BRN 98549

THE EFFECT OF SPINAL MANIPULATIVE THERAPY TO THE ATLANTO-OCCIPITAL AND ATLANTO-AXIAL ARTICULATIONS ON THE BLOOD PRESSURE OF NORMOTENSIVE CAUCASIAN MALE SUBJECTS.

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

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AUGUST 2002

I, Scott Sutherland, declare that this dissertation is representative of my own work.

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DEDICATION

This work is dedicated to my parents who, through their love, support, and faith in me, kept me going and made it all worthwhile. Their sound advice, encouragement, and financial support will always be remembered and appreciated.

ACKNOWLEDGEMENTS

Much appreciation and gratitude must go to the following people:

Dr. Rob Mathews, for his first-class understanding of research procedure, no-nonsense approach, and for being so charitable with his time.

Mr. K. N. Thomas for his time, knowledge, and great sense of humour.

Mrs. Ireland for her encouragement.

My friends and colleagues, who shared all the great times as well as shouldering together all the tough times.

The lecturers who all guided and shaped our minds; in particular:
Dr. B Nook for his endless knowledge and enthusiasm,
Dr. A. Jones and Dr. A van der Meulen for their professional yet approachable manner, which is always necessary when dealing with patients, and
Dr. B. Lewis for showing the importance of being thorough.

'The Sister' for always giving an ear, and to 'Brutus' for the endless distractions.

And, last but by no means least, Nicky, for the encouragement, belief, focus, friendship, and love.

ABSTRACT

Blood pressure, defined as the force per unit area exerted on the wall of a blood vessel by its contained blood, is expressed in terms of millimeters mercury (mm Hg). Hypertension is a common problem in Westernised nations, including South Africa. The nervous system's role in the induction of hypertensive disease is the least understood; however, it is postulated that chiropractic adjustment normalises raised blood pressure via modification of the tonicity of the autonomic nervous system. The treatment of organic-type disorders with manipulative therapy is a controversial topic within and outside the chiropractic profession. However, research has indicated that manipulation may affect blood pressure, and the literature does propose a number of hypotheses on how this may be achieved. The purpose of this study was to determine the effect of spinal manipulative therapy to the atlanto-occipital and atlanto-axial articulations on the blood pressure of normotensive Caucasian male subjects.

This prospective controlled clinical trial consisted of a total of sixty normotensive Caucasian male subjects who were recruited by canvassing for volunteers from the Durban Institute of Technology campus as well as the general Durban area. By simple consecutive randomisation, 30 subjects were entered into a control group, and another 30 were entered into an experimental group. Both groups followed the same procedure with the exception that the control group did not receive any manipulation. Phase one of the study, which covered two visits, was

used to obtain the subjects' basal blood pressures. During the first visit, after the subject had been seated and relaxed for 15 minutes, the first blood pressure reading was taken and dysfunctional joints were identified. At the second visit, approximately one week later, blood pressure was again taken in the same manner after the subject had been seated for 15 minutes. Within one minute of taking this reading, an upper cervical manipulation was administered, beginning phase two. The blood pressure was measured immediately following the manipulation, and again after 15 minutes. All blood pressure readings were recorded using a fully automated digital blood pressure monitor, after a certificate of calibration was obtained and a pilot study demonstrating its accuracy had been completed.

The level of confidence was set at 95% for all statistical analyses. For inter-group analysis, both groups were shown to be similar upon entering the study as well as during the experimental phase of the study. Intra-group analysis showed that the non-adjustment group's blood pressure remained constant throughout the study period. For the adjustment group, however, both the paired t-tests and Friedman's T test demonstrated a significant decrease in the blood pressure readings (systolic and diastolic) after manipulation. This significant decrease was still evident after 15 minutes for the systolic reading only.

The results of this study suggest that blood pressure can be decreased at statistically significant levels in normotensive subjects by a single adjustment to the upper cervical spine more significantly than manipulation directed to other areas of the cervical spine. The results also suggest a sustained effect of the manipulation on the blood pressure.

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CHAPTER 1

INTRODUCTION

Over the more than 100 years since the origin of the chiropractic profession, chiropractors have treated a large variety of conditions, including visceral or organic types of disorders. This has been based on the theory that disorders of the spine cause nerve interference that in turn may cause abnormalities in the visceral organs supplied by those segments (Leboef et al. 1999).

The modern-day chiropractic profession however, predominantly treats painful conditions of the spine, especially low back pain, moving away from treating visceral conditions to more of a mechanical musculoskeletal model (Leboef et al. 1999). The New Zealand Commission of Inquiry into Chiropractic actually states "it is the chiropractors' claims of success in the treatment of type O category which principally strains the credulity of medical practitioners, and in their mind invalidates the whole chiropractic system". (Jamison et al. 1992). According to Leboef et al. (1999), there are two reasons for this shift. One is that fewer chiropractors base their practices exclusively on the anatomic-physiologic-based hypothesis, and the other is a desire for the chiropractic profession to be included into the mainstream health care system.

Despite this shift, Jamison et al. (1992), in their survey to establish whether Australian chiropractors considered spinal manipulative therapy to be a treatment option for patients with organic-type conditions, found that the majority of respondents did support this notion. The choices of organic-type conditions for which chiropractic treatment was considered helpful were consistently asthma, dysmenorrhea, and hypertension. So it seems that chiropractors still have, albeit to a lesser extent today, a role in dealing with certain nonmusculoskeletal conditions.

There is a reasonable amount of literature on the effects of manipulation on blood pressure (Dulgar et al. 1980; Morgan et al. 1985; Yates et al. 1988; McKnight and DeBoer 1988; Nansel et al. 1991; Plaugher and Bachman 1993; Thompson and Webb 2001), and the possible mechanisms of action to support these respondents (Jamison et al. 1992; Sato 1992; Bolton 2000). The majority of this literature shows there to be a decrease in blood pressure post manipulation, while two studies, Morgan et al. (1985) and Nansel et al. (1991), show no post-manipulative effects immediately after manipulation or long term.

Although many of these studies show a decrease in blood pressure (Dulgar et al. 1980; Yates et al. 1988; McKnight and DeBoer 1988; Plaugher and Bachman 1993; Thompson and Webb 2001) none of them attempt to show if this decrease is sustained for any length of time. Nor have any focused on the upper cervical spine, even though many important structures, such as the large ganglia supplying the somatovisceral pathways involved in the regulation of blood pressure, are situated there (Moore 1992: 815). These two questions, and the trend in the chiropractic profession of generally moving away from the treatment of organic-type conditions, despite many chiropractors' still advocating spinal manipulation as part of the treatment regime for a select number of organic-type conditions, including hypertension, prompted the author to carry out this study.

The aim of this investigation was, therefore, to determine the effect of spinal manipulative therapy to the atlanto-occipital and atlanto-axial articulations on the blood pressure of normotensive Caucasian male subjects.

The first objective was to determine the effect of this spinal manipulative therapy on blood pressure of normotensive Caucasian male subjects immediately post manipulation.

The second objective was to determine the effect of this spinal manipulative therapy on blood pressure of normotensive Caucasian male subjects fifteen minutes post manipulation.

The results of this study will augment the already existing body of literature on the somatovisceral effects of manipulation on blood pressure and, should findings indicate a significant decrease in blood pressure, it might result in the inclusion of spinal manipulative therapy to the upper cervical spine in a study aimed at hypertensive patients.

CHAPTER 2

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

This chapter covers the literature relevant to this study dealing with spinal manipulation and blood pressure. It defines what blood pressure is, its importance medically and physiologically, possible mechanisms of action for spinal manipulation, past research on the effects of spinal manipulative therapy on blood pressure, and discusses the levels chosen for manipulation in order to affect blood pressure.

2.2 DEFINITION

"Blood pressure is the force per unit area exerted on the wall of a blood vessel by its contained blood. Blood pressure is expressed in terms of millimeters mercury (mm Hg)" (Marieb 1998: 699).

Pressure is highest during systole when the ventricles are contracting (systolic pressure) and lowest during diastole, when the ventricles are relaxing and refilling (diastolic pressure) (Guyton and Hall 1997: 115). Differences in blood pressure within the vascular system are what drives blood from the arterial (high pressure) to the venous system (low pressure) throughout the body (Marieb 1998: 699). Normal arterial blood pressure of men and women between the ages of 20 and 35 are $^{123-126}/_{76-79}$ and $^{116-120}/_{76-79}$ respectively (Fox 1999: 435).

A person is said to be hypertensive when, under resting conditions, their systolic blood pressure is greater than 140 mm Hg and their diastolic blood pressure is greater than 90 mm Hg (Guyton and Hall 1996: 225 and Marieb 1998: 709). This is in line with Kaplan (1986: 13) who calls this an operational definition for hypertension. Based on his definition, the World Health Organization Criteria, and the Joint National Committee Criteria, he states that a person is hypertensive if the averages of two or more readings taken at two or more visits are:

Men under 45: > 140/90 mm Hg.

Men over 45: > 150/95 mm Hg.

Women: > 150/95 mm Hg.

Kaplan (1986: 13)

For the purpose of this study, only male normotensive subjects under the age of 35 were included. Therefore, using this definition, they had to have a blood pressure of less than 140 mm Hg systolic and less than 90 mm Hg diastolic to be included into the study.

According to Seedat (1989), in South Africa $^{141\text{-}159}/_{90\text{-}94}$ mm Hg is classified as only borderline hypertension, and hypertension is classified from ≥ 160 mm Hg systolic and/or 95 mm Hg diastolic. Steyn (1989), in his report on how to look at epidemiology of hypertension in South African populations, comments on the findings of Seedat (1989). He reports that this classification was largely owing to urbanisation and westernisation of the black community. Kaplan (1986: 115) explains that blacks, owing to their genetic makeup, have a decreased capacity to excrete sodium making it difficult for them to cope with the excess sodium encountered in urban environments. Smith and Kampine (1990: 302) also note that hypertension is more prevalent in black men than white. He suggests that this may be owing to a higher renal vascular resistance in blacks, perhaps related to premature senescence in these patients.

Despite this study being based in Durban, South Africa, only Caucasian males between the ages of 20 and 35 were used as subjects. This was done for three reasons: firstly to keep with past research (which has used only Caucasian subjects in studies) in order to draw comparisons; secondly, because of the higher prevalence of hypertension in the black community as shown in 2.1 and 2.2; and, thirdly, as explained in the inclusion criteria of chapter 3.2.1, for statistical reasons it was preferred to use 140/90 as the cut-off point for normotensive. The work by Seedat (1989) and Steyn (1989) has been included in this literature review in order to put the South African aspect of hypertension into perspective with the rest of the relevant research.

2.3 PREVALENCE

Kaplan (1986: 14) states that, according to the National Center for Health Statistics National Health and Nutrition Examination Surveys (NHANES), over 30 million Americans (21.7% of the US population) between the ages of 25 and 74 are hypertensive or taking hypertensive medication. The prevalence of hypertension in American blacks is greater than in the whites, and they suffer more morbidity and mortality from it (Kaplan 1986: 113). In South Africa approximately 4.5 million people are hypertensive. This is approximately 1 in every 8 people (Seedat 1989). This total includes most ethnic groups. Of the rural Zulus, 10% of males and 12% of females are hypertensive, while of the urban Zulus 27% of males and 34% of females are hypertensive. Rural white males and females had a prevalence of 18% in the South Western Cape and in Durban, although the female prevalence was the same, the male prevalence was 24%, showing a slight rural-urban difference in males only. Among the Indian population, it was found that 16% of males and 22% of females were hypertensive. The highest prevalence was found in the coloured population of the Cape Peninsula with 28% males and 34% females classified as hypertensive (Steyn 1989). As shown by these figures, hypertension is a common problem in South Africa, especially in urban populations, and particularly in the black and coloured populations.

2.4 ANATOMY AND PHYSIOLOGY OF BLOOD PRESSURE

Maintenance of an adequate and constant blood pressure is important for the normal perfusion and functioning of the organs of the body. Short-term alterations are mediated by rapid autonomic nervous system responses controlled by the vasomotor centre, and this includes various negative feedback reflexes. Long-term regulation is achieved by neurohumoral factors that control water and sodium excretion, as well as alterations in blood volume and microcirculatory structure (Smith and Kampine 1990: 161-179; Guyton and Hall 1996: 209-234; and Marieb 1998: 702-709).

2.4.1 LONG-TERM REGULATION

Directly, the kidneys influence blood volume or blood pressure by loosing excess fluid when the filtration rate increases beyond the kidneys' ability to process the filtrate, as when blood pressure increases and when blood pressure or volume is low, water is conserved (Marieb 1998: 707-708).

Indirectly, the kidneys affect blood pressure by secretion of renin from the juxtaglomerular apparatus when blood pressure or volume is low. This, in turn, catalyses a series of reactions, which converts angiotensinogen finally into angiotensin II that produces a rise in blood pressure by causing vasoconstriction, thirst stimulation in the hypothalamus, and secretion of aldosterone from the adrenal cortex. Aldosterone increases sodium reabsorption by the kidneys and stimulates release of antidiuretic hormone (ADH) by the posterior pituitary. ADH causes increased water reabsorption. When the blood pressure or volume is high renin secretion is inhibited (Marieb 1998: 707-708 and Fox 1999: 415-417).

Ultimately, the sympathetic nervous system also controls renin secretion by stimulating its release by the kidneys when blood pressure decreases enough to stimulate the baroreceptors (Marieb 1998: 706, and Smith and Kampine 1990: 166).

2.4.2 SHORT-TERM REGULATION

Key areas in the dorsal reticular matter of the medulla and lower pons, collectively known as the cardiovascular centres, direct acute control of blood pressure. These areas overlap anatomically and functionally, but they can be divided into cardiac and vasomotor divisions, and these have further inhibitory (parasympathetic) and stimulatory (sympathetic) divisions as well (Smith and Kampine 1990: 162, and Little and Little 1989: 252). Sympathetic efferents from the reticular activating system within the cardiovascular centre are constantly sending impulses to control cardiac output and set vascular tone (Marieb 1998: 703, and Little and Little 1989: 253). This activity is altered by:

- **Baroreceptors** (stretch receptors) located in the carotid sinuses, aortic arch, and most large elastic arteries within the neck and thorax. A rise in blood pressure stretches the receptors, increasing their firing rate, which inhibits the vasomotor centre and the cardiostimulatory (sympathetic) centre, causing vasodilatation and decreasing the heart rate and contractile force and the subsequent decrease in blood pressure. The converse occurs when blood pressure drops (Little and Little 1989: 255-257, Guyton and Hall 1997: 155, and Marieb 1998: 703). Although the baroreceptors adapt to long-term alterations in blood pressure, they can alter blood pressure for long periods indirectly when blood pressure drops by stimulation of the cardiovascular centre to cause release of renin by the kidneys (Smith and Kampine 1990: 166).

- **Chemoreceptors** within the carotid and aortic bodies located in large arteries of the neck and the aortic arch respectively are stimulated by a decrease in oxygen, an increase in carbon dioxide or a drop in pH. Signals from these chemoreceptors excite the cardiovascular centre to increase blood pressure (Marieb 1998: 704, and Guyton and Hall 1996: 216).

- **Higher brain centres**, such as the hypothalamus and cerebrum, control alterations in blood pressure necessary during exercise and emotional and temperature changes. Rostral parasympathetic and caudal sympathetic centres in the hypothalamus mediate these changes via vagal activation and inhibition of the sympathetic system, while for temperature regulation the preoptic ganglion of the anterior hypothalamus, when its temperature increases, will cause the sympathetic vasoconstrictor impulse to decrease (Smith and Kampine 1990: 176-177).

- The **cardiovascular centre** itself is strongly stimulated when cerebral ischaemia occurs, as when blood pressure drops below 60 mm Hg. This causes a powerful reflex response, often as a last attempt to increase blood flow to the brain when it becomes seriously low (Guyton and Hall 1996: 217).

- **Hormones** also play an important role in short-term regulation of blood pressure. Adrenal medulla hormones (norepinephrine) and epinephrine cause vasoconstriction and increase cardiac output respectively and are important facilitators of the fight-or-flight response (Marieb 1998: 705).

  Atrial natriuretic peptide produced by the atria of the heart is an antagonist to aldosterone, causing the kidneys to eliminate more sodium and water and in so doing decrease blood volume and blood pressure (Marieb 1998: 705).

  Antidiuretic hormone released by the hypothalamus is important only for short-term regulation of blood pressure when blood pressure levels become dangerously low, whereupon large amounts are released (Marieb 1998: 706).

Nitric oxide released by endothelial cells causes systemic and highly localised vasodilatation. Its effects are very brief, but if its synthesis is inhibited blood pressure rises to extremely high levels (Marieb 1998: 706).

2.5 THE NERVOUS SYSTEM'S ROLE IN HYPERTENSION

As one can see in 2.4, the control of blood pressure by the sympathetic and parasympathetic nervous systems is fairly well understood and documented in many physiology textbooks (Little and Little 1989: 251-255; Smith and Kampine 1990: 161-164; Guyton and Hall 1996: 209-213; Guyton and Hall 1997: 149-155; and Marieb 1998: 702-706).

However, relative to the physiological and anatomical abnormalities of the blood vessels, kidneys, heart, and adrenal glands associated with hypertensive disease, the nervous system's role in the induction of hypertensive disease is the least understood (Crawford et al. 1986).

Guyton and Hall (1996: 233) concur, adding that it has been difficult to prove that abnormalities of the nervous system can cause chronic hypertension. Despite this, Guyton and Hall (1996: 233) write that, despite research studies so far having failed to give proof of continued excess sympathetic activity, most clinicians believe that prolonged nervous tension causes continued increased levels of sympathetic tone in the blood vessels and kidneys, leading to chronically increased blood pressure. As will be shown in 2.6, current thinking in the literature (Jamison et al. 1992; Sato 1992; Bolton 2000; Budgell 2000; and Haldeman 2000) is that, via reflex responses and modifications to the autonomic nervous system, manipulation may affect gastrointestinal, bladder and cardiovascular function, including blood pressure. This would then be a suitable possible explanation as to how blood pressure may be affected by manipulation for prolonged periods.

However, Guyton and Hall (1996: 233) believe it to be more likely that, during short periods of extreme activation of the sympathetic nervous system, renal blood flow is often decreased to extremely low levels owing to severe renovascular constriction. This in turn leads to renal organic changes that in turn become the basis for permanent hypertension. They base this theory on the fact that incidents of extreme sympathetic activation will probably occur in one's life, and on experiments that have shown that introducing excessive amounts of the sympathetic neurotransmitter norepinephrine into the renal arteries sometimes causes permanent damage to the kidneys that could result in hypertension. If this were indeed the case, it would not support any hypothesis that manipulation would have lasting effects on blood pressure unless it could reverse or alter this process, and there is no literature to support this theory.

2.6 MECHANISMS OF ACTION FOR EFFECTS OF SPINAL MANIPULATIVE THERAPY ON BLOOD PRESSURE

According to Jamison et al. (1992), the chiropractic adjustment is postulated to normalise raised blood pressure via modification of the tonicity of the autonomic nervous system.

Sato (1992), in his study in which he applied nociceptive and non-nociceptive stimuli to somatic segments of anaesthetised animals, explains that the mechanism by which these modifications to the tonicity of the autonomic nervous system is achieved is by somatovisceral reflexes. These reflexes were induced by stimulation of joint mechanoreceptors and nociceptors with slow conducting (group III and IV) afferents by manually displacing zygapophysial joints (Sato 1992; Bolton 2000).

Bolton (2000) reviewed chiropractic and scientific peer-reviewed literature concerning human or animal studies of neural responses to vertebral subluxation and movement. He concludes that it is clear that some types of vertebral displacements can modulate heart rate, blood pressure and electrical activity in renal and adrenal nerves and gastrointestinal muscles.

Budgell (2000), in his review of recent findings in basic physiologic research on the effects of somatic stimulation of spinal structures on the autonomic nervous system, concludes that recent neuroscience research supports a neurophysiologic rationale for the concept that aberrant stimulation of spinal or paraspinal structures may lead to segmentally organised reflex responses of the autonomic nervous system, which in turn could alter visceral function. Budgell's (2000) findings concur with those of Bolton's (2000) review and Sato's (1992) study; however, they all caution that further scientific investigation needs to be completed as much remains theoretical.

Haldeman (2000) discussed several neurological theories pertaining to the chiropractic adjustment. These theories included nerve compression theories, reflex theories, and pain relief theories for the adjustment. He concluded that based on the studies he reviewed, which included effects of adjustments on EMG readings of back and limb muscles, and the impact of samatosensory input on autonomic functions, that there is now considerable evidence that stimulation of somatic structures can have substantial effects on cardiovascular, bladder and gastrointestinal function. However, he does caution that there are major obstacles to the acceptance of the somatovisceral reflex theory and the fact that all demonstrated reflex effects have been recorded in brief periods under experimental conditions (most experiments include anaesthetised animals), and that little evidence exists that these reflexes continue for sufficient time to allow a true change in organ function.

This research is on human subjects, is set in as natural a setting as possible, and does make an attempt to see, albeit for only fifteen minutes, whether there is a sustained effect on the blood pressure post manipulation. Although this study does not directly attempt to come to any conclusions on how or why the somatovisceral reflex works, or even whether it is a valid theory for that matter, the somatovisceral reflex model is to date the most plausible and accepted model to work from in order to explain the effects of manipulation on blood pressure.

Haldeman (2000), as did Budgell (2000), Bolton (2000), and Sato (1992), also concludes that considerable research still needs to be done to establish the somatovisceral reflex theory. However, although he believes that there is now sufficient scientific investigation to develop working models to explain the effects of the adjustment, he feels there is insufficient evidence to state that any particular theory can be considered valid (Haldeman 2000).

2.7 PAST RESEARCH PERTAINING TO SPINAL MANIPULATION AND BLOOD PRESSURE

Although some studies have shown there to be no effect on blood pressure after spinal manipulative therapy (Morgan et al. 1985, and Nansel et al. 1991), several studies have shown that spinal manipulative therapy can decrease both systolic and diastolic components of blood pressure (Dulgar et al. 1980; Yates et al.

1988; McKnight and DeBoer 1988; Plaugher and Bachman 1993; Thompson and Webb 2001).

2.7.1 STUDIES SHOWING NO EFFECTS

The Morgan et al. (1985) study, 'A Controlled Trial of Spinal Manipulation in the Management of Hypertension', compared the effects of a sham manipulation consisting of soft tissue massage to mobilisation of three regions of the spine, namely the occipitoatlantal joint, T_1-T_5 and T_{11}-L_1. They used the figure-of-eight manoeuver for five seconds at the occipitoatlantal joint, at T_1-T_5 the patient was brought into extension twice, and at T_{11}-L_1 they used muscle energy techniques. No reason was given as to why only mobilisation techniques and no grade five manipulative procedures were used; however, Morgan et al. do mention that the treatment they administered was more extensive than in past research and that their study was to evaluate the efficacy of a specific treatment protocol.

Nansel et al. (1991) found a number of reports indicating that somatic nociceptive signals may produce pain referral patterns similar to cardiac angina and could possibly produce reflex induced alterations in sympathetic efferent discharge related to lower cervical and upper thoracic cord levels as well. With this in mind, they thought it would be interesting to observe whether lower cervical adjustments, by decreasing biomechanical stresses, would concomitantly induce changes of various parameters known to be influenced by the sympathetic nervous system.

Nansel et al. (1991) delivered a unilateral lower cervical, lateral flexion spinal adjustment to the most restricted side, as assessed by a goniometer, to the cervical spines of healthy asymptomatic male subjects. Although there was a dramatic improvement observed in the degree of restriction as measured by the goniometer, and although this improvement persisted for the entire four-hour post-treatment period, there was no significant difference compared with the control group with regard to the blood pressure, heart rate measurements or plasma concentrations of norepinephrine, epinephrine, and dopamine. One can conclude from this that despite the improved range of motion, a lateral flexion adjustment to the lower cervical spine has no effect on the parameters measured by Nansel et al. (1991). Nansel et al. (1991) do, however, note in their discussion, whether changes would have been displayed had the subjects been symptomatic, or if other manipulative techniques to other regions of the spine such as the upper cervical spine had been used, as in this study, remain unanswered.

2.7.2 STUDIES' SHOWING EFFECTS OR SUPPORT FOR MANIPULATION

In this section, surveys and clinical trials showing some effect on blood pressure are reviewed. Included with the clinical trials is a discussion on the preferred levels for the administration of manipulative treatments chosen in each study.

Jamison et al. (1992) conducted a survey to establish whether Australian chiropractors regarded spinal manipulation as an intervention option for patients presenting with various visceral conditions. Despite this intervention being regarded as an obstacle to the recommendation of public funding, more than half the respondents favoured a role for spinal adjustment. Of these, they found that six per cent considered that in their opinion adjustments were useful in the management of hypertension.

Leboeuf et al. (1999) also conducted a survey. They collected retrospective information obtained by 87 Swedish chiropractors through a standardised interview of patients on a return visit. Of the 1504 valid questionnaires returned, at least one nonmusculoskeletal reaction was reported after the previous treatment in 21% to 25% of cases. Of these, 14% were classified under heart/circulation, and two of these respondents reported subjectively having reduced blood pressure.

For both the above surveys, the percentage of chiropractors or respondents advocating manipulative treatment for blood pressure is rather small. However, it may indicate that there is some basis for a relationship between spinal manipulative therapy and blood pressure.

Most frequent adjustment levels chosen by chiropractors in Jamison's (1992) survey were $T_{1\text{-}5}$, C_1 and C_2. This is supported by previous studies, which have based the area of spinal manipulative therapy administration on the location of autonomic neurological structures at which these reflexes occur (McKnight and DeBoer 1988; Yates et al. 1988; and Thompson and Webb 2001). McKnight and DeBoer (1988) adjusted the cervical spine, and Yates et al. (1988) and Thompson and Webb (2001) adjusted the upper thoracic spine. In the cervical spine, McKnight and DeBoer (1988) discuss the neurophysiology in the superior cervical ganglion, stellate nucleus, and vagus nerve, and the fact that they exert a strong influence on cardiovascular function. Thompson and Webb (2001) mention the cardiac sympathetic nerves, which emerge from the upper thoracic levels (T_1-T_5), as the structures that bring about the reflex effect in the thoracic spine.

Somatic sensory nerves are segmentally organised and, although more vaguely, so, too, are the autonomic efferents to the various organs (Sato 1992). Efferents to the heart originate from the brain stem and upper cervical spine as well as the upper thoracic region, whereas efferents to the adrenal medulla and kidneys stem from the lower thoracic region. Manipulating these regions of the spine would, according to the somatovisceral reflex theory as explained by Haldeman (2000), remove the fixation or subluxation and, in so doing, decrease stimulation from receptors in spinal and paraspinal tissues which in turn would decrease the activation of neural reflex centres that cause somatovisceral responses in autonomic nerves.

Thompson and Webb's (2001) study was a non-randomised, single-blinded controlled study to investigate the short-term effects of spinal manipulative therapy on blood pressure of normotensive patients. They manipulated only T_3/T_4 in a study evaluating 92 normotensive male chiropractic students with no history of cardiovascular or spinal disorders. Blood pressure readings, recorded one minute after a single intervention, were significantly decreased for both systolic and diastolic pressures in the experimental group, while in the TENS and control groups diastolic pressure displayed a non-significant increase, and systolic pressure displayed a significant increase. This led them to conclude that blood pressure, which is mediated through the autonomic nervous system, could be directly influenced by chiropractic manipulation to the upper thoracic spine.

A single blinded, randomised, controlled trial by Yates et al. (1988) examined the effects of adjusting upper thoracic (T_1 – T_5) vertebrae. They used a mechanical adjustment instrument manufactured by Activator Methods Inc., which delivers a

28-pound thrust within 1/300 of a second, to manipulate 21 patients with elevated blood pressure.

According to Brodeur (1995), the Activator adjusting tool may provide a means of stimulating the same high threshold receptors within periarticular tissue without occurrences of the cavitation associated with manipulation. This is possible, as the high velocity of these tools allows rapid stretch to occur, firing the high threshold mechanoreceptors before the muscle stretch reflexes can be initiated.

Elevated blood pressure for the Yates et al. (1988) study was classified as being greater than 130/90 mm Hg. Blood pressure measurements were taken immediately after the subject entered the room, immediately before treatment after a five- to ten-minute relaxation period, and immediately after treatment. Both the mean values for systolic and diastolic blood pressure decreased significantly (14.71 mm Hg and 13 mm Hg respectively) in the active treatment group. There was no significant change in the mean values for the placebo or control conditions. In fact, the placebo group decreased only 1.43 mm Hg and the control group rose 0.71 mm Hg. Although the study shows promising results, the sample sizes of each of the three groups are small, and the authors felt that more effective blinding procedures needed to be explored.

McKnight and DeBoer (1988) conducted a blinded, controlled, study to determine whether chiropractic adjustments cause any significant changes in the blood pressure of normotensive subjects. They separated their findings into statistically and clinically significant changes in blood pressure. Although they give no reason for their decision, they felt that a change of less than 8 mm Hg, although statistically significant, did not warrant any clinical or biological significance. Blood pressure readings were taken immediately before the chiropractic examination and one-minute immediately after the 53 normotensive subjects between the ages of 20 and 35 were given a single specific cervical adjustment. They chose the cervical spine based its close association with several major autonomic nerves and ganglia i.e. the sympathetic fibers from the superior cervical ganglion and parasympathetic fibers from the vagus nerve. The adjustment statistically (<3 mm Hg), but not biologically or clinically (>8 mm Hg), lowered the blood pressure in the experimental group compared to the placebo group. However, in 14 of the subjects the change was considered biologically significant (8-20mm Hg). They felt that this indicated that chiropractic adjustments could have a beneficial therapeutic effect in controlling mild-to-moderate hypertensive patients and that further controlled research studies into this aspect deserved priority.

The somatovisceral pathways involved in blood pressure changes that are situated in the cervical spine have their large ganglia (superior cervical ganglion and inferior vagal ganglion) situated in the upper cervical spine (Moore 1992: 815). The motor impulses in these fibres have their origin from cells in the brain stem known as cardiovascular centres (Little and Little 1989:252; and Smith and

Kampine, 1990: 162). Despite, this McKnight and DeBoer (1988) administered spinal manipulative therapy to the entire cervical spine. They concluded that the adjustment statistically, but probably not clinically, significantly lowered the blood pressure in their test subjects.

It is therefore questioned whether restriction of spinal manipulative therapy to the upper cervical spine, based on the anatomical location of the structures which bring about this effect, will show not only statistical, but also clinically significant reductions in blood pressure. Further analysis of the raw data in the McKnight and DeBoer (1988) study show that the 13 of the 14 subjects in whom a clinically significant reduction in blood pressure occurred received upper cervical spinal manipulative therapy. A tabulation of the level of manipulation relative to the change in blood pressure is shown in Table 1.

	Total subjects per area	**Statistically significant decrease**	**Biologically significant decrease**	**Significant increase**	**No significant change**
Upper cervical spine($C_0/C_1/C_2$)	36	34	13	1	1
Other cervical areas(C_{34567})	17	14	1	1	2
TOTAL	**53**	**48**	**14**	**2**	**3**

(Table 1)

2.8 SUMMARY

Hypertension is a common problem in Westernised nations, including South Africa. Maintenance of an adequate and constant blood pressure is important, and this is achieved by various short-term and long-term regulatory mechanisms involving the cardiovascular centre, the autonomic nervous system, neurohumoral factors, and the kidneys.

The nervous system's role in the induction of hypertensive disease is the least understood. The leading school of thought is that prolonged nervous tension causing increased levels of sympathetic tone in the blood vessels and kidneys causes chronically increased blood pressure. Manipulation is believed to ameliorate this problem by stimulating somatovisceral reflexes, modifying the autonomic nervous system's effects on these organs and structures. Previous studies have based the area of spinal manipulative therapy administration on the location of autonomic neurological structures at which these reflexes occur.

Several studies have shown that spinal manipulative therapy can decrease both systolic and diastolic components of blood pressure. Thompson and Webb's (2001) study showed a significant decrease of systolic and diastolic readings in normotensive subjects after a single manipulation to the T_3/T_4 thoracic levels. Yates et al. (1988) manipulated the upper thoracic region (T_1-T_5) of subjects with elevated blood pressure and also obtained significant decreases.

Despite the large autonomic ganglia controlling blood pressure being situated in the upper cervical spine, McKnight and DeBoer (1988) manipulated the entire cervical spine and found only a statistically significant decrease in blood pressure. Analysis of their raw data prompted the question of whether their results would have shown a clinically relevant change if the adjustments were restricted to the upper (atlanto-occipital and atlanto-axial articulations ($C_0/C_1/C_2$) cervical area only.

CHAPTER 3

MATERIALS AND METHODS

3.1 STUDY DESIGN AND PROTOCOL

This study used a prospective controlled clinical trial design. A total of 60 subjects from the greater Durban area in KwaZulu-Natal, South Africa, were recruited by canvassing for volunteers on the Durban Institute of Technology campus and in the general Durban area. Canvassing for subjects included approaching groups of students as well as members of the general public, explaining the study and asking for volunteers. Apart from the explanation of the study, a short description of the study was included on the canvassing sheet, indicating what was to be expected of volunteers (Appendix A).

Those who were interested were asked to fill in their details on the canvassing sheet, including name and telephone number, so that they could be contacted in order to be entered into the study at a time convenient to both themselves and the research. Non-probability purposive sampling was used in order to draw casual inferences.

3.2 INCLUSION AND EXCLUSION CRITERIA

All the applicants were screened for inclusion into the study by conducting a case history (Appendix B), a physical examination (Appendix C), and a cervical regional examination (Appendix D).

3.2.1 INCLUSION CRITERIA

In order to be accepted, the subjects had to comply with the following criteria:

- All subjects had to be Caucasian male. This was done to ensure homogeneity of the sample group and follows the methodology of Thompson and Webb's (2001) study.

- All subjects had to be normotensive; that is, their blood pressure recorded during the initial physical examination was below $^{140}/_{90}$ mmHg (Marieb 1998: 709). Seedat's (1989) classification of hypertension, i.e. a systolic pressure ≥ 160 mmHg and/or a diastolic pressure ≥ 95 mmHg was not used. This was done for two reasons:

  (1) Seedat's (1989) classification narrows the category for hypertension and broadens the category for normotensive. To decrease the

possibility for error and to increase the validity of the study, it is preferred to narrow the category for the classification of normotensive.

(2) Using Marieb's (1998: 709) classification is in keeping with past research (Thompson and Webb (2001), McKnight and DeBoer (1988), and Yates et al. (1988).

- All subjects had to be between the ages of 20 and 35 years old. This range is the same as for McKnight and DeBoer (1988).

- All subjects had to have a fixation at the ($C_0/C_1/C_2$) segments. Identification of such followed the principles of motion palpation according to Schafer and Faye (1990: 101-106). A qualified independent and blinded examiner corroborated the level and side of these findings.

- All subjects had to agree to abide by the conditions set out in the information sheet (Appendix E) and had to complete the informed consent document (Appendix F).

3.2.2 EXCLUSION CRITERIA

Applicants were excluded from the study if they:

- had a history of hypertension or were on medication for blood pressure management;
- were found to be beyond the normotensive range as set by Marieb (1998: 709), i.e. systolic pressure ≥ 140 mmHg and/or a diastolic pressure ≥ 90 mmHg;
- were using any medication that could alter blood pressure;
- smoked cigarettes on a daily basis;
- had any contra-indications to cervical spinal manipulative therapy. These include vertebral malignancy, tuberculosis, osteomyelitis, infectious arthritis, acute vertebral fracture, extreme osteoporosis, rheumatoid arthritis, and extensive disc prolapse with evidence of severe nerve damage. Relevant relative contra-indications include disc prolapse, spondylolisthesis, severe scoliosis, and vertebrobasilar insufficiencies (Triano 1992: 352).

- during, the examination procedure indicated the need for cervical spine radiographs; or

- suffered from any confirmed anxiety disorders or neuroses including 'white coat hypertension'. These disorders have the potential to variably affect blood pressure (Haslett et al. 1999: 217).

3.3 INTERVENTION

All blood pressure readings were recorded using a fully automated digital blood pressure monitor (Besmed Health Business Corporation, 2 lane 106, Wu-Kong, Taiwan, Republic of China). The manufacturing specifications (Appendix G) specify the unit to a range of 0mmHg to 300mmHg and an accuracy of 3mmHg (Besmed Health Business Corporation, 2001). As the blood pressure monitor has not been used in previous studies and lack of piloting or pre-testing is a common source of error when using new instrumentation (Mouton 2001: 103), a certificate of calibration was obtained from the suppliers (Appendix H) and a pilot study was also conducted in order to establish reliability of the instrument.

For the pilot study, 15 subjects were used. These subjects were chiropractic students and doctors who were present in the Chiropractic Day Clinic at the time. Blood pressure was first measured using the auscultation method with a mercury sphygmomanometer and stethoscope. Immediately afterwards, the blood pressure was again measured, but using the Besmed digital blood pressure unit (BE 300). Results showed the greatest deviation, positive or negative, when comparing readings from the Besmed digital blood pressure unit (BE 300) to the auscultation method at any reading, to be 8 mmHg, and the average deviation to be 3.26 mm Hg for the systolic reading and 2.8 mmHg diastolic reading (Appendix I).

This unit was selected instead of the usual method of sphygmomanometer and stethoscope in order to make the blood pressure measurement an objective rather than subjective measurement open to sources of human error.

Sources of observer error, according to O'Brian and O'Malley (1981: 41-46), include:

(1) training, owing to variability in blood pressure interpretation;

(2) observer bias;

(3) digit preference. Observers show a strong preference for terminal digits 0 and 5;

(4) viewing distance and angle;

(5) taking care and time. If the observer is interrupted, the measurement may be forgotten and estimated; and

(6) partial loss of hearing and background noise.

During the pilot study, these sources of error were minimised as much as possible. Clinicians on duty at the time made sure that blood pressure was taken correctly and that the correct procedure was followed for each subject. For the clinical trial, these sources of error were avoided by using the Besmed digital blood pressure unit (BE 300).

Of the 60 participants in the study, 30 were, by a method of simple consecutive randomisation, entered into a control group or an experimental group. The control group followed the same procedure as the experimental group with the exception that they did not receive any manipulation. The control group was used to eliminate the effects the experimental procedure may have had on the participants' blood pressure.

The initial screening examination formed the first phase of the study. This phase was used to obtain the basal blood pressure readings before the manipulation. The method used for recording the blood pressure was according to the instruction manual for the digital blood pressure unit (Appendix J). These readings were recorded at the initial physical examination, after the subject had been seated and relaxed for 15 minutes, and were recorded as reading A in the data collection sheet (Appendix K). An independent examiner verified the result by checking the reading on the Besmed digital blood pressure unit (BE 300). A cervical regional (Appendix D) was also completed. Dysfunctional joints were identified using Kemp's test and by motion palpation as described by Schafer and Faye (1990: 101-106). These motion palpation findings were also verified for level and side by an independent examiner.

Approximately a week later, the subject once again had his blood pressure taken in the same manner after being seated for 15 minutes, and an independent examiner again verified this. This period of time was used in order to calculate the basal blood pressure in the manner of Thompson and Webb (2001). This reading was recorded in the data collection sheet (Appendix K) as reading B. If these values were within the normal range for blood pressure, then the subject was entered into the experimental phase, phase two. Within one minute of taking blood pressure reading B, an upper cervical manipulation was administered. A post manipulation reading was then recorded within the minute following the manipulation and verified again by an independent examiner. This reading was recorded as reading C in the data collection sheet (Appendix K). This time-frame was used in order to approximate the McKnight and DeBoer (1988) method.

As an additional component, not addressed in previous studies, a further blood pressure reading was recorded 15 minutes after the post-manipulation reading, reading C. This was used to assess whether any changes, if present, were still present after 15 minutes. No previous studies have addressed this question so there was no set precedent from which to compare times to. Also, although 15 minutes can not be considered a long-term effect it would show if there were any sustained effect of the manipulation on the blood pressure. This period of time was also chosen, as it was convenient for the research process as longer periods would have increased consultation times. This reading will be labelled the '15 minute later' reading and shall also be recorded in the data collection sheet (Appendix K).

The Identified fixations were adjusted according to the techniques described by Schafer and Faye (1990: 127-132) and included the occipital lift, occipital posterior rotation on axis fixation, Atlantal posterior rotation on axis fixation, Atlantal lateral flexion on axis fixation, and Atlantal anterior rotation on axis fixation.

According to Brodeur (1995), upon reviewing articles related to joint cavitation and its relevance to manipulation, the cavitation process is a prerequisite to initiating the reflex actions that result from manipulation. Therefore, for the purpose of this study, the manipulation was judged successful upon hearing an audible cavitation.

3.4 ETHICAL CONSIDERATIONS

All subjects took part in the study on a completely voluntary basis. Each subject signed an informed consent form (Appendix F). Subjects all received an information sheet describing the study to them and explaining what was expected of them. They were informed that they could leave the study at any time if they so wished, and that all information would remain confidential.

3.5 DATA COLLECTION

This study made use of both primary and secondary data. The primary data consisted of the blood pressure readings recorded using the fully automated digital blood pressure monitor (Besmed Health Business Corporation, 2 lane 106, Wu-Kong, Taiwan, Republic of China). Other information stored in the patient's personal file included:

- a case history (Appendix B);
- the details for the physical examination (Appendix C);
- the details for the cervical spine regional examination (Appendix D); and
- a signed informed consent form (Appendix F).

Aside from the informed consent form, which is a requirement to comply with research regulations, the above forms are used by the Durban Institute of Technology Chiropractic Day Clinic.

Secondary data consisted of relevant published books and journal articles as well as information from reputable sites on the Internet.

3.6 STATISTICAL ANALYSIS

The Durban Institute of Technology statistician, Mr. K. Thomas, was consulted with regards to the method in which data from the research study should be analysed.

The SPSS computer statistical package version 9.0 (as supplied by SPSS Inc. Marketing Department, 444 North Michigan Avenue, Chicago Illinois, 60611) was used for analysis of the data which was transferred onto a spreadsheet in the SPSS© software package. The SPSS users guide was also referred to when necessary (SPSS Inc. 1999. SPSS base 9.0 users guide SPSS Inc.: Chicago. 740p. ISBN: 0-13-02030-4).

3.6.1 INTER-GROUP ANALYSIS

A comparison between independent samples was carried out using the unpaired t-test, a parametric test that compares the means of matched pairs or case-control study designs. The level of significance was set at 5%.

Hypothesis Testing:

The null hypothesis (H_0) stated that there was no difference in blood pressure (systolic and diastolic) experienced by either group upon entering the study or during the experimental phase. The alternative hypothesis (H_1) was that there was a difference between blood pressure readings measured in either group.

3.6.2 INTRA-GROUP ANALYSIS

As upon performing the unpaired t-test there was a significant difference between the two groups for one reading (B: systolic), a Friedman's T test was used to compare basal blood pressure readings (first visit and B).

Hypothesis testing:

- H_0: There was no difference in blood pressure (systolic and diastolic) experienced by either group.
- H_1: There was a difference in blood pressure experienced by either group.
- $\propto$, The level of significance, was set at 5%.
- Decision rule: If $p < \propto$, reject H_0

  If $p \geq \propto$, accept H_0

3.6.2.1 PAIRED T-TEST

The paired t-test was used to compare the blood pressure readings recorded for each group before and after manipulation.

Hypothesis testing:

- H_0: There was no difference in blood pressure (systolic and diastolic) experienced by either group for before and after manipulation readings.
- H_1: There was a decrease in blood pressure experienced by either group for before and after manipulation readings.
- $\propto$, The level of significance, was set at 5%.
- Decision rule: If $p < \propto$, reject H_0

  If $p \geq \propto$, accept H_0

3.6.2.2 FRIEDMAN'S T TEST

Friedman's T test was performed to corroborate and authenticate the findings of the paired t-tests, also comparing the readings taken before the manipulation phase to those taken after.

- H_0: There was no difference in blood pressure (systolic and diastolic) readings experienced by either group for before and after manipulation readings.

- H_1: There was a difference in blood pressure readings experienced by either group for before and after manipulation readings.
- $\propto$, The level of significance, was set at 5%.
- Decision rule: If $p < \propto$, reject H_0

  If $p \geq \propto$, accept H_0

As the null hypothesis (H_0) was rejected for the adjustment group, a multiple comparison test or Dunn's procedure was done in order to ascertain at which stages a significant change had occurred.

Summary statistics, including the mean, standard deviation and the raw data, were obtained and have been placed in the appendices (Appendix L) for reproducibility purposes.

CHAPTER 4

RESULTS

4.1 INTRODUCTION

This chapter comprises the statistical analyses of the blood pressure readings from the two groups carried out to assess whether manipulation to the upper cervical spine had any effect on the subjects' blood pressure. Inter and intra group comparisons were drawn.

4.2 CRITERIA GOVERNING THE ADMISSIBILITY OF DATA

Subjects who did not meet the criteria for the study were not included. All possible volunteers were screened for exclusion criteria during the canvassing process. Even so, five patients were excluded during the study, as their blood pressure readings were too high, i.e. over $^{140}/_{90}$.

4.3 DATA COLLECTED

A blood pressure reading comprising systolic (sys) and diastolic (dias) components was taken at the initial visit (first visit). During the following visit, three readings were taken. The first reading (B) was taken 15 minutes after being seated. After this, the adjustment group immediately received an upper cervical manipulation and, within the following minute, the second reading (C) was taken. Fifteen minutes later, the third and final reading was taken (15 minutes). All readings were verified by an independent examiner who checked the readings on the Besmed digital blood pressure unit (BE 300). The same format was used for the non-adjustment group with the exception of excluding the actual manipulation.

TABLE 4.3.1

FORMAT EMPLOYED FOR DATA COLLECTION

Visit 1		Visit 2						
First visit		B		Manipulated or not	C		15 minutes	
Sys	Dias	Sys	Dias		Sys	Dias	Sys	Dias

4.4 INTER-GROUP ANALYSIS

The first objective was to determine whether the two groups were similar upon entering the study. A statistical analysis determined whether there was a significant difference between the two groups at the time each reading was taken.

The unpaired t-test (independent or two-sample analysis), a parametric test, was used, as blood pressure is a continuous outcome measurement, and the sample size was 30, ($n \geq 30$). The level of significance for the difference between the two groups was set at 5% ($\propto = 0.05$). The null hypothesis (H_0) states that there is no difference in blood pressure (systolic and diastolic) experienced by either group upon entering the study or during the experimental phase. The alternative hypothesis (H_1) is that there is a difference between blood pressure readings measured in either group.

TABLE 4.4.1
INTER-GROUP ANALYSIS OF BLOOD PRESSURE READINGS

Reading	P Value (unpaired t-test)	
	Systolic	Diastolic
Visit 1	0.233	0.404
B	**0.038**	0.163
C	0.888	0.412
15 minutes	0.952	0.760
Decision rule:	**If $p < \propto$, reject H_0**	**If $p \geq \propto$, accept H_0**

The null hypothesis is accepted for all the readings except for B systolic at the level of 95% confidence level, indicating that there is statistically no difference between the adjustment and non-adjustment groups.

The null hypothesis is rejected for the B systolic reading at the 5% ($\propto$ = 0.05) significance, indicating that there was a statistically significant difference between the two groups for this measurement.

4.5 INTRA-GROUP ANALYSIS

4.5.1 COMPARISON OF BASAL BLOOD PRESSURE

Comparison was made between the reading for blood pressure at the initial visit and the first reading made at the second visit (B) for both groups. This was analysed, as there was a statistical difference between the two groups for the B systolic reading.

For this, Friedman's T test was used to analyse and compare, in both groups, the first visit blood pressure readings to those of the second visit before adjustment (B) readings with the level of significance set at 5% ($\propto$ = 0.05). The null hypothesis (H_0) states that there is no difference in blood pressure (systolic and diastolic) experienced by either group. The alternative hypothesis (H_1) is that there is a difference in blood pressure experienced by either group.

TABLE 4.5.1 INTRA-GROUP ANALYSIS OF BASAL BLOOD PRESSURES		
	P Value (Friedman's T test)	
	Non-adjustment group	Adjustment group
Systolic	0.450	0.433
Diastolic	0.336	0.353
Decision rule:	**If $p < \alpha$, reject H_0**	**If $p \geq \alpha$, accept H_0**

The null hypothesis (H_0) is accepted, as there was no significant change in the basal blood pressure between the initial visit and the second visit for both groups (table 4.5.1).

4.5.2 ANALYSIS OF BLOOD PRESSURE BEFORE AND AFTER MANIPULATION

4.5.2.1 PAIRED T-TEST

The paired t-test was used to compare the blood pressure readings recorded for each group before and during the experimental phase. The level of significance was again set at 5% (α = 0.05). The null hypothesis (H_0) states that there is no difference in blood pressure (systolic and diastolic) experienced by either group between each reading. If there is a difference in blood pressure experienced by either group then the alternative hypothesis (H_1) is accepted.

TABLE 4.5.2

INTRA-GROUP COMPARISON OF BLOOD PRESSURE READINGS

Group	Pair	p-values	t-values
Non-adjustment	B: systolic - C: systolic	0.759	-0.310
	B: diastolic - C: diastolic	0.345	0.960
	B: systolic - 15 minutes: systolic	0.638	0.476
	B: diastolic - 15 minutes: diastolic	**0.020**	2.464
	C: systolic - 15 minutes: systolic	0.526	0.641
	C: diastolic - 15 minutes: diastolic	0.410	0.835
Adjustment	B: systolic - C: systolic	**(< 0.001)**	-4.563
	B: diastolic - C: diastolic	**0.001**	-3.803
	B: systolic - 15 minutes: systolic	**(< 0.001)**	-3.932
	B: diastolic - 15 minutes: diastolic	0.056	-1.987
	C: systolic - 15 minutes: systolic	0.576	0.566
	C: diastolic - 15 minutes: diastolic	0.097	1.716
Decision rule:	**If $p < \alpha$, reject H_0**	**If $p \geq \alpha$, accept H_0**	

For all the statistical tests in the non-adjustment group, with the exception of B: diastolic vs. 15 minute: diastolic, the null hypothesis (H_0) is accepted at the 5% level of significance. For these tests it is evident that all the blood pressure readings, both systolic and diastolic other than B: diastolic vs. 15 minute: diastolic, remained constant throughout the study period.

In the adjustment group, however, the null hypothesis (H_0) is rejected for B: systolic vs. C: systolic, B: diastolic vs. C: diastolic, and B: systolic vs. 15 minutes: systolic. Therefore the alternative hypothesis (H_1), that there was a difference in blood pressure, is accepted for these tests, indicating that both systolic and diastolic blood pressure readings changed after manipulation and that there was still a difference 15 minutes later for the systolic reading.

The null hypothesis (H_0) is accepted for C: systolic vs. 15 minutes: systolic, C: diastolic vs. 15 minutes: diastolic, and B: diastolic vs. 15 minutes: diastolic, indicating that after manipulation both systolic and diastolic readings remained unchanged, although by the time of the 15 minute reading the diastolic pressure reading had returned to a similar level as pre-adjustment levels of the B: diastolic reading.

The t-values for calculations B: systolic vs. C: systolic, B: diastolic vs. C: diastolic, and B: systolic vs. 15 minutes: systolic were all negative (Table 4.5.2). This indicates that at the 95% level of confidence the change in blood pressure for these calculations was a decrease.

4.5.2.2 FRIEDMAN'S T TEST

In order to corroborate and authenticate the findings for the paired t-tests, Friedman's T test was performed on both groups and for both systolic and diastolic readings. Readings taken before the manipulation phase were compared to those taken after. The null hypothesis (H_0) states that there is no difference in blood pressure (systolic and diastolic) experienced by either group. The alternative hypothesis (H_1) is that there is a difference in blood pressure experienced by either group. The level of significance was set at 5% ($\propto = 0.05$).

TABLE 4.5.3 INTRA-GROUP ANALYSIS OF BLOOD PRESSURE		
	P Value (Friedman's T test)	
	Non-adjustment group	Adjustment group
Systolic	0.779	**(< 0.001)**
Diastolic	0.340	**0.010**
Decision rule:	**If $p < \alpha$, reject H_0**	**If $p \geq \alpha$, accept H_0**

The non-adjustment group does not show a change, whereas the adjustment group does for both systolic and diastolic readings. Therefore, the null hypothesis is accepted for the non-adjustment group and rejected for the adjustment group. Thus the alternative hypothesis, that there is a difference in blood pressure experienced, is accepted for the adjustment group at the 5% level of significance.

4.5.2.3 THE DUNN'S PROCEDURE (MULTIPLE COMPARISON TEST)

If for Friedman's T test the null hypothesis (H_0) is rejected, then a multiple comparison test needs to be applied to determine between which stages a significant change (blood pressure decreasing) has occurred.

The null hypothesis (H_0) was rejected for the adjustment group for both systolic and diastolic blood pressure readings, so the Dunn's procedure (shown below) was applied to determine at which stage during the study these blood pressure readings were significantly different.

Each systolic pressure reading (S) = S_j and S_j^1 and each diastolic reading (D) = D_j and D_j^1.

Let S_j and S_j^1 and D_j and D_j^1 be the j^{th} and j_1^{th} treatment rank totals.

Let $\propto$ be the experiment-wise error rate. Usually $\propto = 0.10$

If $/S_j - S_j^1/$ and/or D_j and $D_j^1 \geq Z$ respectively, then S_j and S_j^1 and/or D_j and D_j^1 are declared significant.

In the above formula:

b = the number of blocks.

k = the number of readings.

Z = value in inverse normal distribution corresponding to $(1-[\propto/k\ (k-1)]$

In this case, k=3, b=30, $\propto$=0.10, and Z=2.12

If the difference of systolic rank totals and/or diastolic rank totals $\geq$ 16.42, then S_j and S_j^1 and or D_j and D_j^1 are declared significantly different.

For the purpose of this study:

S1 is the systolic reading and D1 is the diastolic reading for B.

S2 is the systolic reading and D2 is the diastolic reading for C.

S3 is the systolic reading and D3 is the diastolic reading for 15 minutes.

TABLE 4.5.4 DUNN'S PROCEDURE FOR SYSTOLIC AND DIASTOLIC READINGS OF ADJUSTMENT GROUP				
	Rank total	**Difference**	**Rank total**	
S1	78.9	**30.9**	48.0	**S2**
S1	78.9	**25.8**	53.1	**S3**
S2	48.0	5.1	53.1	**S3**
D1	69.9	**22.5**	47.4	**D2**
D1	69.9	7.5	62.4	**D3**
D2	47.4	15	62.4	**D3**

Table 4.5.4 reveals that there was a change in blood pressure for systolic and diastolic readings immediately after manipulation, and that for the 15 minute reading this change was still significant only for the systolic reading. However, no significant change in systolic or diastolic blood pressure is shown between blood pressure readings (C) and 15 minutes.

CHAPTER 5

DISCUSSION

5.1 INTRODUCTION

This chapter considers the statistical analysis and results of Chapter 4 and relates these findings to the current literature discussed in chapter three.

5.2 DEMOGRAPHIC DATA

All subjects that were canvassed had to be Caucasian males between the ages of 20 and 35 years of age. Although this does not give a true reflection of the total population, it was preferred, owing to the variable nature of blood pressure, that the sample group be as homogeneous as possible. It is also in keeping with past research (Dulgar et al. 1980; Morgan et al. 1985; McKnight and DeBoer 1988; Yates et al. 1988; Nansel et al. 1991; Thompson and Webb 2001). All possible volunteers were screened for exclusion criteria during the canvassing process. Even so, five subjects (7.7%) who were previously unaware that they might have high blood pressure were excluded during the study, as their blood pressure readings were over $^{140}/_{90}$ mm Hg on that particular day. Steyn (1989), when commenting on Seedat's (1989) findings, reported the prevalence – that is, the proportion of people who have a condition at any one time (Bland 1995: 300) - of hypertension in white males of all age groups in Durban to be 24%. For this study, subjects were excluded if they had any history of hypertension or were on any hypertensive medication, and so these were not included in any analyses.

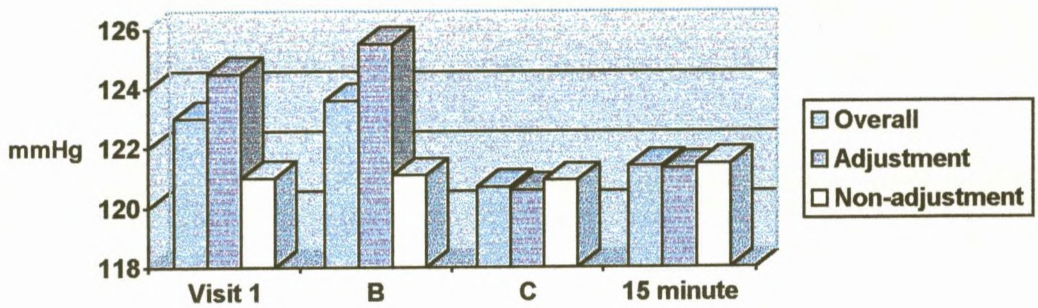
5.3 INTER-GROUP ANALYSIS

The statistical data is located in table 4.3.1.

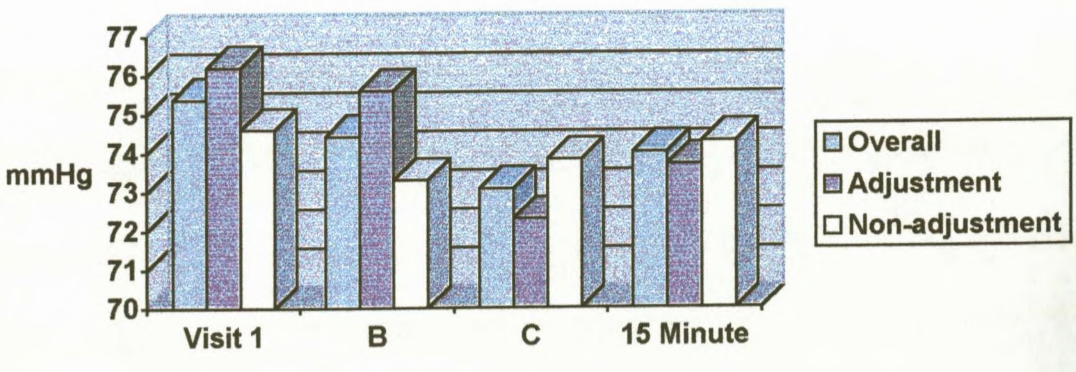
Analysis revealed that for all measurements made throughout the study period, including before and after manipulation readings (with the exception of B: systolic), both adjustment and non-adjustment groups were shown to have no significant statistical difference. Therefore, whether subjects received an upper cervical manipulation or not, with the exception of the B: systolic reading, each group remained statistically similar.

Only Yates et al. (1988) statistically compared the treatment group to non-treatment groups after manipulation. They found that blood pressure (systolic and diastolic) did significantly decrease for the treatment group as compared to the control and placebo groups. Unlike other studies, Yates et al. (1988) included only patients with elevated blood pressure rather than normotensive subjects, which possibly allowed for a larger post manipulative change in blood pressure as compared to the control and placebo groups. Other studies did only intra-group analyses to compare before and after blood pressure readings within each group. These studies, including this one (as is shown in 5.3), show statistical differences only with intra-group analysis.

Graph 1: Comparison of systolic means



Graph 2: Comparison of diastolic means



5.4 INTRA-GROUP ANALYSIS

5.4.1 COMPARISON OF BASAL BLOOD PRESSURE

The statistical data is located in table 4.4.1.

As the B: systolic reading was significantly different between the two groups, an intra-group analysis comparison was made. A Friedman's T test was used to analyse this at a 95% confidence level. It was found that for both groups there was no significant change between the initial visit and the pre-adjustment reading. So although there was a significant difference for this reading between the two groups, within the group it was not a significant change. Possible causes for this slight increase (1.46 mmHg) of the systolic reading was the small sample sizes and some pre-adjustment anxiety, as subjects were made aware of what group they were in during this visit.

5.4.2 ANALYSIS OF BLOOD PRESSURE BEFORE AND AFTER MANIPULATION

The statistical data is located in tables 4.4.2, 4.4.3, and 4.4.4.

First a paired t-test was used to compare the blood pressure readings recorded for each group before and during the experimental phase at the 95% level of confidence. Then to verify and add weight to these analyses, Friedman's T test was performed on both groups, also at the 95% confidence level. For the paired t-tests for the non-adjustment group, with the exception of B: diastolic vs. 15 minute: diastolic, the blood pressure readings (systolic and diastolic) remained constant throughout the study period. Friedman's T test showed for all readings (systolic and diastolic, including the B: diastolic vs. 15 minute: diastolic) that there was no significant difference in blood pressure within the non-adjustment group.

In the adjustment group, however, for both the paired t-tests and Friedman's T test, there was a significant decrease in the blood pressure readings (systolic and diastolic). For the paired t-test and Friedman's T test, systolic and diastolic C vs. 15 minute analyses did not show a significant change, showing that the blood pressure remained constant for the after manipulation readings. As there was a significant difference upon performing the Friedman's T test, a Dunn's procedure was executed. This multiple comparison test was done in order to show between which readings a significant change had occurred. Results were as for the paired t-test.

The results of the intra-group analyses correspond closely with past research, showing a statistical rather than biologically significant decrease in blood pressure immediately after manipulation. McKnight and DeBoer (1988) felt that in their study the less than 3 mmHg decrease that they showed for the adjustment group was not sufficient to be biologically significant. They discuss, however, that 14 patients in the adjustment group (n = 53) did show a biologically significant (8

– 20mmHg) decrease in blood pressure. They write that this could suggest a potential method for controlling mild-to-moderate hypertensive patients.

For this study, the average decrease was 5.53 mmHg for systolic pressure and 3.3 mmHg for diastolic pressure. This is greater than for the McKnight and DeBoer (1988) study, but not greater than the 8 mmHg that they considered biologically significant. The sample size for the adjustment group was 30 (n = 30), and 14 of these showed a greater than 8 mmHg decrease in blood pressure. If there had been a larger sample size, a greater average decrease in blood pressure may have been possible.

McKnight and DeBoer (1988) applied a single manipulation to any fixated level in the cervical spine. Restricting the manipulation to the upper cervical spine only, as was the case in this study, has increased the extent to which blood pressure has been reduced. Also of note was that the number of subjects showing a biologically significant reduction in blood pressure has remained the same despite this study having a smaller sample size (n=30). This could be due solely to the smaller sample size, or it is possible that the average number of subjects showing a biologically significant reduction in blood pressure post manipulation has increased. This reduction, as previously discussed, is still not biologically significant.

After fifteen minutes post-manipulation, the systolic blood pressure readings were still significantly different from the pre-manipulative readings in the adjustment group and, although it had risen slightly with respect to the immediately post manipulation readings, (0.7 mmHg), this was not shown to be significant. The diastolic blood pressure, however, showed a tendency towards significance ($p = 0.056$) rising 1.43 mmHg only from the immediately post manipulation reading, hence not being significantly different from pre-manipulation levels. This indicates that the effect of the manipulation on systolic pressure was sustained for at least fifteen minutes. This is an aspect that has not been addressed in previous studies, so unfortunately no comparisons with any literature can be drawn. However, even though this is only fifteen minutes, it is enough to warrant further investigation into the long-term effect of manipulation on blood pressure.

As can be seen in chapter 2.4 blood pressure is controlled over the short-term as well as the long-term by numerous influences. This makes it difficult to say any one factor causes a change in the blood pressure after a manipulation or that after blood pressure has been effected that any other factor in the many negative feedback mechanisms, could return the blood pressure to its former levels or could be involved in maintaining the altered blood pressure.

CHAPTER 6

RECOMMENDATIONS AND CONCLUSION

6.1 RECOMMENDATIONS

It is recommended that future studies take the following into consideration:

PLACEBO GROUP

The placebo group should rather be incorporated into the study. This could have been done either by:

- using them as their own controls, or
- using a sham procedure known not to affect blood pressure, such as the TENS used in the Thompson and Webb (2001) study. These subjects could then still be used in a cross-over procedure.

These steps would enhance the accuracy of the statistical analyses and in so doing increase the validity of the study. It would also have doubled the sample size of subjects receiving a manipulation, allowing for fewer errors than are encountered with smaller sample sizes.

SAMPLING

A larger sample size would have provided for a more reliable representation of the study population. In future, perhaps stratified sampling could be incorporated to include different racial groups and groups with females. Although for this study different groups were not included in order to gain greater homogeneity within the group, by using subjects as their own controls one can still keep sample sizes to reasonable levels even if different groups are added. This would reflect the South African population in a more representative manner.

ACCURACY OF MEASUREMENTS

All blood pressure readings were recorded using a fully automated digital blood pressure monitor (Besmed Health Business Corporation. 2 lane 106, Wu-Kong, Taiwan, Republic of China). After obtaining the certificate of calibration, completing the pilot study, and completing the data collection phase of the study, the author felt that the fully automated digital blood pressure monitor was accurate and reliable. The machine avoids the errors mentioned in Chapter 3 and keeps the measurements objective. An example of one of the errors that can be avoided is shown in the McKnight and DeBoer (1988) study where all their blood pressure readings are even numbers, which is highly improbable. It also had the advantage of being a simple and time-saving device.

FURTHER RESEARCH

This study perhaps asks more questions than it answers. These questions could be answered in future studies, which could ask:

- Would there be an accumulative effect if other areas, shown to decrease blood pressure, were manipulated as well as the upper cervical spine? Yates et al. (1988) manipulates $T_1 - T_5$ and Thompson and Webb (2001) manipulate $T_{3/4}$, and they both show there to be a statistical decrease in blood pressure after manipulating. Perhaps if both upper thoracic and cervical areas were manipulated, a biologically significant decrease could be revealed.

- As already discussed in 5.3, Yates et al. (1988) included only patients with elevated blood pressure, rather than normotensive subjects in their study, which possibly allowed for the larger biologically significant post manipulative change in blood pressure as compared with the control and placebo groups. The statistical decrease in blood pressure shown in this study should warrant further research of this kind on patients with mild or moderately elevated blood pressure. Of concern for research of this nature would be any vascular compromise of the basilar arteries such as from atherosclerosis, a possible sequel of hypertension (Boyling and Palastanga 1994: 682). Vascular compromise of these vessels can in fact occur even in young adults with normal arteries (Boyling and Palastanga 1994: 682). One could still go ahead with such research as long as the researcher is aware of the potential hazards and takes the necessary precautions. One would have to exclude potential subjects that showed any signs of dizziness, cervical vertigo dysequalibrium, or tested positive for vertebral artery insufficiency tests. These tests include extension and especially rotation of the cervical spine.

- As the statistical decrease in blood pressure was sustained for at least fifteen minutes, further investigation into the long-term effect of manipulation on blood pressure should be done. This could perhaps include an experimental phase of 1-week duration and 2 or 3 adjustments.

6.2 CONCLUSION

The purpose of this investigation was to determine the effect of spinal manipulative therapy to the atlanto-occipital and atlanto-axial articulations on the blood pressure of normotensive Caucasian male subjects. A prospective controlled clinical trial design was employed and the sample comprised sixty Caucasian male subjects who were recruited on a voluntary basis.

The results of this study suggest that blood pressure can be decreased by a single adjustment to the upper cervical spine. Although this effect was only statistically significant, it was shown to be more significant than manipulation directed to other areas of the cervical spine as in the McKnight and DeBoer (1988) study.

The results also suggest a sustained effect of the manipulation on the blood pressure. Although it was for only fifteen minutes and significant only for the systolic blood pressure, it is perhaps enough to warrant further investigation into the long-term effect of manipulation on blood pressure.

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APPENDICES

APPENDIX A

Canvassing Sheet

Research title: **The effect of spinal manipulative therapy to the atlanto-occipital and atlanto-axial articulations on the blood pressure of normotensive Caucasian male subjects.**

The research you are being asked to participate in will attempt to determine the effect of neck manipulation on blood pressure.

During the study you will receive a thorough examination to determine whether you are a suitable candidate. If you are suitable, your blood pressure will be monitored, and you will receive a single neck manipulation. You will be expected to attend two visits spaced over a week.

If you need any further information or require any help, please contact me at 204 2205 or Dr Mathews at 267 0788.

Your participation in this study will be greatly appreciated.

____

S. Sutherland (chiropractic intern).

Name	Telephone number

APPENDIX B

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:.. Date: ....

File # :.. Age : ....

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:** ....

All Conditions met in Visit No.:..

To be signed into PTT:...

Signature:.. **Date:** ....

Signed off:..

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		
▹ **Outcome:**		

4. **Other Complaints:**

5. **Past Medical History:**

▹ General Health Status

▹ Childhood Illnesses

▹ Adult Illnesses

- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. **Current health status and life-style:**

- Allergies
- Immunizations
- Screening Tests incl. xrays

- Environmental Hazards (Home, School, Work)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
  Analgesics/week:
- Tobacco
- Alcohol
- Social Drugs

7. **Immediate Family Medical History:**

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

8. Psychosocial history:

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

9. Review of Systems:

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

APPENDIX C

TECHNIKON NATAL

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:________________________ File#: ________________________ Date:___________
Clinician:________________________ Signature:________________________
Intern:________________________ Signature:________________________

1. VITALS

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

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

Percussion:
- borders of heart

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

4. RESPIRATORY EXAMINATION

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

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

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

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

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

5. ABDOMINAL EXAMINATION

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

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion
- Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

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

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

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:
b. Motor - Masseter:
- Jaw lateral movement:
c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

VII a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance.
- Show teeth:
- Blow out cheeks:
b. Taste - Anterior two-thirds of tongue:

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

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

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

XII Inspection of tongue (deviation):

Motor System:

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

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

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

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

Sensory System:

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

b. Joint position sense
- Finger:
- Toe:

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

Cerebellar function:

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

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

8. SPINAL EXAMINATION:(See Regional examination)

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

9. BREAST EXAMINATION:

Summon female chaperon.

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

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

APPENDIX D

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
REGIONAL EXAMINATION - *CERVICAL SPINE*

Patient: ______________________________ File: __________

Date: ______________ Intern/Resident: ____________________________

Clinician: __________________________ Sign: ________________

OBSERVATION:

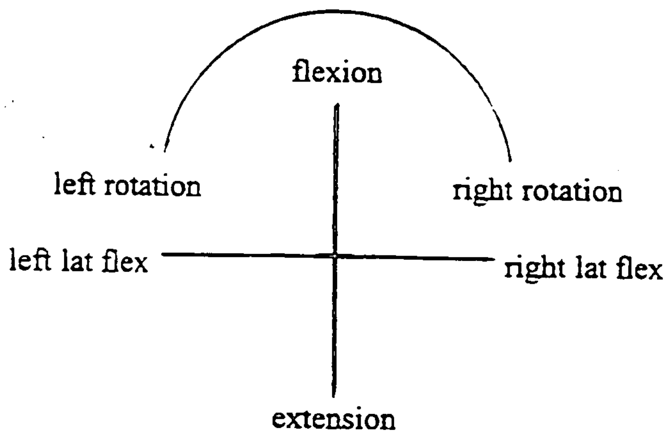
Posture
Swellings
Scars
Discolouration
Hair Line
Bony & Soft Tissue Contours

Shoulder position:
Left:
Right:
Muscle spasm
Facial expression

RANGE OF MOTION:

Flexion (45'):
L/R Rotation (70'):

Extension (70'):
L/R Lat Flex (45'):



PALPATION:

Lymph Nodes
Thyroid Gland

Trachea

ORTHOPAEDIC EXAMINATION:

Tenderness
Trigger Points: SCM
Scalenii
Post Cervicals

Trapezius
Lev Scap

Doorbell sign
Kemp's test
Cervical distraction
Halstead's test
Hyperabduction test
Shoulder abduction test

Cervical compression
Lateral compression
Adson's test
Costoclavicular test
Eden's test
Shoulder depression test

Dizziness rotation test
Brachial plexus tension

Lhermitte's sign

NEUROLOGICAL EXAMINATION:

Dermatomes	Left	Right
C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		

Myotomes	Left	Right
C1		
C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		

Reflexes	Left	Right
C5		
C6		
C7		

VASCULAR:

	Left	Right
Blood Pressure		
Carotid arts.		
Subclavian arts.		
Wallenberg's test		

MOTION PALPATION & JOINT PLAY:

Left: Motion Palpation:
Joint Play:

Right: Motion palpation:
Joint Play:

Basic Exam: Shoulder:
Case History:

ROM: Active:
Passive:
RIM:
Orthopaedic/Neuro/
Vascular:
Observ/Palpation:

Upper T horacics:
Motion Palpation:
Joint Play:

Basic Exam: Thoracic Spine:
Case History:

ROM: Motion Palp:
Active:
Passive:
Orthopaedic/Neuro/
Vascular:
Observ/Palpation:

APPENDIX E

PATIENT INFORMATION

Research title: **The effect of spinal manipulative therapy to the atlanto-occipital and atlanto-axial articulations on the blood pressure of normotensive Caucasian male subjects.**

Welcome to Technikon Natal Chiropractic Day Clinic. The research you will participate in will attempt to determine the effect of chiropractic therapy to the neck on a person's blood pressure.

You will receive a thorough examination to determine whether you are a suitable candidate for the study. If you are suitable your blood pressure will be monitored and you will receive a single chiropractic manipulation to your neck.

Please inform me if you are on any medication of any sort, particularly any drugs used to treat hypertension.

After neck manipulation mild neck pain and discomfort may occur, but this is rare and lasts only a few days.

You will be permitted to leave the study at any time, and all information remains confidential.

Personal information will be collected in a lawful manner by the researcher, and only if it is necessary and directly related to the research purpose. No deception will be used in this study, and no information will be hidden from you. Research will not be conducted if consent is not given or cannot be gained.

Thank you for your participation in this trial. If you need any further information or require further help, please contact:

The undersigned at 204 2205 or
Dr. R. Mathews at 267 0798

____

Scott Sutherland (Chiropractic Intern).

APPENDIX F

INFORMED CONSENT FORM

Date: ____/____/____

Research title: **The effect of spinal manipulative therapy to the atlanto-occipital and atlanto-axial articulations on the blood pressure of normotensive Caucasian male subjects.**

Name of patient:

____

Supervisor: Dr R. Mathews.
Research student: Scott Sutherland.

Please tick the appropriate answer	Yes	No
1. Have you read the research information sheet?		
2. Have you had an opportunity to ask questions regarding this study?		
3. Have you received satisfactory answers to your questions?		
4. Have you had an opportunity to discuss this study?		
5. Have you received enough information about this study?		
6. Do you understand the implications of your involvement in this study?		
7. Do you understand that you are free to withdraw from this study? a) At any time b) Without having to give a reason for withdrawing, and c) Without affecting your future health care.		
8. Do you agree to voluntary participation in this study?		

9. Whom have you spoken to?

____

If your answer to any of the questions above is no, please seek clarity from the researcher before signing below.

Please print in block letters:

Patient/Subject Name: ________________ Signature:____________________

Witness Name: ______________________ Signature: ___________________

Research Student Name: Scott Sutherland Signature: ___________________

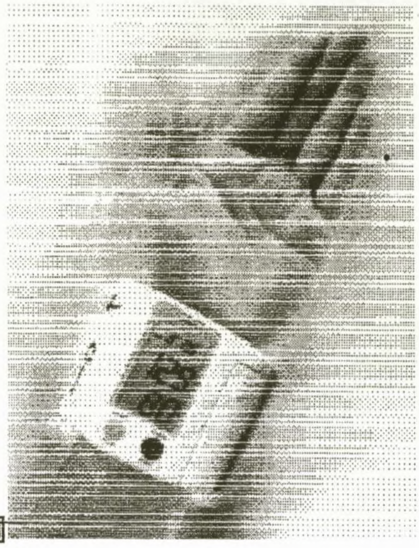
APPENDIX G

Products

Besmed

FUZZY
WRIST WATCH DIGITAL
BLOOD PRESSURE MONITOR

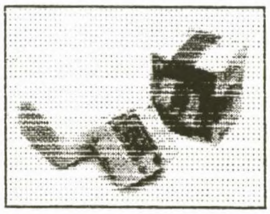
- New large LCD display
- Ergonomically designed cuff
- One touch auto inflation & deflation
- 7 memories function with data and time
- Average values of all measurements
- Automatic power off

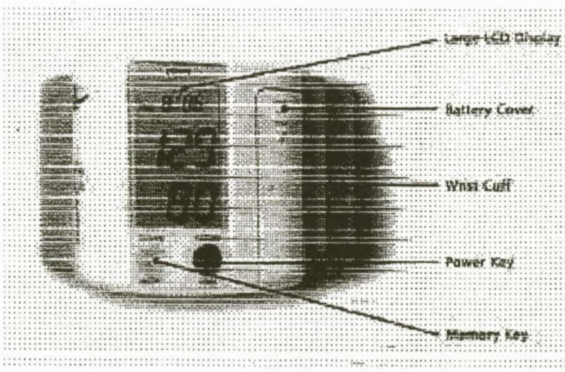


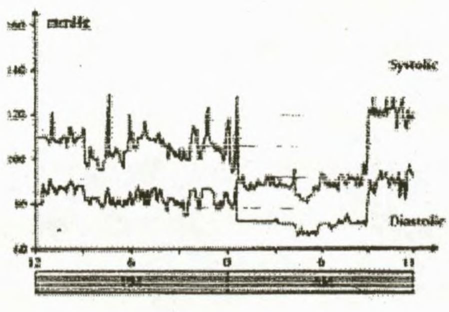
Price

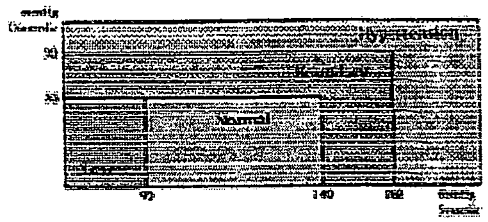
WRIST WATCH DIGITAL BLOOD PRESSURE MONITOR

- **NEW LARGE LCD DISPLAY**
  Designed for easy reading.
- **ONE TOUCH BUTTON FOR EASY OPERATION**
  Automatic cuff inflation & deflation.
- **MEMORY FUNCTION & AVERAGE VALUE**
  7 measurements are automatically stored.
  An average value of the stored datas are computed automatically.
- **ERGONOMICALLY DESIGNED CUFF**
  To eliminate inaccurate readings from wrong cuff wrapping.
- **AUTO POWER OFF**
  3 minutes after use.









SPECIFICATIONS

Function	Blood pressure measurement Pulse rate measurement Automatic inflation and deflation Memories Automatic power off
Indlcator	Systolic/Diastolic/Pulse rate 2 error messages 4 state symbols
B.P. M. Specifications	
Operating principle	Oscillo-metric method
Measuring range	0~300 mmHg(Cuff pressure) 35~160 pulses/min.(pulse rate)
Accuracy	¡Ó3 mmHg(Cuff pressure) ¡Ó5% of reading(pulse rate)
Inflation	Automatic inflation
Deflation	Constant release valve
Exhaust	Automatic exhaust valve
Cuff	Hard cuff
Battery life	6 months or more when used three minutes per day at use alkaline batteries.
Size	Main unit 80(W)¡Ñ80(D)¡Ñ30(H)mm Cuff unit 77¡Ñ280mm Wrist circumference 135~195mm
Weighe (Main unit)	Approx. 130grams including batteries

¡@

Back

APPENDIX H

HI TECH THERAPY NATAL c.c.

80 Clark Road
Glenwood
Durban

NIBP Calibration

CALIBRATION OF THE BESMED WRIST NIBP CHECKED ON THE CLINICAL DYNAMICS SMARTARM - (NIBP SIMULATOR)

Static results as follows

Smart-Arm:	Besmed Wrist NIBP:
200 mmHg	199mmHg
150 mmhg	148mmHg
100 mmHg	99mmHg
50 mmHg	50mmHg

Date: 30/10/2001

Technician J. HARDMAN

APPENDIX I

PILOT STUDY DATA SHEET

Name	Auscultation method	Digital blood pressure unit	Deviation
Lee-anne	127/88	134/80	7/8
Daryl	118/68	121/68	3/0
Caroline	122/82	123/78	1/-4
Dr Kruger	130/80	126/78	-4/-4
Derick	130/72	131/73	1/1
Laura	108/70	101/67	-7/-3
Garrick	130/80	126/76	-4/-4
Dave	118/65	115/65	-3/-2
Nicky	112/65	118/69	6/4
Emile	135/90	136/87	1/-3
Wayne	132/65	137/65	5/0
Charmaine	125/80	124/75	-1/-5
Hayley	97/55	99/52	2/-3
Tamsyn	108/60	106/59	-2/-1
Dr White	122/90	124/89	2/-1

The average deviation = 3.26/2.8

APPENDIX J

Besmed

Fully Auto Digital Wrist
Blood Pressure Monitor
INSTRUCTION

Model
BE-300

Besmed - Concern your Health

CONTENTS

Information you should know before operating the blood

pressure monitor.. 3,4

Parts identification.. 5

Explanation of Display Marks........................ 6

Preparation for use.................................. 7,8,9

How to operate the unit..................... ,10,11,12

Error message.. 13

Care and Maintenance.............................. 14,15

Specification.. 16

Caution

1.Please consult your physician to verify your blood pressure obtained by yourself at home.

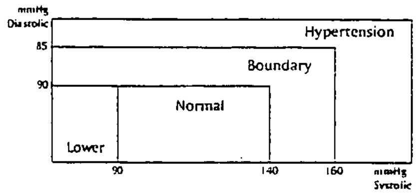
2.Detaching the cuff, if the pressure is more 320mmHg and does not deflate automatically.

Information you should know before operating the Blood Pressure Monitor

What is blood pressure ?
A force is created by the heart as it pushes blood into thearteries and through the biood circulation system. Another force is createcd by the arteries as they resist the blood flow. Blood Pressure is the result of these two forces.

What is Systolic and Diastolic ?
Systolic is the number representing the pressure while the heart is beating. Diastolic is the number representing the pressure when the heart is resting between beats.

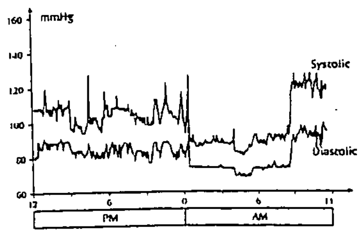
How can I tell my blood pressure ?
See the following chart-WHO(World Health Organization) blood pressure classification.



Information you should know before operating the Blood Pressure Monitor (Continued...)

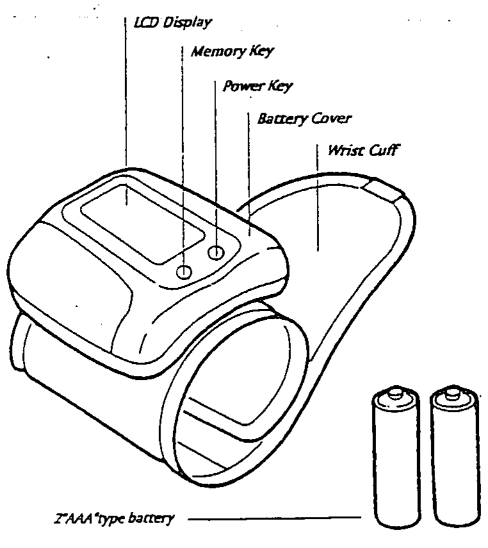
What about low blood pressure ?
In general, the lower blood pressure reading is the better, unless it causes some uncomfortable symptoms such as fainting and lightheadedness.

Fluctuation and Variation in blood pressure ?
The following chart shows the blood pressure fluctuation in a day.

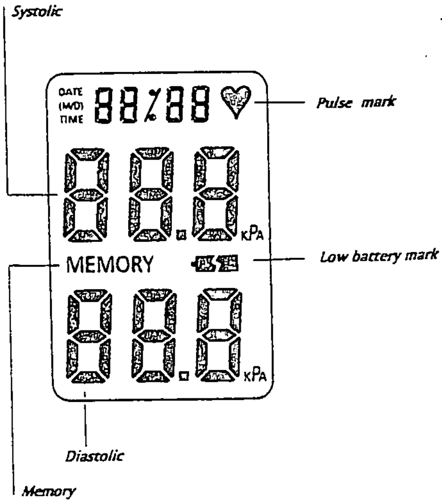


The following causes will influence the result of measuring blood pressure and cause the variations.
❶ Bathing ❷ Breathing ❸ Conversation ❹ Meals
❺ Drinking Alcohol ❻ Exercise ❼ Moving ❽ Thoughts
❾ Mental tension ❿ Temperature change ⓫ Smoking etc.

Parts identification



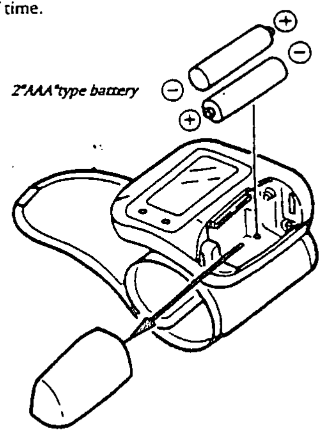
Explanation of Display Marks



Preparation for use

Battery installation/replacement

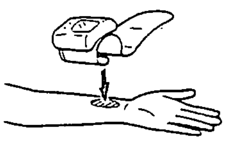
1.Insert the batteries inside the battery compartment with correct polarities"+"and"-".
2.Replace both batteries, if the low battery mark appears.
3.Remove the batteries if the unit will not be used for a period of time.



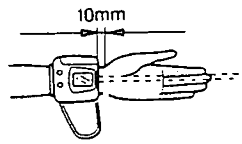
Preparation for use (continued...)

Attaching pressure cuff

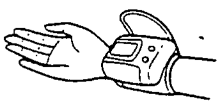
1.Wrap the cuff around the left wrist. The display should be placed on the palm side of the wrist. The wrist should be bare skin.



2.Fasten the cuff. Don't pull it strongly and make the cuff too tight. The cuff's edge should be approximately 1 cm from your palm line.



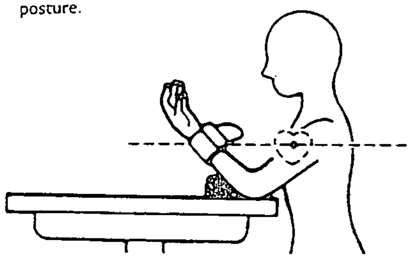
3.Attach the cuff on the right hand as shown in the figure if it is not possible to measure the left.



Preparation for use (continued...)

Correct Measuring

1.Corret posture
Sit with correct posture and place your arm on the storage case, so that the unit is the same height with your heart. Relax yourself and measure in a natural posture.

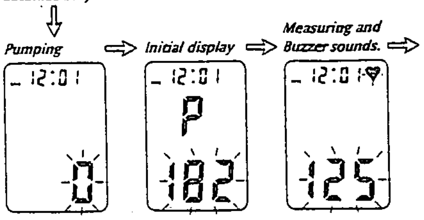


2.Measuring at the same time daily according the fluctuati on Mentioned, it is very important to measure and record the blood pressure at the same time every day in order to get the tendency of your blood pressure.

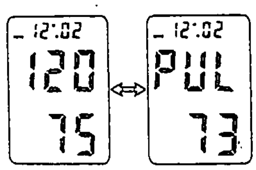
How to operate the unit

1.Measuring blood pressure

Press and release the POWER key to start measuring automatically



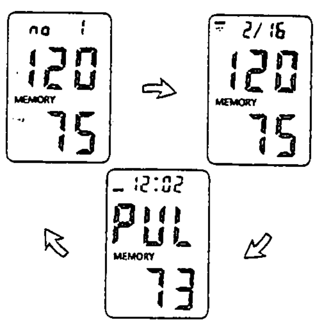
When the measurement was finished, the display will show the measued pressure and pulse value back and forth. Then, press the power key to turn off the unit. Otherwise the unit will trun off automatically in 24 seconds later.



How to operate the unit (continued...)

2.Recall the memories

Press and release the MEMORY key to recall the no.1 memory. The display will show the memorized pressure and pulse value back and forth. Press and release the MEMORY key again to recall the no.2 momory. Press and release repeatedly to read the no 3,4,5,6,7 memorized pressures. Subsequently, you will see the no 8 which is the average of all memorized values.

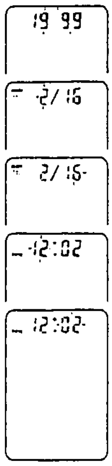


How to operate the unit (continued...)

3.Clock setting

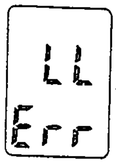
- To enter the setting mode by pressing and holding the memory key lasting for over 3 seconds.
  The display will show a blinking year firstly.
  Press the memory key to adjust the year when it is blinking.
  Secondly, to press and release the memory key, the "month" will appear and blink to be adjusted, and then "date","hour" and "minute"wil follow up as you press and release the memory key again.

  To adjust the clock by pressing the memory key to adjust the values of the "month", "date","hour", and "minute" when they are blinking.

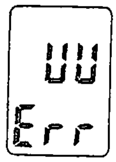


Error Message

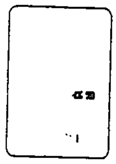
The pressure measured was lower than 20 mmHg
Please measure again.



The pressure measured was higher than 300 mmHg.
Please measure again.



Please replace the 2 batteries.

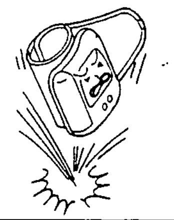


Check or Replace the 2 batteries and try again.

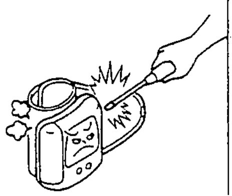
No display

Care and Maintenance

Do not drop the unit.

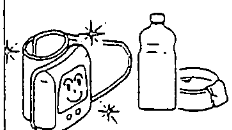


Do not modify or disassemble the body or the wristcuff.



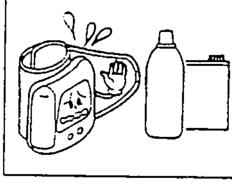
Do not bend or twist the wrist cuff.

Use a moistened cloth with water or neutral detergent to clean the body and then wipe it dry.

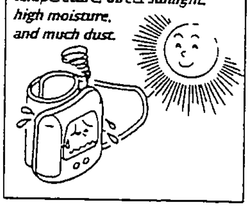


Care and Maintenance (continued...)

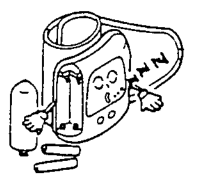
Avoid thinner and benzine.



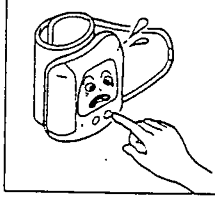
Keep the unit in an suitable place avoiding high temperature, direct sunlight, high moisture, and much dust.



Remove the batteries, if the unit will be not used for a long time.



Do not press the POWER key when the cuff has not been well wrapped.



Specification

Name and model......	Wrist Blood Pressure Monitor BE-300
Display System.........	Liquid Crystal Display
Measuring method...	Fully
Power Source...........	2 Alkaline "AAA" type batteries (1.5V)
Measuring range......	20~30 mmHg (Cuff Pressure) 40~200 Pulse/minute (Pulse Rate)
Accuracy....................	± 3mmHg or 2% (Cuff Pressure) ± 5% of Readings (Pulse Rate)
Inflation.....................	Automatic inflation (Air Pump)
Deflation.....................	Deflation valve
Repid air release......	Electric release valve
Memory......................	7 memories +Average value
Clock..........................	Year, Date, Time
Error Message..........	"Err LL" means the pressure was lower than 20 mmHg. "Err UU" means the pressure was higher than 300 mmHg.
Low battery.............	Replace the batteries if the indicator appears.
Power OFF................	Automatically after 24 seconds of non use.
Battery Life.............	Approximately 150 measurements.
Operating.................	+10°C ~ +40°C,
environment............	less than 85%RH
Storage......................	-10°C~+50°C
environment............	less than 85%RH
Dimensions.............	80(W) × 80(D) × 30mm(H)
Weight.......................	Apporx. 130g (including 2 batteries)

Note : Specifications are subject to change without notice for improvement.

Besmed

全自動數字型手腕型血壓計

操作說明書

BE-300

貝 斯 美 德 一 關 心 您 的 健 康

APPENDIX K

DATA COLLECTION SHEET

Patient number	Phase 1		Phase 2	
	A	B	C	15 minute
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				
20.				
21.				
22.				
23.				
24.				
25.				
26.				
27.				
28.				
29.				
30.				
31.				
32.				
33.				

APPENDIX L

SUMMARY STATISTICS

TABLE 7.1

DESCRIPTIVE STATISTICS FOR SYSTOLIC PRESSURE

Group	Reading	Mean rank	Mean	Minimum	Maximum	Standard deviation
Non-adjustment	B	1.97	121.10	90	136	10.32
	C	1.93	120.93	88	139	10.87
	15 minute	2.10	121.47	90	136	8.54
Adjustment	B	2.63	126.13	106	136	7.86
	C	1.60	120.60	102	134	7.05
	15 minute	1.77	121.33	101	135	8.54
Overall	Visit 1		123			
	B		123.6	90	136	

TABLE 7.2

DESCRIPTIVE STATISTICS FOR DIASTOLIC PRESSURE

Group	Reading	Mean rank	Mean	Minimum	Maximum	Standard deviation
Non-adjustment	B	1.82	73.27	61	87	7.19
	C	2.02	73.83	57	88	7.85
	15 minute	2.17	74.30	59	86	6.96
Adjustment	B	2.33	75.60	63	84	5.49
	C	1.58	72.33	56	82	6.12
	15 minute	2.08	73.73	56	87	7.36
Overall	Visit 1		75.4			
	B		74.4	61	87	

RAW DATA

NON-ADJUSTMENT GROUP

Patient number	Phase 1		Phase 2	
	A	B	C	15 minute
1.	121/70	124/74	121/81	123/75
2.	126/66	123/70	124/83	124/77
3.	105/66	102/63	100/63	104/67
4.	112/72	110/72	106/71	115/73
5.	123/67	123/65	122/66	121/68
6.	123/83	122/86	122/87	121/86
7.	124/75	121/76	113/74	122/76
8.	105/71	101/66	107/64	118/68
9.	126/76	126/67	131/68	127/68
10.	106/74	115/67	118/67	119/73
11.	101/59	107/61	110/60	110/59
12.	115/60	117/65	119/67	118/65
13.	121/80	123/74	122/76	124/75
14.	126/71	124/73	123/73	126/73
15.	135/82	129/76	130/76	127/75
16.	115/75	124/79	120/77	121/77
17.	121/73	127/73	125/75	125/73
18.	139/84	128/75	131/75	130/74
19.	139/89	136/87	139/86	138/87
20.	130/88	127/85	126/86	128/85
21.	124/75	126/75	125/76	125/77
22.	138/88	136/85	138/88	136/86
23.	123/81	125/82	126/78	121/86
24.	136/74	133/75	133/74	126/75
25.	128/76	122/72	123/72	120/70
26.	128/77	124/71	120/74	125/75
27.	108/65	115/70	113/68	116/69
28.	120/76	125/74	124/76	127/77
29.	133/80	128/79	129/77	127/80
30.	85/65	90/61	86/57	90/62

ADJUSTMENT GROUP

Patient number	Phase 1		Phase 2	
	A	B	C	15 minute
1.	132/74	124/75	125/76	125/78
2.	127/79	133/82	129/77	117/82
3.	123/79	115/65	125/73	121/71
4.	119/74	121/78	121/81	119/81
5.	130/90	127/79/	124/82	129/87
6.	110/64	126/68	102/56	105/58
7.	113/73	112/70	110/67	112/71
8.	130/68	130/70	125/67	133/68
9.	120/65	119/63	118/64	120/64
10.	117/78	119/80	118/70	110/76
11.	130/79	134/78	118/80	127/74
12.	131/81	133/76	124/74	122/68
13.	134/75	134/73	132/70	129/69
14.	140/78	136/74	131/65	135/78
15.	133/73	136/76	134/70	122/72
16.	115/82	129/78	118/70	126/74
17.	128/79	129/81	115/78	128/81
18.	129/79	127/80	124/76	122/75
19.	131/76	126/72	125/69	123/63
20.	129/73	134/76	120/71	134/72
21.	95/65	106/68	107/61	101/56
22.	133/79	135/83	123/77	133/85
23.	130/82	130/82	120/78	130/75
24.	121/76	120/79	118/76	113/81
25.	130/77	128/78	124/79	111/79
26.	113/87	113/80	112/73	116/75
27.	121/73	123/74	115/70	116/71
28.	136/85	134/84	121/76	120/75
29.	126/79	130/81	122/76	121/77
30.	114/63	121/71	118/68	118/66