

The efficacy of a conservative chiropractic  
management approach in the treatment of  
symptomatic hallux abductovalgus (bunions)

By

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I, Sioban Guiry do hereby declare that this dissertation represents  
my own work both in conception and execution.

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## DEDICATIONS

This work is dedicated to the following people:

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## ABSTRACT

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The purpose of this study was to determine the efficacy of a conservative chiropractic management approach in the treatment of symptomatic hallux abductovalgus (bunions).

The study was a prospective, randomised clinical trial involving sixty subjects, thirty in each group, which were selected from the general population. Group A received a conservative chiropractic management approach, encompassing progressive mobilization of the first metatarsophalangeal joint, used in conjunction with cryotherapy and adjustment of all other fixations found in the foot and ankle. Group B received a placebo treatment by means of de-tuned Action Potential Therapy administered to the involved foot. Each group received six treatments over a two-week period and attended a one-week follow up consultation for data collection.

Objective assessment was performed by measuring the pressure pain threshold using a digital algometer. Subjective assessment was by means of the Numerical Rating Scale-101 (NRS-101) and the Foot Function Index (FFI). The Hallux-metatarsophalangeal-interphalangeal Scale (HAL) incorporated assessment of both objective and subjective measurements. Assessments were taken at the first, third, sixth and one week follow-up consultations, for all the subjective and objective data.

Statistical analysis was completed under the supervision of Mr K. Thomas at the Technikon Natal, at a 95% confidence interval. The parametric two-sampled paired t-test, the Friedman's test and the Dunn's post test were used to analyse the data within each group (intra-group analysis), whilst the parametric two-sampled unpaired t-test and the non-parametric Mann Whitney unpaired U-test were used to analyse the data between the two groups (inter-group analysis).

In terms of objective findings, analysis of the treatment group revealed a statistically significant improvement in the pressure pain threshold (algometer readings) at each treatment interval, whereas the placebo group had no statistically significant improvement for this measurement.

In terms of the patients' subjective response to treatment, both groups experienced a statistically significant decrease in pain perception (NRS-101) in the overall treatment interval, however, only the treatment group had a statistically significant improvement in pain perception at the early and intermediate intervals. A statistically significant improvement in the foot function index (FFI), in terms of pain and disability experienced by the patient, was noted in the treatment group only.

On assessment of the Hallux-metatarsophalangeal-interphalangeal Scale, both groups revealed a statistically significant improvement in the overall treatment interval, however the improvement in the placebo group was only found to be in the subjective aspect of the scale.

A statistically significant difference was noted between the treatment and placebo groups at the third, sixth and one week follow up consultations, for each measurement parameter assessed. This difference indicated greater improvement in the treatment group when compared to the placebo group, in terms of each measurement parameter.

It was concluded that this conservative chiropractic management approach was effective, in terms of objective and subjective measurements, in the treatment of patients suffering from symptomatic hallux abductovalgus (bunions). It was found that the placebo treatment was effective in alleviating the pain perceived by the patients in the overall treatment interval (NRS-101), however this improvement was not substantiated by any significant improvement in the foot function index (FFI) and the objective assessment of the patients pressure pain threshold levels.

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## ABBREVIATIONS USED IN CHAPTER FOUR

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<b>APT</b>	Action Potential Therapy
<b>FFI</b>	Foot Function Index
<b>HAL</b>	Hallux-metatarsophalangeal-interphalangeal Scale
<b>Me</b>	Mean
<b>NRS-101</b>	Numerical Rating Scale-101
<b>P-Value</b>	Level of significance
<b>Sd</b>	Standard Deviation
<b>Se</b>	Standard Error

## DEFINITION OF TERMS

---

### ADJUSTMENT

The chiropractic adjustment is a specific form of direct articular manipulation utilising either long or short leverage techniques with specific contacts. It is characterised by a dynamic thrust of controlled velocity, amplitude and direction (Bergmann, Peterson and Lawrence, 1993:754).

### ALGOMETER

This instrument measures the patient's sensitivity to pressure in terms of kilograms per squared centimetre (Fischer, 1986).

### BUNION

A bunion complex is composed of three components namely: the big toe deviates laterally towards the second toe, the medial portion of the first metatarsal head enlarges and the bursa over the medial portion of the first metatarsophalangeal joint becomes inflamed and thickened (Cailliet, 1997:163).

### CHIROPRACTIC

A discipline of the scientific healing arts concerned with the pathogenesis, diagnostics, therapeutics and prophylaxis of functional disturbances; pathomechanical states, pain syndromes and neurophysiological effects related to the statics and dynamics of the locomotor system, especially of the spine and pelvis (Bergmann, Peterson and Lawrence, 1993:756).

### FIXATION

The state whereby an articulation has become temporarily immobilised in a position which it may normally occupy during any phase of physiological movement. The immobilisation of an articulation in a position of movement when the joint is at rest, or in a position of rest when the joint is in movement (Bergmann, Peterson and Lawrence, 1993:758).

## **HALLUX ABDUCTOVALGUS (HAV)**

This refers to a common deformity involving a prominence of the medial aspect of the first metatarsal head and a lateral deviation of the big toe (Levy and Hetherington, 1990).

## **JOINT DYSFUNCTION**

Joint mechanics showing area disturbances of function without structural change. Subtle joint dysfunction affecting quality and range of joint motion. It is diagnosed with the aid of motion palpation and stress and motion radiography investigation (Bergmann, Peterson and Lawrence, 1993:759).

## **MANIPULATION**

Therapeutic application of manual force. Spinal manipulative therapy broadly defined includes all procedures where the hands are used to mobilise, adjust, apply traction, massage, stimulate or otherwise influence the patient's health (Bergmann, Peterson and Lawrence, 1993:760).

## **MOTION OF THE FOOT**

To be consistent with the more current literature, this study will refer to motion of the foot, hallux and metatarsals as they relate to the midsagittal plane of the body (Michaud, 1993: 14).

## **OBJECTIVE CLINICAL FINDINGS**

Those findings obtained from recording the patient's pressure pain threshold using the algometer.

## **PALPATION**

The application of variable manual pressure through the surface of the body for the purpose of determining the shape, size, consistency, position, inherent motility and health of the tissues beneath (Bergmann, Peterson and Lawrence, 1993:758).

- **Motion palpation-** palpatory diagnosis of passive and active segmental joint range of motion.



**PLACEBO**

A dummy treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished (Dorland and Newman, 1998:1299). For the purpose of this study the placebo treatment will be the application of de-tuned Action Potential Therapy administered to the involved foot.

**SUBJECTIVE CLINICAL FINDINGS**

Those findings obtained from the subjects' in response to the NRS-101, FFI and part of the Hallux-metatarsophalangeal-interphalangeal Scale.

## Chapter One

---

### 1.1 Introduction

Hallux abductovalgus (HAV) is defined as a "common deformity that involves a prominence of the medial aspect of the first metatarsal head and a lateral deviation of the great toe" (Levy and Hetherington, 1990:828). Brantingham et al. (1994) and Cimon (1999) highlight how the terms hallux abductovalgus and bunion are often used interchangeably in the current literature. Magee (1992:454), however, defines a bunion as a combination of three components namely: callus, thickened bursa and bony exostosis which overlie the HAV deformity. Therefore the abbreviation HAVB (hallux abductovalgus bunion) used by Broodryk (2000) will be used for the purpose of this study.

### 1.2 Aim

The aim of this placebo-controlled study was to determine the efficacy of a conservative chiropractic management approach in the treatment of symptomatic HAVB in terms of objective and subjective clinical findings.

### 1.3 Objectives

#### *1.3.1 Objective One*

The first objective was to determine the efficacy of a conservative chiropractic management approach in the treatment of symptomatic HAVB in terms of objective clinical findings.

### **1.3.2 Objective Two**

The second objective was to determine the efficacy of a conservative chiropractic management approach in the treatment of symptomatic HAVB in terms of subjective clinical findings.

## **1.4 Hypotheses**

### **1.4.1 Hypothesis One**

It was hypothesised that a conservative chiropractic management approach would be effective in the treatment of symptomatic HAVB in terms of objective findings.

### **1.4.2 Hypothesis Two**

It was hypothesised that a conservative chiropractic management approach would be effective in the treatment of symptomatic HAVB in terms of subjective findings.

### **1.4.3 Hypothesis Three**

It was hypothesised that a conservative chiropractic management approach would be more effective than placebo treatment in the management of patients with symptomatic HAVB.

## 1.5 Purpose of the study

HAVB is frequently referred to as a common deformity (Cimons, 1999; Brantingham et al., 1994 and Levy and Hetherington, 1990:827) however few clinical trials seem to be available to accurately determine the incidence and prevalence of this condition. Hattrup and Johnson (1985) estimate that this condition is present in approximately three to seventeen percent of the population dependent on age.

Brantingham et al. (1994) are of the opinion that the controversy concerning the aetiology of HAVB is most likely based on the fact that this condition is caused by a multitude of functional and structural aberrations. Other aetiological aspects such as a familial predisposition and the use of high-heeled shoes with pointed toe boxes are frequently highlighted in the available literature (Klenerman, 1991:59-60; Cailliet, 1997:164; Reid, 1992:148 and Yale, 1987:34).

The more traditional treatment for HAVB is surgery (Khan, 1996), however one must consider the risks of post-operative complications such as recurrence of the deformity, scarring, avascular necrosis, infection and joint hypomobility (Jahss, 1991:943). Yale (1987:397) highlights that more than one hundred surgical procedures exist for the treatment of HAVB, most of which have been discarded. Similarly, Jahss (1991:943) is of the opinion that most of these procedures are biomechanically unsound and that complete recovery from surgical intervention may take up to a full year and thus recommends that all forms of conservative care should first be considered.

Reid (1992:149) is of the opinion that conservative care is mainly preventative, encompassing footwear, footbaths, strapping, relief padding and patient education. A number of studies have been performed to assess the benefit of various conservative interventions in the treatment of HAVB, such as the use of thermoplastic night splints (Groiso, 1992) and the use of in-shoe arch supports (Kilmartin, Barrington and Wallace, 1994), Groiso (1992),

however, is of the opinion that the efficacy of these conservative treatment strategies remains questionable.

Furthermore, in a study performed by Ferrari, Higgins and Williams (2001), the authors evaluated twelve different randomized clinical trials of conservative, surgical and post surgical treatment protocols for HAVB. In all of these trials the authors found little or no difference between the treatment and non-treatment groups and are of the opinion that there is insufficient evidence to determine which treatment strategies are most appropriate for this condition.

The benefits of adjustment and mobilization include restoring normal joint range of motion, reduction of pain and alleviation of associated muscle spasm (Bergmann, Peterson and Lawrence, 1993:137-157). Maitland (1986:287-289) and Edmond (1993:161-163) are of the opinion that mobilization and manipulation of the first metatarsophalangeal joint (MPJ), particularly adduction movements are effective in the treatment of HAVB. Brantingham et al. (1994) report on a case study evaluation in which a patient suffering from HAVB experienced nearly one hundred percent improvement in his symptoms in only five treatments. The patient was treated using a progressive mobilization technique of the first MPJ with adjustment of all other associated dysfunctions found in the foot and ankle. The use of ultrasound, cryotherapy, hydrotherapy baths and orthoses were also incorporated in the treatment protocol.

The possible benefits of adjustment and mobilization in the treatment of HAVB, as highlighted by the aforementioned authors, appear to be based on their extensive clinical experience and knowledge. Little categorical or scientific data is available in the current literature to determine accurately the efficacy of this treatment intervention. The case study evaluation by Brantingham et al. (1994) incorporated a multiple treatment protocol that may have considerably influenced the positive outcome in this patient. Thus, the need for clinical evaluation of the use of mobilization and adjustment in the treatment of symptomatic HAVB was evident.

## Chapter Two: Literature Review

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### 2.1 Introduction

Yale (1987:346) defines hallux abducto valgus (HAV) as a term given to the deformity in which the great toe, to an exaggerated degree, is abducted or abducted and everted. The author highlights how this position is maintained by accommodative changes in the articular cartilage, ligaments, joint capsule and associated tendons.

Brantingham et al. (1994) highlights the interchangeable use of the terms HAV and bunion in the available literature, as is evident in the work of Cailliet (1997:163) and Skinner (1995:388). It is however important to note that HAV refers to a "common deformity that involves a prominence of the medial aspect of the metatarsal head and a lateral deviation of the great toe" (Levy and Hetherington, 1990:828). The term bunion [derived from the Latin word "bunio", meaning turnip (Brantingham et al., 1994)] refers to a combination of callus, inflamed and thickened bursa and bony exostosis (Magee, 1992:454) which overlies the HAV deformity.

Klenerman (1991:57) further categorizes the HAV/bunion complex, where the following conditions may co-exist:

- Rotation of the hallux
- Overriding of the hallux and the second toe
- Overriding of the lateral toes
- Metatarsalgia
- Hammer and claw toe deformities
- Bunionette of the fifth metatarsal

The abbreviation HAVB (hallux abductovalgus bunion) was used for the purpose of this study (Broodryk, 2000).

## 2.2 Epidemiology

HAVB is frequently referred to as a common deformity (Brantingham et al., 1994; Khan, 1996; and Levy and Hetherington, 1990), however little categorical evidence appears to be available to determine accurately it's incidence and prevalence (Ferrari, Higgins and Williams, 2001). In a study performed by Hattrup and Johnson (1985) the authors estimated that HAVB is present in approximately three to seventeen percent of the population dependent on age.

Gould, Schnelder and Ashikaga (1980) devised a questionnaire to ascertain the type and incidence of foot problems in the USA. Forty five thousand copies of this questionnaire were sent to fourteen participating family shoe stores. The number of copies sent to each store was determined by the population in that area, so that the data would be representative of a continental United States.

From the results obtained in the aforementioned study, it was estimated that the incidence of bunions in the four previously determined age groups were as follows:

AGE	INCIDENCE	MALE: FEMALE RATIO
4-14	Rare: 1 in 2500 whites 5x as frequent in blacks and others.	1:1
15-30	1 in 33 whites 4x as frequent in blacks and others.	1:2
31-60	1 in 11 whites 2x as frequent in blacks and others.	1:4
60+	1 in 6 whites 2x as frequent in blacks and others.	1:3.5

This data also portrays an apparent increased incidence of HAVB in females, a fact readily supported in the current literature (Levy and Hetherington, 1990:829; Cailliet, 1997:163 and Magee, 1992:456). Klenerman (1991:58) reports that ninety percent of HAVB cases presenting for surgery are females and Jahss (1991:945) is of the opinion that the use of high-heeled shoes with pointed toe boxes accounts at least in part for the 9:1 greater incidence of HAVB in women.



## **2.3 Structural/functional anatomy and biomechanical considerations**

The foot and ankle are composed of 28 bones and 55 articulations, which function intricately to allow for a multitude of activities throughout the gait cycle (Michaud, 1993:1). "Unaided support and bipedal locomotion are the two main functions of the human foot" (Reid, 1992:129), acting as a rigid structure and flexible lever respectively (Magee, 1992:448). This has led to a high degree of anatomical specialization (Reid, 1992:129).

### **2.3.1 Anatomy**

The foot is divided into three subsections, namely: the hindfoot, midfoot and forefoot (Donatelli, 1990:3). The forefoot comprises the tarsometatarsal, intermetatarsal, metatarsophalangeal (MPJ) and interphalangeal joints (Magee, 1992:449). The MPJ are articulations between the heads of the metatarsal bones and the bases of the proximal phalanges (Moore, 1992:449). These joints are condyloid, synovial articulations (Reid, 1992:131) permitting predominantly flexion/extension movements (Michaud, 1993:13) with some abduction, adduction and circumduction (Moore, 1992:493).

Each MPJ is surrounded by an articular capsule (Cailliet, 1997:164), which passes deep into the dorsal and plantar aspects of the involved bones (Moore, 1992:493). The fibrous capsule of these joints is strengthened on both sides by thick collateral ligaments (Cailliet, 1997:164) and the plantar aspect is thickened into a fibrocartilaginous plate called the plantar ligament (Moore, 1992:493). This plate in turn provides attachment for the fibrous flexor sheath, deep transverse metatarsal ligament and plantar aponeurosis (Donatelli, 1990:25).

The first MPJ is the largest of these joints due to the increased size of the metatarsal head (Moore, 1992:493) and the presence of the sesamoid bones found in the tendon of the flexor hallucis brevis muscle (Cailliet, 1997:166).

The medial and lateral sesamoids are the sites of attachment of several important soft tissue structures such as the oblique head and transverse component of the adductor hallucis muscle, deep transverse metatarsal ligament and the flexor hallucis longus fibrous tunnel (Donatelli, 1990:26). These sesamoid bones maintain correct alignment of the flexor hallucis longus tendon (Moore, 1992:473) and are responsible for absorption of vertical pressure during the push off phase of gait (Donatelli, 1990:26). The first metatarsal head has no muscular insertion and thus is supported in a sling of muscles and tendons, allowing for lateral or medial deviation dependent on the position of the proximal phalanx (Skinner, 1995:390).

### **2.3.2 Biomechanics**

Reid (1992:130) is of the opinion that during walking the maximum force across the first MPJ is approximately equal to the body weight. The load distribution during stance phase is considered to be evenly dispersed between the heel and the metatarsal heads (Soderberg, 1997:331), with twice as much of the load in the forefoot being carried by the first MPJ (Donatelli, 1990:25).

HAVB influences gait due to the impact of the great toe in push off, as the patient is likely (due to discomfort) to attempt push off with greater loading through the lateral aspect of the foot (Soderberg, 1997:329).

Dorsiflexion of the first MPJ is important in the windlass mechanism (Donatelli, 1990:24), as the plantar aponeurosis, which attaches to the calcaneus and proximal phalanges (Moore, 1992:495), curves around the first metatarsal head increasing the longitudinal arch (Cailliet, 1997:164) and thus effectively produces a stable lever for push off (Reid, 1992:131). In the development of HAVB, the altered alignment of the hallux decreases the stabilization

mechanism of the big toe by diminishing the windlass effect. This results in a shift of weight bearing to the lateral toes and metatarsal heads (Cailliet, 1997:164).

Movement of the first MPJ occurs in two cardinal planes, namely sagittal (dorsiflexion/plantarflexion) and transverse (adduction/abduction) plane movements (Donatelli, 1990:24-25). Sagittal plane movement is extremely important for normal locomotion (Michaud, 1993:13-15) whereas abduction/adduction movements occur to a lesser degree (Reid, 1992:131) and are of no significance during the gait cycle (Michaud, 1993:13-15). However Jahss (1991:945) is of the opinion that the abduction/adduction movements play a significant role in the development of metatarsus primus varus, a structural variance thought to predispose to the development of HAVB.

The instant center of rotation of the first MPJ lies within the head of the metatarsal (Michaud, 1993:13). The HAVB deformity alters this axis of rotation (Donatelli, 1990:25) and simultaneously decreases the distal sesamoid displacement (necessary for sufficient dorsiflexion of the first MPJ) due to the associated lateral subluxation of the FHL muscle laterally (Donatelli, 1990:25).

Wadsworth (1988:203) is of the opinion that in order to achieve normal locomotion, dorsiflexion (sixty to ninety degrees) of the first MPJ must be greater than plantarflexion (forty to fifty degrees). Donatelli (1990:24) highlights that at least sixty to seventy degrees of dorsiflexion is needed to develop ample tension in the plantar aponeurosis. Jahss (1991:945) indicates that for athletes to achieve optimal performance at least ninety degrees of dorsiflexion of this joint is needed at toe-off and may be as high as one hundred degrees in ballet dancers. Thus any anatomical variance of the first MPJ may result in aberrant biomechanics and affect normal locomotion. HAVB has a pronounced effect on the biomechanics of the foot (Jahss, 1991:459) by altering both the geometry of the foot and the external forces placed on it.

## 2.4 Aetiology

Several conceptual models have been proposed regarding the aetiology of HAVB (Cailliet, 1997:166 and Yale, 1987:346). However, based on the complexity of the deformity (Klenerman, 1991:57), most authors are of the opinion that a multi-factorial aetiology exists (Brantingham *et al.*, 1994; Magee, 1992:456; Klaue, Hansen and Masquelet, 1994 and Klenerman, 1991:57).

### 2.4.1 Hereditary factors

Yale (1987:346) estimates that approximately thirty percent of HAVB deformities are of congenital origin or hereditary predisposition. Cailliet (1997:167) is of the opinion that congenital factors predispose to HAVB in later life and Magee (1992:456) highlights that although the aetiology of HAVB is varied, the deformity may have hereditary factors as it is often familial.

Klenerman (1991:65) reports that sixty percent of HAVB cases present with a strong family history, although is of the opinion that juvenile HAVB or the congenital forms are extremely rare. Alternatively Groiso (1992) is of the opinion that this condition can be found at any age, even the first few months of life. In Cailliet's (1997:163) experience most individuals suffering from HAVB are adults although most recall the deformity developing at an early age.

Although discrepancies exist pertaining to the extent to which hereditary factors and familial tendency impact the aetiology of HAVB, it is evident in the works of the aforementioned authors that this is an important aetiological consideration.

### **2.4.2 Shoes**

Whilst the use of shoes facilitates a variety of new activities (Broodryk, 2000), they impact on normal foot function by causing unusual stresses in the foot (Yale, 1987:346). In an era where shoes are designed in accordance with the demands of fashion rather than functionality (Klenerman, 1991:60), Reid (1992:148) is of the opinion that high-heeled shoes with pointed toe boxes are the "main offenders" in the aetiology of HAVB. This fact is further emulated by the remarkably lower incidence of HAVB in unshod members in comparison to shoe wearing members of the same communities (Klenerman, 1991:60).

In the opinion of Cailliet (1997:164) HAVB occurs "almost exclusively" in individuals who wear inappropriate shoes and Jahss (1991:945) highlights how the use of high heeled shoes with pointed toe boxes accounts, at least in part, for the 9:1 greater incidence of HAVB in women.

The use of shoes with tight, pointed toe boxes is optimized in dancing "on pointe" in ballet. Quirk (1994) is of the opinion that individuals with a natural predilection to HAVB appear to experience more rapid deterioration of the deformity than usual, if actively dancing "on pointe". Broodryk (2000) proposes that a hereditary predisposition to HAVB combined with the use of inappropriate shoes may result in rapid deterioration of the deformity.

### **2.4.3 Structural and functional considerations**

Brantingham et al., (1994) proposes that HAVB has a multi-factorial aetiology "stemming from a variety of structural and functional aberrations".

Structural malformations such as a rounded first metatarsal head, an elongated great toe (Brantingham et al., 1994) or hyper-laxity and increased obliquity of the first metatarso-medial cuneiform joint (Jahss, 1991:944) may allow lateral migration of the hallux on the metatarsal (Brantingham et al., 1994).

Magee (1992:456) is of the opinion that eighty percent of HAVB cases are caused by metatarsus primus varus (MPV), a structural variance in which the intermetatarsal (IM) angle between the first and second metatarsals exceeds nine degrees (Jahss, 1991:944). Klenerman (1991:58) is of the opinion that HAVB is associated with a varus deformity of the first metatarsal, whereas Cailliet (1997:167) highlights how there is little evidence in the available literature to determine accurately if MPV is the underlying cause of HAVB.

There appears to be little consensus as to the role MPV plays in the development of HAVB and Klenerman (1991:58) highlights the considerable lack of agreement in this matter. Reid (1992:149) however is of the opinion that it predisposes to constant pressure on the phalanx in poorly designed shoes and thus MPV contributes to the pain and disability associated with this condition.

The aforementioned structural abnormalities are more likely to cause HAVB when combined with certain functional aberrations (Brantingham et al., 1994). One such factor is an excessively low medial longitudinal arch, which is highlighted by Klenerman's (1991:59) observation that high proportions of HAVB patients have flat valgus feet. Yale (1987:346) is of the opinion that HAVB is most frequently caused by any condition leading to excessive subtalar pronation.

Other functional aberrations that may contribute to the development of HAVB include hypermobility of the first tarso-metatarsal joint in dorsiflexion (Klaue, Hansen and Masquelet 1994) and muscular imbalance (Klenerman, 1991:59), all of which compromise the mechanical stability of the first MPJ (Michaud, 1993:158).

#### **2.4.4 Other considerations**

The HAVB deformity may be induced by degenerative bony or articular changes following gout, rheumatism, infectious arthritis, traumatic arthritis and neurological lesions (Yale, 1987:346). The presence of an exaggerated hypermobile pes planus in hyper-lax disorders such as Down's and Ehlers-Danlos syndromes may also prelude to the development of this condition (Jahss, 1991:945).

Although little consensus seems to exist as to the aetiology of HAVB, the altered structural and functional characteristics result in pathological changes occurring in and around the first MPJ.

### **2.5 Patho-anatomy of HAVB**

In HAVB the first metatarsal adducts and the great toe abducts (Yale, 1987:346). As the metatarsal bone moves medially, the base of the proximal phalanx is carried with it and the phalanx pivots around the adductor hallucis muscle causing its distal end to deviate laterally (Magee, 1992:454). The extensor hallucis longus (EHL) and the flexor hallucis longus (FHL) deviate their forces laterally (Cailliet, 1997:166) causing a bowstring effect, which may increase the deformity (Klenerman, 1991:59).

The sesamoids are also displaced laterally (Yale, 1987:346), the altered position of which transforms the FHL and brevis muscles from flexors to adductors (Donatelli, 1990:26) with resultant decrease of plantarflexion of the

first MPJ. The abductor hallucis muscle slides beneath the metatarsal head causing pronation of the great toe (Cailliet, 1997:167).

The tissues on the lateral aspect of the first MPJ undergo accommodative shortening (Yale, 1987:346) whilst those on the medial aspect are attenuated (Cailliet, 1997:169). Over time this may lead to osteoarthritic degeneration within the joint (Jahss, 1991:947).

## 2.6 Symptoms

The complications of HAVB are often more significant than the structural deformity itself (Yale, 1987:347) and Levy and Hetherington (1990:828) regard pain and inability to wear shoes comfortably as the main presenting symptoms.

Klenerman (1991:65) describes that pain on the medial aspect of the first MPJ may be as a result of an inflamed bursa or pressure from an overlying callosity. Whereas pain localized on the plantar aspect may result from metatarsalgia of the first metatarsal head or associated acute or chronic sesamoiditis (Yale, 1987:347).

Symptoms arising from the lateral toes may be the main complaint (Klenerman, 1991:65) and could result from metatarsalgia of the second or third metatarsals (Levy and Hetherington, 1990:829). Dorsal subluxation of the second toe (Yale, 1987:347) due to lateral deviation of the hallux may result in a painful hammer toe deformity (Levy and Hetherington, 1990:829).

The inability to wear normal shoes comfortably (Cailliet, 1997:170) or the unacceptable cosmetic appearance of the deformity (Klenerman, 1991:66) may be the only presenting feature. This is common amongst adolescents, where many patients are asymptomatic (Groiso, 1992) and presentation is



often based on parents' concern for deterioration of the deformity (Klenerman, 1991:66).

## **2.7 Clinical Evaluation**

### **2.7.1 Physical Findings**

Levy and Hetherington (1990:829) are of the opinion that the most consistent findings in HAVB are:

- enlargement of the medial eminence of the metatarsal head
- palpable, tender bursa over the bony eminence
- possible pain on palpation
- possible restricted range of motion of the first MPJ, more evident in elderly patients or those with severe deformities.

Khan (1996) is of the opinion that the lateral deviation of the great toe is the most obvious feature and Brantingham et al. (1994) note that the hallux frequently overrides the second toe.

Examination whilst standing accentuates the deformity (Cailliet, 1997:171) and the degree of MPV can roughly be judged by the width of the forefoot (Klenerman, 1991:66).

Tenderness of the metatarsals due to associated metatarsalgia (Levy and Hetherington, 1990:828) and the presence of plantar callosities (Klenerman, 1991:66) may be noted.

Movement of the midtarsals, subtalar and ankle joints may be restricted (Klenerman, 1991:66) as HAVB is often associated with a pronated foot (Yale, 1987:346) and thus observation of the patient's gait allows one to observe if the hallux is used in normal push off (Klenerman, 1991:66).

### ***2.7.2 Radiological evaluation***

Evaluation of the HAVB deformity by roentogram is performed in the weight bearing position (Cailliet, 1997:171) using anteroposterior and lateral films (Klenerman, 1991:66).

The MPJ angle (Magee, 1992:454), more commonly known as the hallux valgus (HV) angle is measured as the angle of intersection between the long axis of the first metatarsal and the proximal phalanx (Cailliet, 1997:173). The intermetatarsal angle (IM) is measured as the angle between the axes of the first and second metatarsals (Klenerman, 1991:66).

Although Levy and Hetherington (1990:829) are of the opinion that the aforementioned angles aid in determining the extent of the HAVB deformity, there appears to be little consensus as to what constitutes normal or abnormal values. For instance, Jahss (1991:944) infers that a IM angle greater than nine degrees is considered abnormal and is known as MPV, whereas Magee (1992:456) is of the opinion that this angle is normally between zero and fifteen degrees and only constitutes MPV at values greater than fifteen degrees.

Cailliet (1997:175) considers a HV angle of up to ten degrees to be normal, with an angle of fifteen degrees or more constituting abnormal. Alternatively Klenerman (1991:66) is of the opinion that a normal HV angle in adults is fifteen point seven degrees, with angulations greater than twenty degrees being pathological.

In a surgical study by Sammarco and Russo-Alesi (1998) the inclusion criteria required patients to have an HV angle greater than twenty degrees and an IM angle greater than ten degrees. Kilmartin, Barrington and Wallace (1994) only

chose children with an HV angle greater than fourteen point five degrees in a study performed to determine the efficacy of orthoses on juvenile HAVB.

The researcher, based on the aforementioned data, decided to consider any HV angle greater than fifteen degrees or more as constituting HAVB and nine degrees or more as constituting an abnormal IM angle. These angles, measured on roentogram, were used to determine the inclusion criteria for this study.

## **2.8 Treatment**

The mutli-factorial aetiology of HAVB (Brantingham et al., 1994 and Klaue, Hansen and Masquelet, 1994) has lead to the development of an array of treatment protocols. Cailliet (1997:173) is of the opinion that the treatment of HAVB must be individualized, based on the age of the patient, degree of deformity, severity and duration of symptoms. Levy and Hetherington (1990:831), however, consider the alleviation of pain to be the practitioner's primary concern. The treatment of HAVB will be discussed under the following headings:

- Conservative intervention
- Juvenile HAVB
- Surgical intervention
- Chiropractic intervention

### ***2.8.1 Conservative Intervention***

#### ***2.8.1.1 Orthotics and footwear***

Reid (1992:149) maintains that the non-operative treatment of HAVB is largely preventative, encompassing patient education and advice on appropriate

footwear. The author is of the opinion that "poor footwear nullifies any therapeutic effort". Jahss (1991:967) highlights how the "last" or shape of the shoe must accommodate the wide forefoot whilst simultaneously having a toe box high enough to accommodate any associated hammer or claw toe deformities. Klenerman (1991:67) maintains that this shoe type has a definite place in the conservative management of HAVB, whilst Jahss (1991:967) highlights that the effectiveness of these shoes is highly dependent on patient compliance and acceptance of "less than stylish" footwear.

Brantingham et al. (1994) and Yale (1987:347) advocate the use of orthoses in addition to well fitting footwear, in order to correct any associated pes planus or hyperpronation (Cailliet, 1997:173).

Kilmartin, Barrington and Wallace (1994) performed a prospective, placebo controlled clinical trial on one hundred and twenty two children between the ages of nine and ten, to determine the effect of orthoses in juvenile HAVB. After the three-year trial period results indicated an increased HV angle in both the treatment and non-treatment groups, with greater deterioration evident in the treatment group. The authors therefore concluded that the use of their orthoses had increased the rate of HAVB progression. The study was based on the biomechanical orthoses reducing excessive pronation/eversion of the hindfoot, a factor considered to predispose to the development of HAVB. The fact that correcting the hindfoot pronation did not restrict the deterioration of the HAVB deformity lead authors to question whether hindfoot pronation was in fact an aetiological consideration in this condition.

Despite the use of randomized selection criteria, the average HV angle in the treatment group was significantly higher than that in the control group at the onset of the trial. Although this may have affected the outcome of the study, the authors maintained the opinion that juvenile HAVB deteriorated in the children regardless of whether they wore biomechanical orthoses or well fitting shoes.

### **2.8.1.2 Splinting**

Several authors advocate the use of night splints in the treatment of HAVB (Yale, 1987:347; Jahss, 1991:970 and Levy and Hetherington, 1990:831) and Cailliet (1997:174) maintains that in a flexible forefoot a splint, which abducts the metatarsal and adducts the two phalanges, may be effective.

Groiso (1992) performed a clinical trial to assess the efficacy of thermoplastic splints used in conjunction with passive and active foot exercises in the treatment of juvenile HAVB. Groiso used an office made low temperature thermoplastic splint as it was easier to accommodate individual anatomical and pathological characteristics. This splint also allowed for resetting at follow up consultations to accommodate the growing foot or altered positions of the hallux. The study was performed on fifty-six patients ranging in age between one month and sixteen years, the management of whom was maintained over a period of two years or more. Satisfactory improvement was found in both the HV and IM angles in fifty percent of the feet, with no recurrence of the deformity noted once treatment was stopped.

Although favorable results were found in the aforementioned study, it should be noted that this was not a randomized trial and it do not refer to the effect this treatment regime may have had on pain. Its validity also remains questionable as no statistical analysis was performed.

### **2.8.1.3 Passive and active exercises**

Reid (1992:149) maintains that in early, mild forms of HAVB, carefully prescribed intrinsic foot exercises supplemented by "faradic type foot baths", may be effective in the treatment of this condition. Yale (1987:347) and Groiso (1992) also advocate the use of active and passive foot exercises, however Cailliet (1997:174) is of the opinion that their efficacy is questionable. Yale (1987:347) advocates a more comprehensive conservative approach

where foot exercises are used in combination with low voltage electrical stimulation, protective latex shields and devices used to stretch or punch out the shoe over the bunion prominence to alleviate pressure.

#### **2.8.1.4 Homeopathic intervention**

Khan (1996) performed a placebo controlled trial to assess the effect of *Tagetes patula* in the treatment of HAVB, in terms of pain, swelling and deformity of the first MPJ. Twenty patients with bilateral HAVB had one foot treated with active tincture and the other with a placebo paste. Forty patients with unilateral deformities were split into two groups, one group receiving active treatment and the other placebo paste. The tincture was held in place using a protective pad, which simultaneously redistributed pressure and friction from the joint.

This treatment protocol was found to be effective in reducing the width of the deformity, hallux valgus angle and pain experienced by the patients in the treatment group. However the improvement of pain in the placebo group was considered to be due to reduction of pressure on this joint from the presence of the protective pad, as the condition worsened on removal of the pad.

Although the term random was used to describe the selection of patients from a larger group, this trial does not appear to be randomized with respect to allocation of patients. The trial was a comparative study utilizing both objective (X-rays) and subjective data analysis. This treatment protocol may provide effective management of patients such as the elderly or diabetic, in whom the more traditional forms of treatment, such as surgery, are contra-indicated.

### **2.8.1.5 Strain Counter-strain mobilization**

Broodryk (2000) performed a placebo controlled clinical trial to evaluate the efficacy of strain counter-strain (SCS) mobilization in the treatment of HAVB. Jones (1992:1) defines SCS mobilization as "relieving spinal or other joint pain by passively putting the joint into its position of greatest comfort". The position of comfort in this study involved abduction, eversion and flexion of the first MPJ. This position was maintained for ninety-seconds and released over a further thirty-second period. Patients received five treatments over a three-week period.

Analysis of the data obtained from this study indicated that although SCS was effective in alleviating pain in the initial stages of treatment, the placebo was found to be more effective in the later stages. Although this study was a prospective randomized trial, no radiological assessment of the HV and IM angles was performed. The study also incorporated subjects over a broad age range allowing for marked variation in degenerative changes of the joint or severity of the deformity.

### **2.8.1.6. Summary of Conservative Care**

From all the aforementioned studies it was apparent that a number of different conservative regimes have developed for the treatment of HAVB, however there appears to be little consensus as to their proposed benefit (Groiso, 1992). For instance Yale (1987:347) is of the opinion that in the early stages, conservative care can be moderately effective whereas Klenerman (1991:67) maintains that splints, insoles and physiotherapeutic modalities have been well tried in the past "with uniform lack of success".

### ***2.8.2 Treatment in juvenile HAVB***

Cailliet (1997:174) is of the opinion that individuals who develop HAVB before twenty years of age and who have a family history of the deformity should be treated conservatively and prophylactically. Alternatively Klenerman (1991:81) maintains that there are good grounds for surgical intervention in adolescents with a familial history and radiological evidence of deterioration in the HV and IM angles. Groiso (1992) highlights that although there are conflicting opinions regarding the benefits of conservative care in these individuals, surgical intervention should be postponed until bone maturation has occurred, as this reduces the risk of recurrence of the deformity.

### ***2.8.3 Surgical Interventions***

The more traditional treatment for HAVB is surgery (Khan, 1996), although it remains a controversial issue (Klaue, Hansen and Masquelet, 1994). Yale (1987:397) highlights that more than one hundred surgical procedures exist for the treatment of HAVB, most of which Jahss (1991:943) considers biomechanically unsound. Klaue, Hansen and Masquelet (1994) are of the opinion that based on the multi-factorial aetiology of this condition, the rationale behind currently used surgical techniques has yet to be conclusively demonstrated.

Reid (1992) is of the opinion that surgery in the young athlete should be avoided or kept to a minimum, as stresses applied to this joint are enormous and long term results are seldom satisfactory and may permanently impair function and thus professional career (Jahss, 1991:967).

Yale (1987:348) considers the presence of marked deformity, bony proliferation or pathology involving the joint as indications for surgical intervention. Jahss (1991:943) maintains that HAVB surgery is elective and



should only be performed "upon the major presenting painful deformities", as surgical intervention based on cosmetic appearance alone is unwarranted (Cailliet, 1997:173).

The age, sex, occupation and level of activity of the patient are important factors that need to be considered when determining which surgical technique to use (Jahss, 1991:943). These factors may affect the risk of surgical and post-surgical complications such as aseptic necrosis, infection, iatrogenic neuromas or delayed wound healing (Jahss, 1991:973).

Klosok et al. (1993) performed a randomized prospective clinical trial comparing Chevron and Wilson distal osteotomies on eighty-seven feet in fifty-one patients. Improved HV and IM angles were noted in both groups. Rehabilitation was found to be more rapid in the Chevron group due to the absence of post surgical plaster casting, however, in a later review, it was noted that the Wilson group had better functional results and the patients were more satisfied with the operation. It should be noted that both groups showed a significant incidence of complications with twenty percent of patients being dissatisfied with the results in terms of pain, shoe fitting or appearance of the joint.

Markbreiter and Thompson (1997) performed a retrospective study comparing crescentic and chevron proximal osteotomies. The authors reported that the two operative techniques provided equally excellent and predictable results however they recommended the chevron procedure for the following reasons:

- It did not require internal screw fixation
- It was inherently more stable
- It decreased the risk of first metatarsal dorsiflexion, both intra-operatively and post-operatively.
- It was easier to perform, as the crescentic procedure required a special blade, oscillating saw and a third incision.

In a retrospective study by Sammarco and Russo-Alesi (1998), this proximal chevron osteotomy was also found to provide successful long term results in the treatment of moderate to severe HAVB. However complications were noted in ten of the fifty-five participating individuals, including mal-union, stress fractures of the second metatarsal, cellulitis and hallux varus, limitus or elavatus.

Selner et al. (1999) performed a comprehensive outcome study assessing a tri-correctional bunionectomy in the treatment of HAVB. The mean post-operative HV and IM angles were 11.65 and 5.72 degrees respectively. Post-operative complications were minor and long-term follow up revealed excellent results in both objective and subjective findings. Cailliet (1997:174) is of the opinion that this procedure appears biomechanically sound as it prevents shortening and deviation of the first metatarsal and thus may be effective in reducing the risk of post-operative complications and recurrence of the deformity.

Jahss (1991:944) highlights that complete recovery from surgical intervention may take up to a full year and recommends that all forms of conservative care should first be considered. Thus, due to the degree of intricacy, risk of complications and long convalescence associated with the aforementioned studies, it becomes apparent that an effective conservative treatment protocol is needed to address, not necessarily the deformity, but the alleviation of pain and disability so often associated with it.

Furthermore, in a study performed by Ferrari, Higgins and Williams (2001), the authors evaluated twelve different randomized clinical trials of conservative, surgical and post-surgical treatment interventions for HAVB. These authors are of the opinion that the methodological quality of all the trials was poor, with no trial acquiring a score of greater than twelve out of the maximum twenty-four points. It was also noted that the majority of treatment interventions for HAVB (conservative or surgical) have not been adequately tested by means of randomized clinical trials. In all of the assessed trials the authors found no difference between the treatment and non-treatment groups

and are of the opinion that there is insufficient evidence to determine which treatment strategy is most appropriate for this condition.

## 2.9 Manipulation

Manipulation refers to mobilization and adjustment (Bergmann, Peterson and Lawrence, 1993:124). Joint manipulative procedures are used to induce motion within a hypomobile joint. This joint hypomobility is known as the "subluxation complex" or joint dysfunction. The adjustive thrust or mobilization is typically delivered in the direction of established joint restriction.

Bergmann, Peterson and Lawrence (1993:131) classify the clinical features of joint dysfunction as:

- Local pain which commonly changes with activity
- Local tissue hypersensitivity
- Increased, decreased or aberrant joint motion
- Altered joint play
- Altered alignment
- Altered end feel resistance
- Local palpatory muscle rigidity

The benefits of manipulation (Edmond, 1993:2-7; Maitland, 1986:10-13 and Bergmann, Peterson and Lawrence, 1993:137-157) include:

- Restoring normal joint range of motion
- Reducing pain
- Improving joint circulation and nutrition
- Alleviating associated muscle spasm

Maitland (1986: 287-289) and Edmond (1993: 161-163) are of the opinion that manipulation of the first MPJ, particularly adduction movements, are effective

in the treatment of HAVB, however there appears to be very little scientific evidence in the current literature to substantiate these claims.

## 2.10 Chiropractic Intervention

According to literature dating as far back as 1906, D.D. Palmer adjusted the first MPJ for the relief of pain and symptoms associated with HAVB (Keating et al., 1992). Brantingham (personal communication, 2000) highlights how adjustment of the HAVB joint has been used on a regular basis in the past for the treatment of this condition.

Brantingham et al. (1994) reported on a case study evaluation of a thirty-nine year old male who presented approximately six months after undergoing a bunionectomy. Unfortunately this procedure had not appreciatively changed the patient's pain pattern and on examination the authors found, in addition to bilateral HAVB deformities, considerable joint dysfunction in the rest of the foot and ankle. After a course of five treatments, involving progressive mobilization, adjustment and ice, the patient reported nearly one hundred percent improvement in his symptoms and was still reporting ninety percent or more relief from pain after one year.

Brantingham et al. (1994) recommend that as a safety precaution, the following treatment protocol be used to initially mobilize and adjust the HAVB patient:

- Radiographic examination may be used to rule out metabolic disease such as gout, severe degenerative joint disease and rheumatoid arthritis. The authors are of the opinion that manipulation of the painful bunion should always be gentle and only performed once all other causes of pain around the first MPJ have been ruled out.

- A light traction of the hallux with gentle, lateral joint play motion can then be initiated at the joint, followed by the application of ice. Mild soreness during this procedure is considered acceptable, however the authors are of the opinion that if severe pain is felt by the patient one must stop mobilization of the bunion joint and treat only the other fixations felt in the foot and ankle.
- The following step (should no adverse response develop) involves axial traction and moderate force adduction (toward the mid-sagittal plane) mobilization of the hallux, once again followed by ice.
- This procedure is then repeated at the following consultations using firstly, a strong mobilization and lastly, a high velocity, low amplitude thrust is applied to this joint. Ice is applied to the joint at the end of each of these procedures.
- The authors highlight the importance of constant patient assessment. The speed at which the patient progresses from mild mobilization to adjustment of this joint is dependent on patient response in terms of pain and function (Brantingham, personal communication, 2001).

This comprehensive protocol was used whilst simultaneously addressing other dysfunctions that were noted in the foot and ankle. For example, warm hydrotherapy baths were used to relieve pain, ultrasound was used to lessen inflammation of the second and third metatarsal heads and other fixations found in the foot and ankle were adjusted. Any biomechanical abnormalities were addressed with the use of orthoses and well fitting footwear.

This case study appears to indicate that a comprehensive conservative approach involving manipulation of the foot and ankle could be effective in the treatment of symptomatic HAVB. Brantingham *et al.* (1994) are of the opinion that although the deformity typically remains the same, individuals suffering

from symptomatic HAVB are often made more comfortable "by improving the flexibility of the soft tissue contracture so often associated with the condition".

In spite of the aforementioned authors' many years of practical experience in this technique, the lack of scientific data to substantiate the validity of the proposed benefits nullifies any reliability in their claims. This case study also involved the use of a multiple treatment protocol, which could have significantly affected the positive outcome. Thus there is a need to objectively assess the impact that a progressive mobilization of the first MPJ, used in conjunction with cryotherapy and adjustment of all other fixations found in the foot and ankle, has on the treatment of HAVB. Therefore the results of this study will help in determining the efficacy of the aforementioned treatment protocol in the management of symptomatic HAVB.

## 2.11 Placebo

The term placebo can be defined as a dummy treatment administered to the control group in a clinical trial in order that the specific and non-specific effects of the experimental treatment may be distinguished (Dorland and Newman, 1988:1299). It is therefore necessary to test this treatment strategy against a placebo treatment, in order to accurately assess its impact on the treatment of symptomatic HAVB.

Any treatment modality can act as a placebo and the patient reactivity will vary according to the supposed potency of the treatment the patient thinks they are receiving (Brody, 1980:12). It is not always easy to distinguish placebo stimulus from active treatment, since cutaneous stimulation of any type may promote pain relief (Melzack and Wall, 1965). The Action Potential Therapy unit (although it passed no current) was "administered" to the foot by means of self-adhesive pads that could, on application, cause some degree of cutaneous stimulation.

Brody (1980:14-15) reviewed factors influencing the placebo and found that a large number of patient variables showed no correlation with its effect. The variables included factors such as the age, sex, intelligence and presence of psychosis and neurosis. The author did however find that stress or anxiety fairly consistently affects patient placebo reactivity. Beecher (1955) estimates the usual placebo effect to be thirty-fifty percent.

## **2.12 Conclusion**

On review of the aforementioned literature pertaining to the treatment of HAVB, it is apparent that a multitude of treatment protocols have developed. However little evidence is available to determine accurately which treatment strategy is most appropriate for this condition (Ferrari, Higgins and Williams, 2001).

The aim of this clinical trial was to assess the efficacy a conservative chiropractic management approach in the treatment of HAVB, in the hope of developing a treatment protocol, that is effective in eliminating the pain and discomfort experienced by patients, but simultaneously easy to implement and cost effective.

## Chapter Three: Materials and Methodology

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### 3.1 Introduction

This chapter is an outline of the general procedures and methods used in performing the research and collecting the data for this study. A detailed description of the study design and protocol, inclusion and exclusion criteria and treatment interventions will be given. The questionnaires used to obtain the subjective data and the measurement of the objective data will also be discussed, followed by methods used for statistical analysis.

### 3.2 Study Design

The design was that of a prospective, randomized placebo controlled clinical trial to assess the efficacy of a conservative chiropractic management approach in the treatment of symptomatic hallux abductovalgus bunions (HAVB).

### 3.3 Patient Selection

A sample size of sixty females with symptomatic HAVB was used. The decision to use only females was based on the belief that there is an increased incidence of symptomatic HAVB in this sex (Gould, Schnelder, and Ashikaga, 1980; Jahss, 1991:945; Cailliet, 1997:163 and Magee, 1992:456). These patients were recruited from the greater Durban metropolitan area by means of advertisements, posters and referrals. Patients who responded to the advertisements were screened to assess whether or not they fulfilled certain inclusion criteria.



### **3.4 Inclusion and Exclusion Criteria**

Only patients who fulfilled the inclusion and had no exclusion criteria were accepted into the study. This was determined at the initial consultation by the following procedure:

- A detailed case history (Appendix 1) was taken.
- A physical examination (Appendix 2) was performed.
- A foot and ankle regional examination (Appendix 3) was completed
- The researcher then explained the nature and importance of the study and each patient was given the patient information sheet (Appendix 4) to read.
- Antero-posterior and lateral weight bearing radiographs were taken of the foot.

Each patient then read and signed the Informed Consent form (Appendix5). Any questions that the patients had were answered accordingly.

#### **3.4.1 Inclusion Criteria**

The inclusion criteria were formulated based on a combination of diagnostic findings as used by Levy and Hetherington (1990:829-830), Klenerman (1991:66-67) and Cailliet (1997:170-173) and are as follows:

- Radiological examination.
  - Hallux valgus/abductus angle greater than fifteen degrees.
  - Intermetatarsal angle greater than nine degrees.
- Enlarged medial portion of the first metatarsal head.
- Mild, moderate or severe lateral deviation of the hallux from the mid-sagittal plane.
- Pain around the first MPJ.
- Inability to wear shoes comfortably.

### **3.4.2 Exclusion Criteria**

- Any patients with systemic or local pathology for example rheumatoid arthritis or gout.
- The use of anti-inflammatory drugs or analgesics.
- The use of tight, narrow pointed high-heeled shoes as, Reid (1992:149) is of the opinion that this type of shoe nullifies any therapeutic benefit derived from conservative care.
- Any contra-indication to manipulation (Bergmann, Peterson and Lawrence, 1993:133):
  - Advanced/ severe degenerative joint disease
  - Anticoagulant therapy
  - Inflammatory arthritis
  - Joint instability
  - Fracture or dislocation
  - Bone tumors or infection
  - Musculo-skeletal injury
- Patients who have had Action Potential Therapy in the past, as these individuals would be familiar with the electrical current normally passed by this machine.

### **3.5 Allocation of the Subjects**

Each patient was randomly assigned into one of two groups. This random assignment occurred as follows: sixty slips of paper (thirty slips with group A and thirty slips with group B written on them) were placed in a bag and randomly drawn out by patients at the initial consultation. Those patients who drew group A were treated using a conservative chiropractic approach involving progressive mobilization, adjustment and cryotherapy. Those patients in group B received a sham/placebo treatment by means of de-tuned

Action Potential Therapy administered to the involved foot. For blinding purposes the patients were not informed as to which group they were in. In the case of patients dropping out of the study, their relevant group letter was placed back in the bag for further selection by patients who replaced them.

### **3.6 Treatment Interventions**

#### **3.6.1 Group A**

The patients in group A had the treatment protocol explained to them. The treatment of the first MPJ (as delineated by Brantingham et al., 1994) progressed as follows:

At the first consultation, the examiner applied a light axial traction to the first MPJ by grasping the great toe between thumb, index and middle finger. Using the other hand the examiner grasped the first ray just proximal to the metatarsal head. Whilst maintaining the axial traction, the examiner applied a light lateral glide and adduction (toward the mid-sagittal plane) mobilization to the first MPJ (Grade 2). At the subsequent consultations, the mobilization of this joint progressed from a Grade 2 to a Grade 5 mobilization. The grades of mobilization implemented were based on those delineated by Maitland (1986:96):

- Grade 1: is a small amplitude movement near the starting position of the range of motion.
- Grade 2: is a large amplitude movement, which carries well into the range of movement. It can occupy any part of the range that is free of any stiffness or muscle spasm.
- Grade 3: is also a large amplitude movement, but one that does move into stiffness and muscle spasm.
- Grade 4: is a small amplitude movement stretching into stiffness and muscle spasm.

Grade 5: adjustment: "high velocity, low amplitude thrust accessing the paraphysiological space but not exceeding the anatomical limit of movement" (Michaud, 1993:134).

Maitland (1986:95-100) highlights the importance of the rhythm of mobilization and how this rhythm is dependent on symptom response and the end feel of the pathological joint. There seems to be little consensus however as to the number of oscillations performed at each grade of mobilization. In this study Grade 2-3 mobilizations were applied ten to twenty times, a Grade 4 mobilization five to ten times and a Grade 5 mobilization (adjustment) without cavitation no more than three times (Brantingham, personal communication, 2001).

The speed of progression from a Grade 2 mobilization to adjustment of this joint was based on the pain or tenderness experienced by the patient and was thus based on patient response. Brantingham et al. (1994) is of the opinion that very mild tenderness is acceptable and treatment can continue. However if the patient experienced any severe pain, the treatment regressed to a lighter grade of mobilization until symptoms subsided. At the end of each consultation ice was applied to the HAVB joint. The aim was to deliver a high velocity low amplitude thrust (Grade 5) to this joint by the sixth treatment.

If the patient progressed to adjustment of this joint in less than the allotted six treatments and no other fixations were found in the foot and ankle, the follow up consultations were still attended in order to allow for the collection of the objective and subjective data.

All other fixations (joint dysfunction) in the foot and ankle were treated by means of adjustment at each consultation. The fixations found were:

- Mortice/Talo-crural joint dysfunction
- Mid-tarsal joint dysfunction
- Decreased intermetatarsal glide
- MPJ and Interphalangeal joint dysfunction

- Restricted dorsiflexion or plantarflexion of the first ray
- Restricted adduction of the forefoot

The adjustments used were:

- Mortice separation
- Plantar to dorsal glide of the mid-tarsal/s
- Long axis distraction of the lesser MPJ and interphalangeal joints (second to fifth digits)
- Intermetatarsal glide
- Figure of eight mobilization of the foot
- Abduction thrust of the first ray
- Dorsiflexion or plantarflexion thrust of the first ray

A detailed explanation of these techniques is available in Bergmann, Peterson and Lawrence (1993:702-722) and Michaud (1993:135-145).

### **3.6.2 Group B**

The patients in this group had the procedure of Action Potential Therapy explained to them. They were informed that the machine worked by means of electromagnetism and that it was effective in alleviating muscle spasm and pain. They were however not informed that the machine to be used in this study was in fact a sham machine that passed no current. The practitioner set the machine to an eight-minute time interval. The Action Potential Therapy was then "administered" to the involved foot by means of self adhesive pads. The patients in group B were still assessed to determine what fixations were found in the foot and ankle, however these fixations were not treated.

The patients in each group received six treatments over a two-week period and were re-examined one week after their last appointment to assess the outcome of the treatment given and allow for comparison of the two groups.

### 3.7 Methods of Measurements

The objective and subjective readings were taken as pre-treatment measurements at the first, third, sixth and one week follow up consultations.

#### 3.7.1 Objective Measurements

##### A. Algometer

Fischer (1986) reported that the algometer could be used to determine any change in the patient's pressure-pain threshold levels in hypersensitive spots or trigger points, thus quantifying their response to treatment. The origin of pain in these tender areas may arise from ligaments, joint capsules, tendons and periosteum (Fischer, 1987). Nussbaum and Downes (1998) report that the algometer has the potential to provide information on the daily changes in soft tissue tenderness.

The algometer used in this study was the Algometer Commander and Digitrack Commander (as supplied by Jtech Medical Industries 4314 ZEVEX Park Lane, Salt Lake City, UT 84123).

The measurements were taken as follows:

- The area of maximal tenderness on the plantar medial aspect of the first MPJ line was located.
- This area was marked using a bright coloured nail varnish for identification in consecutive treatments.
- The foot-plate of the algometer was placed over the area of maximal tenderness with the shaft exerting pressure in the direction that produced pain on palpation.
- The gauge was turned away from the patient and pressure was increased at a rate of approximately 10 Newton/second (1kg/sec).

- Patients had been informed to indicate when they first sensed the pain produced by the pressure by saying "now".
- Three consecutive readings were taken and their scores were averaged to obtain the mean.
- This mean algometer reading was recorded in Newtons (Appendix 6).
- An increased level of pressure tolerated by the patient denoted an improvement in pressure-pain tolerance.

B. The Hallux Metatarsophalangeal-interphalangeal Scale (Kitaoka et al., 1994)

This scale was developed by the American Orthopaedic Foot and Ankle Society (AOFAS) to provide a standard method of reporting clinical status of the foot. The system incorporates both subjective and objective factors into numerical scales to describe function, alignment and pain (Appendix 7). A maximum score of one hundred can be obtained with 40 points allocated to pain, 45 points to function (which include range of motion, shoe wear comfort and activity capabilities) and 15 points to alignment. The score was calculated as an amount out of the maximum score of 100 and recorded as that percentage. The higher the score the greater the improvement denoted.

Kitaoka et al. (1994) reports that validation of this scale is underway and that it will be the subject of a future report. It has however been used in clinical studies pertaining to HAVB in the past (Markbreiter and Thompson, 1997; and Selner et al., 1999).

### **3.7.2 Subjective Measurements**

#### **A. Numerical Rating Scale 101 (NRS –101)**

The NRS-101 consists of asking the patient to rate their perceived level of pain intensity on a numerical scale from zero to one hundred, with zero being no pain and one hundred being the worst pain (Appendix 8). The patient indicates by means of a percentage on a ten centimeter line, when the pain is at its worst and again when the pain is at its least. The average pain intensity was calculated by adding the percentages for the worst pain and the least pain and then dividing by two. These average pain intensity scores were used for statistical analysis. Decreased scores denoted an improvement in the pain experienced by the patient.

This scale was found to be the most practical index when measuring pain intensity as compared to five other scales (Jenson, Karoly and Braver, 1986). Its advantages were

- It is simple to administer and score
- Oral and written responses may be used
- Age does not affect the score

#### **B. Foot Function Index (FFI)**

The FFI was developed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction. The FFI consists of 23 items divided into three sub-scales (Appendix 9). The sub-scales provide information on three aspects of function: foot pain (sub-scale A), disability (sub-scale B) and activity restriction (sub-scale C), as they relate to foot pathology. In sub-scale C the patients were asked to answer either yes or no to the two questions to determine if the HAVB deformity resulted in any activity restriction. The items in sub-scales A and B were scored from zero to ten, with zero meaning "no pain" and ten meaning "pain as bad as it could be". The patient circled the appropriate number between zero and ten for



each item that they perceived as reflecting their level of pain. The circled numbers in each sub-scale were added up giving a total for that section. The maximum score that could be attained in that sub-scale then divided this total. Any item that the patient indicated as not applicable was excluded from the study calculation. A score was thus obtained for sub-scale A and sub-scale B. The overall FFI score was obtained by taking the average score for sub-scales A and B together. The scores obtained from the sub-scales for pain, disability and the overall FFI were used to perform statistical analysis.

Budiman-Mak, Conrad and Roach (1991) examined the FFI for test-retest reliability, internal consistency and construct and criterion validity. This study was performed on eighty-seven patients with rheumatoid arthritis. Strong correlation was found between the FFI total and sub-scale scores and clinical measures of foot pathology supported the criterion validity of the index. The authors suggest that the index should prove useful for both clinical and research purposes. In a study by Saag et al. (1996) findings further supported the FFI as "an easy to use, reliable indicator of arthritis foot pain", however the authors indicate that this index has not been validated in any other population of patients and was unproven for general use.

### **3.8 Location of the Data**

#### ***3.8.1 Primary Data***

The primary data was obtained from the FFI, NRS-101, AOFAS Hallux Metatarsophalangeal-interphalangeal Scale and the algometer readings.

#### ***3.8.2 Secondary Data***

The secondary data was obtained from current journal articles, textbooks, the Internet and CD-medline at the Technikon Natal Library. If the literature was not available on the campus, inter-library loans were used.

### **3.9 Statistical Procedures**

The SPSS (version 9.0) statistical package (as supplied by SPSS Inc., Marketing Department, 444 North Michigan Avenue, Chigaco, Illinois, 60611) was utilized for data analysis.

### **3.9.1 Statistical analysis of the Algometer readings, NRS-101 and the AOFAS Hallux Metatarsophalangeal-interphalangeal Scale**

#### **3.9.1.1 Inter-group comparison (treatment versus placebo)**

Since the sample size was large ( $n \geq 30$ ) the unpaired t-test was used to compare the treatment and placebo groups with respect to each variable of interest, at the first, third, sixth and one week follow up consultations.

In each test, the null hypothesis ( $H_0$ ) stated that there was no difference between the two groups with respect to each variable under consideration. The alternative hypothesis ( $H_1$ ) stated that there was a difference between the two groups with respect to each variable under consideration. The level of significance was set at  $\alpha = 0.05$ .

- $H_0$ : There was no difference between the groups
- $H_1$ : There was a difference between the groups.
- $\alpha = 0.05$  = level of significance of the test

#### Decision Rule:

- If  $p < \alpha$  reject the null hypothesis ( $H_0$ )
- If  $p \geq \alpha$  do not reject the null hypothesis ( $H_0$ )

Where  $p$  is the observed level of significance or P-value (Thomas, 2001).

### **3.9.1.2 Intra-group comparison**

The intra-group analysis was performed for both the treatment and the placebo groups

Since the sample size was large ( $n \geq 30$ ) the paired t-test was used to determine if there was any improvement within the group for each variable under consideration, between the:

- First and third consultations
- Third and sixth consultations
- Sixth and seventh consultations
- First and seventh consultations

The null hypothesis ( $H_0$ ) stated that there was no improvement between the consultations for each variable under consideration. The alternative hypothesis ( $H_1$ ) stated that there was an improvement between consultations for each variable under consideration. The level of significance was set at  $\alpha = 0.05$ .

- $H_0$ : There was no improvement between consultations
- $H_1$ : There was an improvement between consultations
- $\alpha = 0.05$  = level of significance of the test



Decision Rule:

- If  $p < \alpha$  reject the null hypothesis ( $H_0$ )
- If  $p \geq \alpha$  do not reject the null hypothesis ( $H_0$ )
- $p$  was the observed significance level of the test (Thomas, 2001)

**3.9.2.2 Intra-group comparison.**

Intra-group analysis of the FFI was performed using the Friedman's test, which is a non-parametric test that compares three or more matched groups (Instat, 2001). If the P-value was  $< 0.05$ , one could conclude that at least one of the treatments differed from the rest. It was therefore necessary to perform a multiple comparison procedure, the Dunn's post test (Daniel, 1978:231), to determine which groups differ from which other groups (Instat, 2001). The Dunn's post test was only performed when a significant p-value was obtained from the Friedman's test.

a) Hypothesis testing: the Friedman's test.

The null hypothesis ( $H_0$ ) stated that there was no difference between consultations with respect to the variable of interest. The alternative hypothesis ( $H_1$ ) stated that there was a difference between consultations with respect to the variable of interest. The level of significance was set at the  $\alpha = 0.05$

Decision Rule:

For a two-tailed test:

- Reject the null hypothesis ( $H_0$ ) at the  $\alpha$  level of significance if  $p < \alpha$
- Do not reject the null hypothesis ( $H_0$ ) at the  $\alpha$  level of significance if  $p \geq \alpha$  (Thomas, 2001)

b) The Dunn's post test.

If the null hypothesis was rejected for the Friedman's test, then this multiple comparison procedure was applied to determine which of the treatments were significantly different (Daniel, 1978:231).

Decision Rule:

- If  $|R_j - R_{j'}| \geq z \sqrt{\frac{bk(k+1)}{6}}$ , then  $R_j$  and  $R_{j'}$  are declared significant.

Where in the above formula:

$b$  = the number of blocks (subjects)

$k$  = the number of treatments

$z$  = value in the inverse normal distribution corresponding to:

$$(1 - [\alpha/k(k-1)]) = 2.409.$$

$R$  = ranks (Daniel, 1978:231).

On completion of this formula, it was determined that if the difference between ranks is  $\geq 24.09$ , the treatment interval was considered effective.

## Chapter Four: The Results

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### 4.1 Introduction

This chapter covers the results obtained from the statistical analysis of the subjective and objective data namely:

- The Numerical Pain Rating Scale-101 (NRS-101)
- AOFAS Hallux-metatarsophalangeal-interphalangeal Scale (HAL)
- The Foot Function Index (FFI)
- The algometer readings

The results obtained from the inter-group and intra-group data analysis were tabulated. These tables included the mean (Me) value, standard deviation (Sd), standard error (Se) and the level of significance (P-value). Findings for each measurement and questionnaire were recorded according to the relevant statistical tests used.

### 4.2 Criteria governing the admissibility of Data

Only the data collected from patients who met the criteria of the study was utilized. Only responses to the relevant questionnaires that were completed under the researcher's supervision were used. Similarly, only the algometric measurements for pressure-pain tolerance taken by the researcher were used.



### 4.3 The Demographic Data

**Table 1.      Age distribution of patients**

AGE	TREATMENT GROUP	PLACEBO GROUP	TOTAL % OF PATIENTS
18-24	1	2	5%
25-34	4	3	11.67%
35-44	4	3	11.67%
45-54	9	6	25%
55-65	12	16	46.67%

**Table 2.      Average age and age range of patients**

AGE	TREATMENT GROUP	PLACEBO GROUP
AVERAGE AGE	49.43	50.86
YOUNGEST	21	24
OLDEST	64	65

**Table 3.      Race distribution of patients**

RACE	TREATMENT GROUP		PLACEBO GROUP	
	TOTAL NUMBER	%	TOTAL NUMBER	%
WHITES	26	43	23	38.3
BLACKS	1	1.6	2	3.3
MIXED RACE	1	1.6	2	3.3
INDIANS	2	3.3	3	5

**Table 4.      Patient HAVB distribution**

HAVB DISTRIBUTION	TREATMENT GROUP		PLACEBO GROUP	
	TOTAL NUMBER	%	TOTAL NUMBER	%
UNILATERAL	4	6.6	7	11.6
BILATERAL	26	43.3	23	38.3
FAMILY HISTORY				
YES	19	31.6	22	36.6
NO	4	6.6	6	10
UNSURE	7	11.6	2	3.3

**Table 5.     Patient Occupation**

<b>Profession</b>	<b>Treatment Group</b>	<b>% of total patients</b>	<b>Placebo Group</b>	<b>% of total patients</b>
Manager	5	8.33	3	5
Banking	3	5	5	8.33
Nursing	3	5	5	8.33
Housewife	4	6.67	4	6.67
Secretary	8	13.33	3	5
Teaching	2	3.33	2	3.33
PRO	1	1.67	0	0.
Sales Rep	1	1.67	2	3.33
Dance teacher	1	1.67	2	3.33
Psychologist	1	1.67	0	0
Chiropractor	1	1.67	0	0
Catering	0	0.0	2	3.33
C.E.O.	0	0.0	1	1.67
Aromatherapy	0	0.0	1	1.67
Textile Design	0	0.0	1	1.67

## 4.4 Inter-group Results

### 4.4.1 Unpaired T-tests for the Algometric measurements, NRS-101 and Hallux Metatarsophalangeal-interphalangeal Scale (HAL) scores

**Table 6.** Statistical results of the Algometric measurements, NRS-101 and HAL scores comparing the first treatments of the treatment and placebo groups (Baseline measurements)

Scores	Treatment Group Treatment 1			P-value	Placebo group Treatment 1		
	Me	Sd	Se		Me	Sd	Se
Algometer	18.83	6.78	1.24	.000	26.17	8.03	1.47
NRS-101	46.33	9.55	1.74	.159	50.83	14.37	2.62
HAL	38.57	11.17	2.04	.115	42.43	7.07	1.29

The null hypothesis was not rejected for the NRS-101 and Hallux Metatarsophalangeal-interphalangeal scores, indicating no significant difference between the treatment and placebo groups at the first consultation. However, the null hypothesis was rejected for the Algometric measurements, indicating a statistically significant difference between the treatment and placebo groups at this consultation. The placebo group was found to have a mean algometric measurement of 7.34N/cm<sup>2</sup> higher than the treatment group, denoting a higher pressure-pain tolerance in this group at the onset of the trial.

**Table 7. Statistical results of the Algometric measurements, NRS-101 and HAL scores comparing the third treatments of the treatment and placebo groups**

Scores	Treatment Group Treatment 3			P value	Placebo group Treatment 3		
	Me	Sd	Se		Me	Sd	Se
Algometer	33.48	11.54	2.11	.016	27.28	7.41	1.35
NRS-101	26.53	16.92	3.08	.000	46.93	17.67	3.22
HAL	61.47	7.32	1.34	.000	46.30	6.81	1.24

The null hypothesis was rejected for all of the above readings and scores, indicating that there was a statistically significant difference between the treatment and placebo groups at the third consultation. This difference indicated a greater improvement in the treatment group.

**Table 8.** Statistical results of the Algometric measurements, NRS-101 and HAL scores comparing the sixth treatments of the treatment and placebo groups

Scores	Treatment Group Treatment 6			P value	Placebo group Treatment 6		
	Me	Sd	Se		Me	Sd	Se
Algometer	41.32	11.34	2.07	.000	26.91	6.74	1.23
NRS-101	16.05	14.58	2.66	.000	42.13	15.42	2.81
HAL	76.53	7.12	1.29	.000	48.83	6.62	1.21

The null hypothesis was rejected for all of the above measurements and scores, indicating a statistically significant difference between the treatment and placebo groups at the sixth consultation. This difference indicated a greater improvement in the treatment group.

**Table 9. Statistical results of the Algometric measurements, NRS-101 and HAL scores comparing the one week follow up (7) treatments of the treatment and placebo groups**

Scores	Treatment Group Treatment 7			P value	Placebo group Treatment 7		
	Me	Sd	Se		Me	Sd	Se
Algometer	47.03	12.97	2.37	.000	26.63	7.26.	1.33
NRS-101	11.82	14.18	2.59	.000	44.43	19.32	3.53
HAL	82.30	5.28	0.96	.000	49.37	5.89	1.08

The null hypothesis was rejected for all of the above measurements and scores, indicating a statistically significant difference between the treatment and placebo groups at the one week follow-up (7) consultation. This difference indicated a greater improvement in the treatment group.

#### 4.4.2 The Mann Whitney U-Test for Inter-group analysis of the Foot Function Index

**Table 10.** Statistical results of the Foot Function Index, in terms of pain (FFpain), disability (FFdis) and overall (FFtot) scores, comparing consultation one of the treatment and placebo groups (Baseline measurements)

Scores	Treatment group Treatment 1		P value	Placebo group Treatment 1	
	Me	Sd		Me	Sd
FFpain	55.23	16.91	.343	59.93	14.51
FFdis	53.31	22.04	.264	48.33	17.69
FFtot	56.13	17.06	.464	54.16	13.42

The null hypothesis was not rejected for the above readings, indicating no statistically significant difference between the treatment and placebo groups at the first consultation.



**Table 11. Statistical results of the Foot Function Index (FFI), in terms of pain (FFpain), disability (FFdis) and overall (FFtot) scores, comparing consultation three of the treatment and placebo groups**

Scores	Treatment group Treatment 3		P value	Placebo group Treatment 3	
	Me	Sd		Me	Sd
FFpain	33.03	19.50	.000	56.11	18.71
FFdis	30.26	21.88	.004	46.19	16.61
FFtot	31.94	19.51	.000	51.05	16.76

The null hypothesis was rejected for the above readings, indicating a statistically significant difference between the treatment and placebo groups at the third consultation. This difference indicated a greater improvement in the treatment group.

**Table 12. Statistical results of the Foot Function Index (FFI), in terms of pain (FFpain), disability (FFdis) and overall (FFtot) scores, comparing consultation six of the treatment and placebo groups**

Scores	Treatment group Treatment 6		P value	Placebo group Treatment 6	
	Me	Sd		Me	Sd
FFpain	19.27	18.37	.000	58.42	19.06
FFdis	16.19	17.19	.000	44.67	18.07
FFtot	17.82	16.74	.000	51.56	16.77

The null hypothesis was rejected for the above readings, indicating a statistically significant difference between the treatment and placebo groups at the sixth consultation. This difference indicated a greater improvement in the treatment group.

**Table 13. Statistical results of the Foot Function Index (FFI), in terms of pain (FFpain), disability (FFdis) and overall (FFtot) scores, comparing the one week follow-up (7) consultation of the treatment and placebo groups**

Scores	Treatment group Treatment 7		P value	Placebo group Treatment 7	
	Me	Sd		Me	Sd
FFpain	15.30	19.33	.000	58.18	18.05
FFdis	11.98	14.09	.000	47.07	21.32
FFtot	15.61	19.32	.000	52.78	18.02

The null hypothesis was rejected for the above readings, indicating a statistically significant difference between the treatment and placebo groups at the one-week follow-up consultation. This difference indicated a greater improvement in the treatment group.

## 4.5 Intra-group Results

### 4.5.1 Paired T-test for the Algometer readings

**Table 14.** Intra-group comparison between consultations with regards to Algometer readings for the Treatment Group

Intra-group pairs Treatment Group		Mean	Standard deviation (SD)	Standard error (SE)	Reported p-value/2
Pair 1	ALG 1	18.83	6.78	1.24	.000
	ALG 3	33.48	11.54	2.11	
Pair 2	ALG 1	18.83	6.78	1.24	.000
	ALG 6	41.32	11.34	2.07	
Pair 3	ALG 1	18.83	6.78	1.24	.000
	ALG7	47.03	12.97	2.37	
Pair 4	ALG 3	33.48	11.54	2.11	.000
	ALG 6	41.32	11.34	2.07	
Pair 5	ALG 3	33.48	11.54	2.11	.000
	ALG 7	47.03	12.97	2.37	
Pair 6	ALG 6	41.32	11.34	2.07	.000
	ALG 7	47.03	12.97	2.37	

The null hypothesis was rejected for the algometric measurements at each interval, indicating a statistically significant improvement between treatments.

**Table 15.     Intra-group comparison between consultations with regards to Algometer readings for the Placebo group**

<b>Intra-group pairs Placebo Group</b>		<b>Mean</b>	<b>Standard deviation (SD)</b>	<b>Standard error (SE)</b>	<b>Reported p-value/2</b>
Pair 1	ALG 1	26.17	8.03	1.47	<b>0.117</b>
	ALG 3	27.28	7.41	1.35	
Pair 2	ALG 1	26.17	8.03	1.47	<b>0.193</b>
	ALG 6	26.91	6.75	1.23	
Pair 3	ALG 1	26.17	8.03	1.47	<b>0.32</b>
	ALG7	26.63	7.26	1.33	
Pair 4	ALG 3	27.28	7.41	1.35	<b>0.295</b>
	ALG 6	26.91	6.75	1.23	
Pair 5	ALG 3	27.28	7.41	1.35	<b>0.162</b>
	ALG 7	26.63	7.26	1.33	
Pair 6	ALG 6	26.91	6.75	1.23	<b>0.325</b>
	ALG 7	26.63	7.26	1.33	

The null hypothesis was not rejected for the algometric measurements at each treatment interval, indicating no significant improvement between treatments.

#### 4.5.2 Paired T-test for NRS-101 scores

**Table 16.     Intra-group comparison between consultations with regards to NRS-101 scores for the Treatment group**

Intra-group pairs Treatment Group		Mean	Standard deviation (SD)	Standard error (SE)	Reported p-value/2
Pair 1	NRS 1	46.33	9.55	1.74	.000
	NRS 3	26.53	16.92	3.09	
Pair 2	NRS 1	46.33	9.55	1.74	.000
	NRS 6	16.05	14.58	2.66	
Pair 3	NRS 1	46.33	9.55	1.74	.000
	NRS 7	11.82	14.18	2.59	
Pair 4	NRS 3	26.53	16.92	3.09	.000
	NRS 6	16.05	14.58	2.66	
Pair 5	NRS 3	26.53	16.92	3.09	.000
	NRS 7	11.82	14.18	2.59	
Pair 6	NRS 6	16.05	14.58	2.66	.0005
	NRS 7	11.82	14.18	2.59	

The null hypothesis was rejected for the NRS-101 scores at each treatment interval, indicating a statistically significant improvement between treatments.

**Table 17.     Intra-group comparison between consultations with regards to NRS-101 readings for the Placebo group**

Intra-group pairs Placebo Group		Mean	Standard deviation (SD)	Standard error (SE)	Reported p-value/2
Pair 1	NRS 1	50.83	14.37	2.62	.07
	NRS 3	46.93	17.68	3.23	
Pair 2	NRS 1	50.83	14.37	2.62	.004
	NRS 6	42.13	15.42	2.81	
Pair 3	NRS 1	50.83	14.37	2.62	.0175
	NRS 7	44.43	19.32	3.53	
Pair 4	NRS 3	46.93	17.68	3.23	.053
	NRS 6	42.13	15.42	2.81	
Pair 5	NRS 3	46.93	17.68	3.23	.187
	NRS 7	44.43	19.32	3.53	
Pair 6	NRS 6	42.13	15.42	2.81	.185
	NRS 7	44.43	19.32	3.53	

The null hypothesis was rejected for the NRS-101 scores at the treatment intervals between the first and sixth and the first and seventh consultations, indicating a statistically significant improvement between these treatments. However the null hypothesis was not rejected for the remaining treatment intervals, indicating that there was no significant improvement between the first and third, third and sixth, third and seventh and sixth and seventh consultations.

#### 4.5.3 Paired T-test for the Hallux Metatarsophalangeal-interphalangeal Scale (HAL) scores

**Table 18.** Intra-group comparison between consultations with regards to the HAL scores for the Treatment group

Intra-group pairs Treatment Group		Mean	Standard deviation (SD)	Standard error (SE)	Reported p-value/2
Pair 1	HAL 1	38.57	11.17	2.04	.000
	HAL 3	61.47	7.32	1.34	
Pair 2	HAL 1	38.57	11.17	2.04	.000
	HAL 6	76.53	7.12	1.29	
Pair 3	HAL 1	38.57	11.17	2.04	.000
	HAL 7	82.30	5.28	0.96	
Pair 4	HAL 3	61.47	7.32	1.34	.000
	HAL 6	76.53	7.12	1.29	
Pair 5	HAL 3	61.47	7.32	1.34	.000
	HAL 7	82.30	5.28	0.96	
Pair 6	HAL 6	76.53	7.12	1.29	.000
	HAL 7	82.30	5.28	0.96	

The null hypothesis was rejected for the Hallux Metatarsophalangeal-interphalangeal Scale at each treatment interval, indicating a statistically significant improvement between treatments.



**Table 19.** Intra-group comparison between consultations with regards to the HAL scores for the Placebo group

Intra-group pairs Placebo Group		Mean	Standard deviation (SD)	Standard error (SE)	Reported p-value/2
Pair 1	HAL 1	42.43	7.08	1.29	.0015
	HAL 3	46.30	6.81	1.24	
Pair 2	HAL 1	42.43	7.08	1.29	.000
	HAL 6	48.83	6.62	1.21	
Pair 3	HAL 1	42.43	7.08	1.29	.000
	HAL 7	49.37	5.89	1.08	
Pair 4	HAL 3	46.30	6.81	1.24	.0125
	HAL 6	48.83	6.62	1.21	
Pair 5	HAL 3	46.30	6.81	1.24	.011
	HAL 7	49.37	5.89	1.08	
Pair 6	HAL 6	48.83	6.62	1.21	.305
	HAL 7	49.37	5.89	1.08	

The null hypothesis was not rejected for the Hallux Metatarsophalangeal-interphalangeal Scale score at the treatment interval between the sixth and one week follow-up (7) consultations, indicating that there was no statistically significant improvement at this treatment interval. However the null hypothesis was rejected for the scores at the remaining treatment intervals, indicating that there was a statistically significant improvement between the first and third, first and sixth, first and seventh, third and sixth and third and seventh consultations.

#### 4.5.4 Friedman's test for intra-group comparison of the Foot Function Index (FFI)

**Table 20.** Intra-group comparison for the Foot Function Index (FFI), in terms of pain (FFpain), disability (FFdis) and overall scores (FFtot), in the Treatment and Placebo groups

FFI	Treatment group P-value	Placebo group P-value
FFpain	.000	.136
FFdis	.000	.724
FFtot	.000	.515

The null hypothesis was rejected for all three readings in the treatment group indicating a statistically significant improvement in this group. The null hypothesis was not rejected for all three readings in the placebo group indicating no significant improvement in this group.

The Dunn's post test was then performed for the treatment group. The rank values for each treatment, namely the first, third, sixth and one week follow up consultations were calculated (Appendix 10A, B, C) and tabulated for each sub-scale.

**Table 21.** Rank values for the Foot Function Index, in terms of pain (FFpain), disability (FFdis) and overall scores (FFtot), at the first, third, sixth and one week follow up (7) consultations

Rank	FFpain	FFdis	FFtot
1 (treatment 1)	113.5	111.5	115
2 (treatment 3)	86.5	92.5	90
3 (treatment 6)	56	57.5	57.5
4 (treatment 7)	44	38.5	37.5

The following decision rule was then applied to determine which treatment intervals were statistically significant.

**Decision Rule:**

- If  $|R_j - R_{j'}| \geq z \sqrt{\frac{bk(k+1)}{6}}$ , then  $R_j$  and  $R_{j'}$  are declared significant.

Where in the above formula:

b= the number of blocks (subjects = 30)

k= the number of treatments (4)

z= value in the inverse normal distribution corresponding to:

$(1 - [\alpha/k(k-1)]) = 2.409$

$\alpha = 0.10$

R= sum of the rank (Daniel, 1978).

If  $|R_j - R_{j'}| \geq z \sqrt{\frac{bk(k+1)}{6}}$ , then  $R_j$  and  $R_{j'}$  are declared significant.

$$\geq 2.409 \sqrt{\frac{30 \cdot 4(5)}{6}}$$

$$\geq 2.409 \sqrt{100}$$

$$\geq 2.409 (10)$$

$$\geq 24.09$$

Once the aforementioned decision rule was applied to the above-mentioned data, the following results were obtained for the Dunn's post test.

**Table 22.** Dunn's post test for multiple comparisons between consultations in the Treatment group, with regards to the Foot Function Index (FFI), in terms of pain (FFpain), disability (FFdis) and overall FFI (FFtot) scores.

Ranks (R) Treatment group	FFpain	FFdis	FFtot
R1-R2	27	19	25
R2-R3	30.5	35	32.5
R3-R4	12	19	20
R1-R4	69.5	73	77.5

The decision rule stated that if the difference between the relevant ranks was  $\geq 24.09$  then the treatments were considered effective and statistically significant.

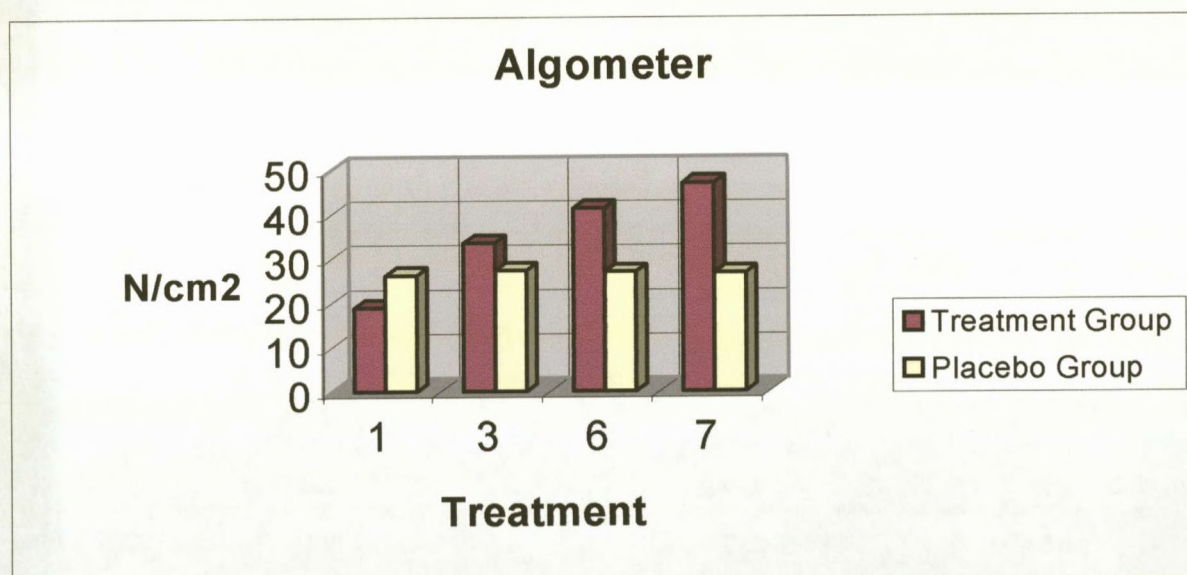
Regarding the sub-scale for pain (FFpain), the treatment was considered statistically significant for the first, second and overall treatment intervals, however it was considered insignificant for the third treatment interval (sixth and one week follow up visits).

The sub-scale for disability (FFdis) was considered statistically significant at the second and overall treatment intervals and was otherwise of no significance.

The overall FFI score (FFtot) was considered statistically significant at the first, second and overall treatment intervals. It was however considered insignificant at the third treatment interval (between the sixth and one week follow-up visits).

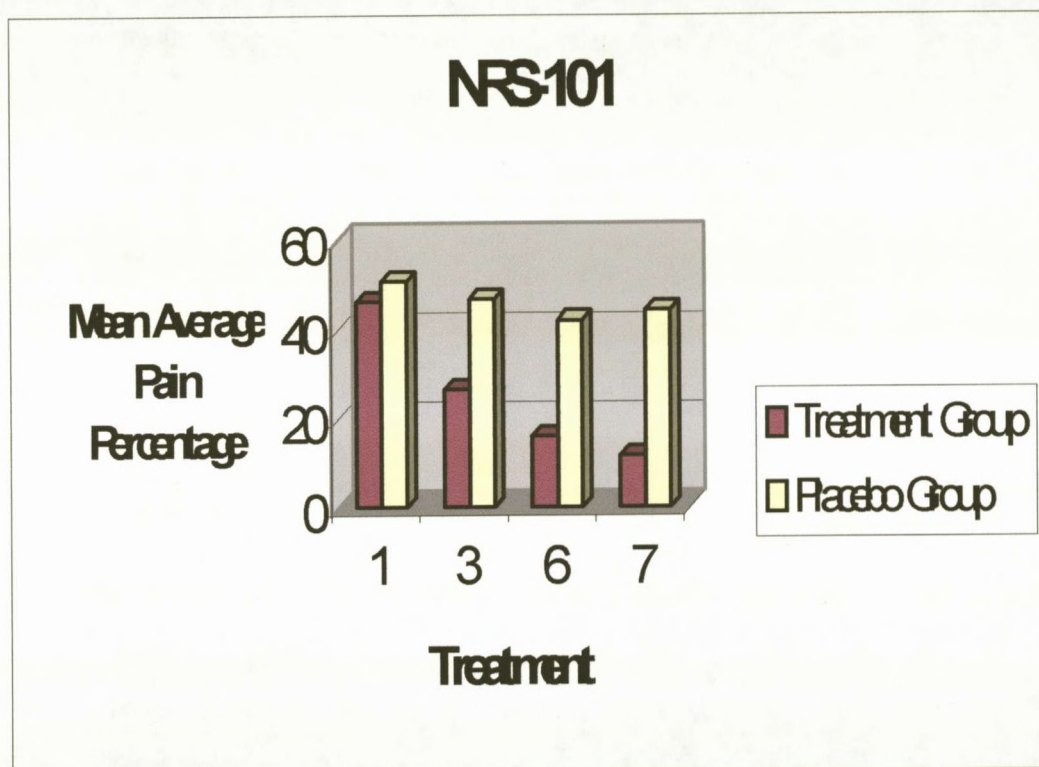
#### 4.6 Bar Graph representation of the inter-group analysis

**Figure 1.** Inter-group comparison between the treatment and placebo groups with regards to the algometer readings at the first, third, sixth and one week follow up consultations

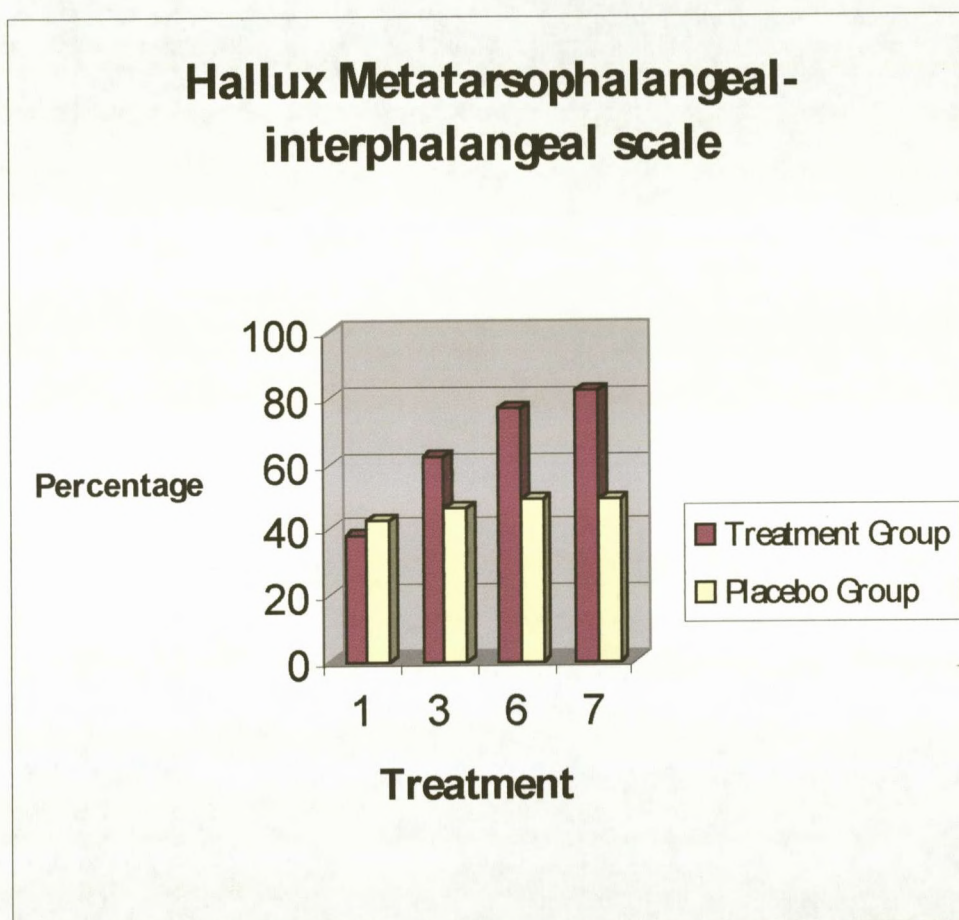




**Figure 2.** Inter-group comparison between the treatment and placebo groups with regards to the NRS-101 scores at the first, third, sixth and one week follow up consultations

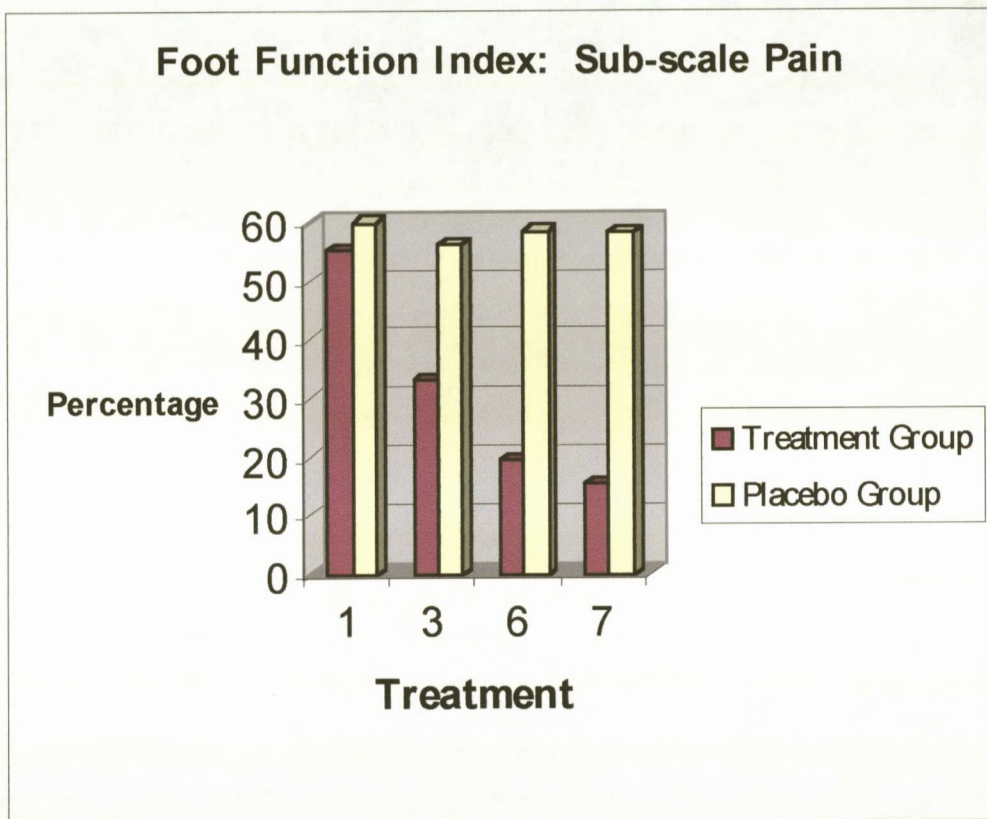


**Figure 3.** Inter-group comparison between the treatment and placebo groups with regards to the Hallux Metatarsophalangeal-interphalangeal scores at the first, third, sixth and one week follow up consultations

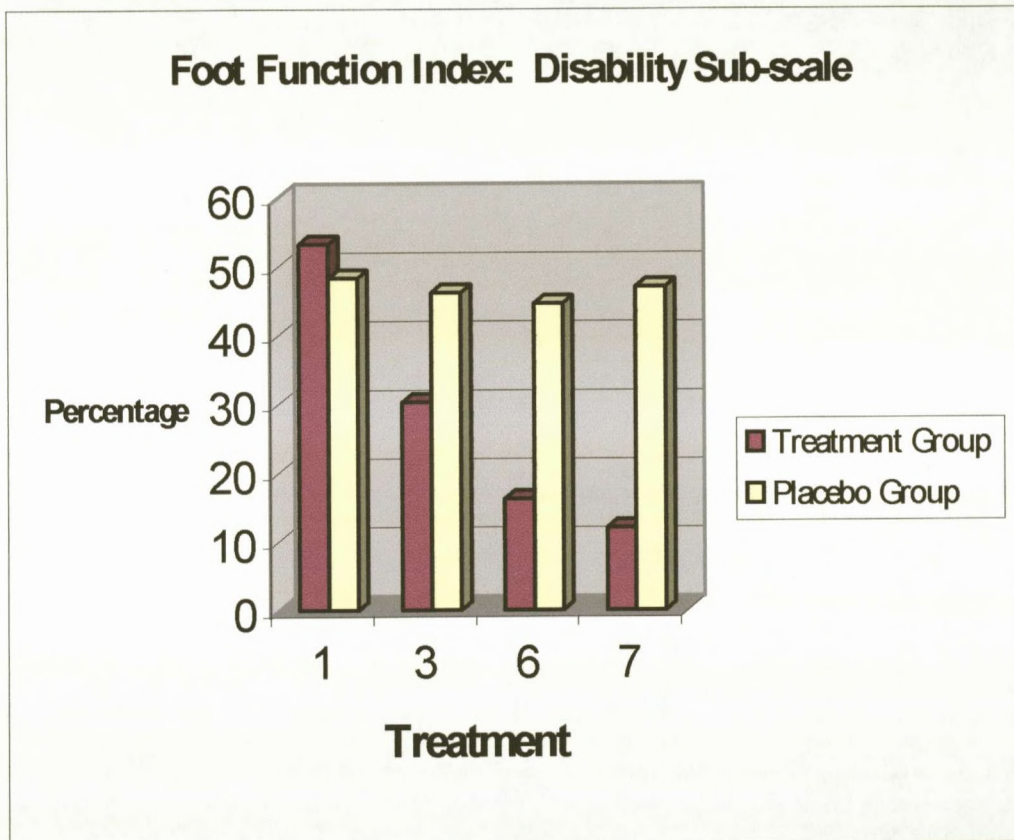




**Figure 4.** Inter-group comparison between the treatment and placebo groups with regards to the Foot Function Index sub-scale pain scores at the first, third, sixth and one week follow up consultations

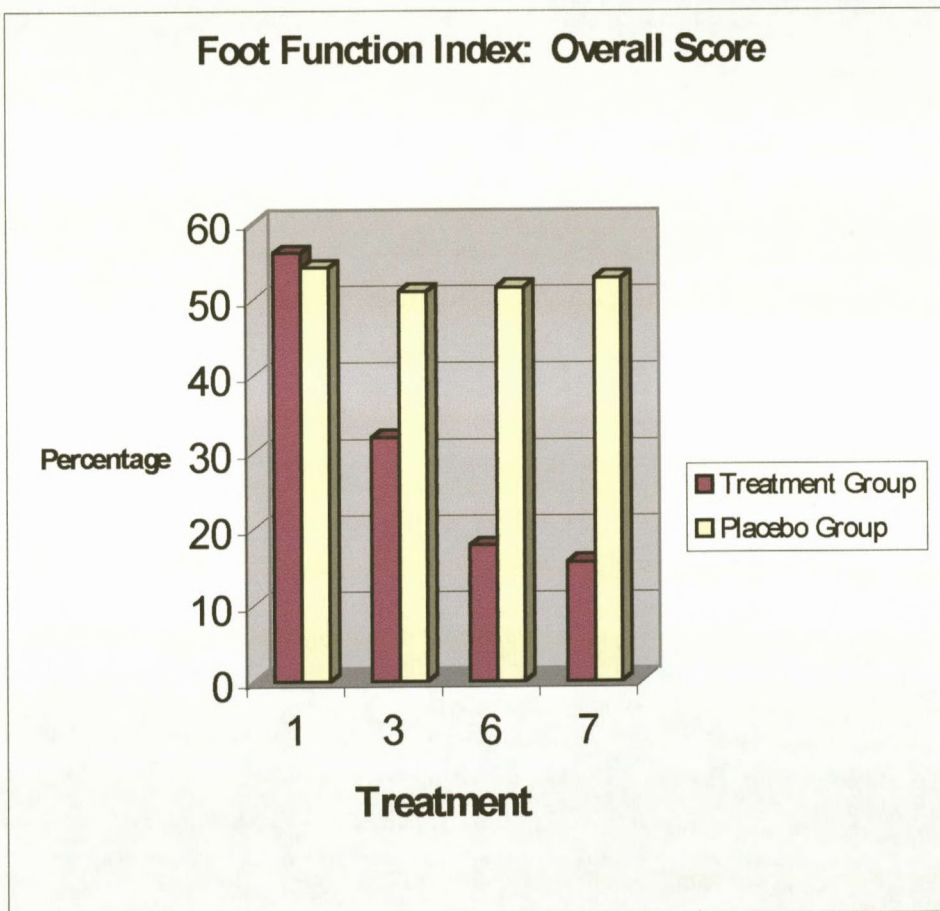


**Figure 5.** Inter-group comparison between the treatment and placebo groups with regards to the Foot Function Index sub-scale disability scores at the first, third, sixth and one week follow up consultations





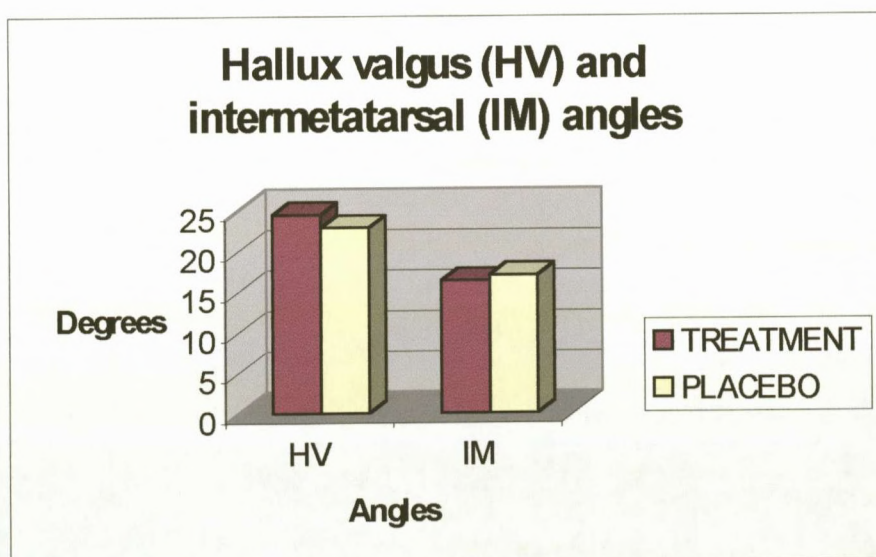
**Figure 6.** Inter-group comparison between the treatment and placebo groups with regards to the Foot Function Index overall scores at the first, third, sixth and one week follow up consultations



## 4.7 Clinical Findings

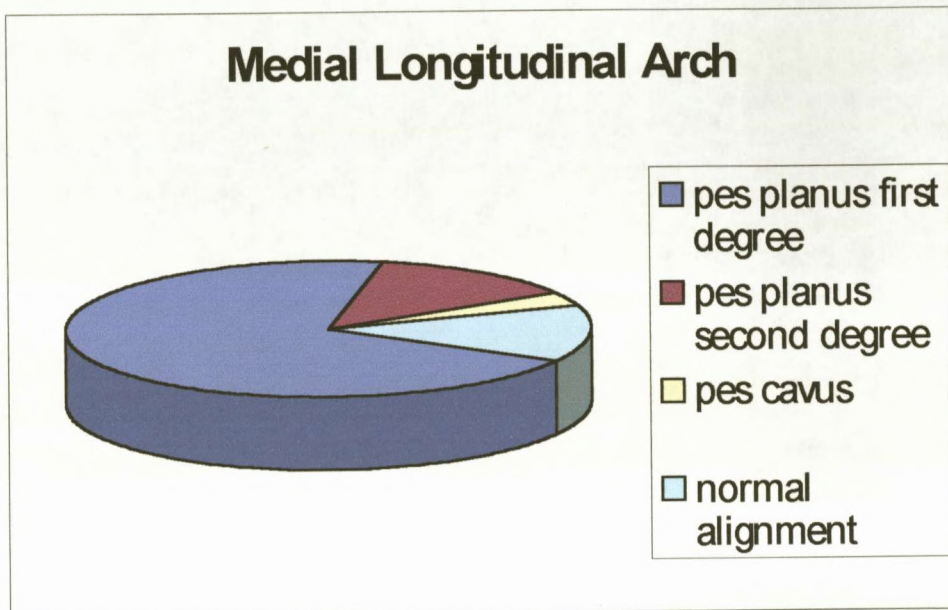
**Figure 7.** Mean hallux valgus (HV) and intermetatarsal (IM) angles in the treatment and placebo groups measured in degrees.

<u>Hallux Valgus angles:</u>	Treatment group:	24.54
	Placebo group:	22.86
<u>Intermetatarsal angles:</u>	Treatment group:	16.33
	Placebo group:	17.01





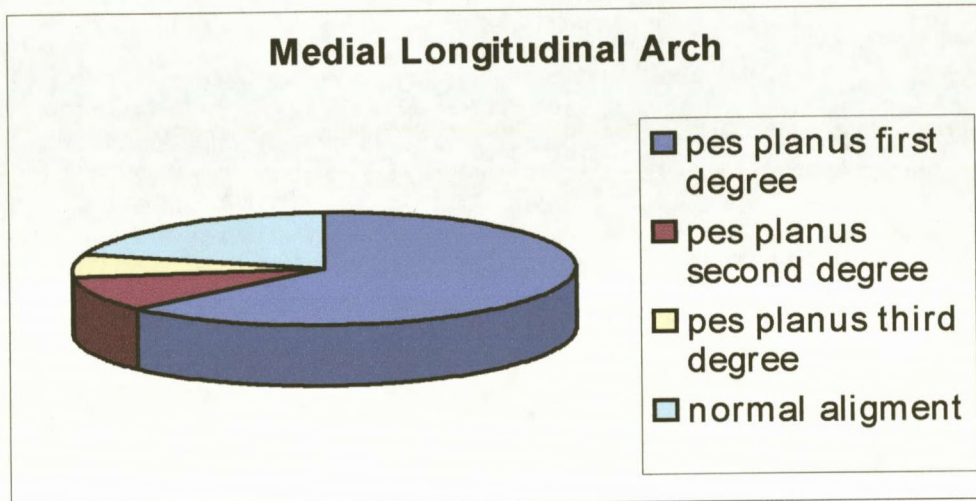
**Figure 8.** Biomechanical assessment pertaining to the medial longitudinal arch of the foot, in the treatment group



Medial longitudinal arch	No of patients
Pes planus, first degree	21
Pes planus, second degree	4
Pes cavus	1
Normal alignment	4



**Figure 9.** Biomechanical assessment pertaining to the medial longitudinal arch of the foot, in the placebo group



Medial longitudinal arch	No of patients
Pes planus, first degree	19
Pes planus, second degree	3
Pes planus, third degree	2
Normal alignment	6

## Chapter Five: Discussion

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### 5.1 Introduction

This chapter involves the discussion of the results after statistical analysis of the data obtained from the:

- algometer readings
- the Numerical Rating Scale-101
- Hallux-metatarsophalangeal-interphalangeal Scale and
- Foot Function index

Interpretation of the results was necessary to ascertain whether or not the premise, that this conservative chiropractic management approach is effective in the treatment of symptomatic HAVB, was substantiated.

### 5.2 Interpretation of the Demographic Data

On analysis of the age distribution of subjects who partook in this study (Table 1), it was apparent that almost half of the subjects (46.67%) were over the age of fifty-five years, with a further 25% over the age of forty-five. This was in accordance with the current literature, highlighted by Cailliet (1997:163) who is of the opinion that HAVB occurs most frequently in older women. The average age in the treatment and placebo groups were 49.43 years and 50.86 years respectively (Table 2.) which demonstrates a relative similarity of the two groups.

The study showed that of the sixty participating females, forty-nine were White, three were Black, five were Indian and three were of mixed race (Table 3.). Gould, Schnelder and Ashikaga (1980) estimated that after thirty years of age, HAVB occurred about twice as frequently in Whites as it did in Blacks and other races. This estimation was however based on a study performed in the United States of America and is therefore not representative of the demographics in a South African population. The researcher did not find any reference to allow for comparative analysis of the racial demographics in South Africa and thus this finding holds little significance.

The HAVB deformity was found to be bilateral in forty-nine of the sixty subjects with the remaining eleven subjects presenting with unilateral deformities (Table 4.). This is in accordance with the current literature as Klenerman (1991:65) is of the opinion that this condition is almost always bilateral, although the symptoms and deformity are often more pronounced on one side (Yale, 1987:346).

Forty-one of the subjects reported a definite family history of the deformity, with nine individuals unsure and ten individuals reporting no familial tendency (Table 4.). This supports the current literature (Yale, 1987:346; Cailliet, 1997:167; Magee, 1992:456 and Klenerman, 1991:65) where, although discrepancy exists as to the extent familial tendency impacts the aetiology of HAVB, there is majority consensus that hereditary factors warrant consideration.

The occupations of the participating individuals were varied (Table 5.), however it is important to note that a large percentage of these individuals were secretaries (18.33%), with nursing, banking and managerial positions accounting for 13.33% each. These occupations often prescribe the use of high-heeled shoes with pointed toe boxes, a known contributor to the development of HAVB (Reid, 1992:148; Klenerman, 1991:60 and Cailliet, 1997:164).



### 5.3 Inter-group Analysis

The evaluation of the inter-group results of the first consultation for the treatment and placebo groups identified any differences in the subjective and objective findings at the onset of the trial. Comparison of the inter-group results at the third and sixth consultations illustrated any differences in the rate of improvement between the two groups at each of these consultations. The evaluation of the one-week follow up consultations indicated any lasting effectiveness, over a short-term period, of the treatment protocol implemented.

#### ***5.3.1 Inter-group analysis of the first consultations (Table 6 and 10)***

The comparison of the first consultation (baseline measurements) between the treatment and placebo groups indicated no statistically significant difference for the NRS-101, FFI and Hallux-metatarsophalangeal-interphalangeal scale scores. This indicated that at the initial consultation the two groups started out with similar values in these measurements, allowing for comparative analysis of any changes between the two groups at consecutive consultations.

There was however a statistically significant difference noted when comparing the algometer readings in these two groups. The mean algometer readings were noted at 18.83 and 26.17 N/cm squared for the treatment and placebo groups respectively. Thus the placebo group started with a mean algometer reading of 7.34 N/cm squared higher than the treatment group, indicating an overall higher pressure-pain tolerance in this group at the onset of the study.

### **5.3.2 Inter-group analysis of the third consultations (Table 7 and 11)**

Analysis of the objective and subjective data at the third consultation revealed a statistically significant difference between the treatment and placebo groups, indicating that there was a difference in the rate of improvement between the two groups over the first treatment interval. Comparison of the mean values in terms of pressure-pain tolerance, perceived pain and impact on foot function highlighted that the treatment group improved to a greater degree than the placebo group. This was in accordance with the third hypothesis.

The algometer reading for the treatment group improved from an initial reading of 18.83 to a value of 33.48 N/cm squared, whereas the placebo group only improved to a value of 27.28. The placebo group initially had a significantly higher pressure-pain tolerance level (as denoted by the algometric reading) than the treatment group. However, at the third consultation, the treatment group was seen to have a significantly higher algometric reading, indicating that the pressure-pain tolerance in this group had significantly improved in comparison to that in the placebo group.

### **5.3.3 Inter-group analysis of the sixth consultations (Table 8 and 12)**

A statistically significant difference was noted between the two groups when comparing the results for each measurement parameter taken at the sixth consultation. Analysis of the mean scores of the relevant measurements indicated that the treatment group improved to a greater extent than the placebo group in terms of pressure-pain tolerance, perceived pain and impact on foot function. This was in accordance with the third hypothesis.

#### **5.3.4 Inter-group analysis of the one week follow up (7) consultations (Table 9 and 13)**

The comparison of the one-week follow up consultations for the treatment and placebo groups indicated a statistically significant difference between the groups, in terms of all the subjective and objective measurements. Analysis of the mean scores of the relevant measurements indicated that the treatment group improved to a greater extent than the placebo group in terms of pressure-pain tolerance, perceived pain and impact on foot function. This was in accordance with the third hypothesis.

### **5.4 Intra-group analysis**

Evaluation of the intra-group results of the first and seventh visits (overall treatment interval) gave an indication of the efficacy of the treatment regimes. The comparison of the first and third visits (first treatment interval), the third and sixth visits (second treatment interval) and the sixth and seventh visits (third treatment interval) were evaluated in order to determine any residual benefits of the treatment program. The results, for the treatment and placebo groups, will be discussed in terms of each measurement parameter.

#### **5.4.1 Algometer Readings**

In the treatment group there was a statistically significant improvement for the algometric readings at each treatment interval (Table 14). On analysis of the mean algometer readings for each interval, it was noted that the greatest improvement was seen to be at the overall treatment interval with the least improvement noted at the third treatment interval. Thus a significant

improvement in the pressure-pain threshold was noted in the patients in this group. These findings supported hypothesis one.

No statistically significant improvement was noted at any of the treatment intervals for the placebo group (Table 15). Although statistically insignificant, a slight improvement of the pressure-pain tolerance, as denoted by the mean algometric readings, was noted at the first treatment interval in this group. This slight improvement may have been due to the placebo effect (Brody, 1980:12) or due to the patient's will to please the researcher.

#### **5.4.2 NRS-101**

In the treatment group a statistically significant improvement was noted at each treatment interval, on assessment of the NRS-101 (Table 16). These findings indicated that the treatment protocol used appeared to be effective in decreasing the pain perceived by the patients in this group at each treatment interval. This was in accordance with hypothesis two.

In the placebo group there was a statistically significant improvement in the NRS-101 scores for the first to sixth and overall treatment intervals, indicating that the subjects in the placebo group perceived an improvement in the pain associated with their condition over the total treatment period (Table 17). However, no significant improvement was noted for the remaining treatment intervals. This indicated that although the subjects perceived an overall improvement in their pain, the improvement was not statistically significant at the first, second and third treatment intervals.

### ***5.4.3 Hallux-metatarsophalangeal-interphalangeal Scale (HAL)***

Intra-group analysis of the treatment group for the above scale indicated a significant improvement in scores at each treatment interval (Table 18). This supported hypothesis one and two. Subjects in this group had improved both objectively and subjectively with the mean score for this scale improving in the overall treatment interval, from 38.57 to 82.30 out of possible 100 points.

Intra-group analysis of the data from the placebo group (Table 19) indicated a significant improvement in the scores for the first, second and overall treatment intervals. There was however no significant improvement noted for the third treatment interval. On analysis of the mean scores, it should be noted that although the improvement in this group was considered statistically significant, it was an improvement of only 6.94 points out of the possible 100 points (from a starting score of 42.43 to a score of 49.37 at the final visit).

As previously described this scale involves both objective and subjective data, of which pain perception accounts for 40 of the overall 100 points. The researcher noted on close review of this scale, that in 26 of the 30 patients in the placebo group, the scores most frequently changed were the patient's pain perception. This was also evident in the assessment of the NRS-101 (Table 17), where a statistically significant improvement was also noted at the overall treatment interval. The researcher is of the opinion that this improvement in pain perception may have been due either to patients seeking to please the researcher or to certain lifestyle changes such as reducing pressure over the bunion joints by not wearing tight narrow high-heeled shoes. The use of such footwear was contra-indicated throughout the duration of the study as the current literature highlights the impact such usage has on symptomatic HAVB (Reid, 1992:148; Cailliet, 1997:164; Jahss, 1991:945 and Yale, 1987:346).

#### **5.4.4 Foot Function Index (FFI)**

The results of the Friedman's test indicated that a statistically significant improvement was noted in the treatment group in the sub-scale for pain, disability and overall FFI scores. There was however no statistically significant improvement noted for the placebo group (Table 20).

The Dunn's post-test, a multiple comparison procedure, was then performed to determine which treatment interval was most significant (Table 21 and 22). This test was only performed on the treatment group as the placebo group was shown to have no statistical significance.

In the analysis of the pain sub-scale a statistically significant improvement was noted at the first, second and overall treatment intervals, with the third treatment interval providing insignificant results. Thus the treatment regime was effective in alleviating the pain associated with HAVB (denoted by the statistically significant improvement) between the first and third, third and sixth and first and seventh consultations.

Analysis of Appendix 10A indicated that although no statistically significant improvement was noted at the third treatment interval, in terms of the pain perceived by the patients, there was however an improvement in the pain scores recorded by these patients between the two consultations.

In the analysis of the disability sub-scale, a statistically significant improvement was noted for the second and overall treatment intervals, with the results of the first and third treatment intervals found statistically insignificant. Thus the treatment regime was found to be ineffective in alleviating the disability associated with HAVB in the earlier stages of treatment, but was however found effective in the more advanced stages of treatment (second treatment interval) and at the conclusion of the study.

The total scores for the FFI (FFtot) indicated a significant improvement at the first, second and overall treatment intervals, but with no statistically significant improvement noted for the third treatment interval. This total score represented the average of the sub-scales and therefore assessed the impact of HAVB on foot function in terms of pain and disability.

The analysis of the total score (FFtot) indicated that this treatment regime was effective at decreasing the pain and disability associated with HAVB at the first, second and overall treatment intervals. Although the improvement between the sixth treatment and the one week follow up was not considered to be statistically significant, an improvement was however noted in the recorded scores between these two consultations (Appendix 10B).

The third sub-scale of the FFI (Appendix 9) was not statistically assessed as this only involved the patient answering "yes" or "no" to two questions pertaining to activity restriction due to their condition. It was however noted that no individual, in either the treatment or placebo group, answered "yes" to this section, indicating that no patient was immobilized from the HAVB deformity.

## 5.5 Interpretation of the results

It was hypothesised that there would be a statistically significant difference between the treatment and placebo groups, in terms of objective and subjective findings, indicating that this conservative chiropractic management approach was effective in the treatment of symptomatic HAVB.

On comparison of the subjective and objective data a statistically significant difference was noted between these groups for each reading and measurement (Figure 1-6). This indicated a significant improvement in pressure-pain tolerance, pain perception and overall foot function in the subjects in the treatment group, when compared to those in the placebo group. This was in accordance with the third hypothesis.

Intra-group analysis of the treatment group indicated a statistically significant improvement between each treatment interval, in terms of each measurement parameter assessed. This was in accordance with the first and second hypotheses, where a statistically significant improvement in both objective and subjective findings was hypothesised.

On examination of the mean scores, at each treatment interval, for each measurement parameter in the treatment group, it was noted that although the third treatment interval showed a statistically significant improvement, this improvement was to a lesser degree than that observed at the other treatment intervals.

The third treatment interval denoted a period of one week from the last consultation and was added to the study to enable the researcher to assess the short-term affects of adjustment of the HAVB joint.

However, on further examination of the patient files, it was noted that 28 of the 30 patients in this group progressed to adjustment of this joint by the fifth



consultation and thus only attended the sixth consultation for data collection. The time frame therefore, between adjustment of this joint and the one-week follow up, was inconsistent.

This may have influenced the analysis of the data and may not necessarily be a true indication of the efficacy of adjustment of the first MPJ in the treatment of HAVB, as no subjective or objective data was recorded at the fifth consultation to allow for comparative analysis.

However the improvement in this treatment interval was still found to be statistically significant which indicated that adjustment of the joint was effective in alleviating the pain and disability that the patients had experienced and that this improvement was maintained over the period of the third treatment interval.

The placebo group achieved a statistically significant improvement in terms of pain perception (NRS-101) in the overall treatment interval. This was further reinforced by significant findings in terms of the Hallux-metatarsophalangeal-interphalangeal Scale scores at the same treatment interval. However no statistically significant improvements were noted in terms of pressure-pain tolerance (algometer readings) and impact on foot function (FFI). The subjects in this group therefore improved in terms of pain perception, however this improvement was not substantiated by significant findings in the objective readings.

## **5.6 Clinical Findings**

### ***5.6.1 Roentogram examination***

The mean values of the hallux valgus (HV) and intermetatarsal (IM) angles for patients in the treatment and placebo group are presented in Figure 7. The inclusion criteria for this study required an HV angle greater than 15 degrees and an IM angle greater than 9 degrees. Although there is little consensus in the current literature as to what angulation is considered to constitute HAVB (Jahss, 1991:944; Magee, 1992:456; Cailliet, 1997:175; Klenerman, 1991:66 and Sammarco and Russo-Alesi, 1998), the mean angles in both the treatment and placebo groups were within the limits delineated by the aforementioned authors.

### ***5.6.2 Medial longitudinal Arch***

The medial longitudinal arches of the feet were assessed using Feiss' line (Magee, 1992:484) to determine if the patient had pes planus (flat feet), pes cavus or normal arch alignment. The available literature highlights that high proportions of individuals suffering from HAVB have flat valgus feet (Klenerman, 1991:59). Jahss (1991: 945) is of the opinion that patients who develop this condition invariably have flexible pes planus. The findings in this study support the aforementioned beliefs, as a high proportion of individuals in both the treatment and placebo groups were found to have first, second or third degree pes planus (Figures 8 and 9).

## **5.7 Problems encountered with the Data**

### **5.7.1 Algometer**

The problems encountered with the use of the algometer as an objective tool were:

- Some of the patients reported feeling bruised after the usage of the algometer which, may at consecutive consultations have resulted in lower reported values for this reading.
- The researcher is of the opinion that the use of three successive algometric readings may have skewed results. Some patients may have become sensitized after the pressure from the first reading, resulting in lower second and in turn even lower third reading values.
- Although the same point was used for algometric readings at consecutive consultations, certain factors may have affected the outcome, namely the direction of pressure applied through the shaft of the algometer, skin slack or the emotional state of the patient.

### **5.7.2 Hallux-metatarsophalangeal-interphalangeal Scale**

- This scale involved the assessment of both objective and subjective data. This allowed for a more clinically orientated assessment of the impact the treatment intervention had upon the condition, however it simultaneously caused difficulty in the interpretation of the results.

- The researcher is of the opinion that the subjective scoring for pain may have resulted in the statistical significance of this scale in the placebo group. Further assessment of this scale, indicated that in 26 of the 30 patients in the placebo group, improvement was only noted in the subjective components of the scale.
- 15 of the maximum 100 points obtainable in this scale were allocated to the degree of the deformity/alignment of the hallux. This study was directed at the alleviation of pain and disability associated with symptomatic HAVB, as Brantingham et al. (1994) noted that the deformity typically remains unchanged. Thus elimination of this section of the scale would have given a more realistic assessment of the impact this treatment regime had on this condition, in terms of the pain and disability experienced by the patients.
- Although the validity of this scale has yet to be shown (Kitaoka et al., 1994), it has been successfully used in surgical studies (Markbreiter and Thompson, 1997 and Selner et al., 1999) to evaluate the clinical status of patients with HAVB. However the researcher found no reference to the use of this scale in assessing the impact of conservative care on this condition.

### **5.7.3 NRS-101 and the FFI**

In the utilization of questionnaires, the probability of two types of error occurring should be taken into account. Type I errors occur when the patients answer the questionnaires based on what they recall filling in on the previous questionnaires, whilst Type II errors are calculation errors with regards to questionnaire results. The researcher is of the opinion that some of the patients may have been eager to please the researcher by recording an improvement in subjective scores, despite requests from the researcher to the contrary.

The researcher was also of the opinion that the FFI was not sufficiently specific in its need to classify the extent of pain and disability of the bunion deformity. This is confirmed by Saag et al. (1996) who maintain that although this questionnaire shows validity in the measurement of arthritic foot pain, its use for other foot pathology has not yet been established.

## Chapter Six: Conclusions and Recommendations

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### 6.1 Conclusions

The results of this study indicated that a conservative chiropractic treatment protocol (encompassing progressive mobilization of the first MPJ used in conjunction with cryotherapy and adjustment of all other joint dysfunctions found in the foot and ankle), as opposed to placebo treatment, was effective in the treatment of symptomatic HAVB.

The placebo treatment was found to be effective in improving the pain perceived by the patients in this group, as denoted by a statistically significant improvement seen in the NRS-101 scores in the overall treatment interval. However, this improvement in pain was not substantiated by a statistically significant improvement in the objective measurements, as denoted by the pressure-pain threshold.

This conservative chiropractic management protocol was found to be effective in the alleviation of symptoms experienced by the patients, as was denoted by a statistically significant improvement in both the objective and subjective measurements taken. This implies that this treatment regime was a valuable tool in the treatment of symptomatic HAVB, in terms of alleviating the pain and disability associated with this condition.

## **6.2 Recommendations**

### ***6.2.1 Homogeneity***

More stringent inclusion and exclusion criteria with regards to the case history, physical findings and radiographic changes may have strengthened this study. The use of a radiographic grading scale may have improved the homogeneity of the sample.

### ***6.2.2 Pre and post treatment X-rays***

The incorporation of post treatment x-ray measurements would have allowed for objective assessment of the deformity at the conclusion of the study.

### ***6.2.3 Independent Observer***

The use of an independent observer to record the objective and subjective data could have eliminated any bias that may have occurred, thus improving the credibility of the study.

### ***6.2.4. Objective measurements***

The use of other objective data such as measurements for joint range of motion or force plate analysis may be of value for future studies.

### **6.2.5 Subjective measurements**

The use of questionnaires, tested for reliability and validity, pertaining to the assessment of conservative care of the foot is recommended for future studies.

### **6.2.6 Number of treatments**

The researcher recommends that this treatment protocol be tested over 5 consultations, as 28 of the 30 patients in this group, treated conservatively, progressed to adjustment of the first MPJ by the fifth consultation.

### **6.2.7. Data Collection**

As this was a progressive study, the researcher was unsure as to when the patient would receive the adjustment of the first MPJ. This resulted in inconsistent time frames between the adjustment of this joint and the one-week follow up consultation. The researcher recommends that data collection be performed at the consultation that the patient received the adjustment and that the one-week follow up be set from this appointment. Thus if patients received a different number of treatments, data collection would still occur at the same interval from the last treatment.

### **6.2.8 Orthotics**

The researcher recommends investigating the benefits of this conservative chiropractic management approach used in conjunction with other treatments such as orthotics, to correct any structural abnormalities that may be present. This may be effective in decreasing the recurrence rate of the joint dysfunction found in conjunction with the HAVB deformity. Brantingham et al. (1994) prescribe the use of a multiple treatment protocol.



### **6.2.9 *Follow up consultation***

A further follow up consultation may be helpful in determining the long-term effects of this treatment protocol.

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Appendix 1

**TECHNIKON NATAL CHIROPRACTIC DAY CLINIC**  
**CASE HISTORY**

Patient: \_\_\_\_\_ Date: \_\_\_\_\_  
file #: \_\_\_\_\_ X-Ray#: \_\_\_\_\_  
Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Occupation: \_\_\_\_\_  
Intern: \_\_\_\_\_ Signature: \_\_\_\_\_

**FOR CLINICIAN'S USE ONLY**

Initial visit clinician: \_\_\_\_\_ Signature: \_\_\_\_\_

**Case History:**

**Examination:**

Previous:

Current:

**X-Ray Studies:**

Previous:

Current:

**Clinical Path. lab:**

Previous:

Current:

**Case Status:**

PTT:            Conditional:            Signed Off:            Final Sign out:

Recommendations:

**Intern's Case History**

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



3. Present Illness:

- ▶ Location
- ▶ Onset
- ▶ Duration
- ▶ Frequency
- ▶ Pain (Character)
- ▶ Progression
- ▶ Aggravating Factors
- ▶ Relieving Factors
- ▶ Associated S & S
- ▶ Previous Occurrences
- ▶ Past Treatment and Outcome

4. Other Complaints:

5. Past 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
- ▶ Environmental Hazards (Home, School, Work)
- ▶ Safety Measures (seat belts, condoms)
- ▶ Exercise and Leisure
- ▶ Sleep Patterns
- ▶ Diet
- ▶ Current Medication
- ▶ 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 2

### 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 &   Gag reflex:
- X      Uvula deviation:
- Speech quality:
  
- XI    Shoulder lift:
- S.C.M. strength:
  
- XII   Inspection of tongue (deviation):

### **Motor System:**

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

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

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

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

### Sensory System:

- a. Dermatomes
- Light touch:
  - Crude touch:
  - Pain:
  - Temperature:
  - Two point discrimination:
- b. Joint position sense
- Finger:
  - Toe:
- c. Vibration:
- Big toe:
  - Tibial tuberosity:
  - ASIS:
  - Interphalangeal Joint:
  - Sternum:

### Cerebellar function:

Obvious signs of cerebellar dysfunction:

- = Intention Tremor:
- = Nystagmus:
- = Truncal Ataxia:



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

8. **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 3

## Foot and ankle regional examination

Patient: \_\_\_\_\_ File no: \_\_\_\_\_ Date: \_\_\_\_\_  
Intern / Resident \_\_\_\_\_ Signature: \_\_\_\_\_  
Clinician: \_\_\_\_\_ Signature: \_\_\_\_\_

### Observation

Gait analysis (antalgic limp, toe off, arch, foot alignment, tibial alignment).

\_\_\_\_\_

Swelling \_\_\_\_\_  
Heloma dura / molle \_\_\_\_\_  
Skin \_\_\_\_\_  
Nails \_\_\_\_\_  
Shoes \_\_\_\_\_  
Contours (achilles tendon, bony prominences) \_\_\_\_\_

### Active movements

<i>weight bearing:</i>	<i>Non weight bearing:</i>
Plantar flexion _____	50° _____
Dorsiflexion _____	20° _____
Supination _____	
Pronation _____	
Toe dorsiflexion _____	40° (mtp) _____
Toe plantar flexion _____	40° (mtp) _____
	Big toe dorsiflexion (mtp) (65-70°) _____
	Big toe plantar flexion (mtp) 45° _____
	Toe abduction + adduction _____
	5° first ray dorsiflexion _____
	5° first ray plantar flexion _____

### Resisted Isometric movements:

Knee flexion \_\_\_\_\_  
Plantar flexion \_\_\_\_\_  
Dorsiflexion \_\_\_\_\_  
Supination (inversion) \_\_\_\_\_  
Pronation (eversion) \_\_\_\_\_  
Toe extension (dorsiflexion) \_\_\_\_\_  
Toe flexion (plantar flexion) \_\_\_\_\_

### Passive movement motion palpation

(Passive ROM quality, ROM overpressure, joint play)

Ankle joint: Plantarflexion \_\_\_\_\_ Dorsiflexion \_\_\_\_\_  
Talocrural: Long axis distraction \_\_\_\_\_  
Subtalar joint: Varus \_\_\_\_\_ Valgus \_\_\_\_\_  
First ray: Dorsiflexion \_\_\_\_\_ Plantarflexion \_\_\_\_\_  
Circumduction of forefoot on fixed rearfoot: \_\_\_\_\_  
Midtarsal: A-P glide \_\_\_\_\_ P-A glide \_\_\_\_\_ rotation \_\_\_\_\_  
Tarso metatarsal joints: A-P \_\_\_\_\_

Intermetatarsal glide: \_\_\_\_\_  
Metatarsophalangeal dorsiflexion (with associated plantar flexion of each toe) \_\_\_\_\_

Interphalangeal joints: *long axis distraction* \_\_\_\_\_ *A-P glide* \_\_\_\_\_  
*lat and med glide* \_\_\_\_\_ *rotation* \_\_\_\_\_

**Neurological:**      Dermatomes \_\_\_\_\_  
                                 Reflexes \_\_\_\_\_

### Special tests

Anterior drawer test \_\_\_\_\_  
Talar tilt \_\_\_\_\_  
Thompson test \_\_\_\_\_  
Homan sign \_\_\_\_\_  
Tinel's sign \_\_\_\_\_  
Subtalar neutral position \_\_\_\_\_  
Balance/proprioception \_\_\_\_\_  
Test for rigid/flexible flatfoot \_\_\_\_\_  
Kleiger test (med. deltoid) \_\_\_\_\_

### Alignment

Heel to ground \_\_\_\_\_  
Feiss line \_\_\_\_\_  
Tibial torsion \_\_\_\_\_  
Heel to leg (subtalar neutral) \_\_\_\_\_  
Forefoot to heel (subtalar & Midtarsal neutral) \_\_\_\_\_  
First ray alignment \_\_\_\_\_  
Digital deformities \_\_\_\_\_  
Digital deformity flexible \_\_\_\_\_

### Palpation

#### *Anteriorly*

Medial malleoli \_\_\_\_\_  
Med tarsal bones, tibial (post) artery \_\_\_\_\_  
Lat. malleolous, calcaneus, sinus tarsi, and cuboid bones \_\_\_\_\_  
Inferior tib/fib joint, tibia, mm of leg \_\_\_\_\_  
Anterior tibia, neck of talus, dorsalis pedis artery \_\_\_\_\_

#### *Posteriorly*

Calcaneus \_\_\_\_\_  
Achilles tendon \_\_\_\_\_  
Musculotendinous junction \_\_\_\_\_

#### *Plantarily*

Plantar muscles and fascia \_\_\_\_\_  
Sesamoids \_\_\_\_\_

## Appendix 4

The efficacy of a conservative chiropractic management approach in the treatment of symptomatic hallux abductovalgus (bunions).

### Patient Information Sheet

Dear Patient

Welcome to my research project. The aim of this study is to determine the efficacy of a chiropractic treatment protocol in the management of painful hallux abductovalgus (bunions). To best assess the efficacy of this treatment protocol we need to test it against a placebo/ sham treatment.

You will be allocated into one of two groups by drawing a number, (representative of a treatment group) from a bag. You will then receive a treatment in an attempt to determine how effective this treatment is in the management of hallux abductovalgus (bunions).

Your treatment will be free of charge and you are permitted to withdraw from this research project at any stage should you wish to do so.

You will receive six treatments over a two -week period and need to attend a one week follow-up consultation. You will be asked to fill in simple questionnaires in order for the progress during the study period to be assessed.

You will not be allowed to undergo any other form of treatment for your bunions through out the duration of this study, including the use of analgesics and anti-inflammatory drugs.

You will be asked to refrain from using tight, pointed, narrow and high- heeled shoes through out the duration of this study as these shoes are known to aggravate this condition.

You will be asked to inform the researcher if any of the conditions of this study have been breached in any way.

If you have any of the following conditions you will be excluded from the study, as they are contra-indicated for the treatment protocols used in this research:

Advanced/ Severe Degenerative Joint Disease

Anti- coagulant therapy  
Inflammatory Arthritis  
Joint instability  
Fracture/ Dislocation  
Bone Tumours/ Infections

There are minimal risks involved in the treatment offered in this study, however the overall benefits may include decrease pain and discomfort associated with this condition. I must stress that individual results may vary and that this treatment will in no way alter the cosmetic appearance of the HAVB deformity.

If you have any questions or doubts with regards to this study, please do not hesitate to ask me for clarification.

Yours Sincerely,

Sioban Guiry. (Chiropractic Intern)

**INFORMED CONSENT FORM**

(To be completed by patient / subject )

ate

:

Title of research project

:The efficacy of a conservative chiropractic management approach in the treatment of symptomatic hallux abducto valgus (bunions).

Name of supervisor

:Dr H. Kretzmann

Name of research student

:S. Guiry

Please circle the appropriate answer**YES NO**

Have you read the research information sheet?

Yes No

Have you had an opportunity to ask questions regarding this study?

Yes No

Have you received satisfactory answers to your questions?

Yes No

Have you had an opportunity to discuss this study?

Yes No

Have you received enough information about this study?

Yes No

Who have you spoken to? \_\_\_\_\_

Do you understand the implications of your involvement in this study?

Yes No

Do you understand that you are free to withdraw from this study?

Yes No

a) at any time

b) without having to give any a reason for withdrawing, and

c) without affecting your future health care.

Do you agree to voluntarily participate in this study

Yes No

**If you have answered no to any of the above, please obtain the necessary information before signing****Please Print in block letters:**

Patient /Subject Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Parent/ Guardian: \_\_\_\_\_

Signature: \_\_\_\_\_

Witness Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Research Student Name: \_\_\_\_\_

Signature: \_\_\_\_\_

## Appendix 6

### Algometer Readings

Patient Name: -----

File Number: -----

Consultation	Date	Newtons/cm2
One		
Three		
Six		
One week F/U		

## Appendix 7

### Hallux Metatarsophalangeal-Interphalangeal Scale (100 Points Total)

Pain (40 points)	
None	40
Mild, occasional	30
Moderate, daily	20
Severe, almost always present	0
Function (45 points)	
Activity limitations	
No limitations	10
No limitation of daily activities, such as employment responsibilities, limitation of recreational activities	7
Limited daily and recreational activities	4
Severe limitation of daily and recreational activities	0
Footwear requirements	
Fashionable, conventional shoes, no insert required	10
Comfort footwear, shoe insert	5
Modified shoes or brace	0
MTP joint motion (dorsiflexion plus plantarflexion)	
Normal or mild restriction ( $75^{\circ}$ or more)	10
Moderate restriction ( $30^{\circ}$ – $74^{\circ}$ )	5
Severe restriction (less than $30^{\circ}$ )	0
IP joint motion (plantarflexion)	
No restriction	5
Severe restriction (less than $10^{\circ}$ )	0
MTP-IP stability (all directions)	
Stable	5
Definitely unstable or able to dislocate	0
Callus related to hallux MTP-IP	
No callus or asymptomatic callus	5
Callus, symptomatic	0
Alignment (15 points)	
Good, hallux well aligned	15
Fair, some degree of hallux malalignment observed, no symptoms	8
Poor, obvious symptomatic malalignment	0



Appendix 8

Numerical Rating Scale - 101 Questionnaire

Date: \_\_\_\_\_ File no: \_\_\_\_\_ Visit no: \_\_\_\_\_

Patient name: \_\_\_\_\_

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

Please write only **one** number.

\_\_\_\_\_

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

Please write only **one** number.

\_\_\_\_\_

## Appendix 9

## FOOT FUNCTION INDEX

**INSTRUCTIONS:** Please fill in a value somewhere between **0** and **10** describing your pain

**0** indicates no pain and **10** indicates the worst pain (✓)

If the question is not applicable then indicate this by writing **N/A** next to it

Section A:	0	1	2	3	4	5	6	7	8	9	10	
Worst pain												
Morning Pain												
Pain walking barefoot												
Pain walking with shoes												
Pain standing with shoes												

Section B :Can you	0	1	2	3	4	5	6	7	8	9	10	
Walk in the house												
Walk outside												
Climb stairs												
Descend stairs												
Stand on tip toe												
Get up from a chair												
Climb curbs												

Section C: Do you have to?	Yes	No
Stay inside all day		
Stay in bed all day		

# Appendix 10A Rank scores for FFI-pain sub-scale in the treatment group

SUBJECTS	Tx1/ RANK 1	Tx3/ RANK 2	Tx6/ RANK 3	Tx7/ RANK 4
1	84 (4)	68 (3)	48 (2)	36 (1)
2	54 (4)	22 (2)	34 (3)	6 (1)
3	30 (1)	56 (2)	64 (3.5)	64 (3.5)
4	62 (4)	34 (2)	44 (3)	33 (1)
5	60 (4)	0 (2)	0 (2)	0 (2)
6	38 (3)	36 (2)	26 (1)	44 (4)
7	22 (3)	30 (4)	10 (2)	8 (1)
8	56 (4)	44 (3)	22 (1)	24 (2)
9	44 (4)	36 (3)	26 (1)	34 (2)
10	60 (4)	42 (2)	38 (1)	46 (3)
11	70 (4)	56 (3)	26 (1)	52 (2)
12	80 (4)	6 (3)	0 (1.5)	0 (1.5)
13	70 (4)	14 (3)	4 (2)	0 (1)
14	56 (4)	26 (3)	6 (2)	0 (1)
15	72 (4)	20 (3)	4 (2)	0 (1)
16	32 (4)	24 (3)	6 (2)	1 (1)
17	56 (3)	62 (4)	18 (1.5)	18 (1.5)
18	58 (4)	22 (3)	6 (2)	0 (1)
19	34 (4)	12 (3)	4 (2)	0 (1)
20	75 (3.5)	75 (3.5)	62 (2)	50 (1)
21	64 (4)	40 (3)	0 (1.5)	0 (1.5)
22	66 (4)	20 (3)	18 (2)	4 (1)
23	68 (4)	56 (3)	26 (2)	10 (1)
24	74 (4)	54 (3)	38 (2)	20 (1)
25	38 (4)	24 (3)	12 (2)	0 (1)
26	72 (4)	20 (3)	18 (2)	8 (1)
27	50 (4)	4 (3)	0 (1.5)	0 (1.5)
28	72 (4)	46 (3)	2 (2)	0 (1)
29	36 (4)	24 (3)	6 (2)	0 (1)
30	54 (4)	18 (3)	10 (1.5)	10 (1.5)
TOTAL	113.5	86.5	56	44

**Appendix 10B** Rank scores for FFI-disability sub-scale for the treatment group

SUBJECTS	Tx1/ RANK 1	Tx3/ RANK 2	Tx6/ RANK 3	Tx7/ RANK 4
1	77 (4)	71.43 (3)	45.7 (2)	42.85 (1)
2	25.71 (4)	8.57 (3)	0 (1.5)	0 (1.5)
3	14.28 (1)	44.28 (3)	52.85 (4)	40 (2)
4	78.57 (4)	22.85 (2)	28.57 (3)	18.57 (1)
5	54.28 (4)	0 (2)	0 (2)	0 (2)
6	27.14 (3)	28.57 (4)	20 (1.5)	20 (1.5)
7	12.85 (3)	25.7 (4)	10 (1.5)	10 (1.5)
8	54.28 (4)	10 (3)	1.43 (1)	8.57 (2)
9	35.7 (3)	50 (4)	34 (2)	25.7 (1)
10	65.7 (4)	58.57 (3)	47 (2)	42.8 (1)
11	58.57 (4)	50 (3)	22.85 (1)	27.1 (2)
12	68.57 (4)	5.7 (3)	2.85 (2)	0 (1)
13	84.28 (4)	38.57 (3)	5.7 (2)	0 (1)
14	64.3 (4)	31.4 (3)	4.28 (2)	0 (1)
15	81.4 (4)	11.4 (3)	4.3 (2)	2.85 (1)
16	94 (4)	42.8 (2.5)	42.8 (2.5)	2.8 (1)
17	51.4 (3)	57 (4)	20 (2)	17.14 (1)
18	31.4 (4)	2.85 (3)	0 (1.5)	0 (1.5)
19	32 (4)	7 (3)	2.8 (2)	1.4 (1)
20	90 (4)	64.2 (3)	36 (2)	23 (1)
21	53 (4)	28.5 (3)	0 (1.5)	0 (1.5)
22	50 (4)	17 (3)	15.07 (2)	10 (1)
23	66 (3)	72 (4)	15 (2)	8.5 (1)
24	54 (3.5)	54 (3.5)	46 (2)	34 (1)
25	18 (4)	8 (2.5)	8 (2.5)	0 (1)
26	65.7 (4)	36 (3)	7 (1)	8.5 (2)
27	54 (4)	4.28 (3)	0 (1.5)	0 (1.5)
28	45.72 (4)	10 (3)	0 (1.5)	0 (1.5)
29	45.72 (4)	21.43 (3)	1.43 (2)	0 (1)
30	45.71 (4)	25.71 (3)	17.14 (2)	15.71 (1)
TOTAL	111.5	92.5	57.5	38.5

## Appendix 10C

Ranks for the FFI overall scores for the treatment group

SUBJECTS	Tx1/ RANK 1	Tx3/ RANK 2	Tx6/ RANK 3	Tx7/ RANK 4
1	80.5 (4)	69.71 (3)	46.85 (2)	39.43 (1)
2	67.5 (4)	15.28 (3)	17 (2)	3(1)
3	22.14 (1)	50.14 (2)	58.42 (4)	52 (3)
4	70.28 (4)	38.42 (3)	36.28 (2)	26.28 (1)
5	57.14 (4)	0 (2)	0 (2)	0 (2)
6	35.57 (4)	31.28 (3)	23 (1)	32 (2)
7	17.43 (3)	27.85 (4)	10 (2)	9 (1)
8	55.14 (4)	27 (3)	11.72 (1)	16.3 (2)
9	39.85 (4)	43 (3)	30 (2)	28.95 (1)
10	62.85 (4)	50.28 (3)	42.5 (2)	44.4 (1)
11	64.28 (4)	53 (3)	24.42 (1)	39.55 (2)
12	74.3 (4)	5.85 (3)	1.43 (2)	0 (1)
13	77.14 (4)	26.28 (3)	4.85 (2)	0 (1)
14	60.15 (4)	28.7 (3)	5.14 (2)	0 (1)
15	76.7 (4)	15.7 (3)	4.15 (2)	1.43 (1)
16	63 (4)	33.4 (3)	24.4 (2)	1.9 (1)
17	53.7 (3)	59.5 (4)	19 (2)	17.57 (1)
18	44.7 (4)	12.4 (3)	3 (2)	0 (1)
19	33 (4)	9.5 (3)	3.4 (2)	0.7 (1)
20	82.5 (4)	69.6 (3)	49 (2)	36.5 (1)
21	58.5 (4)	34.25 (3)	0 (2)	0 (1)
22	58 (4)	18.5 (3)	16.85 (1)	17 (2)
23	67 (4)	64 (3)	20.5 (2)	9.25 (1)
24	64 (4)	54 (3)	42 (2)	27 (1)
25	28 (4)	16 (3)	10 (2)	0 (1)
26	69 (4)	28 (3)	12.5 (2)	8.25 (1)
27	52 (4)	4 (3)	0 (1.5)	0 (1.5)
28	58.86 (4)	28 (3)	1 (2)	0 (1)
29	40.86 (4)	22.71 (3)	3.71 (2)	0 (1)
30	49.85 (4)	21.85 (3)	13.57 (2)	12.85 (1)
TOTAL	115	90	57.5	37.5