redly 2000). However, all three reports involved a single patient, had no control and could therefore not exclude the possibility of coincidental findings.

The outcomes of these case studies have supported the many research outcomes that have suggested that the effects of spinal manipulation extend beyond the musculoskeletal system (Korr 1976, Sato 1992, Sato1995, Nansel and Szlazak 1995, Lebouef-Yde et al 1999). In addition some studies have presented findings that point towards improved function of the gastro- intestinal system following spinal manipulation, suggesting the existence of a somatovisceral reflex effect (Korr 1976, Hewitt 1993, Sato 1995, Lebouef-Yde et al 1999, Redly 2000).

To further support the above, segmental abnormalities such as segmental tenderness, and restricted range of motion can be found in the thoraco-lumbar spines of patients with functional abdominal pain (Jorgensen and Fosgreen 1990). The sympathetic innervation of the colon arises from these same segments (Crossman and Neary 1998:144p) and this therefore supports a hypothesis of the existence of a connection between the abdominal discomfort and back pain (Jorgensen and Fosgreen 1990).

The results of this study may thus provide further evidence to support the existence of a somatovisceral reflex between the spine and intestine and demonstrate the efficacy of spinal manipulation in the management of chronic idiopathic constipation.

1.4 LIMITATIONS OF THE STUDY

Many researchers have suggested that the effects of spinal manipulation extend beyond the musculoskeletal system (Korr 1976, Sato 1992, Sato1995, Nansel and Szlazak 1995, Lebouef-Yde et al 1999). Some studies have presented

findings that point towards improved function of the gastro- intestinal system following spinal manipulation, suggesting the existence of a somatovisceral reflex effect (Korr 1976, Hewitt 1993, Sato 1995, Lebouef-Yde et al 1999, Redly 2000).

The segmental relationship of sympathetic innervation of the colon supports the hypothesis of the existence of a connection between abdominal discomfort and back pain (Jorgensen and Fosgreen 1990).

The results of this study could provide further evidence to support the existence of a somatovisceral reflex between the spine and intestine and demonstrate the efficacy of spinal manipulation in the management of chronic idiopathic constipation. However, the study was limited to the clinical outcomes, and therefore does not attempt to investigate nor explain the mechanism whereby spinal manipulation could have affected chronic idiopathic constipation either in a positive or negative manner. This is further limited by the fact that the budget for this study could not cater for a blinded examiner to independently evaluate patients subjecting this study to possible researcher bias.

1.5 CONCLUSION

This chapter therefore provided an introduction to the study, presenting the problem and its setting, the objectives and their related hypotheses as well as the limitations of the study. Chapter two will provide an expansion to the literature

discussed thus far in order to expand the reader's understanding of the available literature while chapter three will detail the study design, including the materials and methods. The results achieved as well as the discussion of these results in the context of the current literature will be presented in chapter four, which will be followed by the conclusions and subsequent recommendations for future studies.

CHAPTER TWO

LITERATURE REVIEW

2.1 FUNCTIONAL ANATOMY AND BIOMECHANICS OF THE THORACIC AND LUMBAR SPINE

2.1.1 The Thoracic Spine

Functional Anatomy

The thoracic spine consists of 12 thoracic vertebrae (Moore and Dalley 1999:435p). The body of a typical thoracic vertebra is heart shaped with anterior to posterior and side to side dimensions of equal length (Bergman et al 1993:197p). Both superior and inferior surfaces of the body are flat, with a ring (ring apophysis) around the margin for the attachment of the intervertebral disc (Chaurasia 1998:175p). Thoracic vertebrae have short pedicles, large and deep inferior vertebral notches and short, broad, overlapping laminae. The spinous processes are long and slender and point inferiorly (Bergman et al 1993:293p; Moore and Dalley 1999:435p). Thick, strong and long transverse processes with concave facets on the anterior sides arise from behind the superior articular processes (Bergman et al 1993:294p).

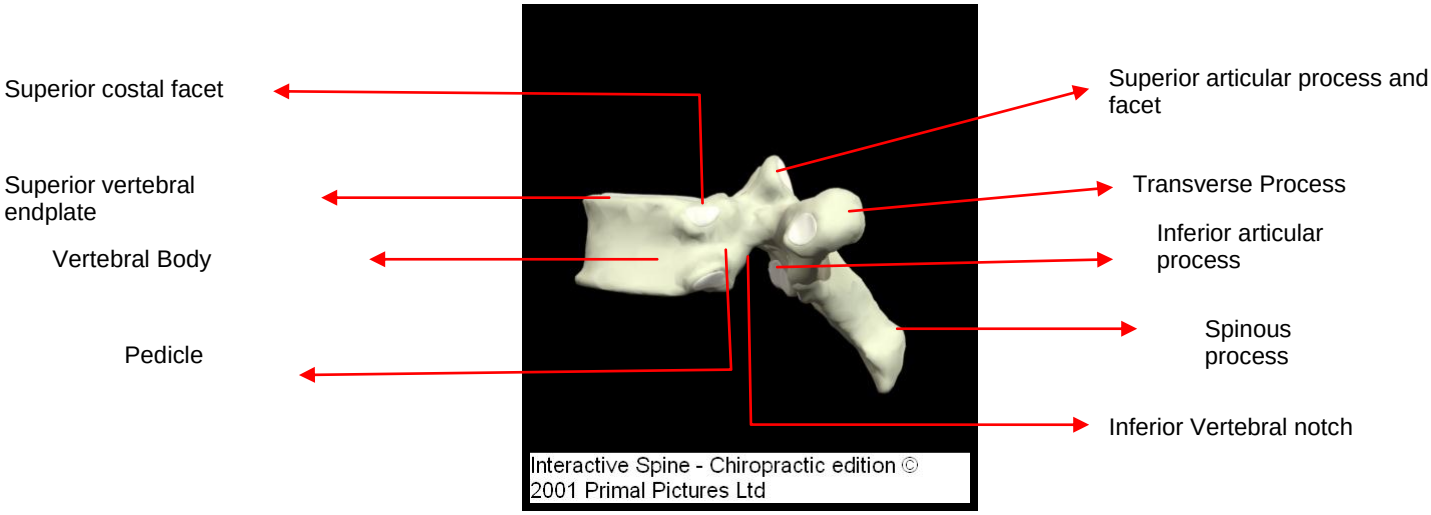

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Figure 1 – A typical thoracic vertebra

The thoracic spine has an average kyphotic curve of 45º (Bergman et al 1993:295p and Yochum, Rowe 2000). This structural curve begins at T1 and extends to T12, being maintained by the wedge shaped vertebral bodies that are two millimeters higher posteriorly, the T6/T7 disc space marks the apex of the curve (Bergman et al 1993:295p).

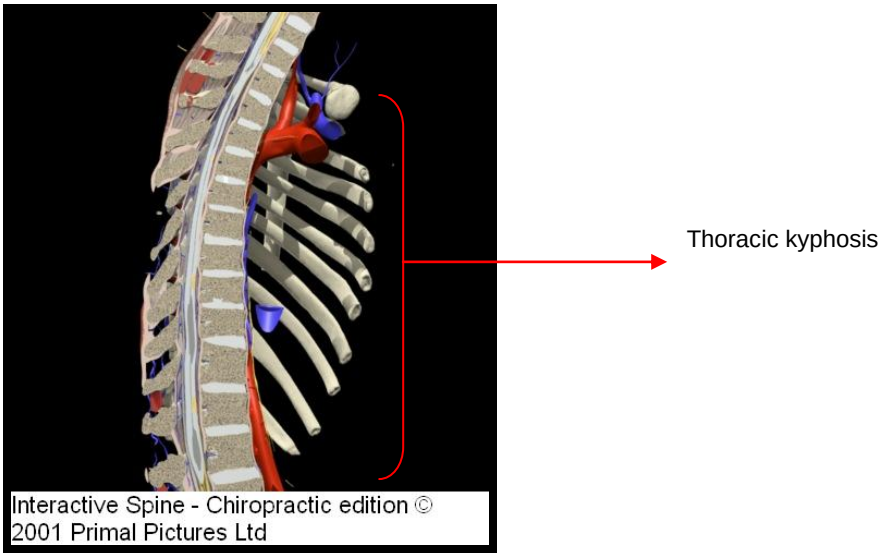

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Figure 2 – Saggital section of the thorax showing thoracic kyphosis

The zygopophyseal (facet) joints

Facet joints are synovial joints consisting of superior, inferior articular facets and a capsule (Magee 1997:425p). The superior articular facets of T1 face upward and backward. The inferior facet faces downward and forward (Chaurasia 1998:177p). The T2-T11 superior facets face upward, backward and slightly laterally, with their inferior counterparts facing downward, forward and slightly medially, a configuration that permits slight rotation in the thoracic spine. The superior facets of T11 and T12 face upward, backward and medially with the inferior facets facing forward and slightly laterally (Magee 1997:426p, Chaurasia 1998:177p). The ligaments between the vertebral bodies include the ligamentum

flavum, the anterior and posterior longitudinal ligaments, the interspinous, supraspinous and intertransverse ligaments (Magee 1997:425p and Tobias et al 1998).

Innervation of the facet joint:

The capsule of the facet joint receives rich sensory innervation from the medial branch of the posterior primary division (dorsal ramus) at the level of the joint, and a branch from that of the level above (Gatterman 1995:21p). In addition, the capsule of the facet joint has three types of sensory receptors, type I, type II and type IV (type III are not found in the facet joint), the table below gives a short description of these receptors and their function (Bergman et al 1993:39p).

Sensory Receptors of the Zygopophyseal Joint Capsule	***Description***	***Functions***
Type I	Very sensitive mechanoreceptors confined to the outer joint capsule, fire continually, even when joint is not moving.	1. Constant monitoring of outer joint tension. 2. Perception of posture and movement. 3. Inhibition of centripetal flow from pain receptors. 4. Tonic effects on lower motor neuron pools.

Type II	Less sensitive mechanoreceptors, found in the deeper layers of the capsule, fire only during joint movement.	1. Monitoring of movement for reflex actions and perhaps perceptual sensations. 2. Inhibition of centripetal flow from pain receptors. 3. Phasic effects on lower motor neuron pools.
Type IV	Network of free nerve endings and unmyelinated fibres, slow conducting nociceptive mechanoreceptors.	1. Evoke pain. 2. Central reflex connections for pain inhibition. 3. Central reflex connections for autonomic effects.

Bergman et al 1993, Gatterman 1995)

Table 1 – Types of Sensory Receptors in the Zygopophyseal Joint Capsule

2.1.2 The Lumbar Spine

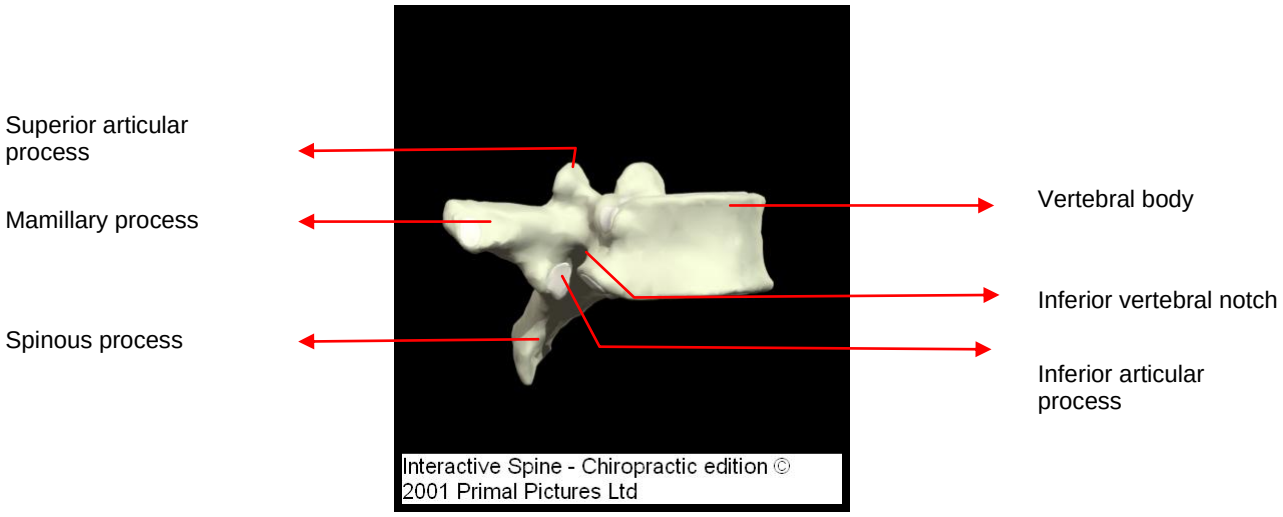


Figure 3 – A typical lumbar vertebra

Functional Anatomy

The five lumbar vertebrae are clearly distinguishable by their massive bodies, sturdy laminae and absence of costal facets (Moore and Dalley 1999:437p). A typical lumbar vertebra is large and kidney shaped, designed for weight bearing (Bergman et al 1993:402p, Moore and Dalley 1999:438p). It is wider from side to side than front to back. The lumbar pedicles originate from the upper part of the body of the vertebra, extending horizontally and posteriorly, they are short and strong. Lumbar vertebrae have a deep inferior and shallow superior vertebral notch (Bergman et al 1993:402p, Chaurasia 1998:152p). The spinous processes are broad, pointing posteriorly while the long slender transverse processes, originating from the lamina-pedicle junction, are flattened on their anterior and posterior surfaces (Bergman et al 1993:403p). The superior articular processes face posteromedially, while the inferior articular processes have an anterolateral orientation. This configuration limits rotational flexibility, allowing for greater flexion and extension.

The lumbar spine's lordotic curve has its apex at the level of the L3/L4 disc. The curve of the lumbar lordosis ranges between 20 to 60 degrees (Bergman et al 1993:407p).

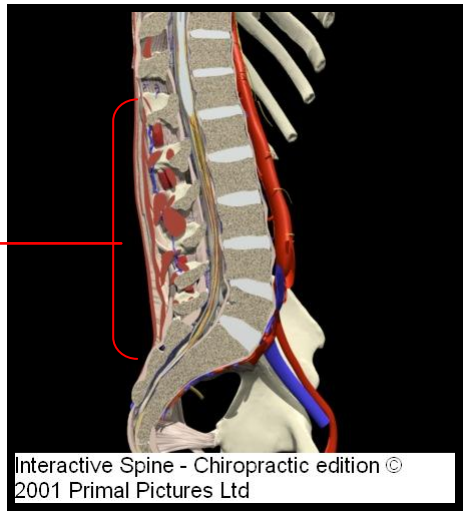
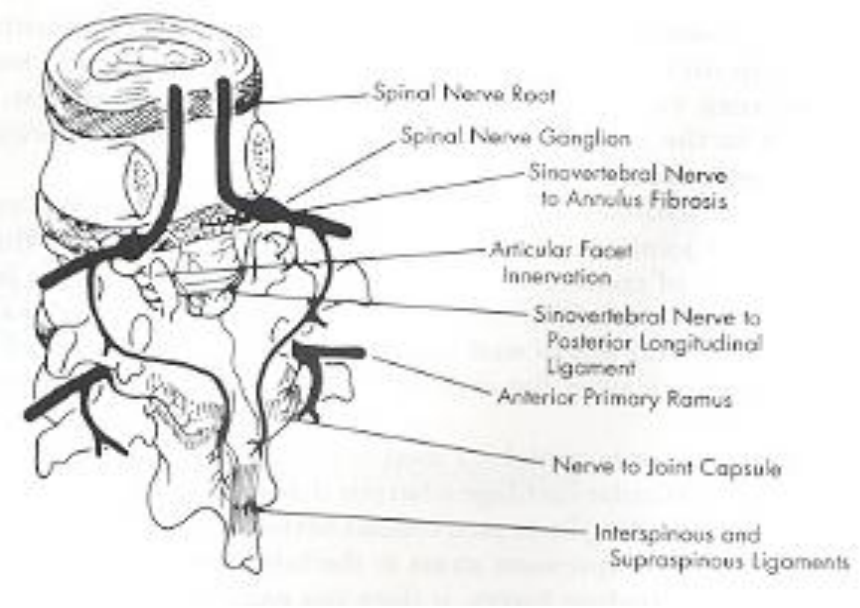


Figure 4 – Sagittal section of lumbar spine showing lumbar lordosis

The zygopophyseal (facet) joints

These are diarthrodial joints consisting of superior and inferior articular facets and a joint capsule, of which there are five pairs in the lumbar spine. With a normal and intact disc, the facet joint, carries 20-25% of the axial load, providing 40% of the torsional and shear strength (Magee 1997:467p).



Taken from Chiropractic Technique (Bergman et al 1993)

Figure 5 – Diagram of a Facet joint showing its innervation

2.1.3 Biomechanics

Introduction

The range of movement in the spine varies according to both the region of the spine concerned as well as the individual concerned (Moore and Dalley 1999:450p). Mobility results primarily from the compressibility and elasticity of the intervertebral discs; the movements possible in the vertebral column are

flexion, extension, lateral flexion (side bending) and rotation (Chaurasia 1998:153p). The range of movement of the vertebral column is limited by the thickness of the intervertebral discs, shape and orientation of the zygopophyseal joints and resistance of the muscles and ligaments of the back (Magee 1997:486p, Moore and Dalley 1999:450p). Although movements between adjacent vertebrae may be small, the summation of these small movements, produce considerable range of motion in the vertebral column as a whole (Moore and Dalley 1999:451p).

2.1.3.1 Range of motion of the Thoracic Spine

Combined flexion and extension in the thoracic spine averages approximately six degrees per motion segment; the average value for gross thoracic flexion / extension is 45º (Magee 1997:436p). Lateral bending is approximately 6º to 9º per segment with the range of gross thoracic lateral flexion lying between 20º-40º. Rotation per segment is approximately 9º in the upper thoracic spine and 2º in the T11-T12 region; average gross thoracic rotation is approximately 35º (Bergman et al 1993:312p, Magee 1997:437p).

2.1.3.2 Range of motion of the Lumbar Spine

Combined flexion and extension in the lumbar spine, averages 15º per segment with an average gross flexion value of 60º and extension value of 40º (Magee 1997:487p). Approximately 6º of lateral flexion occurs at each lumbar segment; the average gross lateral flexion in the lumbar spine is 20º. Rotation averages 2º per motion segment with the value for gross lumbar rotation ranging between 9º – 18º (Bergman et al 1993:419p, Magee 1997:487p).

2.2 ANATOMY AND PHYSIOLOGY OF THE LARGE INTESTINE

2.2.1 Introduction

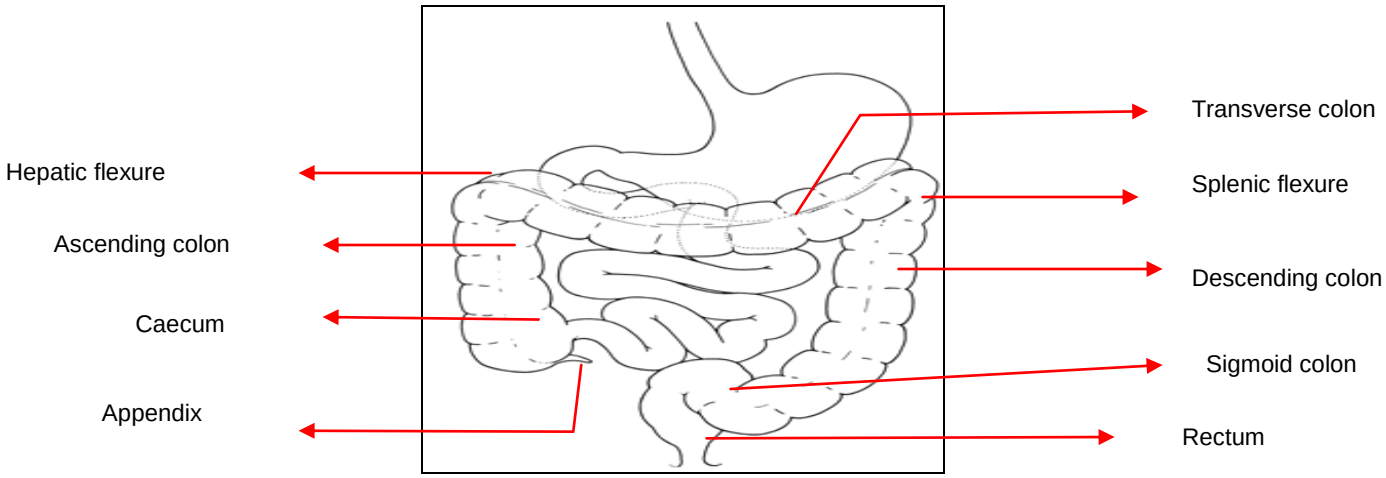
The large intestine extends from the ileocaecal junction to the anus (Chaurasia 1998:219p). It can be divided into the caecum, vermiform appendix, ascending, transverse, descending and sigmoid colon, rectum and anal canal (Moore and Dalley 1999:249p). The structure of the large intestine is adapted for the storage of matter from the small intestine, its principal functions, being the absorption of water and electrolytes from the same and the storage of faecal matter until it can be expelled (Guyton and Hall 1997:511p, Chaurasia 1998:220p).

2.2.2 General Structure of the Large Intestine

The large intestine is wide in caliber (as compared with the small intestine); the greater part of the large intestine is fixed, with the exception of the appendix, transverse and sigmoid colon segments (Chaurasia 1998:221p). The longitudinal muscle coat of the large intestine forms three bands called the taeniae coli, except in the appendix and rectum (Moore and Dalley 1999:249p). The taenia are shorter than the intestine, thus the colon has the typical sacculated appearance formed by the haustra (Chaurasia 1998:220p, Moore and Dalley 1999:250p). The caecum (first part of the large intestine), is continuous with the ascending colon and has a blind ending pouch in the right lower quadrant of the abdomen, the ileocaecal opening (at the junction between the ileum and caecum) is guarded by the ileocaecal valve (Chaurasia 1998:221p). The appendix, a blind intestinal diverticulum, arises from the posteromedial aspect of the caecum, inferior to the ileocaecal junction (Moore and Dalley 1999:249p).

The ascending colon extends from the caecum to the inferior surface of the right lobe of the liver; here it bends to the left to form the right colic (hepatic) flexure. The transverse colon extends across the abdomen from the right to the left colic (splenic) flexure. The descending colon extends from the splenic flexure to the sigmoid colon (Chaurasia 1998:225p). The sigmoid colon, characterized by its

"S" – shaped loop, forms the link between the descending colon and rectum, as it extends from the left iliac fossa to the third sacral segment were it is continuous with the rectum (Moore, Dalley 1999:250p). The rectum, the distal part of the large intestine is placed between the sigmoid colon above and anal canal below, distension of the rectum causes the desire to defaecate. The anal canal, the terminal part of the large intestine lies in the anal triangle, between the right and left ischiorectal fossae, the internal anal sphincter is involuntary in nature while the external anal sphincter is under voluntary control (Chaurasia 1998:226p).



Taken from www.msjensen.gen.umn.edu

Figure 6 – General structure of the Large Intestine

2.2.3 Blood supply to the Large Intestine

The caecum receives its blood supply from the ileocolic artery, the terminal branch of the superior mesenteric artery. The appendicular artery, a branch of the ileocolic artery, supplies the appendix. A tributary of the superior mesenteric vein, the ileocolic vein drains blood from both caecum and appendix (Moore and Dalley 1998:251p).

The arterial supply to the ascending colon and hepatic flexure is via the right colic and ileocolic arteries (branches of the superior mesenteric artery), here, venous drainage is effected by the ileocolic and right colic veins (tributaries of the superior mesenteric vein) (Chaurasia 1998:231p). The middle colic artery and the right and left colic arteries (to a lesser extent) are responsible for supplying blood to the transverse colon, while the venous drainage is via the superior mesenteric vein. Branches of the inferior mesenteric artery (the left colic and superior sigmoid arteries) supply the descending and sigmoid colon, blood from here is returned via the inferior mesenteric vein (Chaurasia 1998:231p, Moore and Dalley 1999:252p). The continuation of the inferior mesenteric artery, the superior rectal artery forms an anastomoses with the middle and inferior rectal arteries to supplies the rectum and anal canal. The internal and external rectal venous plexuses and superior and middle rectal veins, drain the anal canal and rectum respectively (Moore and Dalley 1999:252p).

2.2.4 Nervous innervation of the Large Intestine.

The gastrointestinal tract is under the neural control of the enteric nervous system (a division of the autonomic nervous system), which lies in the wall of the gut, it controls gastrointestinal movements and secretions. The enteric nervous system comprises of the myenteric and submucosal plexuses. The submucosal plexus is responsible for the control of gastrointestinal epithethial secretions and local blood flow, while it is the myenteric plexus that exerts control over the movements of the gastrointestinal tract (Gatterman 1995:248p,Guyton and Hall 1997:512p). Sympathetic and parasympathetic fibres connect with both the plexuses, and stimulation by these systems can inhibit or excite gastrointestinal function respectively (Hewitt 1993, Chaurasia 1998:224p).

2.2.4.1 Parasympathetic innervation

Almost all parasympathetic nerves to the gut are carried by the vagus nerves (Chaurasia 1998:224p). Parasympathetic stimulation acts to increase the activity of the entire enteric nervous system, which in turn can increase movements in the gastrointestinal tract (Guyton and Hall 1998:512p).

2.2.4.2 Sympathetic innervation

Sympathetic fibres originating in the spinal cord between segments T5-L2 innervate the gastrointestinal tract (Crossman and Neary 1998:145p). Sympathetic stimulation is inhibitory (Chaurasia 1998:224p). This is achieved by direct effect of norepinephrine on the smooth muscle of the gut (to a small extent), thus inhibiting contraction; and more especially by the effect of norepinephrine on the neurons of the enteric nervous system (Guyton and Hall 1998:513p). Strong sympathetic stimulation can, totally block movement through the gastrointestinal system (Guyton and Hall 1998:513p, Korr 1976).

Stressors (physical or emotional), can lead to sympathetic activation (Guyton and Hall 1999:513p). Motion segment dysfunction in the spine perceived as a stressor, may be responsible for the stimulation of the sympathetic nervous system, this could possibly contribute to decreased gut motility (Gatterman 1995:112p).

2.3 CHRONIC IDIOPATHIC CONSTIPATION

2.3.1 Introduction

The word constipation is derived from the latin word *constipare,* which means to crowd together (Leung et al 1996). "Constipation" can thus be defined as the infrequent or difficult evacuation of faeces, with "idiopathic" denoting that the

condition occurs in the absence of any known cause and “chronic” implying that it has persisted for a long time (Anderson 1989).

2.3.2 Defining Chronic Idiopathic Constipation

Even with the ambiguity in respect of the clinical definition of chronic idiopathic constipation, the literature seems to suggest that the definition of constipation may include infrequent bowel movements, difficulty during defaecation, a subjective sensation of hard stools or, the sensation of incomplete evacuation (Basson 2005, Redly 2000).

2.3.3 Prevalence

Constipation is one of the most common GI disorders and in the United States alone, it is the reason behind more than 2.5 million physician visits per year, with 2% of the population, describing constant or frequent episodes of constipation (Browning 1999, Basson 2005). With the exact prevalence of the condition being largely unknown, it is reported to range from 2.0% – 12.8% in the general population (Duowu et al 2000; Browning 1999). The prevalence of self-reported constipation varies substantially, internationally, due to differences among ethnic groups and the way in which constipation is perceived (Basson 2005).

2.3.4 Race, sex and age

Chronic Idiopathic Constipation is especially prevalent in the elderly, women, people with daily inactivity, little leisure or exercise, poor education and individuals from lower socio-economic levels; more than 500 million US Dollars is spent on prescription & non-prescription laxatives per year (Tramonte et al 1997, Orr et al 1997, Browning 1999).

The trend displayed in the United States, is that chronic constipation is more commonly seen in the black than white population (Browning 1999). In contrast, chronic constipation is less frequent in black than in white Africans; while constipation is less common in the Asian population, it is frequent in those who have adopted a western diet, these different trends, suggest that dietary and environmental factors seem to play a role (Basson 2005).

Chronic constipation is generally more frequent in females than in males (Tramonte et al 1997, Browning 1999).

2.3.5 Pathophysiology of Chronic Idiopathic Constipation

The symptom of constipation may result from any alteration in stool consistency, colonic motility or calibre; it may also be seen in association with other conditions such as dehydration, electrolyte disturbances (e.g. hypercalcaemia and hypokalaemia), neurological disorders (e.g. diabetic autonomic neuropathy, cerebrovascular accidents, multiple sclerosis or spinal cord lesions), hypothyroidism, inflammatory bowel disease (ulcerative colitis or Crohn's disease), irritable bowel syndrome, narrowing of the colon (as occurs with strictures or neoplasms), as a side effect of certain drugs (e.g. opiates, anticholinergics, tricyclic antidepressants or calcium channel blockers) or present idiopathically, in the absence of underlying pathology (Berkow 1992, Edwards et al 1999, Kumar et al 1997). Sometimes constipation can be due to psychogenic causes, being seen in association with anxiety, depression or obsessive compulsive behaviour (Berkow 1992).

A link between coffee consumption and the worsening of constipation has been shown, (the diurectic effect of coffee (and tea), decreases the water available in the colon), cow's milk has also been implicated. Chronic laxative abuse may

cause refractory constipation (Basson 2005). Coffee, due to its caffeine content, has been known to promote activation of the sympathetic nervous system, this could further contribute to decreased colonic motility (Guyton and Hall 1999:512p).

Thus constipation is the resultant effect of several factors such as poor diet, lack of exercise, disordered colonic motility (possibly due to sympathetic overactivity), anatomic defect or psychological factors (Meshkinpour et al 1998, Browning 1999). Literature suggests that cumulative exposure to neurotoxins, chronic pelvic injury and the development of anatomic abnormalities such as rectal prolapse or rectocoele may play a role (Basson 2005).

2.3.7 Diagnosis

The challenge of determining the incidence of chronic idiopathic constipation lies in the defining of this problem (Browning 1999), as the diagnosis is often largely based upon what the patient believes constitutes normal bowel function. It has been demonstrated that patients, in their complaint of chronic constipation, may be referring to several different aspects of bowel behaviour the like of infrequent stooling, straining or a sensation of incomplete evacuation. One third of patients who report being chronically constipated cite infrequent defaecation as the defining symptom, more often the definition involves straining at stools (52% of cases), the passing of hard stools (44% of cases) or the inability to pass stools when desired (34%of cases)(Orr et al 1997, Tramonte et al 1997).

Literature defining chronic idiopathic constipation demonstrates this ambiguity, with patients showing a tendency toward defining constipation on the basis of symptoms whereas health professionals more often consider the frequency of bowel movements (Tramonte 1997, Redly 2000). Compounding the challenge is that apart from the subjective report gleaned from the patient, there is little by way of physiologic or anatomic markers to make a diagnosis of chronic idiopathic

constipation coupled with our poor understanding of the underlying pathophysiology of the complaint (Orr et al 1997, Tramonte et al 1997, Redly 2000). The diagnosis of chronic idiopathic constipation is therefore often one of exclusion and depends largely on the particular patient's perception of normal bowel function (Orr et al 1997, Tramonte et al 1997).

Nevertheless, the currently accepted diagnostic criteria for chronic idiopathic constipation is less than three bowel movements per week and one or more of straining at stools, a sensation of incomplete evacuation or the passing of pellet like stools at least 25% of the time (Redly 2000).

2.3.8 Chronic Idiopathic Constipation and Quality of life

Chronically constipated people find the problem annoying and tend to perceive their quality of life or sense of well being as being diminished (Tramonte et al 1997, Redly 2000). The conventional medical approach for managing chronic constipation usually begins with a high fibre diet. Many agents to alleviate chronic constipation are widely available; these range from bulking agents (e.g. bran, psyllium or methylcellulose), to osmotic laxatives (e.g. Saline osmotic, lactulose) or stimulant cathartics such as senna and its derivatives; however, the actual indications for and benefits of laxative therapy are poorly characterised (Berkow 1992,Tramonte et al 1997). Many individuals tend toward the use of laxatives to try and alleviate their symptoms, believing that these agents do not have any serious side effects (Tramonte et al 1997). Fibre and laxatives provide a modest increase in bowel movement frequency, while certain non-bulk agents (eg. Cisapride, Lactitol and Lactulose) effect an improvement in stool consistency but evidence to establish whether other non bulk laxatives improve stool consistency or abdominal pain remains inadequate. The side effect profiles of many laxative agents include abdominal pain/cramping, nausea and vomiting, diarrhoea, dehydration, loss of electrolytes and possible electrolyte imbalances.

Literature documenting these side effects is limited and short term and more research into this area in needed (Tramonte et al 1997, Snyman 2003).

Traditionally, patient-based outcomes used in research focus on absence of symptoms, emphasizing the negative end of the health continuum, this is inconsistent with the World Health Organisation's definition of health as "a state of complete physical, mental and social well being and not the mere absence of disease or infirmity." The patient's global sense of wellbeing (patient's perception of his/her physical functioning, role function related to emotions, energy level or fatigue, social functioning and general health) is more in keeping with assessing the effect of treatment while viewing the patient as a whole, not a mere collection of symptoms (Hawk et al 1995). Gastro-intestinal complaints have been known to manifest in people who perceive themselves to be tense or upset (Redly 2000). Visceral sensations also lead to a conscious awareness of a feeling of fullness in hollow organs such as the intestine and contribute to a feeling of wellbeing or malaise (Gatterman 1995). In a meta-analysis of literature with respect to chronic constipation, neither laxative nor fibre therapies for managing chronic constipation have been conclusively shown to improve general well being (Tramonte et al 1997).

2.4 CHRONIC IDIOPATHIC CONSTIPATION, SOMATOVISCERAL REFLEXES AND SPINAL MANIPULATION

2.4.1 Introduction

The concept of a somatovisceral reflex which alludes to abnormalities in the spinal column causing nerve interference and thereby inducing disorders in segmentally related visceral structures is not new (Korr 1976, Sato 1992). Literature concerning spinal manipulation and somatovisceral reflex theories (Hewitt 1994, Leboeuf-Yde 1999), could suggest that somatic spinal dysfunction, may create signs and symptoms that mimic organic or true visceral disease.

Chronic Idiopathic Constipation is common, yet its pathogenesis remains poorly understood (Duowu, 2000). There are three case reports which suggest that spinal manipulative therapy may relieve Chronic Idiopathic Constipation (Hewitt 1993, Marko 1994, Redly 2000). All three cases involved a single patient. Patients received manipulation to the cervical (Hewitt 1993, Marko 1993), thoracic and lumbar spines (Hewitt 1993, Marko 1994, Redly 2000). All cases reported a vast improvement in bowel function within three weeks. One case report was able to document a steady increase in the patient's sense of wellbeing (Redly 2000).

2.4.2 The concept of somatoautonomic Reflexes

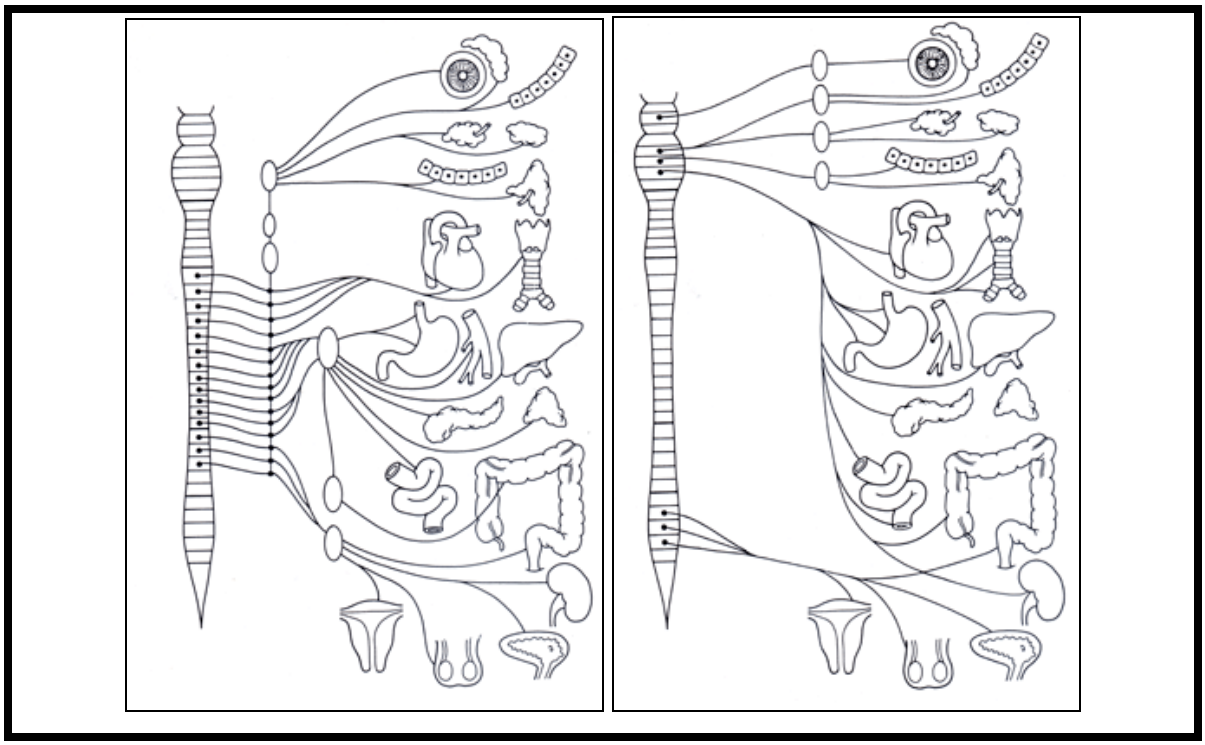
The autonomic nervous system although predominantly self regulated, is not limited to self regulation, this is of clinical significance, since therapeutic intervention that alters somatic or visceral function, may have effects on body systems apparently remote from the site of intervention (Nansel et al 1993, Suter et al 1994, Gatterman 1995:112p, Dixon 2004, Botha 2005). Literature suggests a possible association between somatic (sensory and motor) function and visceral (sensory and motor) function (Lebouef-Yde et al 1999). It appears that somatic and visceral functions are co-ordinated closely through somatovisceral and viscerosomatic reflex mechanisms involving the autonomic, peripheral and central nervous systems (Gatterman 1995:157p). Therapeutic interventions such as vertebral manipulation, could alter somatic sensations (eg. proprioception) in a way that visceral function may become altered, however, the underlying neuronal mechanism requires further scientific investigation (Gatterman 1995:158p).

The central nervous system mechanism whereby autonomic neuronal activity is regulated, originates in somatic and visceral sensations and is reflexogenic. Under normal circumstances, impulses of visceral sensation reach the central

nervous system along peripheral processes of primary sensory neurons like those of somatic sensations and provoke reflex responses in organs (Gatterman 1995:182p). When organs function abnormally because of a pathological condition or injury, visceral afferent neurons may conduct painful sensations to spinal cord segments that supply the organ in question, these painful sensations can be referred to regions of the body wall or limbs that are innervated by the same spinal cord segment, commonly referred to as “referred pain” (Korr 1976, Gatterman 1995:30p). Visceral afferent neurons are localized in the sensory ganglia of the cranial nerves and posterior root ganglia of the spinal nerves; their peripheral processes (efferents) are distributed with autonomic pre-ganglionic and post-ganglionic axons to reach the viscera (Gatterman 1995:109p).

Somata of autonomic afferent neurons are localized in the sensory ganglia of the vagus, glossopharyngeal nerves and the thoracic, upper lumbar and mid-sacral spinal nerves. Peripheral processes of general efferent neurons are distributed to thoracic and abdominal viscera through the white ramus communicantes of the thoracic and upper lumbar spinal nerves and follow sympathetic pre-ganglionic and post-ganglionic autonomic ganglia to terminate in the wall of the viscus (Gatterman 1995:260p,Crossman and Neary 1998:144p).

Although general visceral afferent stimuli play a significant reflexogenic regulatory role at an unconscious level in the autonomic nervous system, somatic sensations also control autonomic activity by reflex pathways (Korr 1976). When sympathetic activation is required, somatic sensations involving special or general sensation, often initiate autonomic responses. Viscerosomatic reflexes are also recognized, for example, visceral pain is known to cause an increase in tone and even spasm of skeletal muscle (Gatterman 1995:111p).



A **B**

Taken from www.msjensen.gen.umn.edu

Figure 7 – Sympathetic (A) & Parasympathetic (B) Visceral Innervation

Clinically recognized links between certain spinal segments and visceral structures lead to the development of the meric system to graphically represent these links (Gatterman 1995), this was later supported by the anatomic (neurological) relationship between the spinal segments and visceral structures as depicted above.

2.4.3 Somatovisceral Reflex Theories

One of the earliest somatovisceral reflex theories was that put forward by Korr (Nansel and Slazak 1995). Korr's theory suggests that spinal muscles under strain or tension cause proprioceptive nerve receptors embedded in these muscles to fire (Gatterman 1995:110p). This proprioceptive information, synapses with second order neurons located in the spinal cord and 'facilitates' or lowers the firing threshold of second order neurons (Korr 1976). These facilitated

second order neurons are hyper-responsive to impulses reaching them from any source in the body, this hyper-irritability, Korr termed 'chronic segmental facilitation' (Gatterman 1995:111p). Although second order neurons synapse with various cells in the nervous system, Korr's theory focuses on local segmental connections in the spinal cord. In the spinal cord, second order neurons synapse with the anterior horn cells which innervate muscle and with the lateral horn cells which are part of the sympathetic nervous system (Gatterman 1995:111p). Continual irritation of the lateral horn cells, causes these neurons to become facilitated, a facilitated or hyperirritable sympathetic nervous system is a major factor in the perpetuation of musculoskeletal or visceral dysfunction, as could be expected in the case of the bowel where increased sympathetic tone will result in decreased motility of the gastro-intestinal tract (Korr 1976).

In addition the presence of segmental muscle spasm at the site of spinal dysfunction supports the notion of reflex connection to the anterior horn cell and the presence of vasomotor, sudomotor and pilomotor changes at the site of spinal dysfunction support reflex connections to the sympathetic nervous system (Jorgensen and Fosgreen 1990, Gatterman 1995:112p). Since hyperactivity is demonstrated in sympathetic fibres innervating the skin, sympathetic fibres innervating the viscera would also be hyperactive (Korr 1976). Segmental tenderness and abnormalities in range of motion have been identified in the thoraco-lumbar spines of some patients with abdominal pain (in the absence of organic pathology); at the same segmental levels from which the sympathetic innervation of visceral structures such as the colon is derived (Jorgensen and Fosgreen 1990, Crossman and Neary 1998:145p, Redly 2000). Numerous conditions have been linked to hyperactivity of the sympathetic nervous system, including cardiac, gastrointestinal and genitourinary disorders (Gatterman 1995).

It has been suggested that nociceptors are the primary receptors causing chronic segmental facilitation and sustained sympatheticonia (Gatterman 1995:112p). Alteration in blood pressure and renal and adrenal sympathetic nerve activity has

been observed in rats, following the application of mechanical pressure to the spine (Sato and Swenson 1984). It has been found that the stimulation of periarticular nociceptors results in significant sympathetic neuronal reflex activity, however the threshold of stimulation required to cause nociceptor activity capable of producing chronic segmental facilitation in the living human is unknown (Gatterman 1995:112p).

Although, it has been shown that somatic pain can elicit global or regionally related somatovisceral reflex responses, it is questionable, whether these autonomic responses are capable of initiating frank tissue disease, as is implied by some practitioners (Nansel and Slazak 1995). Review of literature suggests that somatic pain, together with the autonomic reflex responses it induces, is known to create complex patterns of signs and symptoms that can be virtually identical to and mistaken for primary visceral disease, these pseudo or simulated disease syndromes can be responsible for a significant number of medical misdiagnoses (Nansel and Slazak 1995). Advances in knowledge of anatomy, have established that visceral afferent nerves transmitting nociceptive information from organs and somatic afferents carrying nociception from deep connective tissues (muscle, fascia, tendons, ligaments, joint capsules or bone), converge on common pools of interneurons within the spinal cord and brainstem, with subsequent transmission of information into other equally common central nervous system pathways, this afferent neuron convergence can result in overt patterns of signs and symptoms indistinguishable in so far as a somatic versus visceral etiology is concerned (Nansel and Slazak 1995, Budgell 2000). This can include referred pain, reflex induced muscle spasm or weakness, altered sensory perception and manifestations of altered parasympathetic or sympathetic activity (Nansel and Slazak 1995).

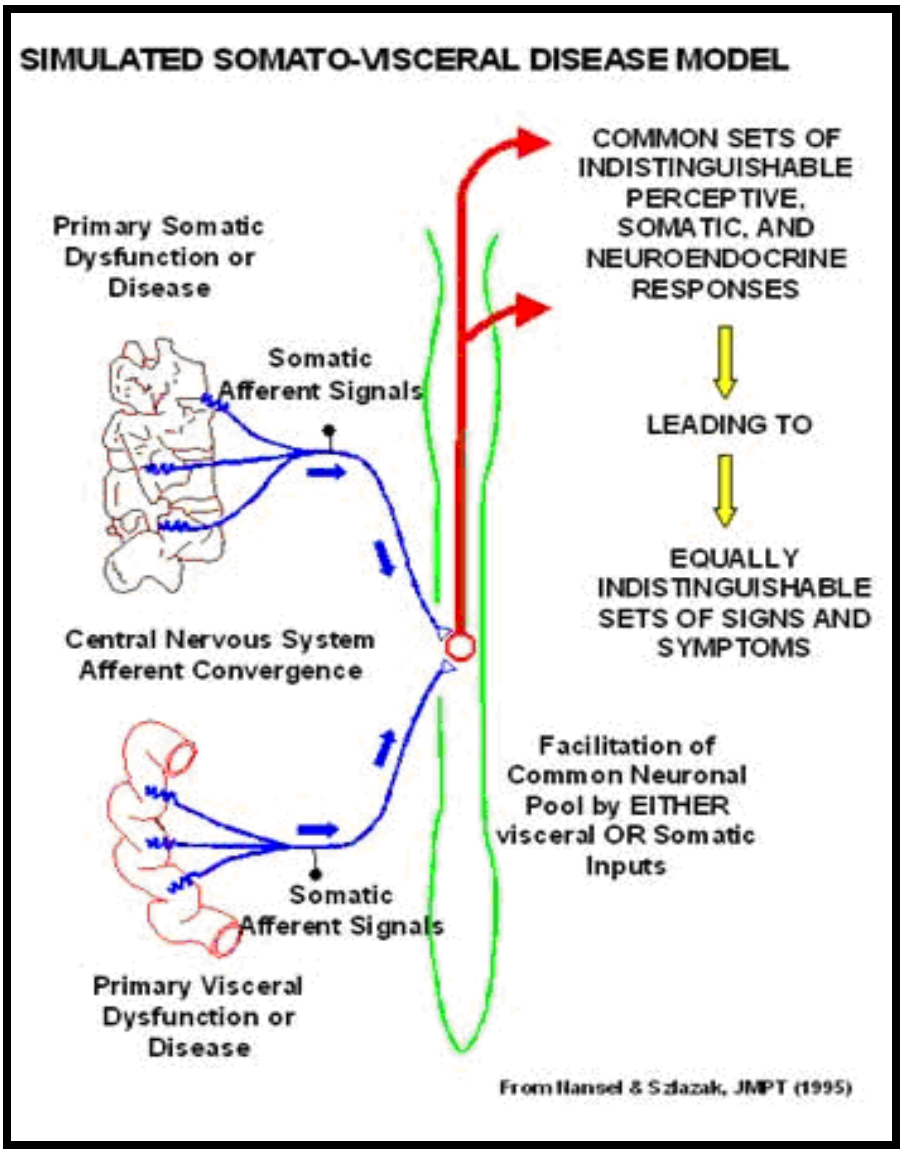


Figure 8 – The simulated somatovisceral disease model proposed by Nansel and Slazak 1995

This theory suggests that any intervention that is applied to the somatic tissues could have an effect on a patient's visceral signs and symptoms.

2.4.4 Spinal Manipulation and its effects

Manipulation, is a unique form of manual therapy, that employs controlled force, leverage, direction, amplitude and velocity, directed at a specific joint or subluxation (determined by motion palpation); spinal manipulation like other forms of manual therapy produces mechanical, soft tissue, neurologic and psychologic effects (Gatterman 1995:106p).

Changes brought about by manual therapy
Mechanical – changes in:
• Joint alignment
• Motion dysfunction
• Spinal curvature dynamics
• Entrapment
Soft Tissue – changes in:
• Muscle tone and strength
• Dynamics of supportive capsuloligamentous connective tissue
Neurologic Effects
• Reduction in pain
• Alteration in motor and sensory function
• Regulation of the autonomic nervous system
Psychologic Effects
• Laying on of hands
• Placebo factor
• Patient satisfaction

(Adapted from Gatterman 1995)

Table 2 – Changes brought about by manual therapy

2.4.5 Spinal manipulation and its mechanical effect

Improved joint mobility has been documented in patients receiving spinal manipulation (Bergman et al 1993:139p). Experimental manipulation to the spines of cadavers has shown increased joint mobility of manipulated segments, further goniometrically verified studies using, live subjects have been able to demonstrate this biomechanical effect of spinal manipulation (Gatterman 1993:178p). The proposed mechanism whereby spinal manipulation produces this effect (mechanical hypothesis), is through physical separation of the joint, stretching of the periarticular tissue (often accompanied by cavitation) and stimulation of the joint mechanoreceptors and nociceptors, thereby alleviating pain, muscle spasm, joint hypomobility and articular soft tissue inflexibility; the break down of intra-articular adhesions has also been suggested to play a role (Bergman et al 1993:140p).

2.4.6 Spinal manipulation, somatic referred pain and pain inhibition

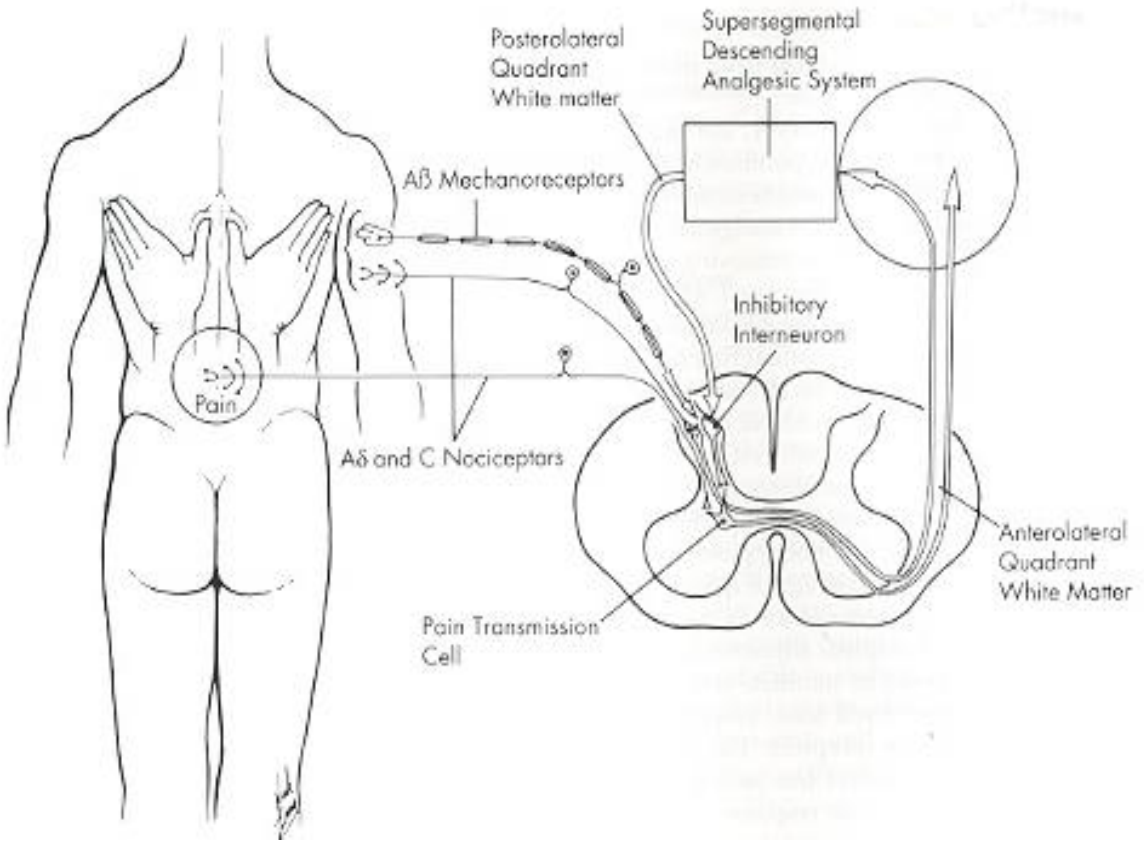
Abdominal pain is a frequent complaint among sufferers of chronic idiopathic constipation (Redly 2000). Segmental tenderness and range of motion abnormalities have been demonstrated in the thoracolumbar spines of patients with functional abdominal pain; this could suggest that such abdominal pain may in fact, have a somatic (spinal) etiology (Jorgensen and Fosgreen 1990). Pain referral from somatic structures, could well be attributed to the internal organization of the spinal cord, pain stimuli are dispersed onto different tract neurons and nociceptive information entering several vertebral levels, may converge on the same interneuron pool, this may decrease the ability of the central nervous system to localize pain. The back and neck, have small allocations on the sensory homunculus, this may also contribute to the poor localization of spinal pain (Gatterman 1995:280p, Crossman and Neary 1998:145p). Tract neurons for ascending pain pathways most often carry nociceptive information from cutaneous / somatic areas and when tract neurons

are stimulated to fire, the cerebral cortex may interpret the pain as coming from a related cutaneous area (Gatterman 1995:280p).

The reduction of pain following spinal manipulation has been clinically documented and proposed to be via stimulus produced analgesia (Melzack and Wall1965), however the exact mechanism whereby this occurs, remains speculative (Bergman et al 1993:151p). Experimental evidence suggests that spinal manipulation produces enough force to simultaneously activate both superficial and deep somatic mechanoreceptors, proprioceptors and nociceptors, inducing strong segmental afferent input, capable of inhibiting the central transmission of pain (Bergman et al 1993:152p, Gatterman 1995:295p). Brief (phasic) inhibition of neuronal discharge (both ongoing and stimulus induced) has been noted following the application of innocuous mechanical stimulation to the skin, inhibition ceased when the stimulus was removed; noxious mechanical pressure applied to deep tissues of the back, produced a more marked, long lasting (tonic) inhibition of neuronal discharge (Gatterman 1995:295p). Spinal manipulation may activate both phasic and tonic antinociceptive systems to decrease pain. The short term (phasic) response, triggered by the stimulation of superficial mechanoreceptors would cease with the cessation of therapy and is perhaps related to the spinally mediated gate control theory proposed by (Melzack and Wall 1965, Bergman et al 1993:152p). The long lasting tonic response, initiated by the stimulation of deep mechanoreceptors and nociceptors, shows similarities to segmental / suprasegmental / descending modulatory inhibition; evidence suggests these mechanisms use both GABA-ergic and opiod-ergic neurotransmitter pharmacology to suppress nociceptor neuron excitability (Gatterman 1995:297p).

Pain inhibition, post spinal manipulation, has also been suggested to involve increased levels of neurochemical pain inhibitor substances. A local release of enkephalins initiated by the stimulation of neurons in the substantia gelatinosa and a systemic increase in plasma and cerebrospinal fluid endorphin levels,

initiated by the stimulation of the hypothamlamic pituitary axis, have been proposed; both these substances, as endogenous opiod pain inhibitors, may participate in producing the analgesic effect of spinal manipulation (Bergman et al 1993:153p).



Taken from Chiropractic technique (Bergman et al 1993)

Figure 9 – Spinal manipulation and pain inhibition

2.4.7 Spinal manipulation and global wellbeing

Chronic idiopathic constipation is associated with subjective reports of diminished quality of life and sense of wellbeing (Redly 2000). The mainstay treatment of laxative therapy has not been shown to improve patients' sense of wellbeing (Tramonte et al 1997). Global wellbeing outcomes are important since an overall sense of wellbeing is consistent with the World Health Organisation's definition of health (Hawk et al 1995). However spinal manipulation has been shown to

improve wellbeing in a patient suffering from chronic idiopathic constipation (Redly 2000). Improvement in wellbeing post spinal manipulation could be the result of the analgesic or perhaps psychologic effect of the adjustment (Gatterman 1995). Doctor reassurance, the laying on of hands and the contact established during examination indicating the practitioner's level of skill and concern, followed by treatment and perhaps the audible cavitation associated with manipulation has the potential to exert a placebo effect which could lead to increased sense of wellbeing (Bergman et al 1993).

2.4.8 Spinal manipulation and regulation of the autonomic nervous system

Subtle somatic changes such as changes in tissue texture, joint position and joint mobility have been observed in patients with visceral dysfunction (Gatterman 1995). Segmental tenderness and range of motion abnormalities have been found in patients suffering from functional abdominal pain (Jorgensen and Fosgreen 1990). In a blind study, Beal (1983) was able to differentiate patients with cardiovascular from those with gastrointestinal dysfunction, based on palpatory findings of soft tissue texture and segmental range of motion; Beal and Dvorak (1984) in a further blind study, were able to identify palpatory characteristics specific for patients with cardiovascular, pulmonary, gastrointestinal or musculoskeletal dysfunction (Gatterman 1995:264p).

Some studies, were able to show that somatic stimulation by manipulation affects gastric function and angina pain (Sato and Schmidt 1973, Rogers and Rogers 1976). More recently it has been, shown that experimental manipulation of the thoracic spine in conscious rabbits, produces inhibition of myoelectrical activity in the gastrointestinal tract. A definite effect on blood pressure and pupillary diameter has been noted following spinal manipulation in humans (Gatterman 1995:265p). There have been numerous instances of patients and practitioners reporting non-musculoskeletal reactions post spinal manipulation (Gatterman 1995:265p, Lebouef-Yde et al 1999). This supports the notion that chronic

idiopathic constipation may in fact, through somatovisceral reflex activity, have a somatic etiology (Hewitt 1993, Redly 2000).

2.5 CONCLUSION

Primary (somatic) joint dysfunction, may lead to sympathetic hyperactivity and chronic sympathetic control of the colon, which acts to reduce colonic motility, possibly producing chronic idiopathic constipation (Hewitt 1993). Spinal manipulation of dysfunctional segments, may result in the re-establishment of coherent patterns of afferent input, by 'normalizing' articular afferent input to the central nervous system. It is proposed that normalized articular sensory input re-establishes normal nociceptive and kinesthetic reflex thresholds, causing recovery of muscle tone, joint mobility and sympathetic activity (Gatterman 1995:267p). This subsequent decrease in the sympathetic over activity, (which may in fact be, the offending factor in causing decreased colonic motility), would therefore act to restore normal bowel motility and alleviate chronic idiopathic constipation (Korr 1976, Hewitt 1993, Redly 2000). The analgesic effect associated with spinal manipulation may work to reduce abdominal pain associated with chronic idiopathic constipation (Gatterman 1995:113p). The analgesia, psychological effect and perhaps a placebo effect, could potentially produce an improved sense of wellbeing in subjects. The mechanism, whereby spinal manipulation, may affect chronic idiopathic constipation, is however, beyond the scope of this study. This study however may support or refute the possibility of such an association or causal relationship.

CHAPTER THREE

MATERIALS AND METHODS USED

3.1 THE OBJECTIVE

The aim of the study was to investigate the effect of spinal manipulative therapy on Chronic Idiopathic Constipation, in terms of subjective and objective clinical measures, and to compare this effect with that of placebo.

3.2 STUDY DESIGN

The study took the form of a cross-over type study involving a total of 30 patients assigned to one of two groups (Friedman et al 1998). Thirty patients were used since previous case studies involving spinal manipulation and chronic idiopathic constipation, presented findings for only single patient case studies (Hewitt 1993, Marko 1994, Redly 2000), had no control and thus could therefore not exclude the placebo effect. Some case studies reported that the improvement in patients' symptoms persisted for an extended period even after treatment ceased (Hewitt 1993, Redly 2000) in the absence of a control or natural history group, thereby potentially biasing the results obtained (Mann and Djulbegovic 2003).

Furthermore a cross over study is a special type of randomised controlled clinical trial that allows each subject to serve as his/her own control (Friedman et al 1998). A simple two period cross over design was used, with each patient receiving either the intervention (spinal manipulation) or the control (placebo) in the first period and the alternative in the succeeding period. In this way, subjects' response to the intervention and the control can be documented and compared.

3.3 ADVERTISING

Subjects were recruited through advertising in local newspapers, posters placed in and around the Durban Institute of Technology and pamphlets placed in post office boxes (APPENDIX K). Patients were also recruited through referrals from other interns at the Chiropractic Day Clinic as well as through advertisements on community radio stations.

3.4 TELEPHONIC INTERVIEW

All respondents had to undergo telephonic screening, to determine whether they were suitable for the admission into study, whereupon they were asked questions related to the following:

- Age (subjects had to be between the ages of 20-60 years).
- Diagnostic criteria for chronic idiopathic constipation (i.e. symptoms of : less than 3 bowel movements per week and one or more of straining, passage of hard stools or sensation of incomplete evacuation, at least 25% of the time).
- Low back pain or a previous history thereof, but no low back pain at the time of entering the study.
- Any diseases related to the gastro-intestinal tract (e.g. Cancers, Crohn's disease, Ulcerative Colitis, strictures etc).
- Whether they were prepared to commit to attending this research study.
- Whether they were prepared to abstain from any other manual or medicinal forms of therapy for the duration of the study (e.g. Analgesics, laxatives, dietary changes etc.).

At this point, unsuitable and unwilling candidates were excluded from this study, however if they requested further treatment they were referred to another intern at the Chiropractic Day Clinic as a standard outpatient.

3.5 SAMPLE

3.5.1 SAMPLE SIZE AND METHOD

Participants were obtained by means of convenience sampling (Friedman et al 1998), as and when the patients presented at the Chiropractic Day Clinic.

All participants accepted into the study were randomly divided into two equal groups. The participants accepted were randomly assigned numbers 1 – 30, by drawing numbers out of an envelope. Patients with odd numbers were placed into group A and those with even numbers into group B (see table below).

3.5.2 SAMPLE ALLOCATION

	Sample Size	*Treatment allocation at research outset.*
Group A	**15**	**Spinal manipulation**
Group B	**15**	**Placebo**

Table 3 - Sample allocation

3.5.3 SAMPLE CHARACTERISTICS

Following the telephonic interview, subjects were asked to present themselves for an initial consultation where they underwent a case history (APPENDIX C), full physical examination (APPENDIX D) as well as a regional examination of the thoracic (APPENDIX E) and lumbar (APPENDIX F) spines, to include or exclude them from the study.

The following inclusion and exclusion criteria were applied in the assessment of the subjects:

3.5.3.1 INCLUSION CRITERIA

a. Patients who fell between the ages of 20-60 years were included in the study. Patients under the age of 20 were not accepted into the study since constipation is often a source of embarrassment which brought the willingness to discuss this with the researcher and the accuracy of reporting bowel habits, into question, in such subjects. Patients over the age of 60 years were excluded due to the likelihood of phase 3 degeneration being present in their spines (Kirkaldy-Willis 1992). Older patients may also have been more dependent on laxatives (Tramonte et al 1997).
b. Subjects who were prepared to avoid the use of laxatives or other therapies as well as analgesics for the duration of the study were included (Redly 2000).
c. Subjects who were prepared not to make any dietary changes for the duration of the study were included (Redly 2000).
d. Subjects who reported having symptoms of: less than three bowel movements per week and one or more of (Browning 1999, Redly 2000):
    a. Straining
    b. Passage of hard or pellet like stools
    c. A sensation of incomplete evacuation,

    At least 25% of the time, were included in the study.

3.5.3.2 EXCLUSION CRITERIA

a. Patients younger than 20 years or older than 60 years of age were excluded from the study.
b. Patients who took laxatives during the study were excluded from the study (Redly 2000).

c. Patients who were experiencing low back pain at the time of entering the study were excluded, to prevent confusion (between abdominal discomfort and low back pain) that could have arisen when patients were instructed to rate their level of pain. It has already been established that spinal manipulation is effective in alleviating low back pain (Licciardone et al 2005), one study (Redly 2000) documented the frequency of low back pain but failed to show the effect of treatment on abdominal discomfort, a common symptom of chronic idiopathic constipation (Browning 1999).
d. Patients, who took any new medication (laxatives or analgesics / NSAIDS) or had made any recent dietary alterations, required a 3 -7 day wash-out period before they were allowed to enter the study (Poul et al 1993).
e. Patients who made any dietary alterations or took any new medication during the study were excluded from the study (Redly 2000), and referred to other interns to be treated as an outpatient at the Chiropractic Day Clinic.
f. Patients with illnesses / symptoms, which were contra-indications to spinal manipulation or required further clinical assessment, where excluded. Examples included (Gatterman 1990, Berkow 1992):
    - Tumours / cancers anywhere in the body, traumatic injuries to the spine (e.g. Fractures), arthritis (i.e. Rheumatoid arthritis, Ankylosing Spondylitis, Psoriatic arthritis), neurological complications such as disc lesions with associated neurological deficits, malaena / frank rectal bleeding, patients with known primary pathologies responsible for their state of constipation e.g.
        - Crohn's disease, Irritable bowel syndrome, Ulcerative Colitis, Intestinal tumours or other space occupying lesions such as benign strictures, electrolyte imbalances or severe dehydration, diabetic autonomic neuropathy

- Hypothyroidism, Multiple sclerosis, cerebrovascular accidents or spinal cord lesions.

g. Patients who were pregnant were excluded since pregnancy in itself is a common cause of constipation, making these subjects unsuitable for inclusion in this study.
h. Patients with a previous history of bowel surgery, were excluded, since post operative complications such as strictures could be responsible for constipation in such individuals. (Browning 1999, Berkow 1992)
i. Patients with any other identified contra-indication to spinal manipulative therapy such as (Gatterman 1990):
    - Osteomyelitis, spinal tuberculosis, tumours of the spine (primary or metastatic), spondylolisthesis, severe osteoporosis, severe trauma or surgery to the lower back, were excluded from the study.
j. Patients who refused to sign the informed consent were also excluded from the study.

3.6 THE CLINICAL PROCEDURE

Patients who underwent the above case history (Appendix C), full physical examination (Appendix D) and examination of the thoracic and lumbar spines (Appendices E & F) and were deemed suitable to enter the study based on the inclusion and exclusion criteria above, received a patient information letter (Appendix A), detailing the purpose of and all relevant information related to the research study. Patients were given the opportunity to ask questions related to the study. Patients were then asked to complete and sign the informed consent (Appendix B), if they agreed to participate in the study.

A baseline set of readings (reading 1) was then taken. This consisted of an assessment of the range of motion of the patient's thoracic and lumbar spines using an inclinometer (Appendix G), a measure of the patient's level of abdominal discomfort using the numerical rating scale (Jensen et al 1986 detailed on Appendix H) and an assessment of the patient's sense of wellbeing using the Global Wellbeing Scale (Hawk et al 1995 - Appendix I). The patients were then given a copy of the bowel habit diary (Appendix J) and asked to record their bowel movement frequency, consistency and absence or presence of straining for a period of one week before commencing with treatment.

3.7 THE INTERVENTION

Two types of interventions were used during this study. These were spinal manipulative therapy and placebo respectively.

3.7.1 SPINAL MANIPULATIVE THERAPY

Spinal manipulation was applied to areas of motion restriction, in four standard regions in the thoracic and lumbar spines of subjects.
Motions restrictions in the:

- ☑ T1- T6,
- ☑ T7 – T12,
- ☑ L1-L5 and
- ☑ right and left sacroiliac regions were determined by motion palpation.

Motion palpation has been found to be a valid and reliable method for determining spinal motion restrictions (Humphreys, Peterson and Delahaye, 2004). Manipulations were applied to at least one segment in each of these regions.

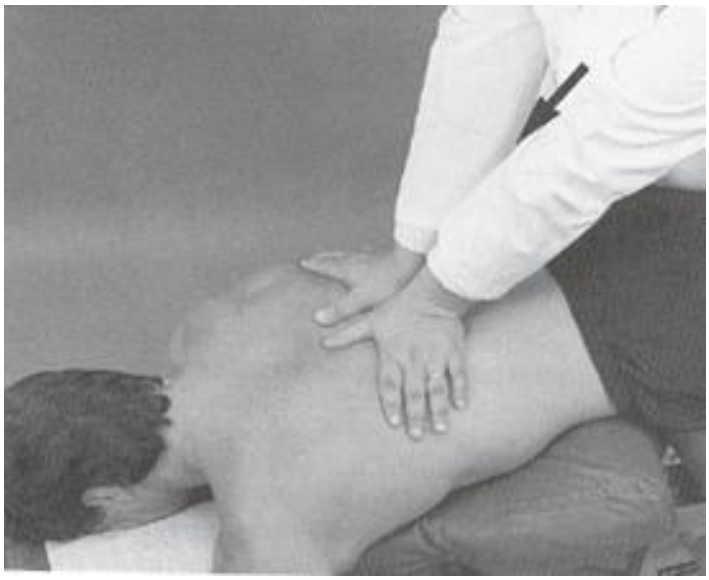
These regions were selected since they represented a commonality in the three existing case reports (Hewitt 1994, Marko 1994, Redly 2000) where manipulation was affected in the thoracic, lumbar and sacroiliac regions, furthermore, restricted range of motion in thoracic and lumbar spinal segments has been documented in patients with functional abdominal pain (Jorgensen and Fosgreen 1990).

Patients were manipulated using any of the following methods (Bergman et al 1993):

- Cross Bilateral
- Bilateral thenar transverse
- Bilateral hypothenar transverse
- Sternal spinous
- Fist transverse, in the thoracic spine

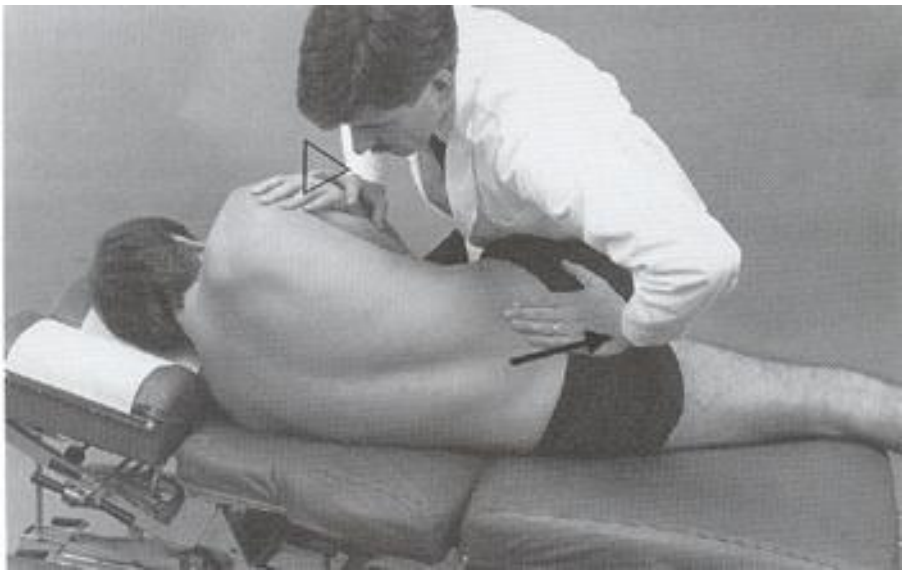
And

- Lumbar roll
- Reverse lumbar roll
- Seated pisiform facet
- Spinous push, spinous pull or spinous push pull
- Fist transverse, in the case of the lumbar spine.



Taken from Chiropractic Technique (Bergman et al 1993**)**

Figure 10 – Bilateral thenar transverse



Taken from Chiropractic Technique (Bergman et al 1993**)**

Figure 11 – Lumbar roll

3.7.2 PLACEBO

Placebo was used in this study since previous case studies (Hewitt 1993, Marko 1994, Redly 2000), were not able to exclude the placebo effect in the presentation of their findings.

Placebo was administered with a detuned ultrasound machine being applied over the thoracolumbar spine.

Patients were asked to lie prone, ultrasound gel (a coupling agent) was applied over the skin of the thoracolumbar area and the ultrasound head was applied over the skin of the patient's spine without turning up the intensity. Administering placebo in this way was chosen since instead of sham manipulation, since the possibility of effecting a manipulation existed in the case of the latter. Detuned ultrasound in particular was chosen since the patient is not meant to feel any sensation (besides the coolness of the coupling agent and movement of the ultrasound head) during a normal treatment with ultrasound and the timer on the ultrasound unit still sounded at the end of the treatment despite the fact that the intensity of the device was not turned up, therefore, patients felt as though they had received a normal ultrasound treatment and would not be alerted to the fact that no improvement in symptoms was expected by the researcher in the placebo phase of treatment, this was done with a view to minimising the Hawthorne Effect (Mouton 2000).

At each visit, all patients received a standard intervention / assessment, being abdominal palpation. This was done to minimise the chances of patients becoming aware of which phase of treatment (experimental or placebo) they were receiving (Hrobjartsson and Gotzsche, 2001). This also ensured that both patients receiving manipulation and placebo, received "touch"; however, the possibility of patients receiving placebo, showing improvement because of this, could exist.

3.7.3 CROSS OVER

Patients who fell in group A, received spinal manipulation at the outset of the study. Patients who fell into group B, received placebo using detuned ultrasound at the outset of the study. The two groups then crossed over as depicted below in the table showing the frequency of the intervention (table 2).

3.8 THE INTERVENTION FREQUENCY

Interventions, spinal manipulation and placebo were carried out twice weekly for two weeks as follows:

Week	*Visit no.*	*Group A*	*Group B*
1	1	*Reading 1(baseline)*	
		Completion of diary for 1 week by patients	
2	2	**Treatment 1**	**Treatment A**
	3	**Treatment 2**	**Treatment B**
3	4	Reading 2	Reading 2
		Treatment 3	**Treatment C**
	5	**Treatment 4**	**Treatment D**
4		Reading 3	Reading 3
	6	***Cross over***	
		Treatment A	**Treatment 1**
5	7	**Treatment B**	**Treatment 2**
	8	Reading 4	Reading 4
		Treatment C	**Treatment 3**
6	9	**Treatment D**	**Treatment 4**
	10	Reading 5	Reading 5

Table 4 - Intervention frequency

Key :	**Treatment 1, 2, 3, 4**	**- Spinal manipulation**
	Treatment A, B, C, D	**- Placebo using detuned ultrasound**
	Reading 1, 2, 3, 4, 5	**- Spinal range of motion**
		- NRS
		- Global Well being scale
		- Constipation Index (calculated using bowel habit diary)

3.9 THE READINGS / MEASUREMENTS

Five readings in all were taken over the period of the study, as indicated in the table above.

Each reading consisted of :

Spinal range of motion (inclinometer reading)

NRS

Global Well being scale

Constipation Index (calculated using bowel habit diary)

3.10 THE DATA

The data used in this study was both primary and secondary data

3.10.1 The Primary Data – Objective Data

3.10.1.1 The Constipation index (Meshkinpour et al 1998)

The Constipation index was devised to assess the extent of a patient's constipation, taking into account all three parameters involved in the accepted diagnostic criteria (Meshkinpour et al 1998). It was calculated, by the researcher, using the data recorded in the bowel habit diary according to the formula:

Constipation Index = C x S/N where,

N = total number of bowel movements per week

C = score for stool consistency

S = straining at bowel movements

C (consistency) was scored as follows:

5 = hard consistency

3 = formed stools

1 = soft stools

S (straining) was scored as follows:

4 = straining associated with 75% of bowel movements

3 = straining associated with 50% of bowel movements

2 = straining associated with 25% of bowel movements

1 = no associated straining

The larger the index, the more severe the constipation.

3.10.1.2 Range of motion of the thoracic/lumbar spine using Inclinometer (Livingstone 1992)

This is an objective method of checking for improvement in spinal motion restrictions and therefore joint dysfunction which may be associated with the patient's symptoms. This was carried out using a device called the "Saunders Digital Inclinometer "(The Saunders Group Inc., available from http://www.thesaundersgroup.com/index.asp?PageAction=VIEWPROD&ProdID=13). The device was attached to the patient using the Velcro strap, the device was then "zeroed", the patient was asked to carry out the motion as instructed by the examiner and at the end of this motion; the reading displayed on the inclinometer was recorded.

3.10.2 The Primary Data – Subjective Data

3.10.2.1 Numerical rating scale (Jensen, Karoly and Braver 1986)

The Numerical rating scale is a statistically significant method for obtaining a subjective measurement of pain intensity. The Numerical rating scale was used in this study to determine the intensity of abdominal discomfort. Subjects were asked to indicate the number that corresponds to the amount of pain they were experiencing, where 0 represented no pain at all and 10 represented the greatest intensity of pain that he/she has ever experienced.

3.10.2.2 Global Well being scale (Hawk et al 1995)

The Global Well being scale has been tested for reliability and validity and represents a subjective measurement of the patient's general sense of well being. The global well being scale takes the form of a 10cm long horizontal line with a vertical line drawn at either end. The patient was instructed that the extreme left hand end represented the "worst they could possibly feel" while the extreme right hand end represented "the best they could possibly feel". The patient was then asked to make a vertical mark along the line to indicate how he/she felt at that moment. This scale could prove to be effective in detecting the placebo effect if patients receiving placebo showed an increase in wellbeing (Hawk et al 1995)

Since the above two scales work in opposite directions, patients are likely to be prevented from reporting similarly on both scales, however, this could also provide room for confusion, where patients do not read the accompanying instructions.

3.11 READING / MEASUREMENT FREQUENCY

A total of five readings were taken during the study.

A set of readings was taken at the initial consultation (Reading 1), this served as the baseline reading before treatment commenced. Thereafter, a reading was taken after treatment 2 / treatment B (Reading 2) and after the treatment 4 / treatment D (Reading 3). The groups then crossed over. The next reading was taken after treatment B / treatment 2 (Reading 4) and the last reading after treatment D / treatment 4 (Reading 5), according to the table below:

Week	*Visit no.*	*Group A*	*Group B*
1	1	***Reading 1(baseline)***	
		I week constipation diary	
2	2	Treatment 1	Treatment A
	3	Treatment 2	Treatment B
3	4	**Reading 2**	**Reading 2**
		Treatment 3	Treatment C
	5	Treatment 4	Treatment D
4		**Reading 3**	**Reading 3**
	6	*Cross over*	
		Treatment A	Treatment 1
5	7	Treatment B	Treatment 2
	8	**Reading 4**	**Reading 4**
		Treatment C	Treatment 3
6	9	Treatment D	Treatment 4
	10	**Reading 5**	**Reading 5**

Table 5 – Reading Frequency

3.12 STATISTICAL METHODS

Data analysis was done in SAS version 9.1 (SAS Institute Inc., Cary, NC). Baseline comparisons between the categorical baseline variables and the group to which the participant was assigned were done using Fisher's exact test. Continuous normally distributed baseline data were compared using the two sample t-test.

The follow-up measures were summarised according to the treatment received. The baseline measurement is the measurement for both groups before they received any manipulation (Reading 1). The measurement immediately before and after the treatment and control is summarised.

The treatment effect was evaluated by getting the difference between the pre- and post-treatment values. The differences obtained in each of the periods of the cross-over design were then analysed using a repeated measures analysis of variance (ANOVA). There are three main issues to consider in a crossover trial, namely period, treatment, and group or carryover effects.

To determine whether the treatment had a long term effect in patients treated with the manipulation first (Group A), the readings were summarised for Group A only at all readings. No statistical analysis was done on this, since the same datapoints did not exist for the control.

CHAPTER FOUR

Statistical Methods, Results and Discussion

4.1 INTRODUCTION

This chapter presents results of statistical analysis of the data collected during this study and brief discussion thereof. Analysis is presented as follows:

Data:

Demographic Data

Continuous

Categorical

Objective Data

Constipation Index

Spinal Range of motion

Subjective Data

Numerical Rating Scale

Global Wellbeing scale

Key

N	:	number of subjects
SD	:	standard deviation
Trt	:	treatment
ANOVA	:	analysis of variance
PA	:	posterior-anterior

4.2 DEMOGRAPHIC DATA OF STUDY SAMPLE

4.2.1 Baseline analysis

	N	Mean	SD	Minimum	Median	Maximum	p-value
Age (years)							
Total	30	37.4	8.5	22	35	59	0.1861[1]
Group A	15	35.3	6.9	24	35	48	
Group B	15	39.5	9.6	22	36	59	

[1] t-test for independent groups for comparison between Group 1 and Group 2

Table 6 - Continuous demographic data

		Group 1		*Group 2*		*Total group*		
		N	**%**	**N**	**%**	**N**	**%**	**p-value**
Age	20-29 years	3	20.0	1	6.7	4	13.3	0.5565[1]
	30-39 years	8	53.3	8	53.3	16	53.3	
	40-49 years	4	26.7	4	26.7	8	26.7	
	50-59 years	0	0.0	2	13.3	2	6.7	
Race	Indian	10	66.7	12	80.0	22	73.3	0.0834[1]
	Coloured	3	20.0	2	13.3	5	16.7	
	Black	1	6.7	1	6.7	2	6.7	
	White	1	6.7	0	0.0	1	3.3	
Sex	Male	4	26.7	3	20	7	23.3	1.0000[1]
	Female	11	73.3	12	80	23	76.7	

[1] Fisher's exact test for comparison between Group 1 and Group 2

Table 7 - Categorical demographic data

Discussion

The patients ranged in age from between 20 – 59 years, however there was no significant difference (p=0.5565) between the two groups as shown above. Literature states that constipation is more common in the elderly (Orr 1997, Redly 2000), however, this study was limited to patients between the ages of 20 and 60 years, and most patients (53.3% in each group) fell within the age range of 30-39 years.

Although no significant difference in race is noted (p=0.0834), it is interesting to note that just 6.7% of patients in each group were black, this is in keeping with the notion that constipation is common among the American but not African black population (Basson 2005).

Seventy six point seven percent of patients were female, this is consistent with literature indicating that the condition is more common in females (Browning 1999).

None of the baseline variables showed a significant difference between Group 1 and Group 2, indicating that both groups were reasonably similar from a demographic point of view.

4.2.2 Follow up over time

The N for each entry in each table in this section is 30, unless otherwise indicated, and is not included in every table.

4.3 PRIMARY DATA - OBJECTIVE DATA

A. CONSTIPATION INDEX

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	4.88	4.00	2.0	3.5	20.0
Before active treatment	4.43	3.88	1.0	3.0	20.0
After active treatment	1.32	1.27	0.0	1.0	5.0
Before control	3.05	2.94	0.5	3.0	12.0
After control	2.63	2.44	0.4	2.0	10.0

Table 8 - Constipation index

The mean constipation index decreased during manipulation from 4.88 to 1.32 and decreased slightly during control from 3.05 to 2.63. This illustrates that manipulation was able to relieve constipation, the control (placebo) also decreased constipation but to a far lesser extent than manipulation. This is consistent with literature indicating that manipulation relieves constipation (Hewitt 1993, Redly 2000). The changes seen in the control could be attributed to the placebo effect, with patients showing an improvement due to the fact that they were interacting with the researcher and believed that they were receiving treatment for their condition.

These results should be read with caution as, this variable is not normally distributed (Appendix M) and it was found that, the constipation index does not provide for the patient who has no bowel movements in a week, resulting in a potential zero reading, which is in opposition to the stated function of the questionnaire, where a higher reading indicates more severe constipation (Meshkinpour et al 1998).

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (After-Before)	-3.11	4.21	-19.4	-2.00	2.0
Control (After-Before)	-0.41	1.10	-3.0	-0.05	2.0

Table 9 - Average change from pre- to post constipation index measurement

A large decrease in constipation index was observed when the treatment was done and a small decrease in constipation index was observed when the control was done. It can be inferred that manipulation is more effective than placebo in alleviating constipation.

Effect	*p-value*
Period	0.2209
Treatment (group*period)	0.0027
Group (order of treatments)	0.9230

Table 10 - Repeated measures ANOVA

Constipation index showed a significant treatment effect (p = 0.0027) The effect of period or group was not significant, indicating that manipulation produced a significant effect regardless of whether manipulation was given in the first or second period; it produced a significant decrease in constipation in all patients. This may support literature which suggests that spinal manipulation may affect the nervous system and through a somatovisceral reflex, produce changes in visceral function (Korr 1976, Nanasel and Slazak 1995. Gatterman 1995, Redly 2000).

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	4.88	4.00	2.0	3.50	20.0
Reading 2	3.19	2.27	0.0	3.00	10.0
Reading 3	2.60	2.45	0.5	2.00	10.0
Reading 4	1.40	1.21	0.0	1.00	5.0
Reading 5	1.35	1.28	0.0	1.00	5.0

Table 11 - Constipation index at the different visits

The constipation index decreased over time, with the lowest value recorded after both treatments were given. This could imply that patients showed improvement due to manipulation and continued to show improvement due to the placebo effect, or that manipulation has a lasting effect on constipation.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	4.83	4.84	2.0	3.00	20.0
Reading 2	2.32	1.29	0.0	2.00	5.7
Reading 3	1.17	0.83	0.5	1.00	3.0
Reading 4	1.13	0.76	0.5	1.00	3.0
Reading 5	1.23	0.86	0.4	1.00	3.0

Table 12 - Readings for Group A only, N = 15, Constipation Index

All readings for group one only are considered here to demonstrate the lasting effect of the treatment (manipulation), group one was used since this group received manipulation in the first period and placebo in the second, group two is

not shown since comparison is not possible since the same datapoints do not exist for the two groups.

The mean constipation index at Readings 2 and 3 were lower than at Reading 1, indicating that the patients had lower constipation index after the treatment. The mean constipation index at Reading 4 and 5 were almost the same as at Reading 3, indicating that the control did not lead to any improvement. The treatment had a long lasting effect, since the mean value at Reading 5 was still lower than at baseline.

B. RANGE OF MOTION

THORACIC SPINE

FLEXION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	88.47	9.81	70	90.0	100
Pre treatment 1 and 2	87.87	9.14	70	90.0	100
Post treatment 1, 2 / Pre trt 3, 4	90.87	8.46	70	92.5	100
Post treatment 3 and 4	91.27	8.08	74	94.0	100
Pre treatment A and B	91.10	8.98	70	92.5	100
After treatment A, B / Pre C, D	90.57	8.51	70	90.5	100
After treatment C and D	90.27	8.46	70	90.5	100

Table 13 - Flexion (degrees)

The normal average range of motion is 45 degrees. The average reading at baseline for all participants was 88.47 degrees. This is above the normal range of motion. During treatment the readings increased to 91.27 (after Treatments 1 to 4). During control the mean range of motion decreased slightly from 91.10 to 90.27. After the second active treatment (Treatment 3 and 4), the value

increased more than after the first active treatment indicating that the second treatment added value above that of a single treatment. Manipulation increased thoracic flexion while control (placebo) did not.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	3.40	4.00	0.0	1.50	12.0
Control (post-pre)	-0.83	1.66	-5.0	0.00	3.0

Table 14 - Average change from pre- to post-flexion reading (degrees)

There was an increase in the flexion during treatment and a slight decrease during control.

It can be inferred that manipulation, increases thoracic flexion while placebo does not.

Effect	*p-value*
Period	0.0513
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.0036

Table 15 - Repeated measures ANOVA

Flexion showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the flexion score. There was no effect of the period, while there was a significant effect of group. The carryover effect is the same as the effect for group, thus there was a carryover effect for flexion from the one period to the other. This means that the cross-over design should not be used since the treatment effect cannot be evaluated independently from the carryover or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	88.47	9.98	70.0	90.00	100.0
Reading 2	93.33	7.39	78.0	95.00	100.0
Reading 3	93.73	7.25	78.0	95.00	100.0
Reading 4	93.40	7.21	78.0	95.00	100.0
Reading 5	93.27	7.53	76.0	95.00	100.0

Table 16 - Readings for Group A only, N = 15, Flexion (degrees)

The mean flexion improved from Reading 1 (baseline) to Reading 2, after the first two treatments. Slight improvement is seen from Reading 2 to Reading 3 (after Treatments 3 and 4). No improvement is seen thereafter, during control treatment; although the improvement is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study. However, these findings should be interpreted with caution since this variable was not normally distributed (Appendix O).

EXTENSION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	40.07	6.58	30.0	40.00	49.0
Pre treatment 1 and 2	40.10	6.18	30.0	40.50	49.0
Post treatment 1, 2 / Pre trt 3, 4	41.97	5.12	33.0	42.50	49.0
Post treatment 3 and 4	43.40	3.65	37.0	44.00	49.0
Pre treatment A and B	41.73	5.62	30.0	42.50	49.0
After treatment A, B / Pre C, D	41.60	5.46	30.0	42.50	49.0
After treatment C and D	41.60	5.12	31.0	42.00	49.0

Table 17 - Extension (degrees)

The normal range of motion is 45 degrees. The average reading at baseline for all participants was 40.07 degrees. This is below the normal range of motion. During treatment the readings increased from 40.1 to 41.97 (after Treatments 1 and 2) and continued to improve to 43.40 after Treatments 3 and 4. During control the mean range of motion decreased slightly from 41.73 to 41.60.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	3.30	3.72	-2.0	2.50	12.0
Control (post-pre)	-0.13	0.90	-2.0	0.00	2.0

Table 18 - Average change from pre- to post-extension reading (degrees)

There was an increase in the extension during treatment, and a slight decrease during control. This means that when patients received manipulation, range of motion for thoracic extension improved, however, when placebo was administered, thoracic extension actually decreased.

Effect	*p-value*
Period	0.7277
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.8270

Table 19 - Repeated measures ANOVA

Extension showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the extension score. There was no effect of the period or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	40.07	6.69	30.0	40.00	49.0
Reading 2	42.47	5.25	33.0	44.00	49.0
Reading 3	43.40	3.83	37.0	44.00	49.0
Reading 4	43.20	3.90	37.0	44.00	49.0
Reading 5	43.07	3.90	37.0	42.00	49.0

Table 20 - Readings for Group A only, N = 15, Extension (degrees)

The mean extension improved from Reading 1 (baseline) to Reading 2, after the first two treatments. Slight improvement is seen from Reading 2 to Reading 3 (after Treatments 3 and 4). No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

RIGHT PA ROTATION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	6.27	1.14	4.0	6.0	9.0
Pre treatment 1 and 2	6.33	1.12	4.0	6.0	9.0
Post treatment 1, 2 / Pre trt 3, 4	7.63	1.10	6.0	7.5	10.0
Post treatment 3 and 4	8.37	0.81	7.0	8.0	10.0
Pre treatment A and B	7.40	1.52	4.0	7.5	10.0
After treatment A, B / Pre C, D	7.43	1.48	4.0	7.5	10.0
After treatment C and D	7.43	1.45	4.0	7.0	10.0

Table 21 - Right PA Rotation in degrees

The normal average range of motion is 35 degrees. The average reading at baseline for all participants was 6.27. This is below the normal range of motion, this could suggest that patients with chronic idiopathic constipation have restricted rotational range of motion. During treatment the readings increased from 6.33 to 7.63 (after Treatments 1 and 2) and continued to improve to 8.37 after Treatments 3 and 4. During control the mean range of motion stayed almost the same (changed from 7.40 to 7.43).

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	2.03	1.38	0.0	2.0	4.0
Control (post-pre)	0.03	0.32	-1.0	0.0	1.0

Table 22 - Average change from pre- to post-(degrees)

There was an increase in the Right PA rotation during treatment, and no change during control.

Effect	*p-value*
Period	0.1855
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.6256

Table 23 - Repeated measures ANOVA

Right PA rotation showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the right PA rotation score. There was no effect of the period or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	6.27	1.16	4.0	6.0	9.0
Reading 2	7.80	1.21	6.0	8.0	10.0
Reading 3	8.53	0.83	7.0	8.0	10.0
Reading 4	8.53	0.83	7.0	8.0	10.0
Reading 5	8.47	0.92	7.0	8.0	10.0

Table 24 - Readings for Group A only, N = 15, Right PA rotation (degrees)

The mean Right PA rotation improved from Reading 1 (baseline) to Reading 2, after the first two treatments. It further improved at Reading 3, after Treatments 3 and 4. No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

LEFT PA ROTATION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	6.40	1.10	5.0	6.0	9.0
Pre treatment 1 and 2	6.37	1.10	5.0	6.0	9.0
Post treatment 1, 2 / Pre trt 3, 4	7.90	1.30	6.0	8.0	12.0
Post treatment 3 and 4	8.27	1.20	6.0	8.0	12.0
Pre treatment A and B	7.53	1.66	5.0	7.5	12.0
After treatment A, B / Pre C, D	7.40	1.59	5.0	7.0	11.0
After treatment C and D	7.37	1.59	5.0	7.0	11.0

Table 25 - Left PA Rotation (degrees)

The normal average range of motion is 35 degrees. The average reading at baseline for all participants was 6.40. This is below the normal range of motion, this finding may suggest that patients with chronic idiopathic constipation have restricted rotational range of motion. During treatment the readings increased from 6.37 to 7.90 (after Treatments 1 and 2) and continued to improve to 8.27 after Treatments 3 and 4. During control the mean range of motion stayed almost the same (changed from 7.53 to 7.37), implying that placebo did not improve left PA rotation.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	1.90	1.52	0.0	2.0	7.0
Control (post-pre)	-0.17	0.38	-1.0	0.0	0.0

Table 26 - Average change from pre- to post-(degrees)

There was an increase in the Left PA rotation during treatment and a slight decrease during control.

Effect	*p-value*
Period	0.1205
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.3337

Table 27 - Repeated measures ANOVA

Left PA rotation showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the left PA rotation score. There was no effect of the period or group.

Delayed effect of treatment in Group A only

	Mean	SD	Minimum	Median	Maximum
Reading 1	6.40	1.12	5.0	6.0	9.0
Reading 2	8.27	1.44	6.0	8.0	12.0
Reading 3	8.67	1.29	7.0	8.0	12.0
Reading 4	8.47	1.25	7.0	8.0	11.0
Reading 5	8.40	1.30	7.0	8.0	11.0

Table 28 - Readings for Group A only, N = 15, L PA rot (degrees)

The mean Left PA rotation improved from Reading 1 (baseline) to Reading 2, after the first two treatments. It further improved at Reading 3, after Treatments 3 and 4. No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study, suggesting the lasting impact of manipulation on left PA rotation.

RIGHT LATERAL FLEXION

Visit	Mean	SD	Minimum	Median	Maximum
Baseline	14.80	3.00	10.0	15.0	20.0
Pre treatment 1 and 2	14.60	2.84	10.0	15.0	20.0
Post treatment 1, 2 / Pre trt 3, 4	15.43	3.41	10.0	15.0	24.0
Post treatment 3 and 4	15.77	3.16	11.0	15.5	24.0
Pre treatment A and B	15.73	3.43	10.0	15.5	24.0
After treatment A, B / Pre C, D	15.50	3.36	10.0	15.5	24.0
After treatment C and D	15.40	3.47	9.0	15.0	24.0

Table 29 - Right lateral flexion (degrees)

The normal average range of motion is 20-40 degrees. The average reading at baseline for all participants was 14.80 degrees. This is below the normal range of motion, this may suggest that patients with chronic idiopathic constipation have restricted range of lateral flexion. During treatment the readings increased from 14.60 to 15.43 (after Treatments 1 and 2) and continued to improve to 15.77 after Treatments 3 and 4. During control the mean range of motion decreased slightly from 15.73 to 15.40.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	1.17	1.42	-2.0	1.0	4.0
Control (post-pre)	-0.33	0.76	-3.0	0.0	0.0

Table 30 - Average change from pre- to post-reading (degrees)

There was an increase in right lateral flexion during treatment, and a slight decrease during control. This suggests that manipulation acted to increase right lateral flexion and placebo did not.

Effect	*p-value*
Period	0.0222
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.0089

Table 31 - Repeated measures ANOVA

Right lateral flexion showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the score. There was a significant effect of the period. The period effect indicates that there was a change over time, regardless of treatment group. There was a significant effect

of group. The carryover effect is the same as the effect for group, thus there was a carryover effect for flexion from the one period to the other. This means that the cross-over design should not be used since the treatment effect cannot be evaluated independently from carryover or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	14.80	3.05	10.0	15.0	20.0
Reading 2	16.27	3.99	10.0	16.0	24.0
Reading 3	16.67	3.64	11.0	16.0	24.0
Reading 4	16.53	3.70	11.0	16.0	24.0
Reading 5	16.40	3.94	9.0	16.0	24.0

Table 32 - Readings for Group A only, N = 15 (degrees)

The mean Right lateral flexion improved from Reading 1 (baseline) to Reading 2, after the first two treatments. Slight improvement is seen from Reading 2 to Reading 3 (after Treatments 3 and 4). No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

LEFT LATERAL FLEXION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	14.73	3.12	10.0	15.0	20.0
Pre treatment 1 and 2	14.43	3.00	10.0	15.0	20.0
Post treatment 1, 2 / Pre trt 3, 4	15.83	3.48	10.0	16.0	22.0
Post treatment 3 and 4	15.97	3.32	11.0	16.0	22.0
Pre treatment A and B	15.73	3.48	10.0	15.5	22.0
After treatment A, B / Pre C, D	15.47	3.49	10.0	15.0	22.0
After treatment C and D	15.30	3.53	10.0	15.0	22.0

Table 33 - Left lateral flexion (degrees)

The normal average range of motion is between 20-40 degrees. The average reading at baseline for all participants was 14.73 degrees. This is below the normal range of motion. During treatment the readings increased from 14.43 to 15.83 (after Treatments 1 and 2) and continued to improve to 15.97 after Treatments 3 and 4. During control the mean range of motion decreased slightly from 15.73 to 15.30.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	1.53	1.70	-1.0	1.0	5.0
Control (post-pre)	-0.43	1.14	-5.0	0.0	0.0

Table 34 - Average change from pre- to post-reading (degrees)

There was an increase in the extension during treatment and a slight decrease during control.

Effect	*p-value*
Period	0.4840
Treatment	< 0.0001
(group*period)	
Group (order of	0.0452
treatments)	

Table 35 - Repeated measures ANOVA

Left lateral flexion showed a significant treatment effect (p<0.0001) and we can conclude that the treatment made a significant change to the score. There was no effect of period. There was a significant effect of group. The carryover effect is the same as the effect for group, thus there was a carryover effect for Left lateral flexion from the one period to the other. This means that the cross-over design should not be used since treatment effect cannot be evaluated independently from carryover or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	14.73	3.17	10.0	15.0	20.0
Reading 2	16.80	3.51	11.0	16.0	22.0
Reading 3	16.73	3.59	11.0	16.0	22.0
Reading 4	16.67	3.64	11.0	16.0	22.0
Reading 5	16.47	3.81	11.0	16.0	22.0

Table 36 - Readings for Group A only, N = 15, Left Lateral Flexion (degrees)

The mean Left lateral flexion improved from Reading 1 (baseline) to Reading 2, after the first two treatments. No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 2 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

LUMBAR SPINE

FLEXION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	82.40	9.50	70.0	80.0	100.0
Pre treatment 1 and 2	82.30	9.52	70.0	80.0	100.0
Post treatment 1, 2 / Pre trt 3, 4	84.67	8.81	70.0	84.0	100.0
Post treatment 3 and 4	85.77	7.70	74.0	85.5	100.0
Pre treatment A and B	84.20	8.85	70.0	85.5	100.0
After treatment A, B / Pre C, D	83.77	8.94	70.0	83.0	100.0
After treatment C and D	83.70	8.82	70.0	83.0	100.0

Table 37 - Flexion (degrees)

The normal average range of motion is 60 degrees. The average reading at baseline for all participants was 82.40 degrees. This is above the normal range of motion. During treatment the readings increased from 82.30 to 85.77 (after Treatments 1 to 4). During control the mean range of motion decreased slightly from 84.20 to 83.70. After the second active treatment (Treatment 3 and 4), the value increased more than after the first active treatment indicating that the second treatment added value above that of a single treatment.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	3.47	3.03	-1.0	3.0	10.0
Control (post-pre)	-0.50	1.22	-4.0	0.0	1.0

Table 38 - Average change from pre- to post-flexion reading (degrees)

There was an increase in the flexion during treatment and a slight decrease during control.

Effect	*p-value*
Period	0.4710
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.7879

Table 39 - Repeated measures ANOVA

Flexion showed a significant treatment effect (p<0.0001) and we can conclude that the treatment made a significant change to the flexion score. There was no effect of the period or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	82.40	9.67	70.0	80.0	100.0
Reading 2	84.87	8.94	70.0	86.0	100.0
Reading 3	86.00	7.86	74.0	88.0	99.0
Reading 4	85.40	8.00	74.0	88.0	99.0
Reading 5	85.20	7.88	74.0	88.0	99.0

Table 40 - Readings for Group A only, N = 15, Flexion (degrees)

The mean flexion improved from Reading 1 (baseline) to Reading 2, after the first two treatments. Further improvement is seen from Reading 2 to Reading 3 (after Treatments 3 and 4). No improvement is seen thereafter, during control treatment; although the improvement is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

EXTENSION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	40.20	5.38	30.0	40.0	47.0
Pre treatment 1 and 2	40.23	5.41	30.0	40.0	47.0
Post treatment 1, 2 / Pre trt 3, 4	41.87	3.96	32.0	43.0	49.0
Post treatment 3 and 4	43.90	3.08	36.0	44.0	49.0
Pre treatment A and B	41.57	4.78	30.0	43.0	49.0
After treatment A, B / Pre C, D	41.47	4.87	30.0	43.0	49.0
After treatment C and D	41.30	4.72	30.0	43.0	48.0

Table 41 - Extension (degrees)

The normal average range of motion is 40 degrees. The average reading at baseline for all participants was 40.20 degrees. This is close to the normal range of motion. During treatment the readings increased from 40.23 to 41.87 (after Treatments 1 and 2) and continued to improve to 43.90 after Treatments 3 and 4. During control the mean range of motion decreased slightly from 41.57 to 41.30.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	3.67	4.12	0.0	2.0	15.0
Control (post-pre)	-0.27	1.01	-4.0	0.0	1.0

Table 42 - Average change from pre- to post-extension reading (degrees)

There was an increase in the extension during treatment, and a slight decrease during control.

Effect	*p-value*
Period	0.4326
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.1149

Table 43 - Repeated measures ANOVA

Extension showed a significant treatment effect (p<0.0001) and we can conclude that the treatment made a significant change to the extension score. There was no effect of the period or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	40.20	5.48	30.0	40.0	47.0
Reading 2	41.93	4.43	32.0	43.0	49.0
Reading 3	42.93	3.65	36.0	43.0	49.0
Reading 4	42.60	4.00	33.0	43.0	49.0
Reading 5	42.33	3.66	33.0	43.0	48.0

Table 44 - Readings for Group A only, N = 15, Extension (degrees)

The mean extension improved from Reading 1 (baseline) to Reading 2, after the first two treatments. Improvement is seen from Reading 2 to Reading 3 (after Treatments 3 and 4). No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

RIGHT PA ROTATION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	7.53	1.43	5.0	7.0	10.0
Pre treatment 1 and 2	7.57	1.38	5.0	7.0	10.0
Post treatment 1, 2 / Pre trt 3, 4	8.47	1.59	6.0	9.0	13.0
Post treatment 3 and 4	8.90	1.60	7.0	9.0	13.0
Pre treatment A and B	8.50	1.96	5.0	8.5	13.0
After treatment A, B / Pre C, D	8.53	1.81	6.0	8.5	12.0
After treatment C and D	8.50	1.78	6.0	8.5	12.0

Table 45 - Right PA Rotation (degrees)

The normal average range of motion is between 9 -18 degrees. The average reading at baseline for all participants was 7.53. This is below the normal range of motion. During treatment the readings increased from 7.57 to 8.47 (after Treatments 1 and 2) and continued to improve to 8.90 after Treatments 3 and 4. During control the mean range of motion stayed the same (8.50).

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	1.33	1.35	0.0	1.0	5.0
Control (post-pre)	0.00	0.37	-1.0	0.0	1.0

Table 46 - Average change from pre- to post-(degrees)

There was an increase in the Right PA rotation during treatment and no change during control.

Effect	*p-value*
Period	0.0117
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.0213

Table 47 - Repeated measures ANOVA

Right PA rotation showed a significant treatment effect (p<0.0001) and we can conclude that the treatment made a significant change to the score. There was a significant effect of the period. The period effect indicates that there was a change over time, regardless of treatment group. There was a significant effect of group. The carryover effect is the same as the effect for group, thus there was a carryover effect for right PA rotation from the one period to the other. This means that the cross-over design should not be used since treatment effect cannot be evaluated independently from carryover or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	7.53	1.46	5.0	7.0	10.0
Reading 2	8.87	1.85	6.0	9.0	13.0
Reading 3	9.47	1.96	7.0	9.0	13.0
Reading 4	9.47	1.77	7.0	9.0	12.0
Reading 5	9.40	1.72	7.0	9.0	12.0

Table 48 - Readings for Group A only, N = 15, R PA rot (degrees)

The mean Right PA rotation improved from Reading 1 (baseline) to Reading 2, after the first two treatments. It further improved at Reading 3, after Treatments 3 and 4. No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that

patients improved during active treatment and this improvement lasted at least until the end of the study.

LEFT PA ROTATION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	7.60	1.33	5.0	8.0	10.0
Pre treatment 1 and 2	7.53	1.31	5.0	8.0	10.0
Post treatment 1, 2 / Pre trt 3, 4	8.57	1.41	6.0	8.0	12.0
Post treatment 3 and 4	9.00	1.31	8.0	9.0	13.0
Pre treatment A and B	8.53	1.74	5.0	8.0	13.0
After treatment A, B / Pre C, D	8.50	1.76	5.0	8.0	13.0
After treatment C and D	8.53	1.83	5.0	8.0	13.0

Table 49 - L PA Rot (degrees)

The normal average range of motion is between 9 to 18 degrees. The average reading at baseline for all participants was 7.60. This is below the normal range of motion. During treatment the readings increased from 7.53 to 8.57 (after Treatments 1 and 2) and continued to improve to 9.00 after Treatments 3 and 4. During control the mean range of motion stayed the same (8.53).

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	1.47	1.50	0.0	1.5	5.0
Control (post-pre)	0.00	0.69	-3.0	0.0	1.0

Table 50 - Average change from pre- to post-(degrees)

There was an increase in the Left PA rotation during treatment and no change during control.

Effect	*p-value*
Period	0.3987
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.0692

Table 51 - Repeated measures ANOVA

Left PA rotation showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the Left PA rotation score. There was no effect of the period or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	7.60	1.35	5.0	8.0	10.0
Reading 2	9.07	1.62	6.0	9.0	12.0
Reading 3	9.47	1.60	8.0	9.0	13.0
Reading 4	9.53	1.55	8.0	9.0	13.0
Reading 5	9.60	1.68	8.0	9.0	13.0

Table 52 - Readings for Group A only, N = 15, L PA rot (degrees)

The mean left PA rotation improved from Reading 1 (baseline) to Reading 2, after the first two treatments. It further improved at Reading 3, after Treatments 3 and 4. Only slight improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

RIGHT LATERAL FLEXION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	9.87	2.94	5.0	10.0	17.0
Pre treatment 1 and 2	9.67	2.67	5.0	9.5	17.0
Post treatment 1, 2 / Pre trt 3, 4	13.87	3.60	10.0	12.0	23.0
Post treatment 3 and 4	15.60	3.54	11.0	15.0	23.0
Pre treatment A and B	14.07	5.17	5.0	14.5	23.0
After treatment A, B / Pre C, D	13.50	4.98	5.0	12.5	23.0
After treatment C and D	13.33	4.78	5.0	12.5	21.0

Table 53 - Right Lateral flexion (degrees)

The normal average range of motion is 20 degrees. The average reading at baseline for all participants was 9.87 degrees. This is below the normal range of motion. During treatment the readings increased from 9.67 to 13.87 (after Treatments 1 and 2) and continued to improve to 15.60 after Treatments 3 and 4. During control the mean range of motion decreased slightly from 14.07 to 13.33.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	5.93	4.14	0.0	5.5	15.0
Control (post-pre)	-0.73	1.34	-4.0	0.0	1.0

Table 54 - Average change from pre- to post-reading (degrees)

There was an increase during treatment and a slight decrease during control.

Effect	*p-value*
Period	0.0002
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.0028

Table 55 - Repeated measures ANOVA

Right lateral flexion showed a significant treatment effect ($p<0.0001$) and we can conclude that the treatment made a significant change to the score. There was a significant effect of the period. The period effect indicates that there was a change over time, regardless of treatment group. There was a significant effect of group. The carryover effect is the same as the effect for group, thus there was a carryover effect from the one period to the other. This means that the cross-over design should not be used since treatment effect cannot be evaluated independently from carryover or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	9.87	3.00	5.0	10.0	17.0
Reading 2	16.00	3.85	11.0	15.0	23.0
Reading 3	18.27	2.94	14.0	19.0	23.0
Reading 4	17.47	3.42	12.0	19.0	23.0
Reading 5	17.20	3.10	12.0	19.0	21.0

Table 56 - Readings for Group A only, N = 15 (degrees)

The mean right lateral flexion improved from Reading 1 (baseline) to Reading 2, after the first two treatments. Slight improvement is seen from Reading 2 to Reading 3 (after Treatments 3 and 4). No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 4 is

maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

LEFT LATERAL FLEXION

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	10.67	2.87	6.0	11.0	16.0
Pre treatment 1 and 2	10.60	2.75	6.0	11.0	16.0
Post treatment 1, 2 / Pre trt 3, 4	13.90	3.40	9.0	12.0	22.0
Post treatment 3 and 4	16.13	3.27	12.0	16.0	22.0
Pre treatment A and B	14.60	4.84	6.0	15.5	22.0
After treatment A, B / Pre C, D	14.50	4.77	6.0	14.5	22.0
After treatment C and D	14.43	4.76	7.0	14.5	22.0

Table 57 - Left Lateral flexion (degrees)

The normal average range of motion is 20 degrees. The average reading at baseline for all participants was 10.67 degrees. This is below the normal range of motion. During treatment the readings increased from 10.60 to 13.90 (after Treatments 1 and 2) and continued to improve to 16.13 after Treatments 3 and 4. During control the mean range of motion decreased slightly from 14.60 to 14.43.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (post-pre)	5.53	3.64	0.0	6.0	12.0
Control (post-pre)	-0.17	0.79	-2.0	0.0	2.0

Table 58 - Average change from pre- to post-reading (degrees)

There was an increase in the left lateral flexion during treatment and a slight decrease during control.

Effect	*p-value*
Period	0.0002
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.0001

Table 59 - Repeated measures ANOVA

Left lateral flexion showed a significant treatment effect (p<0.0001) and we can conclude that the treatment made a significant change to the score. There was a significant effect of period. There was a significant effect of group. The carryover effect is the same as the effect for group, thus there was a carryover effect for left lateral flexion from the one period to the other. This means that the cross-over design should not be used since treatment effect cannot be evaluated independently from carryover or group.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	10.67	2.92	6.0	11.0	16.0
Reading 2	15.73	3.56	11.0	17.0	22.0
Reading 3	18.53	2.61	14.0	18.0	22.0
Reading 4	18.40	2.75	14.0	18.0	22.0
Reading 5	18.33	2.69	14.0	18.0	22.0

Table 60 - Readings for Group A only, N = 15 (degrees)

The mean left lateral flexion improved from Reading 1 (baseline) to Reading 2, after the first two treatments. No improvement is seen thereafter, during control treatment; although the improvement made during Treatments 1 to 2 is maintained. This means that patients improved during active treatment and this improvement lasted at least until the end of the study.

Discussion

As was hypothesized, spinal manipulation produced a significant improvement on spinal range of motion. From the trends in the tables above, it is noted that the most restricted movements appear to be those of lateral flexion and PA rotation. All ranges of motion in the thoracic and lumbar spines, in both groups improved after active treatment, there was no improvement in range of motion seen in either group during control, indicating that placebo did not improve range of motion, however, the improvement noted during active treatment was maintained during the control period in the case of group one and lasted at least until the end of the study, suggesting that spinal manipulation is capable of producing a lasting effect on spinal range of motion.

It is noted that all patients demonstrated flexion readings above the normal values for both the thoracic and lumbar spines at baseline, this is followed by further increases in these values being seen after active treatment. The increased flexion scores, could be attributable to hypertonicity of the extensor musculature, which could have held the spine in a “more extended” position, with patients actually starting movement from this extended position (as opposed to neutral) when asked to flex for readings to be taken; alternatively, the increased flexion scores, could represent compensative hypermobility in response to the decreases documented in other ranges of motion.

The improvement in spinal range of motion documented in this study, is consistent with goniometrically verified improvement in joint mobility following spinal manipulation, in the literature (Bergman et al 1993, Gatterman 1995).

4.4 SUBJECTIVE DATA

A. PAIN (Numerical Rating Scale)

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	5.67	1.49	2	6	8
Before active treatment	5.77	1.57	2	6	8
After active treatment	2.63	1.30	1	2	6
Before control	4.10	2.14	1	4	7
After control	4.87	1.85	1	5	8

Table 61 – Numerical Rating Scale

The mean pain measurements decreased during manipulation from 5.8 to 2.6 and increased during control from 4.1 to 4.9.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (After-Before)	-3.13	1.80	-7	-3	0
Control (After-Before)	0.77	1.68	-3	1	5

Table 62 - Average change from pre- to post pain measurement

A large decrease in pain was observed when the treatment was done and a small increase in pain was observed when the control was done.

Effect	*p-value*
Period	0.2871
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.1140

Table 63 - Repeated measures ANOVA

Pain showed a significant treatment effect ($p<0.0001$). The effect of period or group was not significant. We can conclude that the treatment provided significant pain relief to a patient.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	5.67	1.49	2	6	8
Reading 2	4.80	1.77	1	4	8
Reading 3	4.20	2.27	1	4	8
Reading 4	3.53	1.38	1	3	8
Reading 5	3.30	1.47	1	3	6

Table 64 - Pain measurement at the different visits

The pain measurement decreased over time, with the lowest value recorded after both treatments were given.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	5.60	1.72	2	6	8
Reading 2	3.60	1.24	1	4	6
Reading 3	2.47	1.46	1	2	6
Reading 4	3.53	1.68	1	3	8
Reading 5	3.80	1.61	1	4	6

Table 65 - Readings for Group A only, N = 15, Pain

The mean pain scores at Readings 2 and 3 were lower than Reading 1, indicating that the patients had lower pain after the treatment. The mean pain scores at Reading 4 and 5 were slightly higher than at Reading 3, indicating that the control did not lead to any improvement, in fact the pain worsened slightly

during control. The treatment had a long lasting effect, since the value at Reading 5 was still lower than at baseline.

Discussion

Numerical Rating scale readings (pain rating) decreased significantly during active treatment, this is in keeping with the reported analgesic effect of spinal manipulation. A small increase in pain rating was documented during the control, however readings at the end of the study were still lower that those taken at baseline, this could suggest that the analgesic effect of the treatment was long lasting. The fact that patients reported a decrease in abdominal pain intensity, could suggest that the pain associated with chronic idiopathic constipation, may in fact be referred pain of somatic aetiology. This is consistent with literature based suggestions to this effect (Bergman et al 1993, Gatterman 1995, Redly 2000).

B. GLOBAL WELL BEING SCALE

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Baseline	3.67	1.04	2.0	3.50	6.0
Before active treatment	3.38	1.01	2.0	3.20	6.0
After active treatment	7.02	0.87	5.0	7.00	9.0
Before control	5.38	2.02	2.5	5.75	9.0
After control	5.25	2.38	2.0	5.15	9.0

Table 66 - Global well being scale

The mean global well being scale measurements, increased during manipulation from 3.38 to 7.02 and decreased during control from 5.38 to 5.25.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Treatment (After - Before)	3.65	1.25	1.0	3.65	6.0
Control (After - Before)	-0.13	0.73	-2.0	0.00	1.4

Table 67 - Average change from pre- to post global well being scale

A large increase in global well being was observed when the treatment was done and a small decrease in global well being was observed when the control was done.

Effect	*p-value*
Period	0.0218
Treatment (group*period)	< 0.0001
Group (order of treatments)	0.3052

Table 68 - Repeated measures ANOVA

Global wellbeing, showed a significant treatment effect ($p<0.0001$). The effect of group was not significant, while the effect of period was significant. The period effect indicates that there was a change (increase in mean values) over time, regardless of treatment group. This does not influence the comparison of treatments. We can conclude that the treatment provided significant increase in global well being.

Visit	*Mean*	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	3.67	1.04	2.0	3.50	6.0
Reading 2	4.18	1.52	2.0	4.00	7.0
Reading 3	5.09	2.25	2.0	4.80	9.0
Reading 4	6.05	1.33	4.0	6.00	8.8
Reading 5	7.18	0.85	5.0	7.30	9.0

Table 69 - Global well being at the different visits

The global well being increased over time, with the highest value recorded after both treatments were given.

Delayed effect of treatment in Group A only

	Mean	*SD*	*Minimum*	*Median*	*Maximum*
Reading 1	3.75	1.18	2.0	3.80	6.0
Reading 2	5.36	1.07	4.0	5.50	7.0
Reading 3	7.17	0.86	5.6	7.00	9.0
Reading 4	7.15	0.77	6.0	7.00	8.8
Reading 5	7.49	0.70	6.3	7.50	9.0

Table 70 - Readings for Group A only, N = 15, Global Well Being scale

The mean global well being scores increased at each Reading, with the lowest score recorded at baseline and the highest mean score recorded at Reading 5. This is probably due to the placebo effect, patients feel better when they receive treatment; regardless whether this treatment is active manipulation or placebo.

Discussion

Spinal manipulation was shown to increase global wellbeing significantly during the study, as depicted by the tables above. This is in keeping with the notion that spinal manipulation has the propensity to effect an overall increase in the way in which patients feel, this is of clinical relevance since wellbeing plays a role in chronic idiopathic constipation, and treatment with laxatives have not shown such an effect; the effect observed, may be related to the analgesic and/or psychological effects of manipulation (Bergman et al 1993, Gatterman 1995). While there was a significant treatment effect, the global wellbeing scale readings increased over time, the highest reading was documented at the end of the study; it is possible that the placebo effect came into play here, with patients

feeling better since they were receiving a treatment, regardless of whether this was active or inactive. It is also possible that patients felt obliged to respond favourably when global wellbeing readings were taken due to the Hawthorne effect (Mouton 2000).

With regard to the hypotheses:

- it was hypothesized that spinal manipulation would effect a decrease in the subject's abdominal pain intensity and level of constipation and an increase in the subject's sense of wellbeing and spinal range of motion; based on the results of the study, this hypothesis can be accepted.
- it was hypothesized that placebo would effect an increase in the subject's abdominal pain intensity and level of constipation and a decrease in the subject's sense of wellbeing and spinal range of motion; based on the results of the study, this hypothesis can be accepted abdominal pain intensity and spinal range of motion but rejected for sense of global wellbeing.
- it was hypothesized that spinal manipulation would be more effective than placebo in bringing about a decrease in the subject's abdominal pain intensity and level of constipation and an increase in the subject's sense of wellbeing and spinal range of motion; based on the results of the study, this hypothesis can be accepted.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The aim of this study was to investigate the possible effect of spinal manipulation on chronic idiopathic constipation in terms of subjective and objective clinical measures.

Analysis of the results, revealed a significant improvement in constipation index in patients receiving spinal manipulation. This effect appeared to have persisted, since no appreciable increase in the constipation index was demonstrated when patients crossed over to placebo. The constipation index readings decreased after the first and second active treatment and more so after the third and fourth active treatments, this would suggest that the third and fourth manipulations, added value to the first and second. Spinal manipulation was found to be effective in decreasing the level of constipation in sufferers of chronic idiopathic constipation.

A significant improvement in patients' sense of global wellbeing was demonstrated, however, global wellbeing also was found to increase during control, this could indicate the placebo effect, where patients experienced an improved sense of well being from being part of the study and receiving treatment, irrespective of whether this was active or inactive treatment.

Improvement in patients' level of pain was also observed, this effect was seen when patients received spinal manipulation, a slight increase in pain was demonstrated during control, however, the pain reading at the end of the study

was still lower than that at baseline, suggesting the long lasting effect of spinal manipulation.

5.2 Recommendations

A relatively small sample size was used in this study; further studies should use a larger sample size, which would strengthen the conclusions made in this study. It would also ensure that subtle changes in the objective and subjective data could be more accurately noted without the influence of single outliers. This however was limited as a result of the available budget for this project.

Future studies should discourage the use of a cross-over design. A cross-over study is not ideal for use when evaluating a treatment which demonstrates a lasting effect, where this is the case, a washout period is required. Findings suggest that spinal manipulation has a lasting effect, it would be extremely difficult to determine the duration of washout period required for spinal manipulation and therefore cross over designs should not be used.

Researcher bias may have affected the outcome of the study; future research studies should consider the use of a blinded examiner in order to minimize this effect. The patient information sheet used in this study, may have contributed to the patients becoming aware that one of the two treatments received was a placebo, future studies should guard against this and also perhaps elicit from patients their preconceived expectations of the study and control for this.

The homogeneity of the two groups at baseline in terms of the severity of constipation and how long they had the condition for, is questionable in this study, future studies should endeavour to ensure that the subjects in the

groups are as similar as possible, perhaps by using more stringent inclusion and exclusion criteria for chronic constipation or by using a questionnaire at the outset of the study to document and then compare patient symptoms.

In an attempt to present more objective clinical findings, future studies could opt for the use of imaging techniques at the beginning and end of the study to show whether spinal manipulation increases actual colonic motility/transit time.

The use of a manual inclinometer in various settings could have influenced the results; therefore consistency with respect to application and readings would have been better achieved at a single setting with a device that would have been able to measure the parameters in more than one manner, thereby allowing for 2 sets of independent readings that can be used as a cross-reference for statistical purposes.

Future studies into the topic, may find it worthwhile to evaluate the effect of manipulations given in the thoracic as opposed to the lumbar spine, this may help to isolate the particular spinal region/s (if any) that produce the effects observed in this study.

Studies planning to use global wellbeing outcomes, could opt for the use of a laxative agent as a control, this could work to avoid the placebo effect observed in this study where an increase in sense of wellbeing was demonstrated during the control period.

This study was not able to make any statements about improvement in clinical terms, future studies should determine and set the parameters for clinical improvement before hand.

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Appendix A

DURBAN INSTITUTE OF TECHNOLOGY : CHIROPRACTIC DAY CLINIC PATIENT INFORMATION LETTER

TITLE OF RESEARCH: A clinical investigation into the effect of spinal manipulative therapy on chronic idiopathic constipation in adults.
Research Student: Ruwaida Vadachia
Supervisor: Dr C.M Korporaal

Dear Participant,

Thank you for considering enrolment into this study.

Purpose of this study:
Chronic Constipation is a common patient complaint. Many patients often self medicate themselves with laxatives or fibre which provides only temporary relief. Patients suffering from chronic constipation often complain of a diminished quality of life. This study is being conducted to ascertain whether spinal manipulation can assist in the alleviation of chronic constipation.

What will happen during the course of the study?
Upon enrolling into this study, you will undergo a complete physical examination. Your spinal range of motion, sense of global well being and pain intensity will then be recorded, you will be given a "Bowel Log" and be required to keep a record of your bowel habits for a period of one week. You will then be randomly assigned to one of two groups. Two standard clinical treatments will be used in the study. Some patients may experience mild discomfort following treatment application, but this is temporary.

What are you required to commit to ?
The total duration of the study is six weeks. This includes the initial consultation, one type of treatment that you will receive twice weekly for two weeks and then another type of treatment given twice weekly for another two weeks..
After the 2^{nd} , 4^{th} , 6^{th} and 8^{th} treatments, your spinal range of motion, sense of global well being and pain intensity will again be measured and recorded. You will be required to attend all 10 appointments over the six week period.

What would result in my being excluded from the study once I have been accepted ?
During the study, you will not be allowed to consume any laxatives, pain killers or start any new medication. Dietary alterations are also prohibited and patients who do not adhere to this requirement will have to be excluded from the study. You may also be excluded from the study if you:

- fail to comply with the requirements of the study.
- Undergo any form of surgery
- Sustain any injury to the thoracic or lumbar spine.
- Undertake any new treatment/begin any new medication for any other condition.
- Develop any illness or condition that may be a contraindication to spinal manipulation:

  Infections and fevers, Arthritis, Severe osteoporosis, Neurological disorders, Pregnancy.

Costs and remuneration

All treatments will be free of charge for as long as you remain a part of the study.

Risks or discomforts expected during the course of the study

You may experience some mild initial discomfort following treatment, however this is temporary.

Expected benefits of the study

It is hypothesised that you will experience relief from your chronic constipation and an improved sense of well being/quality of life as a result of the treatment you will receive.

Withdrawal from the study:

You will be free to withdraw from my study at any time, without giving reasons for doing so.

Confidentiality of data

Patient confidentiality will be maintained at all times, including after the study is completed. No patient names or personal information will be revealed in any published literature.

Problems, questions or queries:

Should you have queries/ require further information, please feel free to contact:

Dr C.M Korporaal	031 – 2042611
Ruwaida Vadachia	031 - 2042512

Or alternatively the Faculty Research and Ethics Committee, via Mr Vikesh Singh at 031 – 2042701.

Kind regards

_____	_____
Ruwaida Vadachia	Dr Charmaine Korporaal
(Research Student)	(Research Supervisor)

Appendix B

Informed Consent Form
(To be completed in Duplicate by Patient/Subject)

Date : _____

Title of Research : A clinical investigation into the effect of spinal manipulative therapy on chronic idiopathic constipation in adults.

Name of Supervisor : Dr Charmaine Korporaal (PH: 031-2042611)

Name of Research Student : Ruwaida Vadachia (PH: 031-2042512)

Please Circle the Appropriate Answer

1. Have you read the information sheet? Yes No
2. Have you had an opportunity to ask questions regarding the study? Yes No
3. Have you received satisfactory answers to your questions? Yes No
4. Have you had an opportunity to discuss the study? Yes No
5. Have you received enough information about this study? Yes No
6. Who have you spoken to?_____
7. Do you understand the implications of your involvement in the study? Yes No
8. Do you understand that you are free to withdraw from this study Yes No
   a. at any time
   b. without having to give any reason for withdrawing, and
   c. without affecting your future health care.
9. Do you agree to voluntarily participate in this study? Yes No

If you have answered 'No' to any one of the above, please obtain the information before signing.

Please print in block letters:

Patient's Name _____

Signature_____

Witness's Name_____

Signature _____

Research Student's Name_____

Signature _____

Appendix C

DURBAN INSTITUTE OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:_____ Age: _____

File # _____

Sex: _____ Occupation:_____

Intern: _____ Signature:_____

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature:

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:

Case Summary Signed off:	Date:

Intern's Case History:

1. Source of History:

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

3. Present Illness:

	Complaint 1	**Complaint 2**
Location Onset : Initial: Recent: Cause: Duration Frequency Pain (Character) Progression Aggravating Factors Relieving Factors Associated S & S Previous Occurrences Past Treatment (a) **Outcome:**		

4. Other Complaints:

5. Past Medical History:

General Health Status
Childhood Illnesses
Adult Illnesses
Psychiatric Illnesses
Accidents/Injuries
Surgery
Hospitalisation

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests incl. x-rays
- 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 D

DURBAN INSTITUTE OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
PHYSICAL EXAMINATION

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

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

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

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

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

4. <u>RESPIRATORY EXAMINATION</u>

1) Is this patient in **Respiratory Distress**?
Inspection - Barrel chest:
- Pectus carinatum/cavinatum:
- Left precordial bulge:
- Symmetry of movement:
- Scars:

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

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

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

5. <u>ABDOMINAL EXAMINATION</u>

1) Is this patient in **Liver Failure**?
Inspection - Shape:
- Scars:
- Hernias:

Palpation - Superficial:
- Deep = Organomegally:
- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia**:**
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

Higher Mental Function - Information and Vocabulary:
- Calculating ability:
- Abstract Thinking:
G.C.S.: - Eyes:
- Motor:
- Verbal:

Evidence of head trauma:

Evidence of Meningism: - Neck mobility and Brudzinski's sign:
- Kernigs sign:
Cranial Nerves:
I Any loss of smell/taste:
Nose examination:
II External examination of eye: - Visual Acuity:
- Visual fields by confrontation:
- Pupillary light reflexes = Direct:
= Consensual:
- Fundoscopy findings:
III Ocular Muscles:
Eye opening strength:
IV Inferior and Medial movement of eye:
V a. Sensory- Ophthalmic:
- Maxillary:
- Mandibular:
b. Motor - Masseter:
- Jaw lateral movement:
c. Reflexes- Corneal reflex
- Jaw jerk

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

b. Taste - Anterior two-thirds of tongue:
VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function - Nystagmus:
- Rombergs:
- Wallenbergs:
Otoscope examination:
IX & Gag reflex:
X Uvula deviation:
Speech quality:
XI Shoulder lift:
S.C.M. strength:
XII Inspection of tongue (deviation):
Motor System:
a. Power
- Shoulder = Abduction & Adduction:
= Flexion & Extension:
- Elbow = Flexion & Extension:
- Wrist = Flexion & Extension:
- Forearm = Supination & Pronation:
- Fingers = Extension (Interphalangeals & M.C.P's):
- Thumb = Opposition:
- Hip = Flexion & Extension:
= Adduction & Abduction:
- Knee = Flexion & Extension:
- Foot = Dorsiflexion & Plantar flexion:
= Inversion & Eversion:
= Toe (Plantarflexion & Dorsiflexion):

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

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

Sensory System:

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

b. Joint position sense
- Finger:
- Toe:

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

Cerebellar function:

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

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

8. <u>SPINAL EXAMINATION:</u>(See Regional examination)

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

9. <u>BREAST EXAMINATION:</u>

Summon female chaperon.

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

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

Appendix E

DURBAN INSTITUTE OF TECHNOLOGY REGIONAL EXAMINATION

THORACIC SPINE

Patient:_____ **File:**_____

Date:_____

Intern:_____

Signature: _____

Clinician:_____

Signature: _____

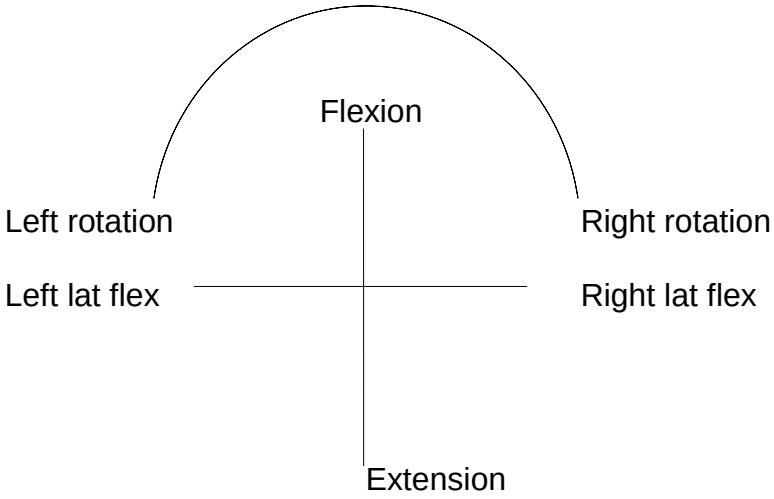
STANDING

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

Scars
Chest Deformity
(pigeon, funnel, barrel):

RANGE OF MOTION:

Forward Flexion	20 – 45 degrees (15cm from floor)
Extention:	25 – 45 degrees
L/R Rotation:	35 – 50 degrees
L/R Lat flex:	20 – 40 degrees



RESISTED ISOMETRIC MOVEMENTS: (in neutral)
Forward Flexion Extension
L/R Rotation L/R Lateral Flexion
SEATED:
Palpate Auxillary Lymph Nodes
Palpate Ant/Post Chest Wall
Costavertabral Expansion (3 – 7cm diff. at 4th intercostals space)
Slump Test (dural stretch test)
SUPINE:
Rib Motion SLR
Soto Hall Test (#, sprains) Palpate abdomen
PRONE:
Passive Scapular Approximation
Facet Joint Challenge
Vertebral Pressure (P-A central unilateral, transverse)
Active Myofascial trigger points:

	Active	**Latent**		**Active**	**Latent**
Rhomboid Major			Rhomboid Minor		
Lower Trapezius			Spinalis Thoracic		
Serratus Posterior			Serratus Superior		
Pectoralis Major			Pectoralis Minor		
Quadratus Lumborum					

NEUROLOGICAL EXAMINATION:

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

Basic LOWER LIMB neuro:

Myotomes	
Dermatomes	
Reflexes	

KEMPS TEST:

MOTION PALPATION:

Ribs: Calliper: Left:

Right:

Joint play

Bucket Handle: Left:

Right:

Joint play

BASIC EXAM	History	ROM	Neuro/Ortho
LUMBAR			
CERVICAL			

Appendix F

REGIONAL EXAMINATION - LUMBAR SPINE AND PELVIS

Patient:_____ File#:_____
Date:_________

Intern\Resident:_____ Clinician:_____

_____

STANDING:

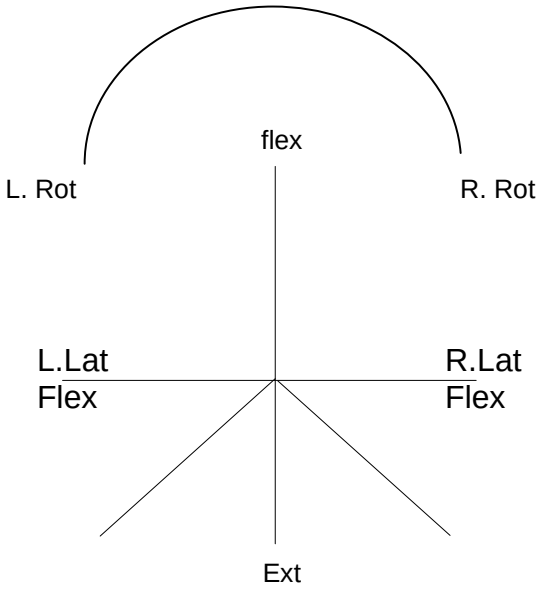
Posture– scoliosis, antalgia, kyphosis
Body Type
Skin
Scars
Discolouration

Minor's Sign
Muscle Tone
Spinous Percussion
Scober'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

SLR		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

TRIPOD 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		

MF tp's	**Latent**	**Active**	**Radiation**
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				Proproception		
L4						
L5						
S1						
S2						
S3						

Action	Muscles	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			

BASIC THORACIC EXAM

History
Passive ROM
Orthopedic

BASIC HIP EXAM

History ROM: Active
Passive : Medial rotation : A) Supine (neutral) If reduced - hard \ soft end feel
B) Supine (hip flexed): -
Trochanteric bursa

Appendix G

DURBAN INSITUTE OF TECHNOLOGY CHIROPRACTIC DAY CLINIC

Title of Research: A Clinical investigation into the effect of spinal manipulative therapy on chronic idiopathic constipation in adults..

Name of patient:

Thoracic & Lumbar Spine Range of Motion – Record Sheet

		THORACIC SPINE							LUMBAR SPINE					
Reading No.	**Date**	**Flex**	**Ext**	**R PA rot**	**L PA rot**	**R LF**	**L LF**		**Flex**	**Ext**	**R PA rot**	**L PA rot**	**R LF**	**L LF**
1														
2														
3														
4														
5														

Appendix H

DURBAN INSTITUTE OF TECHNOLOGY CHIROPRACTIC DAY CLINIC

Title of Research: A Clinical investigation into the effect of spinal manipulative therapy on chronic idiopathic constipation in adults..

Name of patient:

Date:

NUMERICAL RATING SCALE 101

Please indicate on the line below the number between **0** and **10** that best describes the pain of your major problem at this point, when it is at its WORST. A zero (0) would mean “no pain at all” and a ten (10) would mean “pain as bad as it could be”
Please write only one number.

0_____10

Appendix I

DURBAN INSTITUTE OF TECHNOLOGY CHIROPRACTIC DAY CLINIC

Title of Research: A Clinical investigation into the effect of spinal manipulative therapy on chronic idiopathic constipation in adults..

Name of patient:

Date:

GLOBAL WELL BEING SCALE

Think about how you are feeling right now – your general sense of health and well being. The left end of the line below represents the "worst you could possible feel", the right end represents the "best you could possibly feel".

Make a vertical mark on the line to show how you feel right now.

Appendix J

DURBAN INSTITUTE OF TECHNOLOGY CHIROPRACTIC DAY CLINIC

Title of Research: A Clinical investigation into the effect of spinal manipulative therapy on chronic idiopathic constipation in adults..

Name of patient:

Week no.

Bowel Habit Diary

Date:								**Leave**	**Blank**
Day No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Total**	**%**
No. of Bowel movements per day									
Straining experienced at stools (Circle appropriate answer)	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No		
Consistency of Stools (Circle appropriate answer)	Hard Formed Soft	Hard Formed Soft	Hard Formed Soft	Hard Formed Soft	Hard Formed Soft	Hard Formed Soft	Hard Formed Soft		

C = _____

S = _____

N = _____

CI =

Appendix K

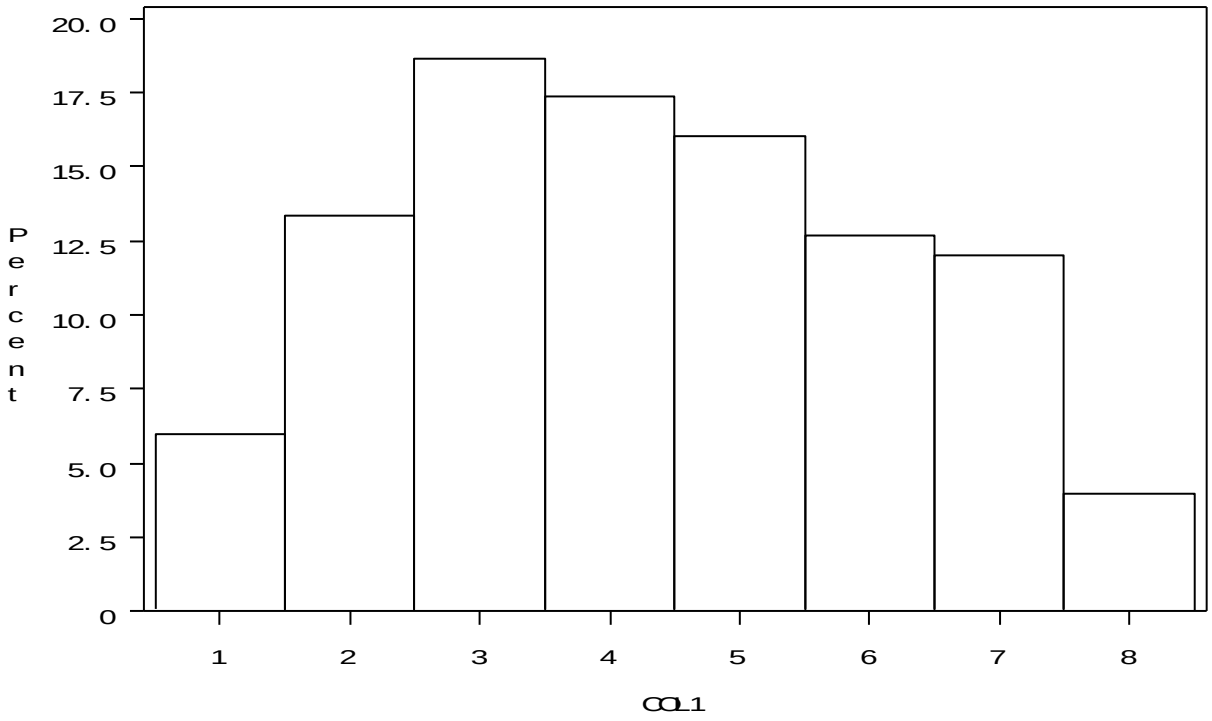
Do you suffer from Chronic Constipation?

Research is Currently being done at DIT Chiropractic Day Clinic

If you are between the ages of 20-60 and fit the inclusion criteria you could qualify for FREE treatment.

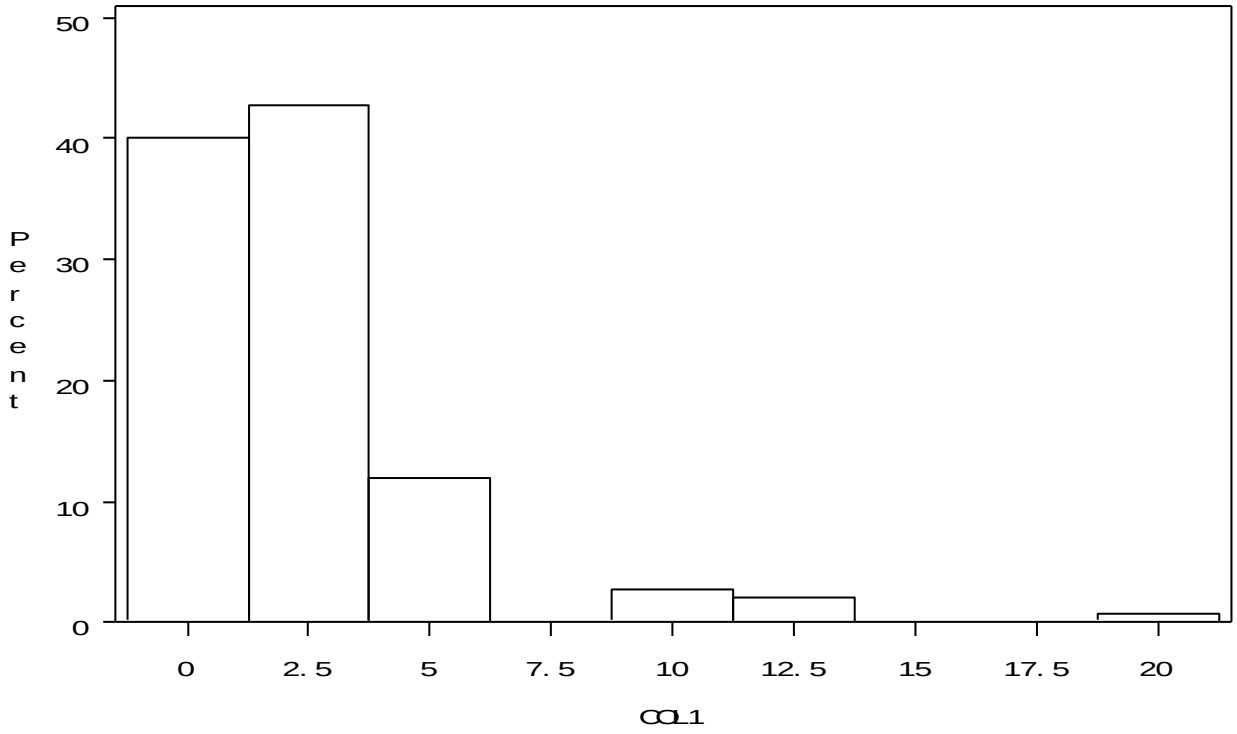
Contact
Ruwaida
031 2042512
031 2042205
082 8383154

Appendix L



Histogram for NRS showing normal distribution

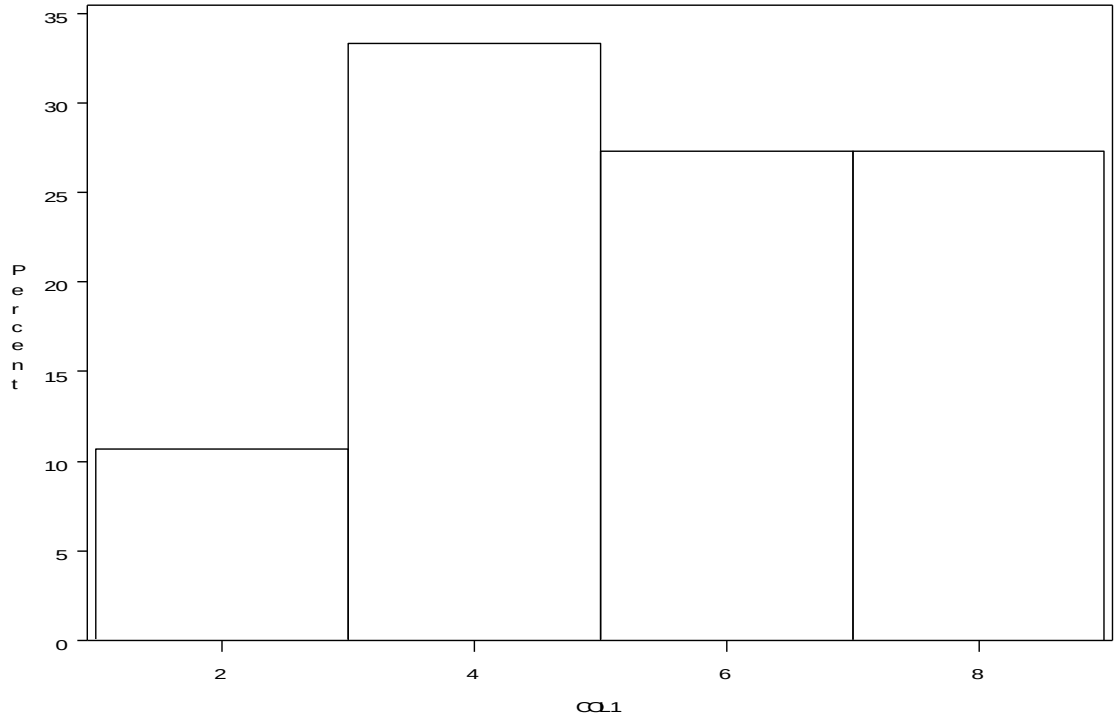
Appendix M



Histogram for Constipation Index

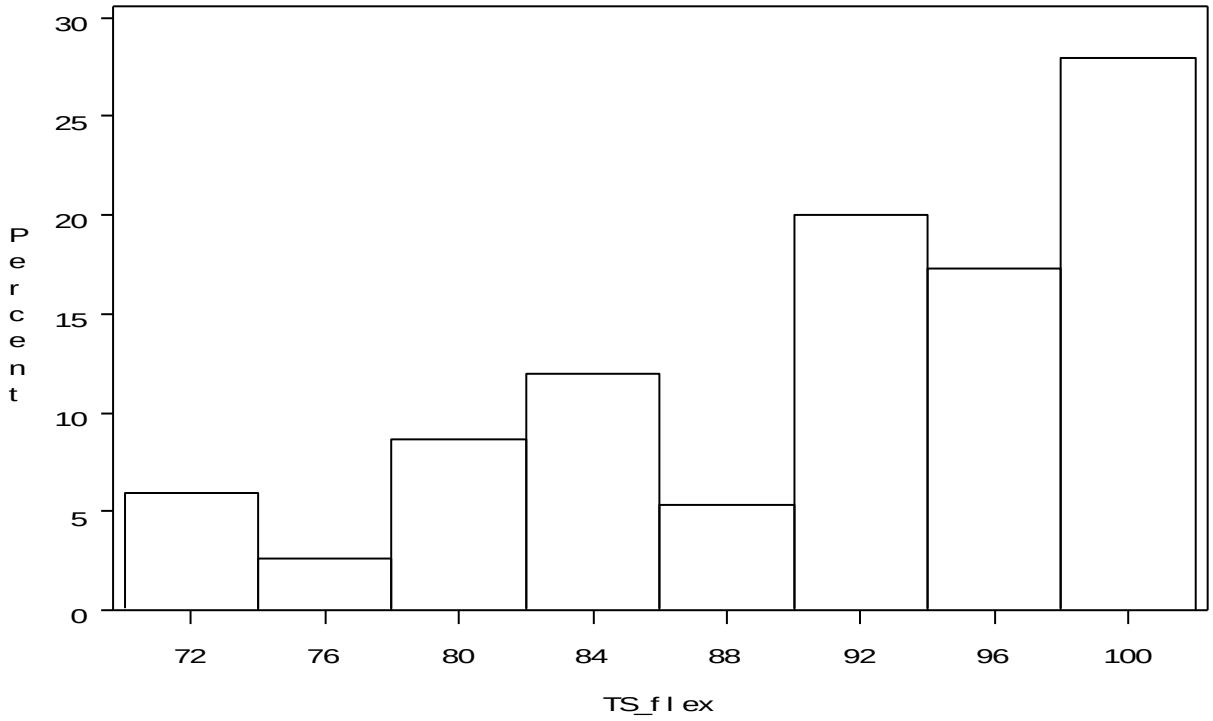
This variable is not normally distributed

Appendix N



Histogram for Global Wellbeing Scale showing normal distribution

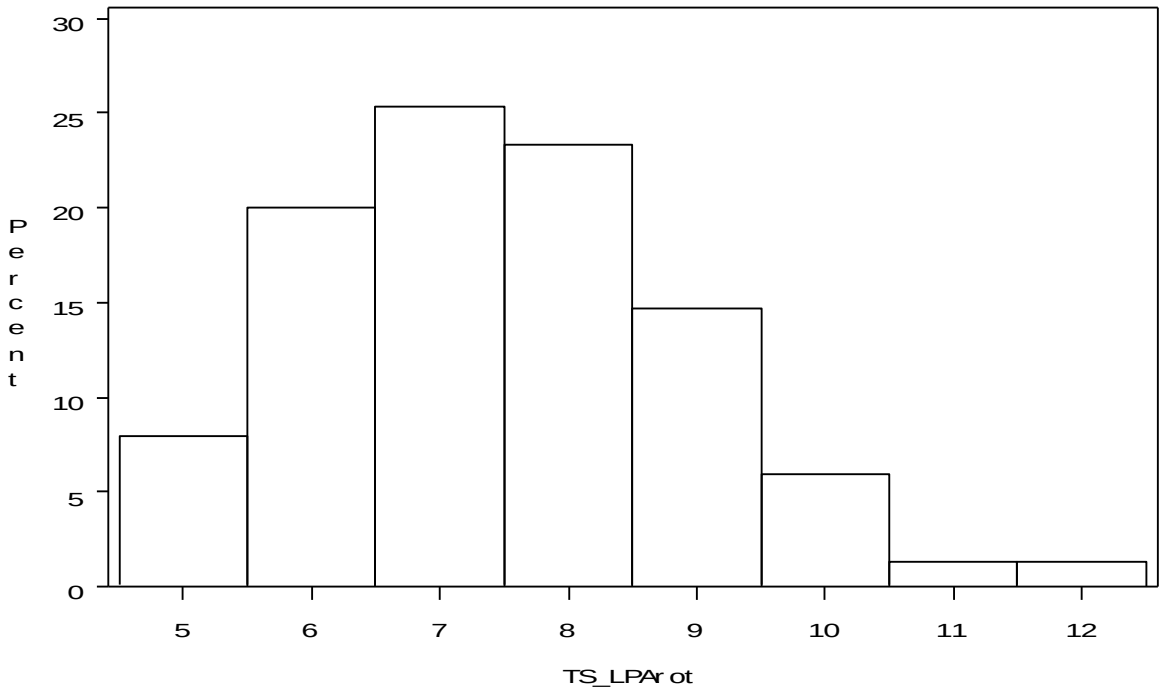
Appendix O



Histogram for Thoracic Flexion

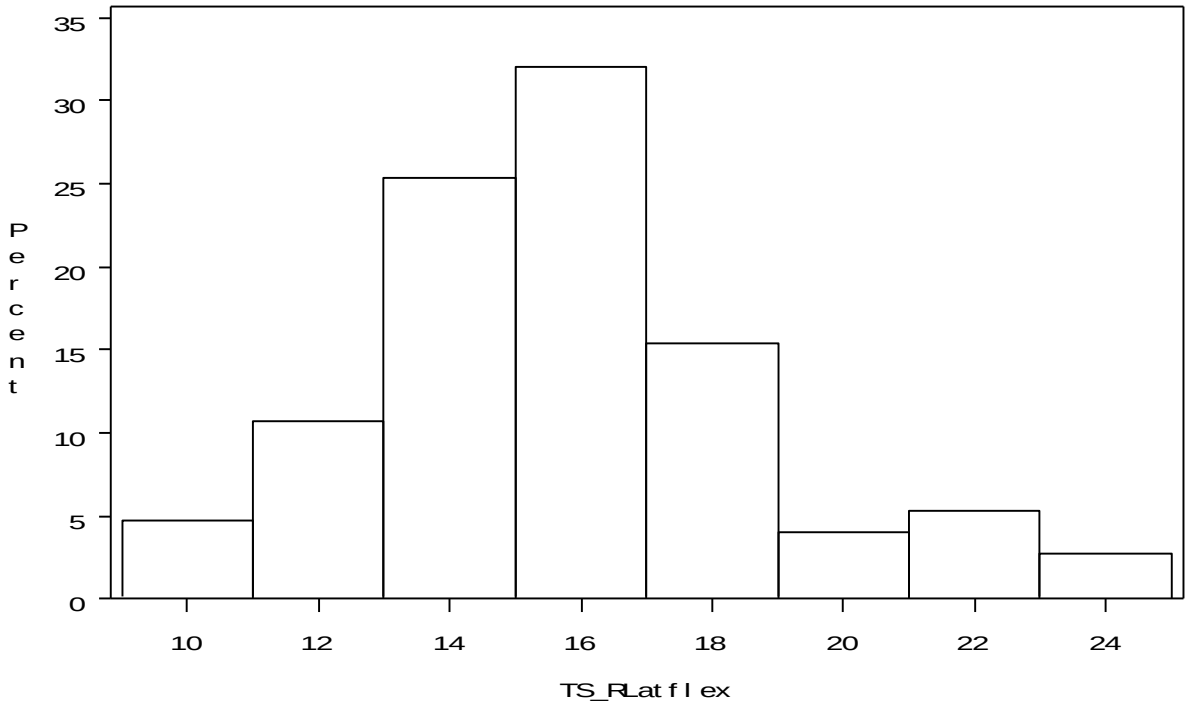
This variable is not normally distributed

Appendix P



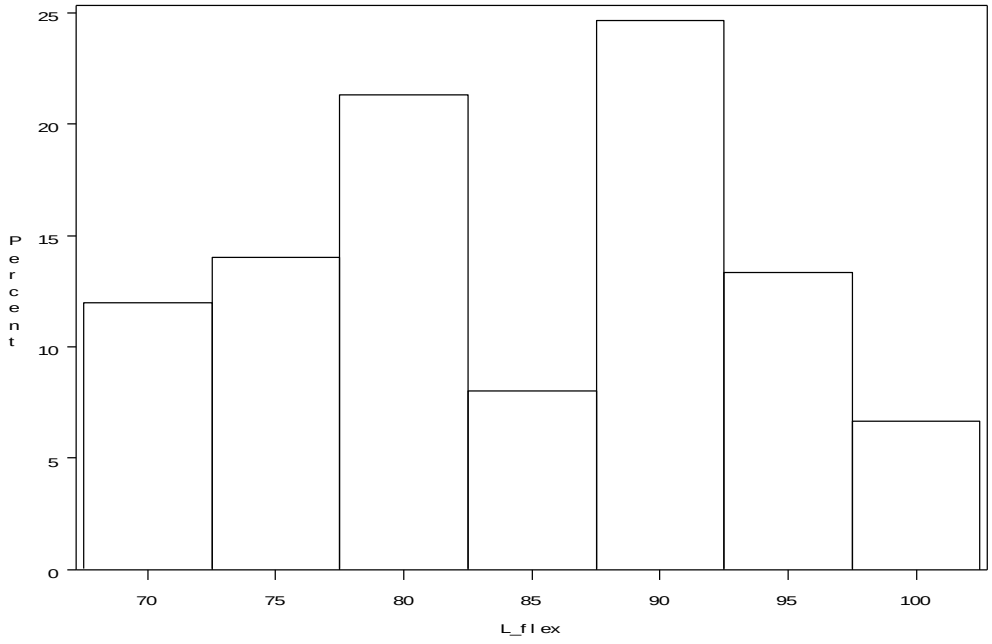
Histogram for Left Thoracic PA Rotation showing normal distribution

Appendix Q



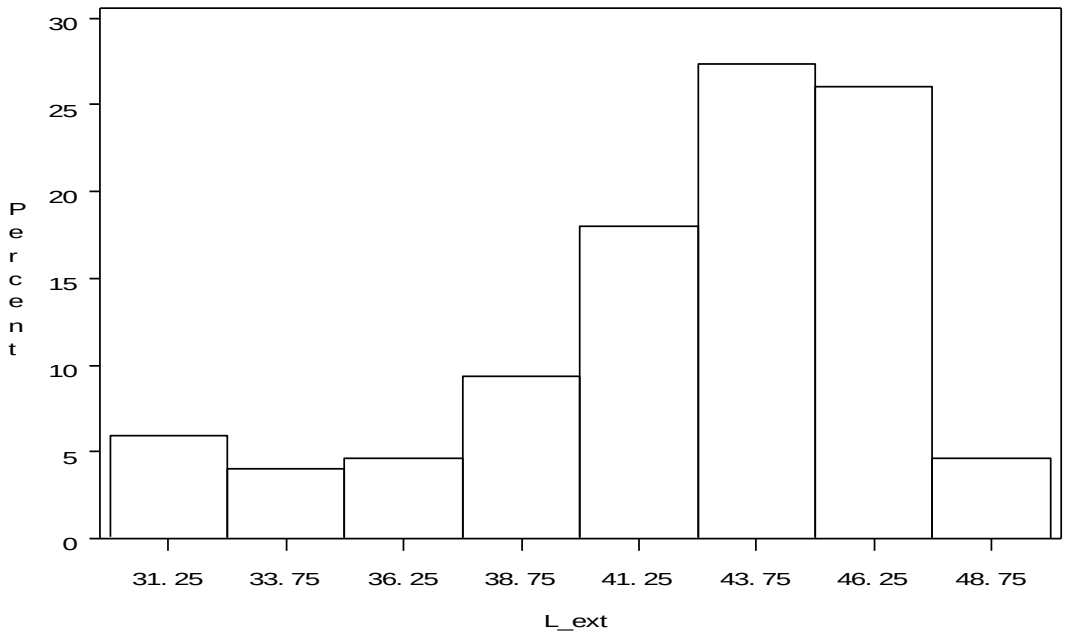
Histogram for Right Thoracic Lateral Flexion showing normal distribution

Appendix R



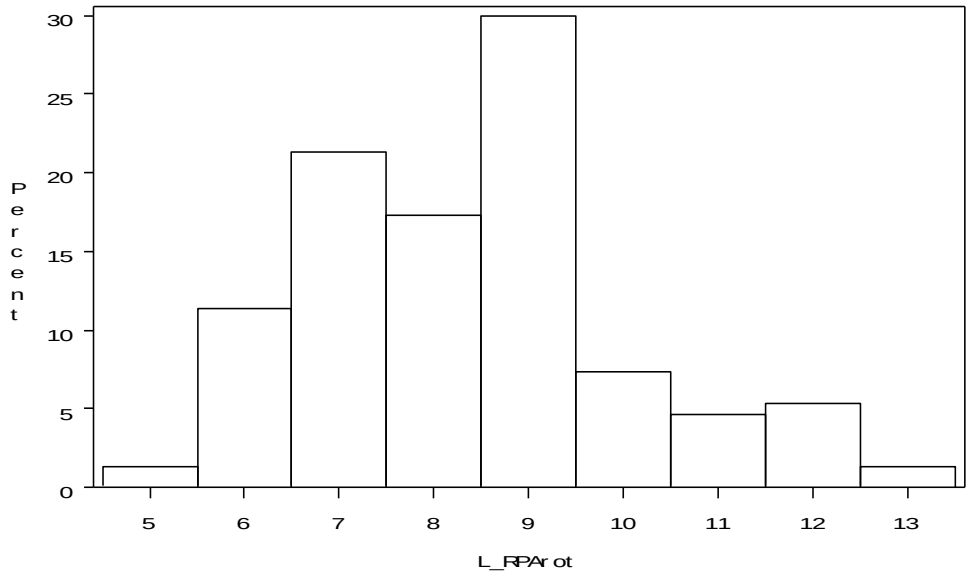
Histogram for Lumbar flexion showing normal distribution

Appendix S



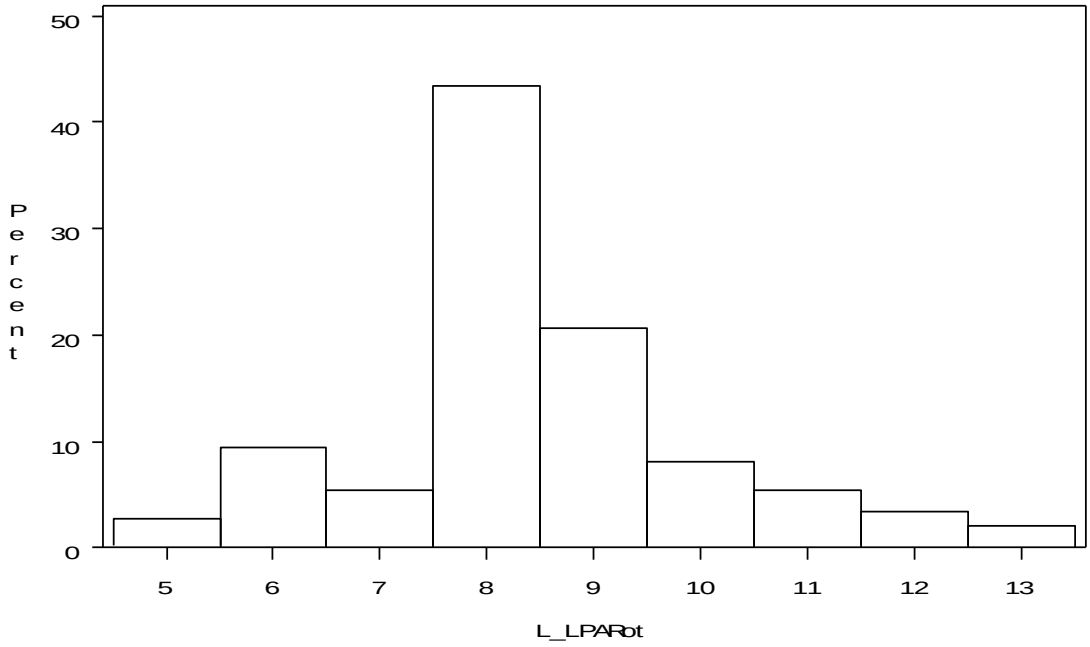
Histogram for Lumbar Extension showing normal distribution

Appendix T



Histogram for Right Lumbar PA Rotation showing normal distribution

Appendix U



Histogram for Left Lumbar PA Rotation showing normal distribution