The effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in the treatment of acute and subacute ankle sprains

By

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I, **Morris Kahere**, do declare that this dissertation is a representation of my own work in both conception and execution (except where acknowledgement indicates to the contrary)

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Dedication

This dissertation is dedicated to:

My Lord and Saviour Jesus Christ

Through him everything was possible (Matthew 19 v 26)

My mom, Katu Kahere, who gave me all the emotional support and believed in me. If it wasn't for you I wouldn't have even come this far.

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Abstract

Background: Ankle sprains are a frequently occurring injury sustained by sports individuals accounting for approximately 20% to 40% of all sports injuries (DiStefano et al. 2008; LeBrun and Krause, 2005). Ankle sprains are mainly caused by excessive inversion (Takao et al., 2005; Andersen et al., 2004), when the foot is twisted inwards and lands at a high velocity damaging the lateral capsule-ligamentous complex (Beynnon et al., 2005). According to Naqvi, Cunningham and Lynch (2012) untreated or inappropriately managed ankle sprains can lead to a cascade of negative alteration to both the joint structures and the individual's lifestyle. According to Hale, Hertel and Olmsted-Kramer (2007) 30% of ankle sprains result in chronic ankle instability (CAI) and 78% of the CAI cases develop into post-traumatic ankle osteoarthritis. This poses a negative impact on an individual's athletic performance. Ankle sprains can be managed conservatively with the utilization of the PRICE protocol during the acute stage, cross friction massage or instrument assisted soft tissue mobilization techniques (for example Graston®, FAKTR© Concept) for both acute and subacute ankle sprains (Bleakley, 2010).

Aim: The purpose of this study was to determine the effectiveness of a myofascial treatment protocol (FAKTR© Concept) combined with cryotherapy compared to cryotherapy and sham laser in the treatment of sub-acute and acute ankle inversion sprains.

Objectives:

1. To determine the effectiveness of a myofascial treatment protocol combined with cryotherapy in terms of subjective (numerical pain rating scale [NRS] and foot function index [FFI]) and objective (oedema measurements [EDM], digital inclinometer readings [DIR], algometer readings [AR] and stork balance stand test score [STR]) measurements in the treatment of acute and sub-acute ankle sprains.
2. To determine the effectiveness of sham laser combined with cryotherapy in terms of subjective (NRS and FFI) and objective (EDM, DIR, AR and STR) measurements in the treatment of acute and sub-acute ankle sprains.

3. To compare the relative improvement between the two groups in terms of subjective (NRS and FFI) and objective measurement (EDM, DIR, AR and STR).

Study design: This was a quantitative randomised controlled clinical trial.

Methods: Forty participants with sub-acute or acute ankle sprains of not more than three weeks were recruited into the study. All participants had a full case history, physical, and foot and ankle regional examination to assess for their eligibility for entry into the study in terms of inclusion and exclusion criteria. These participants were randomly allocated using the hat method into one of two study groups, Group A (treatment group) or Group B. Participants in Group A received a myofascial treatment protocol (FAKTR© Concept) combined with cryotherapy and Group B received cryotherapy and sham laser. These participants had four treatments in two weeks where the appropriate treatment was administered. Pre-treatment subjective (NRS and FFI) and objective (EDM, DIR, AR and STR) measurements were taken at each consultation. This data was analysed using SPSS software version 24.0.

Results: The General Linear Model for repeated measures was used for the intra-group and inter-group analysis of the data. Intra-group analysis of the FAKTR© treatment group showed that the group had statistically significant improvements in terms of the subjective and objective measurements of the study with the p-value < 0.05 between all treatment periods. Intra-group analysis of the control group showed no statistically significant improvements in terms of subjective and objective measurements of the study. Inter-group analysis showed no statistically significant difference in terms of the DIR and EDM. The NRS, AR, STR and FFI readings showed statistically significant differences between the two groups with a p-value of < 0.05 mainly on the last two consultations.

Conclusion: This study concluded that the myofascial treatment protocol (FAKTR© Concept) combined with cryotherapy was more effective than cryotherapy and sham laser in the treatment of sub-acute and acute inversion ankle sprains. The FAKTR© Concept treatment group appeared to show statistically significant improvements compared to the control group.

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List of Abbreviations

AITFL	Anterior Inferior Tibiofibular Ligament
AR	Algometer Reading
ATFL	Anterior Talofibular Ligament
CAI	Chronic Ankle Instability
CFL	Calcenofibular Ligament
DIR	Digital Inclinometer Reading
DUT CDC	Durban University of Technology Chiropractic Day Clinic
EDM	Oedema Measurements
FAKTR	Functional Kinetic Treatment with Rehab
FFI	Foot Function Index
GLM	General Linear Model
IASTM	Instrument assisted soft tissue mobilization
ITTFL	Inferior Transverse Tibiofibular Ligament
NRPS	Numerical Pain Rating Scale
NSAIDs	Non-Steroidal Anti-inflammatory Drugs
PITFL	Posterior Inferior Tibiofibular Ligament
PRICE	Protection, Rest, Ice, Compression, and Elevation
PTFL	Posterior Talofibular Ligament
p-value	Probability Value
STR	Stork Balance Stand Test Score
TENS	Transcutaneous Electrical Nerve Stimulation
VAS	Visual Analogue Scale

CHAPTER 1 : INTRODUCTION

1.1 Introduction

Ankle sprains are one of the most commonly occurring sports injuries (Bahr and Reese, 2003; Fong et al., 2007) constituting about 4.7% to 24.7% of all sports injuries. Approximately 23 000 ankle sprains occur in the United States per day which amounts to one sprain in 10 000 people daily (Hertel, 2002). About 80% of people who develop ankle sprains return to pre-injury activity with conservative management while 20% progress to mechanical or functional instability (Lin et al, 2015). Eighty five percent of ankle sprains occur on the lateral ligament complex (Borreani et al, 2014; Dubin et al, 2011). A recent study by Fong et al. (2007) highlighted that ankle sprains account for 46% of all volleyball injuries, 40% of all netball injuries, 21% of soccer injuries and 16% of all basketball injuries in China. Smith and Reischl (1986) found that there is a 70% recurrence rate of ankle sprains in basketball players.

Ankle sprains occur as a result of landing on an inverted foot as the body's centre of gravity rolls over the ankle with subsequent damage to the lateral capsulo-ligamentous complex of the ankle (Bleackley et al, 2007; Chan, Ding and Mroczek, 2011). Poor balance also contributes to increased likelihood of ankle sprains (Mackeon and Hertel, 2008: McGuine et al. 2000). However, the greatest risk factor of an ankle sprain is the previous history of an ankle sprain (Beynnon et al. 2005).

A common consequence of an ankle sprain is limited range of motion in talocrural dorsiflexion (Davenport, Kulig and Fisher, 2010). Limited talocrural dorsiflexion can result in biomechanical alterations that predispose the individual to further lower limb injuries (Pellow and Brantingham, 2001). According to Borreani et al. (2014), consequences of ankle sprains most commonly involve long term postural control alterations as well as ankle joint proprioceptive and neuromuscular malfunctioning (Zech *et al.,* 2009).

There are various treatment protocols for the treatment and management of ankle sprains. These treatment protocols may include, but are not limited to, different combinations of talocrural joint adjustments, taping (rigid and kinesiotape), Cyriax transverse friction massage, Graston® Technique, bracing, cast immobilisation and surgery. Different grades of ankle sprains are treated differently. The main objective in the management of acute ankle sprains is to reduce pain and swelling, and return to the pre-injury state. Therefore, acute ankle sprains are mostly managed using the PRICE protocol (Bleakley et al., 2007). Cryotherapy has been shown to be beneficial as the first line of treatment, as it helps in increasing the pain threshold and in reducing inflammation when applied on an acute injury (Bleakley, McDonough and MacAuley, 2004).

Despite the high occurrence of ankle sprains, no comprehensive treatment protocol exists. This study compared a known standard treatment, cryotherapy with a myofascial treatment protocol, the Functional and Kinetic Treatment with Rehab (FAKTR [FAKTR© Concept]), to compare the relative effectiveness of both.

1.2 Aims and Objectives of the Study

1.2.1 Aim

The aim of this study was to determine the effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy with a sham treatment in terms of subjective (numerical pain rating scale [NPRS] and foot function index [FFI]) and objective (ankle dorsiflexion range of motion by means of digital inclinometer readings [DIR], stability by means of stork balance stand test score [STR], oedema by means of oedema measurements [EDM] and pressure pain threshold by means of algometer readings [AR]) measurements in the treatment of acute and or sub-acute ankle inversion grade I or II sprain.

1.2.2 Objectives

1. To determine the effectiveness of a myofascial treatment protocol combined with cryotherapy in terms of subjective and objective measurements in the treatment of acute and or sub-acute ankle inversion grade I or II sprain.
2. To determine the effectiveness of cryotherapy and sham laser in terms of the subjective and objective measurements in the treatment of acute and or sub-acute ankle inversion grade I or II sprain.
3. To compare the two groups (Group A and Group B).

1.3 Hypothesis

A hypothesis is a statement that is presumed to be true for the purpose of testing its validity.

1.3.1 Null Hypothesis

The Null hypothesis stated that there will be no difference between the two study groups in terms of subjective and objective measurements.

1.3.2 Alternative Hypothesis

The alternative hypothesis stated that the myofascial treatment protocol combined with cryotherapy group will have a statistically significant difference compared to the cryotherapy and sham laser group in terms of subjective (NPRS and FFI) and objective (DIR, STR, EDM, and AR) measurements.

1.4 Rationale

Ankle sprains are one of the most common sports injuries accounting for approximately 20% to 40% of all sports injuries (DiStefano et al., 2008). It has been estimated that 73% of all athletes have had recurrent ankle sprains and 59% of these have had significant disability and residual symptoms which led to impairment of their athletic performance (Hertel, 2002). There are, however, many treatment concepts that are employed in the management of ankle sprains including: protection, rest, ice, gentle compression, and elevation (PRICE) combined with non-steroidal anti-inflammatory drugs (NSAIDs) which is a frequent treatment choice for uncomplicated injuries (Bleakley et al., 2007; Ivin, 2006), talocrural joint manipulation, strapping (rigid and kinesiotape), cross friction, and instrument assisted soft tissue mobilisation (Looney et al., 2011).

Most literature on the treatment of ankle sprains favours early exercise, balance training, and neuromuscular and proprioceptive training exercise. More recent studies highlight the importance of restoring proprioception to damaged muscle fibres and ligaments after an ankle sprain (Zouita. et al., 2013). Good proprioception plays a vital role in promoting dynamic joint and functional stability (Clarck and Burden, 2005). Balance training has also been shown to reduce the chances of recurrence (Zouita et al., 2013). Once injured, there is a greater chance of re-injury predisposing the whole kinematic chain to ongoing problems. Whatever method is chosen; it is important to treat the ankle sprain effectively the first time a sprain occurs.

CHAPTER 2 : LITERATURE REVIEW

2.1 Introduction

This chapter reviews the current literature available on the anatomy and biomechanics of the ankle joint, incidence and prevalence of ankle sprains, classification of ankle sprains into different grades of injury and chronicity, and the mechanism of injury. It also highlights the common treatment protocols available in the treatment of ankle sprains including cryotherapy, instrument assisted soft tissue mobilisation (IASTM), strapping, talocrural joint manipulation, and FAKTR© Concept, as well as their mechanisms of action.

2.2 Osteology of the Ankle Joint

The ankle joint complex contains four bony structures, the tibia, fibula, talus and the calcaneus (Figure 2.1).

The tibia is a long bone located on the anteromedial aspect of the leg and is the second largest bone in the body. It is responsible for weight transfer from the upper body to the foot and ankle (Moore and Dalley 2013).

The fibula is a smaller bone of the leg which lies on the posterolateral aspect of the tibia and is firmly attached to the tibia by the tibiofubular syndesimosis. The fibula has no function in weight-bearing, but functions mainly as a muscle attachment area. (Moore and Dalley 2013).

The talus is located between the calcaneus and the tibia and fibula. The talus consists of a body, a neck and a head which articulates with the tibia, calcaneus and the navicular, therefore almost 60% of its surface is covered with articular cartilage. The superior surface, or trochlea of the talus, is dome shaped and is attached to the medial and the lateral malleoli of the tibia and the fibula. The talus receives the weight of the body from the tibia and transfers the body weight to the foot (Moore and Dalley 2013).

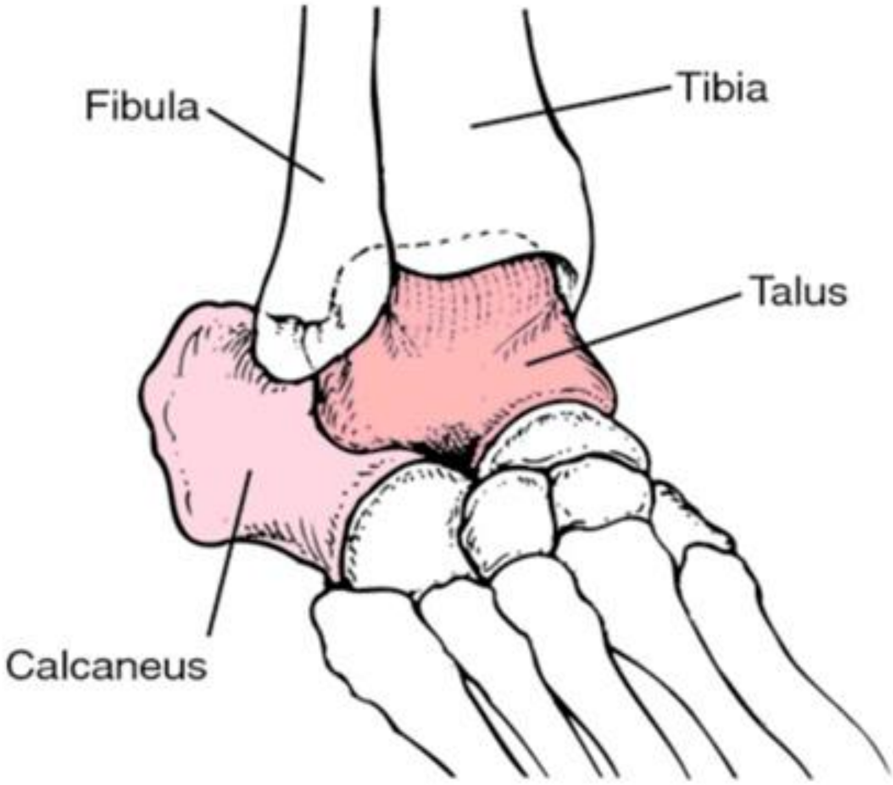

Figure 2.1: Bones of the ankle joint
Source: Pinnacle Orthopaedic Group

2.3 Ligaments of the Ankle Joint

The ankle joint is stabilised by the lateral and the medial ligament complex. The stability of the lateral aspect of the ankle is reinforced by the lateral ligament complex which is a compound structure made up of three completely separate ligaments (Moore and Dalley 2013). These ligaments are the anterior talofibular ligament (ATFL), calcaneofibular ligament (CFL) and the posterior talofibular ligament (PTFL). The medial aspect of the ankle is stabilised by the deltoid and the medial malleolar ligaments (Moore and Dalley 2013)

2.3.1 Function of Ligaments

The main functions of ligaments include passive joint stabilisation, and help in guiding joints through their normal range of motion. Ligaments also provide joint homeostasis through their viscoelastic properties and proprioception which is called conscious perception of limb position in space.

2.3.2 Microscopic Structure of the Ankle Ligaments

Ligaments are defined as bands of collagen fibres that span a joint and then insert at either end of the bones. The ligaments have an overlying layer called the epiligament which is a vascular layer comprising more sensory and proprioceptive nerves than the actual ligament. This layer is indistinguishable from the ligament itself (Hauser and Dolan, 2011) The nerves are denser close to the ligament bony insertion.

Microscopically, ligaments are composed of cells called fibroblasts enclosed in a matrix. Fibroblasts are few in number and are responsible for matrix synthesis. These cells communicate via gap junctions and/or cytoplasmic extensions to coordinate cellular and metabolic responses of the tissue.

The collagen fibres are aligned in a longitudinal pattern with an underlying crimp (Frank, 2011). Crimp plays a pivotal biomechanical role during the ligament loading phase. Initial loading results in some part of the ligament uncrimping, allowing the ligament to elongate without sustaining damage (Amiel, Chu and Lee, 1995).

The ligaments are primarily composed of water which constitutes approximately two-thirds of its composition. The other third is the solid component of the ligament which is mainly collagen and accounts for about 75% of the dry weight of the ligament with the remainder being made up of proteoglycans, elastin, proteins and glycoproteins. Water contributes to the cellular function and the viscoelastic behaviour of the ligament (Frank, 2011).

2.3.3 Gross Structure of the Ankle Ligaments

2.3.3.1 Lateral Ligaments

- The ATFL extends anteromedially from the lateral malleolus to the neck of the talus. It functions primarily to resist inversion of the plantarflexed foot. The ligament also resists external rotation of the tibia and anterior draw of the talus.
- The CFL passes posteroinferiorly from the tip of the lateral malleolus to the lateral surface of the calcaneus (Moore and Dalley 2013). This ligament lies horizontally during ankle plantarflexion and vertically during ankle dorsiflexion.

The CFL is under tension during this dorsiflexion/plantarflexion movement, even though tension is greatest during dorsiflexion where the ligament effectively resists inversion (Burks and Morgan, 1994).

- The PTFL runs horizontally, medially and slightly posteriorly from the malleolar fossa to the lateral tubercle of the talus. The PTFL plays a supplementary role in ankle stability when the ATFL and the CFL are intact. The short fibres of the PTFL restrict internal and external rotation, talar tilt and dorsiflexion while its long fibres inhibit external rotation, talar tilt and dorsiflexion. This sequence of events happens following the rupture of the ATFL and CFL ligaments during an ankle sprain (Rasmussen, Jensen and Hedeboe, 1983)

2.3.3.2 Medial Ligaments

The medial side of the ankle is stabilised by the medial malleolar and deltoid ligaments. The deltoid ligament is the strongest ligament of the ankle joint complex. This ligament fans out from the medial malleolus, attaching distally to the talus, calcaneus and navicular via four adjacent parts, the tibionavicular part, the tibiocalcaneal part and the anterior and posterior tibiotalar parts. This ligament resists eversion and helps to prevent partial dislocation of the joint (Moore and Dalley, 2013). The medial malleolar ligament (also known as the calcaneonavicular ligament) function as a static stabiliser of the medial longitudinal arch and head of the talus. Its originates from the sustentaculum tali and inserts on the inferior aspect of the navicular.

2.4 Muscles of the Leg That Move the Foot and Ankle

Muscles are contractile tissues of the human body that are responsible for force production and which initiate motion (Vizniak, 2012). The belly of the muscle is its contractile portion which is anchored to the bones via non-contractile tendons.

Most of the foot and ankle movement are produced by the extrinsic muscles of the leg which insert within the foot. These muscles are categorised into anterior, posterior and lateral compartments which produce specific foot and ankle movements. The anterior compartment of the leg consists of four muscles (dorsiflexors of the foot and ankle) which include the tibialis anterior, extensor digitorum longus, extensor hallucis longus and fibularis tertius. The posterior leg compartment consists of the ankle plantarflexors and invertors of the foot and ankle which include the gastrocnemius, soleus, plantaris, popliteus, flexor hallucis longus, flexor digitorum longus and tibialis posterior muscles (Moore and Dalley 2013). Lastly, the lateral compartment consists of foot and ankle evertors which are the fibularis longus and brevis muscles (Drake, Vogl, and Mitchell; 2015).

Table 2.1: Muscles of the leg, foot and ankle

Muscle	Origin	Insertion	Innervation	Action
Anterior Compartment				
Tibialis anterior	Lateral condyle of tibia	Medial cuneiform Base of 1st metartasal	Deep fibular nerve (L4/5)	Dorsiflexion & inversion
Extensor digitorum longus	Lateral condyle Proximal fibula	Middle/distal phalanges of lateral four digits	Deep fibular nerve (L4/5)	Extends lateral four digits & dorsiflexes ankle
Extensor hallux longus	Anterior medial shaft of fibula	Distal phalynx of great toe	Deep fibular nerve (L4/5)	Extends great toe & dorsiflexes ankle
Fibularis tertius	Anterior surface (inferior 1/3) of fibular	Base of 5th metatarsal	Deep fibular nerve (L4/5)	Dorsiflex ankle
Posterior leg compartment				
Gastrocnemius	Medial/lateral condyle	Calcaneus	Tibial nerve (S1/2)	Plantarflexes ankle
Soleus	Posterior surface of proximal tibia & fibular	Calcaneus	Tibial nerve (S1/2)	Plantarflexes ankle
Plantaris	Inferior surface of posterior femur	Calcaneus	Tibial nerve (S1/2)	Plantarflexes ankle
Tibialis Posterior				
Lateral leg compartment				
Fibularis longus	Proximal 2/3 of the lateral surface of fibula	Base of 1st metatarsal & medial cuneiform	Superficial fibular nerve (L5,S1/2)	Everts foot
Fibularis brevis	Inferior 2/3 of the lateral surface of the fibula	Base of 5th metatarsal	Superficial fibular nerve (L5,s1/2)	Everts foot

Source: Moore and Dalley (2013);

2.5 The Ankle Joint Articulations

The ankle joint complex is comprised of three main articulations (1) the talocrural joint joint, (2) the subtalar joint, and (3) the inferior tibiofibular syndesimosis.

2.5.1.1 The Talocrural Joint

The talocrural joint is formed by the distal ends of the tibia and fibula and the superior aspect of the talus (Figure 2.3). The talocrural joint is a hinge-type synovial articulation, with movement only possible in one plane; plantarflexion and dorsiflexion are the only movements possible at the talocrural joint (Moore and Dalley 2013). The inferior ends of the tibia and fibula together with the inferior transverse part of the posterior tibiofibular ligament forms a mortise which the dome shaped trochlea (the rounded superior aspect of the talus) of the talus fits into (Brockett and Chapman, 2016).

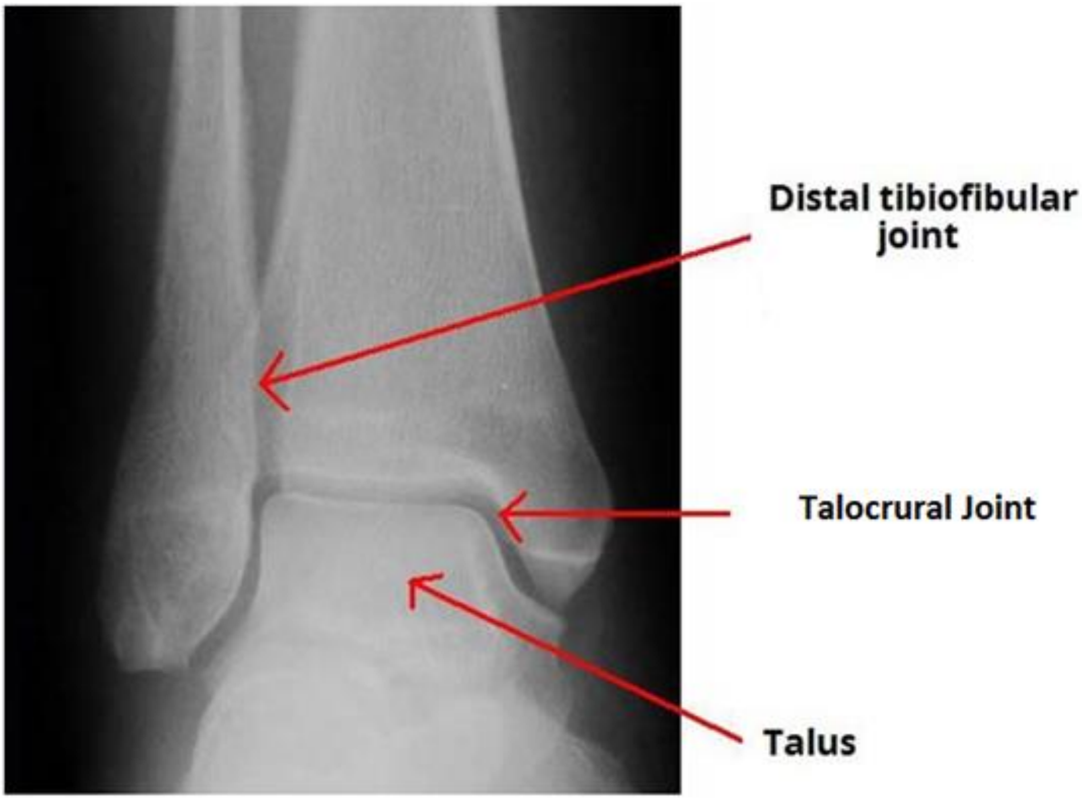

Figure 2.2 The Talocrural Joint (Mortise)
Extracted from: http://teachmeanatomy.info/lower-limb/joints/the-ankle-joint/

Figure 2.2: The talocrural joint (mortise)

Source: http://teachmeanatomy.info/lower-limb/joints/the-ankly-joint

The medial surface of the lateral malleolus of the fibula articulates with the lateral aspect of the talus. The inferior surface of the tibia forms the roof of the malleolar mortise which transfers the body’s weight to the talus and the medial malleolus articulates with the medial aspect of the talus.

2.5.1.2 The Subtalar Joint

The subtalar joint is a synovial type joint surrounded by an articular capsule. The subtalar joint is formed by the talus resting on and articulating with the calcaneus. This joint permits eversion and inversion movements. The anterior articulation is formed by the talar head, anterosuperior facet and the concave surface of the navicular. The joint is formed posteriorly by the inferoposterior talar facet and the superoposterior calcaneal facet. These two articulations (anterior and posterior) are separated by the sinus tarsi and each has its own joint capsule although they all share the same axis of rotation (Dawe and Davis, 2011).

2.5.1.3 The Inferior Tibiofibula Joint

The inferior tibiofibular joint is a syndesmosis stabilised by three supporting ligaments, namely: the anterior inferior tibiofibular ligament (AITFL), the posterior inferior tibiofibular ligament (PITFL) and the inferior transverse tibiofibular ligament (ITTFL). The AITFL is a strong ligament running from the anterior tip of the lateral malleolus and inserts onto the anterolateral tubercle of the talus (Dawe and Davis, 2011). The PITFL forms the inferior tibiofibular joint by joining the distal ends of the tibia and fibula. The integrity of the inferior tibiofibular joint is important for the stability of the ankle joint as it keeps the lateral malleolus firmly against the lateral surface of the talus. The ITTFL connects the distal ends of the tibia (medial malleolus) and the fibula (lateral malleolus), forming a posterior square socket wall, the malleola mortise, for the talus to fit into (Moore and Dalley 2013)

2.5.2 The Joint Capsule

The anterior and posterior portions of the ankle joint capsule are thin but are supported by strong lateral and medial collateral ligaments on each side. Superiorly, the fibrous layer of the capsule is attached to the edges of the articular surface of the tibia and the malleoli, and inferiorly it is attached to the talus. This fibrous layer of the capsule is lined by loose synovial membrane which extends as far as the interosseous tibiofibular ligament, superiorly (Moore and Dalley 2013).

2.5.3 The Blood Supply and Innervation of the Ankle Joint

The arteries of the ankle joint are derived from the malleolar branches of the fibular and anterior and posterior tibial arteries (Moore and Dalley 2013).

The nerves are derived from the tibial nerve and the deep fibular nerve, a division of the common fibular nerve (Moore and Dalley 2013).

2.5.4 Biomechanics of the Foot and Ankle

The foot and ankle has a complex anatomical structure that enables it to transmit forces between the lower limb and the ground. During the gait cycle, the foot and ankle function as a flexible shock absorber that deforms on uneven terrain then undergoes a series of biomechanical changes allowing it to function as a rigid lever to transmit force. The joint complex is stabilised by the bony congruence, joint capsule and ligamentous support (Dawe and Davis, 2011).

2.5.4.1 Axis of Rotation of the Ankle Joint

The ankle joint has been described as a simple hinge joint that only permits movement in one plane, however there is evidence suggesting that it is a multi-axial joint because of its simultaneous motions with internal rotation coupled with dorsiflexion and external rotation coupled with plantarflexion. The ankle joint has three axes of rotation, namely: the x-axis, y-axis and the z-axis. In the sagittal plane, the axis of rotation of the ankle joint occurs around the x-axis (a line passing through the midpoints of the lateral and medial malleoli). The axis of rotation of the ankle joint complex in the coronal plane occurs around the z-axis (the intersecting point between the malleoli and the long axis of the tibia). The transverse plane axis of rotation of the ankle joint occurs around y-axis, the long axis of the tibia intersecting the midline of the foot (Brockett and Chapman, 2016).

2.5.4.2 Range of Motion of the Ankle Joint

The primary movements of the ankle joint are dorsiflexion-plantarflexion which occur in the sagittal plane around the horizontal x-axis. Ankle dorsiflexion is brought about by the contraction of the dorsiflexor muscles located in the anterior compartment of the leg, mainly the tibialis anterior muscle. Dorsiflexion is limited by the tension of the posterior leg muscles (plantarflexors). Contraction of the triceps surae, which consists of the gastrocnemius, soleus and plantaris muscles result in plantarflexion of the ankle (Moore, 2013). The ankle dorsiflexion-plantarflexion range of motion differs across individuals depending on the methods of measurements, ethnicity and activities of daily living (Grimston et al., 1993).

The total dorsiflexion-plantarflexion range of motion has been shown to be between 65^o and 75^o, with 10^o to 20^o of dorsiflexion and 40^o to 55^o of plantarflexion (Grimston et al., 1993; Stauffer, Chao and Brewster, 1977). However, according to Nordin and Frankel (2001) the normal ankle dorsiflexion-plantarflexion range of motion required to carry out activities of daily living is reduced to a maximum of 30^o. This differs to Stauffer, Chao and Brewster's (1977) findings which showed that the overall range of motion required during the stance phase of the gait cycle is limited to 25^o, with 15^o plantarflexion and 10^o dorsiflexion. In the transverse plane, the ankle rotates 5^o around the vertical y-axis (Michael et al., 2008).

Abduction-adduction occurs in the transverse plane and inversion-eversion occurs in the frontal plane (Zwipp and Randt, 1994). According to Nordin and Frankel (2001), supination and pronation are three dimensional movements which result from a combination of motions across the talocrural and subtalar joints. Supination results from a combination of plantarflexion, inversion and adduction resulting in the sole of the foot facing medially. During pronation, a combination of dorsiflexion, eversion and abduction causes the sole of the foot to face laterally. According to Stauffer, Chao and Brewster (1977), the overall inversion-eversion range of motion is 35^o, with 23^o inversion and 12^o eversion.

2.6 Ankle Sprain

2.6.1 Epidemiology

Ankle sprains are one of the most common sports injuries accounting for approximately 20% to 40% of all sports injuries (DiStefano et al., 2008). The incidence and prevalence of ankle sprains is thought to be the same between men and women, although Hosea, Carey and Harrer (2000) suggest that interscholastic and intercollegiate female basketball players have a 25% higher chance of recurring ankle sprains than their male counterparts. Approximately 23 000 ankle sprains occur in the United States per day which equals to one ankle sprain in 10 000 people daily (Hertel, 2002). Eighty percent of ankle sprains return to pre-injury activity with conservative management while 20% progress to mechanical or functional instability (Lin, 2015).

The greatest risk factor for developing an ankle sprain has been identified as a previous history of ankle sprain (McKay et al 2001; Hertel 2002). It has been estimated that 73% of all athletes have recurrent ankle sprains and 59% of these have significant disability and residual symptoms which lead to impairment of their athletic performance (Lin, 2015).

2.6.2 Mechanism of Ankle Sprains

According to Dubin (2011), ankle inversion sprains occur when the centre of gravity of the body is shifted over the lateral aspect of the weight-bearing leg, resulting in the ankle rolling inwards at a high speed. The commonly described mechanism is that a sprain occurs when the foot strikes the ground awkwardly at a high velocity in an inverted and plantarflexed position, stretching or tearing the lateral ligament complex of the ankle joint (Beynnon et al., 2005).

In a case report by Gehring (2012), the etiological conditions of ankle sprains are not related to the ankle joint complex alone but rather to the biomechanics of the whole body. The upper leg mechanics, prelanding adjustments and neuromuscular contributions should be considered in the mechanism of ankle sprains, with most ankle sprains resulting from contact injuries of the foot (Woods et al, 2003) occurring at the subtalar joint (Fong, 2007. The ATFL is frequently injured first because of its function as the primary stabiliser of the ankle during plantarflexion (Ranawat and Positano, 1999). The CFL may also be damaged in more severe sprains (Hollis, Blasier and Flahiff, 1995).

The greatest risk factor for the development of ankle sprains is a history of at least one previous ankle sprain. About 30% of the population with ankle sprains do not seek medical attention due to the natural history of the injury. A study by Hertel (2002) showed that about 40% of ankle sprains have residual symptoms at six months after the initial injury. Poorly treated ankle sprains can result in chronic ankle pain, instability and early osteoarthritis (Benette, 2011). Therefore, proper initial treatment is of paramount importance in the management of ankle sprains. The treatment of ankle sprains should therefore be aimed at preventing or reducing the chances of recurrence.

2.6.3 Metabolic Response to Ankle Sprains

Acute soft tissue injuries such as ankle sprains result in an increase in local metabolism which increase the demand for oxygen. As the oxygen gets used up at a faster rate, ischaemia can start to occur resulting in inflammation (Hubbard, Aronson and Denegar, 2004). This contributes to the pain, oedema and joint dysfunction that the patient experiences (Denegar, Saliba and Saliba 2009). Pain results from the chemicals released by the injured tissues which directly damage the nerves, and compression of uninjured nerves by local oedema. This pain can result in muscle spasm, which is the body's mechanism to protect against further injury (Knight et al., 2000). Therefore, treatment should aim to address pain, oedema and inflammation (Hubbard, Aronson and Denegar, 2004).

2.7 Diagnosis of Ankle Sprains

The diagnosis of ankle sprains depends on the duration (acute, sub-acute or chronic), severity (grade I, grade II or grade III) and location (medial or lateral) of the injury.

2.7.1 Duration

An ankle sprain is described as an acute injury if it is not more than one week after the onset of injury (Procter and Paul 2013). The word "acute" refers to an illness that is of sudden onset or of short duration.

Subacute ankle sprains sit within a timeframe of day 4 to 3 weeks after the injury (Procter and Paul 2013). Subacute refers to conditions that are not yet chronic but have passed the acute phase.

Chronic ankle sprains occur as a result of mechanical and functional instability resulting in repetitive re-occurrences of ankle sprains (Holmes and Delahunt, 2009). An ankle sprain is described as chronic if its more than 8 weeks or more after the injury (Procter and Paul 2013).

2.7.2 Severity

Ankle sprains are graded into three grades (grade I-III) according to the severity of the injury, with a grade I ankle sprain being less severe and grade III ankle sprain being most severe (Kaplan et al, 2014). A common classification system for ankle sprains is the West Point Ankle Sprain Grading System.

2.7.2.1 Grading of Ankle Sprains Using the West Point Ankle Sprain Grading System

The West Point Ankle Sprain Grading System classification criteria for grading of ankle sprains is shown in Table 2.2.

Table 2.2: Classification criteria for grading of ankle sprains

Criterion	**Grade 1**	**Grade 2**	**Grade 3**
Location of tenderness	ATFL	ATFL, CFL	ATFL, CFL, PTFL
Oedema, Ecchymosis	Slight	Moderate	Diffuse
Weight-bearing ability	Full or partial	Diffuse without crutches	Impossible without crutches Significant pain
Ligament damage	Stretched	Partial tear	Complete tear
Instability	None	None or slight	Definite

2.7.3 Location

Ankle sprains according to location can be categorised into inversion or eversion ankle sprains

Inversion ankle sprains involve injury to the lateral ligament complex of the ankle (ATFL, CFL and PTFL). Inversion ankle sprains usually occur as a result of the ankle rolling inward damaging the lateral ligament complex (Mazzara, 2014).

Eversion ankle sprains occur with eversion or external rotation injury or landing at a high speed with the ankle rolling outward. Eversion ankle sprains cause injury to the medial deltoid and the mallelolar ligaments (Puffer, 2001).

2.7.4 Examination Findings of Ankle Sprains

Physical examination findings of the inversion ankle sprain may reveal swelling that is observed distal to the lateral malleolus of the ankle, tenderness palpated over the ATFL and in more severe cases the PTFL, decreased talocrural dorsiflexion range of motion (Davenport, Kulig and Fisher, 2010), reduced balance (Zouita et al., 2013), and reduced function of the ankle joint complex.

In grade I ankle sprains there will be pain upon palpation of the ATFL and less commonly pain on palpation of the CFL. This can sometimes be accompanied by moderate swelling. A positive anterior drawer test could indicate a complete tear of the ATFL (which resists the anterior translation of the talus) found in grade III ankle sprains. A positive talar tilt test also reveals a complete tear of the CFL (which prevents excessive inversion of the foot) found in grade III ankle sprains. Grade III ankle sprains result in severe swelling and petechial haemorrhaging.

2.7.4.1 Examination Findings for Grade I Ankle Sprains

- Slight swelling that is observed distal to the lateral malleolus of the ankle.
- Tenderness palpated over the ATFL.
- Moderate pain on anterior drawer test.
- Patient is able to bear weight (Pellow and Brantingham, 2001.

2.7.4.2 Examination Findings for Grade II Ankle Sprains

- Moderate swelling that is observed distal to the lateral malleolus of the ankle.
- Tenderness palpated over ATFL and CFL.
- Positive anterior drawer test.
- Pain on talar tilt test.
- Patient has difficulty bearing weight (Pellow and Brantingham, 2001.

2.7.4.3 Examination Findings for Grade III Ankle Sprains

- Diffuse swelling.

- Tenderness to palpation of the ATFL, CFL and PTFL.
- Positive anterior drawer and talar tilt test.
- Reduced balance and function.
- Unable to bear weight (Pellow and Brantingham, 2001.

2.8 Common Treatments Administered for Acute Ankle Sprains

Despite the high frequency of ankle sprains, there is no universally accepted protocol for the treatment of ankle sprains. Once an accurate diagnosis has been made, treatment is administered based on the grade of the ankle sprain. The primary objective in the management of acute grade I and II ankle sprains is to reduce pain and swelling (Brantingham, Globe and Jansen, 2009). Management of chronic ankle sprains/CAI is mainly aimed at improving balance and postural stability (Pellow, 2001).

Treatment of ankle sprains can include no intervention, PRICE protocol (protect, rest, ice, compression and elevation), prophylactic bracing, cast immobilisation, NSAIDs (Beynnon et al., 2006), talocrural joint high-velocity low-amplitude thrust manipulation, transcutaneous electrical nerve stimulation (TENS), cryotherapy, Cyriax transverse friction massage and IASTM. There are several types of IASTM which include, but are not limited to, Graston® technique, ASTYM®, Gua Sha®, and FAKTR© Concept.

For many years, athletic tape has been used as a preventative treatment, however current literature has shown that while athletic tape provides a 10% increase in maximum resistance to inversion sprains; after about 40 minutes of strenuous activity the tape provides insignificant levels of protection (Mazzara, 2015). All symptoms of ankle sprain which include pain, loss of range of motion, loss of function, reduced stability, decreased proprioception and decreased strength should be addressed during the initial treatment plan. These can be achieved through sports specific exercises (Verhagen and Meesen, 2004).

2.8.1 The PRICE Protocol

The PRICE protocol is advised in the treatment of grade I or II ankle sprains. This incorporates a period of protection, rest, ice, compression and elevation. The PRICE protocol helps promote a fast recovery with few complications (Bleakley et al., 2007), and is the first line of treatment that is aimed at reducing pain, oedema, and inflammation.

Bleakley et al (2007) investigated the effectiveness of combining intermittent ice application with periods of therapeutic exercises in the first week of an acute ankle sprains. The study was a randomized controlled trial which included 120 participants with acute grade I or II ankle sprains recruited from an accident and emergency department. These participants were divided into two groups, one receiving standard cryotherapy application and the other receiving cryokinetic ice application. The primary outcome measures for the study were function that was assessed using the lower extremity functional scale, pain (visual analogue scale) and swelling (modified figure of eight). After one week of follow up consultations the cryokinetic group outperformed the standard intermittent ice application group in terms of function, pain and oedema. The cryokinetic group had statistically significant improvement at a significance level p-value < 0.05 in terms of primary outcome measures.

Steffen and Nilstad (2010) investigated intermittent ice application in combination with ankle exercise. This study concluded that subjects who completed the exercise protocol had a statistically significant improvement in short-term function of the ankle after one week compared to the control group.

Steffen and Nilstad (2010) also investigated the effectiveness of intermittent ice application in combination with exercise. The study was a randomized controlled trial which constituted men and women of the ages 16 to 65 years with acute grade I or II ankle sprains. One hundred and one participants were recruited into the study and were divided equally into between the two study groups, one receiving the standard intermittent ice application and the other one receiving an accelerated intervention incorporating early therapeutic exercises (cryokinetic). This study concluded that participants who completed the exercise protocol had statistically significant improvement (p-value < 0.05) in short term function of the ankle after one week compared to the control group.

2.8.2 Non-steroidal Anti-inflammatory Drugs (NSAIDs)

In a study by van den Bekerom et al. (2015) the use of NSAIDs to treat acute ankle sprains was found to be cost effective as compared to placebo. However, there was a noted increase in instability in those participants who received NSAIDs which is assumed to have been caused by too-early mobilisation. NSAIDs have been shown by Bahamonde and Saavedra (1990) to have short term effects in the reduction of pain as compared to placebo. Non-steroidal anti-inflammatory drugs interfere with collagen synthesis during the healing (proliferative) phase (Almekinders, Baynes and Bracet, 1995) and stimulate protein synthesis during the maturation phase of healing.

2.8.3 Talocrural Joint Manipulation for subacute

Krueger et al. (2015) reported using high-velocity, low-amplitude (HVLA) thrust manipulation of the talocrural joint to address dorsiflexion range of motion and function. This is also supported by a recent study by Dananberg, Shearstone and Guilliano (2000) which investigated the effect of two HVLA techniques on the talocrural joint. This study found a substantial increase in dorsiflexion range of motion. These results are also consistent with a study by Nield et al. (1993). However, Fryer, Mudge and Mclaughlin (2002) found that talocrural joint manipulation does not improve range of motion in asymptomatic subjects but rather only in subjects where an audible popping sound is heard.

2.8.4 Transcutaneous electrical Nerve Stimulation (TENS)

Transelectrical nerve stimulation (TENS) is the application of electric current to the body using an external device through surface electrodes (Deneger, 2009). The excitable tissue is targeted to reduce pain, muscle spasm, facilitate muscle re-education, reduce disuse atrophy, strengthen muscles, and assist in minimising oedema (Giggins, Fullen and Coughlan, 2012). Thus, TENS is used mainly to promote recovery following acute ankle sprains by means of reducing pain, oedema, and facilitating neuromuscular function (Deneger, 2009). The application of TENS is theorised to minimise oedema by affecting cellular and vascular permeability, improving lymphatic drainage through muscle contractions, and affecting membrane potentials (Deneger, Saliba and Saliba, 2009; Mendel and Fish, 1993).

2.8.5 Laser Therapy for subacute

Laser therapy has been used in clinical trials to treat acute ankle sprains and has shown favourable results (Rabel et al., 2013). Makihara and Masumi (2008) investigated the effects of laser therapy on the temporomandibular joint of asymptomatic subjects and an increased blood flow and local vasodilation was noted. Increased blood flow improves cellular recruitment and facilitates healing. Kulekcioglu et al. (2003) investigated the effects of laser on temporomandibular range of motion and pain. He found that post-treatment there was significant improvement in active and passive mandibular depression and lateral deviation. Conti (1997) performed a similar study on the temporomandibular joint and produced similar findings. Hakguder et al. (2003) studied the analgesic effects of laser on myofascial pain syndrome and chronic pain and found that only the participants who received laser had significant improvement in pain pressure threshold. A study by de Bie et al. (1998) looked at the immediate effects of laser treatment on pain, oedema and function. After 12 treatment sessions there was significant improvement in the functional outcome measure, but there was no significant difference reported on the primary outcome measure of pain between the laser group and the placebo group.

Cryotherapy and IASTM will be explained in detail in terms of their mechanism of action, advantages and disadvantages, types of cryotherapy and IASTM, and their use in the treatment of ankle sprains. These are explained in detail because they are the variables of concern in this study.

2.8.6 Cryotherapy

2.8.6.1 Introduction

Cryotherapy is the application of ice for therapeutic purposes (Bleakley et al., 2007). Cryotherapy has long been regarded as the first line of treatment for acute injuries. Cryotherapy is usually used together with compression and elevation making it difficult to evaluate the effect of cryotherapy alone (McDonough, 2008).

2.8.6.2 Mechanism of Action of Cryotherapy

Cryotherapy has been shown to be effective in increasing the pain threshold and reducing inflammation when applied on an acute injury (Bleakley, McDonough and MacAuley, 2004). According to Knight et al. (2000), the application of ice immediately post-injury is used to reduce metabolism, thereby minimising secondary hypoxic damage and the degree of tissue injury. Cryotherapy has also been shown to have local analgesic effects by limiting nerve conduction velocity (Algafly and George, 2007).

2.8.6.3 Application of Cryotherapy

Cryotherapy application may involve alternating short-term ice application followed by passive rewarming with cooling time limited to 10-30 minutes, whereas others advocate continuous application of ice with no breaks in cooling for days or weeks. Cryotherapy may lead to functional impairment or even tissue necrosis or nerve injury in the treated area (Craik and Diller, 2014) if not administered appropriately. According to Craik and Diller (2014) prolonged cryotherapy application may result in vasoconstriction which may culminate in ischaemia.

2.8.6.4 Advantages of Cryotherapy

- Reduces pain;
- Reduces swelling; and
- Reduces metabolic rate and oxygen demand, promoting tissue healing (Hubbard, Aronson and Denegar, 2004).

2.8.6.5 Disadvantages of Cryotherapy

- Tissue injury – there is potential of tissue damage if the ice is too cold; and
- Heat transfer – when an ice pack is applied to an injured area there will be heat transfer from the body with the ice pack becoming warmer. This is not a health risk but the treatment gets less effective over time (Michael et al., 2012).

2.8.6.6 Types of Cryotherapy

There are several types of cryotherapy including:

- Ice pack cryotherapy;
- Ice massage;
- Ice towels;
- Cryokinetics (alternation cold with active exercises) (Knight, 1989;
- Cryostretch (alternating cold with muscle stretch); and
- Cold water baths containing menthol gel (Bishop et al; 2009).

2.8.6.6.1 Ice Pack Cryotherapy in the Treatment of Ankle Sprains

Ice pack cryotherapy is the most commonly used cryotherapy modality (Kanlayanaphotporn and Janwantanakul, 2005). Ice packs are commonly prepared by filling plastic packs with water and alcohol in the ratio 4:1 and then cooling in the home freezer. The melting point of alcohol is -114°C so the mixture becomes semi-solid below 0°C which can easily be conformed to body contours (Hills and Petrucci, 2002).

Kanlayanaphotporn and Janwantanakul (2005) compared the skin surface temperature during the application of four different icing modalities (ice pack, gel pack, frozen peas and a mixture of water and alcohol). This repeated measure design had a convenience sample of 50 women of the age group 20 to 23 years. Each of the four icing modalities were applied randomly over the skin of the quadriceps femoris muscle and the skin surface temperature was recorded every minute for 20 minutes. Throughout the 20 minutes of cryotherapy application, the ice pack and a mixture of water and alcohol showed statistically significant (p-value < 0.01) lower skin surface temperatures than the gel pack and frozen peas. This study therefore concluded that, ice pack and a mixture of water and alcohol were significantly more efficient in reducing skin surface temperatures as compared to the gel pack and frozen peas.

According to a study by Merrick et al (2003), ice packs do not transfer cold to deeper structures but rather the deeper tissues lose heat to more superficial structures. The more superficial structures loose heat into the ice pack hence warming the ice pack. This is known as heat conduction, with the variant of temperature change being minimal in the deeper tissues compared to the more superficial tissues. This hemodynamic interchange between the fascial layers contributes to the reduction in pain, muscle spasm, and oedema.

In a case report by Brown and Hahn (2009), a 16-year-old female underwent bilateral foot surgery for the hallux valgus deformities correction. Standard metatarsal and hallux osteotomics were performed and an ankle block was prescribed for postoperative analgesia. She was then discharged with an ankle cryocuff and the ankle block for pain relief. Four days postoperatively, the patient reported to the treating doctor with bilateral feet pain and her feet were noted to be very cold. Bilateral plantar compartment pressures were documented to be 40 mmHg which is 25-30 mmHg above the normal reading. This case report concluded that prolonged unmonitored exposure to ice conditions can result in limb-threatening conditions. The skin passes through four stages of sensation (cold, burning, aching and numbness) during ice application. Simple cryotherapy should be applied with a protective covering on the skin for not more than 10-20 minutes and should be discontinued once the skin feels numb. According to Christensen (1996), ice pack cryotherapy should not be applied for more than 10 minutes.

Christensen (1996) documented that during the acute inflammatory phase of healing, the examination findings include varying levels of pain, swelling, heat and redness. It is therefore inappropriate in the acute stage to aggravate any of these four primary signs and symptoms. Thus, early heat application is contraindicated during the initial phase of the injury. Therefore, cryotherapy becomes the initial therapy during the acute phase of the injury to decrease blood flow and control the resulting inflammation. A 15-30 minutes' ice application can decrease tissue temperatures by approximately 3-7^{o}C. Pappenheimer (1948) revealed that there is a decreased blood flow as the tissue temperature decrease from 40^{o}C to 25^{o}C. as body temperatures continue to decrease below 25^{o}C, however the blood flow is increased. This shows that initial cryotherapy application result in blood vessel constriction and prolonged cryotherapy application (i.e below 25^{o}C) result in vessel dilation. Therefore, Christensen (1996) concluded that excessive cryotherapy is counterproductive due to cold vasodilation resulting in increased hemorrhage and inflammatory response.

2.8.7 Instrument Assisted Soft Tissue Mobilisation

2.8.7.1 Introduction

Instrument assisted soft tissue mobilisation is used in the treatment of myofascial restrictions and is based on James Cyriax's rationale (Cheatham et al., 2016). Unlike Cyriax's digital transverse cross friction, IASTM utilises specially modified tools to produce a mobilisation effect on soft tissues. Indications of use include scar tissue and myofascial adhesions to help improve pain, range of motion, and function. The utilisation of IASTM instruments is to provide a mechanical advantage to the clinician by allowing deeper soft tissue penetration, a more precise treatment and reducing stress on the clinician's hand (Baker, Nasypany and Seegmiller, 2015).

2.8.7.2 Mechanism of Action of IASTM

The use of IASTM instruments for soft tissue mobilisation has been theorised to increase vibration sensation of the patient and the clinician, therefore helping the clinician to detect altered soft tissue properties (Lee, Lee and Kim do, 2014; Baker, Nasypany and Seegmiller, 2013). Repeated gliding movement of the IASTM instruments over the injured ligaments induce controlled microtrauma which result in microvascular trauma and facilitate the normal alignment of soft tissue fibres (Lee, Lee and Kim do, 2014; Gulick, 2014). This ultimately results in a localised area of inflammation that stimulates the body's reparative system Hammer, 2003a; Hammer and Pfefer, 2005). According to Hammer and Pfefer (2005), IASTM enhances the proliferation of extra cellular fibroblasts, improves ion transport and minimises cell matrix adhesions. According to Strunk, Pfefer, and Dube (2014) IASTM treatment helps stimulate connective tissue remodelling which in turn results in the breakdown of scar tissue, adhesions and fascial restrictions.

2.8.7.3 Types of IASTM Techniques

There are several different IASTM techniques and companies that have different approaches to treatment and different tool design, these include:

- Graston® Technique
- Hawk Grip®
- Adhesion Breakers
- Fascial Abrasion Techniques™
- ASTYM®
- Gua Sha®
- Cyriax Transverse Friction
- Functional and Kinetic Treatment with Rehab (FAKTR© Concept)

2.8.7.4 Efficacy of IASTM

Instrument assisted soft tissue mobilisation has been shown to be effective as a therapeutic intervention of myofascial restrictions (Baker, Hansberger and Warren

2015). However, a systematic review by Cheatham et al. (2016) challenged the efficacy of IASTM as it found conflicting results. This has questioned IASTM as a common treatment of musculoskeletal pathology. Blanchette and Normand (2011) compared IASTM versus natural history in the treatment of lateral epicondylitis and found that post intervention and at a 3-month follow-up all groups showed improvements in pain free grip strength and on the visual analogue scale. Balance training plus IASTM versus balance training plus sham IASTM for CAI demonstrated that post intervention both groups showed improvement in all outcome measures (Schaefer and Sandrey, 2012). Gulick (2014) investigated the effect of IASTM on myofascial trigger points of the upper back. They identified two trigger points on each subject; one trigger point was treated for a maximum of 5 minutes and the other trigger point was left as a control. These interventions were administered 6 times in three weeks (2 times per week). Both trigger points showed improvements on pressure sensitivity with the algometer post intervention, therefore IASTM did not outperform control.

2.8.8 FAKTR Concept

To date there have been no studies validating the efficacious nature of the FAKTR© Concept treatment. This treatment protocol has never been used in a randomised clinical trial to investigate its effectiveness. The FAKTR© Concept was developed by Thomas Hyde and Greg Doerr. This concept originated from the Graston® Technique and it directly addresses patient complaints of pain and incorporates movement into treatment. The FAKTR© Concept utilises four stainless steel instruments (Figure 2.5) which are hypothesised to detect and treat soft tissue lesions by using a variety of multidirectional stroking techniques over the involved structure. There are three main components for the utilisation of the FAKTR© Concept which are (1) soft tissue mobilisation, (2) movement, and (3) proprioception. The FAKTR© Concept incorporates rehabilitation into the treatment.

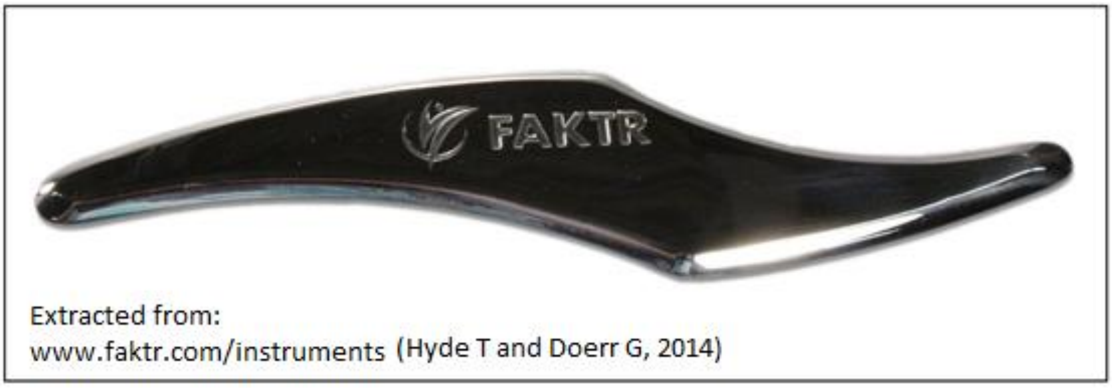

Figure 2.3: A FAKTR© Concept tool
Source: Hyde and Doerr (2014)

2.8.8.1 Indications for use of FAKTR© Concept

- Tendinopathies:
    i. Tennis elbow;
    ii. Rotator cuff tendinopathy;
    iii. Achilles tendinopathy; and
    iv. Patella tendinopathy.
- Fascial syndromes:
    i. Iliotibial band syndrome; and
    ii. Trigger finger.
- Entrapment syndromes:
    i. Carpal tunnel syndrome; and
    ii. Thoracic outlet syndrome.
- Ligament pain:
    i. Medial collateral ligament sprain;
    ii. Ankle sprains; and
    iii. Anterior cruciate ligament sprains.
- Scar tissue or adhesions.
- Oedema (Hyde, 2013).

2.8.8.2 The Use of FAKTR© Concept in the Treatment of Acute Ankle Sprains

According to Hyde (2013), treatment of acute ankle sprains using the FAKTR© Concept is directed to the ATFL, PTFL, calcaneofibular ligament (CFL), retinaculum, the dorsum of the foot, medial and lateral sides of the foot, along the Achilles tendon and extending to the anterolateral leg 8 cm to 12 cm above the malleolus.

Baker et al (2015) investigated in a case report the efficacy of total motion release in treating an apparent tissue tightness/extensibility dysfunction and to determine if instrument assisted soft tissue mobilization would improve outcomes if total motion release techniques fails to produce maintained improvement. A 27-year-old speed walker presented with a chronic history of bilateral pain and posterior leg tightness. The patient was diagnosed with bilateral tissue extensibility dysfunction in the posterior lower extremity and was treated with total motion release and instrument assisted soft tissue mobilization. After one week of treatment, the patient increased her sit and reach by 5cm and her straight leg raise by an average of 31.5^{o}. This report demonstrated the potential use of total motion release and IASTM in improving mobility (improving range of motion). The noted improvement was clinically significant.

Gulick 2014 investigated the influence of IASTM on myofascial trigger points. This study had two phases where in the first phase two myofascial trigger points (right and left) were identified in the upper back. One trigger point was treated with IASTM and the other one was left as a control. In the second phase, one myofascial trigger point was identified in the treatment and a control group. In both phases the myofascial trigger points received six treatments of IASTM. The sensitivity threshold was assessed using a dolorimeter. This study showed that there was a significant improvement in both group over time but there was no difference between the treatment and control groups.

MacDonald, Baker and Cheatham (2016) investigated the effects of IASTM on muscle performance to asses if typical treatment application affected measures of muscular performance. A convenience sample of 48 participants were randomly assigned into one of the three study groups, quadricpe treatment, tricep surae treatment or a control. The participants performed a 5 minutes warm up. Immediately after the warm up, IASTM treatment was applied by one researcher for three minutes on each leg at a specified site for those who were assigned to a treatment group. Those in the control group rested for 6 minutes. Immediately after treatment, participants performed three countermovement vertical jumps. Pre and post testing included measures of vertical jumps height, peak power and peak velocity.

The FAKTR© Concept has been shown to be effective in reducing swelling, improving function, reducing pain, improving proprioceptive function and promoting an early return to the pre-injury activity. It is effective in improving circulation and minimising adhesion formation, breaking down of scar tissue or myofascial restrictions and stimulation of the body's reparative system (Perle, 2003). Early mobilisation and rehabilitation during the FAKTR© Concept treatment promotes ankle ligament healing with a proper collagen alignment. This is important in preventing the chances of recurrent ankle sprains (Borreani, 2013). The FAKTR© Concept has mechanical (collagen remodeling), neural (touch, afferent stimulation) and vascular (tissue viscosity) effects when applied to soft tissues (Gulick, 2014).

2.9 Conclusion

The primary objective in the management of ankle sprains is to reduce pain and swelling, improve range of motion, improve function and stability, and get an early return to pre-injury activity (Brantingham, Globe and Jansen, 2009). Cryotherapy has been known to be beneficial especially in the reduction of pain and swelling during the acute and or subacute phase of the injury (Bleakley, 2010. The FAKTR© concept has been shown to be effective in improving range of motion, function, stability and an early return to play. There is however no literature to validate this hypothesis. The treatment outcomes for FAKTR© Concept are all desirable outcomes in the effective treatment of ankle sprains. However, the effects of FAKTR© Concept treatment on ankle sprains has not been investigated. The aim of this study was to demonstrate if the treatment outcomes of FAKTR© Concept treatment can have favorable results in treating acute/subacute grade I/II inversion ankle sprains. This efficacy will be investigated using FAKTR© Concept versus a control (sham laser) in combination with cryotherapy, a known beneficial treatment of ankle sprains.

CHAPTER 3 : RESEARCH METHODS

3.1 Introduction

This chapter discusses the methodology of the study. It explains the study design, sampling methods, interventions used, inclusion and exclusion criteria, randomisation, measurement tools and statistical analysis used in executing this study.

3.2 Study Design

The study was a single blinded quantitative randomised placebo controlled clinical trial using a non-probability convenience sampling technique. The objective of this study was to determine the relative effectiveness of the FAKTR© Concept combined with cryotherapy compared to sham laser combined with cryotherapy in the treatment of acute or subacute inversion grade I or II ankle sprains. Ethical approval was obtained from the faculty of health sciences at the Durban University of Technology to contact this study (Appendix P).

3.3 Advertisement and Participant Recruitment

Participants of the study were recruited via a poster advertisement (Appendix O) that was placed on notice boards at the Durban University of Technology (DUT) and University of KwaZulu-Natal

3.4 Sampling Technique

Volunteers who responded to the advertisements were telephonically contacted by the researcher. Possible participants were interviewed telephonically to assess their eligibility to be included in the study. Table 3.1 shows the screening questions that were asked.

Table 3.1: Questions asked during the telephonic interview to assess volunteer eligibility

Question	*Answers expected to be included in the study*
Have you recently twisted, rolled or sprained your ankle	Yes
When did you sprain your ankle?	Not more than three weeks ago
How did you sprain your ankle?	Only inversion ankle sprain suits the criteria
How old are you?	Between 18 and 40 years

How severe is the pain on a scale of 0-10, where 0 is no pain and 10 is the worst imaginable pain	Greater than or equal to 3 and less than or equal to 7 (3-7)

3.5 Inclusion Criteria

The criteria for inclusion into the study are outlined below:

1. The participants were required to be between the age of 18 and 40. Age is an important factor as age related changes can affect the healing process (Vaghmaria, 2005; Pillay, 2003).
2. The participants needed to have read and signed the letter of informed consent (Appendix B).
3. The participants needed to be proficient in English as they were required to complete an English language questionnaire that had already been reliably tested, the FFI (translation into other languages is for future studies), and understand the instructions in English from the researcher on how to apply ice at home..
4. The sprain occurred less than 3 weeks previous to initial consultation (acute to subacute).
5. One of the following orthopaedic tests were positive: (a) anterior drawer (b) talar tilt test.
6. Participants had to have a pain rating between 3 and 7 on the NPRS (more severe pain is mostly related with grade III ankle sprains which were excluded from this study).
7. A diagnosis of an acute or subacute grade I or II inversion ankle sprain as described by the West Point Ankle Sprain grading system (Kaplan, 2014).
    - 7.1. Grade I ankle sprain is described as pain on the ATFL, slight oedema and ecchymosis, full or partial weight-bearing ability and no tear of ligaments but rather slight stretch.
    - 7.2. Grade II ankle sprain is described as pain on the ATFL and CFL, moderate oedema and or ecchymosis, diffuse weight-bearing ability and partial tear of the ATFL.

3.6 Exclusion Criteria

Outlined below are the criteria for exclusion from the study:

1. Complete grade III rupture of the ATFL and CFL ligaments and some capsular and PTFL tears with diffuse swelling, ecchymosis, tenderness over anterolateral capsule, ATFL, CFL and unable to bear weight (Chan et al 2011).
2. Participants presenting with contraindications to cryotherapy including but not limited to cold allergy, hypertension (vasoconstriction induced), Raynaud's disease, rheumatoid arthritis, local limb ischaemia and history of vascular impairments.
3. Participants who did not follow the home icing regiment were excluded from the study.
4. Contraindications to FAKTR for example open wounds or external trauma to the area where the FAKTR instrument will be applied.
5. Participants that used any medication for their ankle sprain (including NSAIDs, herbal/homeopathic or any other medication for pain, inflammation or injury) whilst participating in the study were excluded as the effects of the medication could have affected the study results.
6. Participants that used any other form of treatment that could also affect the results e.g. compression or wearing of any form of ankle support, rest or elevation. Participants were instructed not to do the above mentioned.

3.7 The Sample Size and Allocations

The total sample population was 40 participants. The participants were divided into one of the two study groups (20 in each group), with one group (Group A) receiving FAKTR© Concept treatment and home icing, and the other group (Group B) receiving sham laser and home icing. A hat was left at the reception which had 40 pieces of paper, representing the 40 participants (20 with the letter A and 20 with the letter B). Once a letter was picked by the participant it was given to the receptionist to be discarded. In case of a drop out, a paper was returned to the hat. There was no sample frame for the study as the researcher was using a non-probability convenience sampling method which was that whoever responded and arrived first was recruited provided they fitted the inclusion criteria of the study.

3.8 Outline of the Research Procedure

After the telephonic interview, participants that were found to be suitable to be included in the study were invited to join the study. An initial consultation was scheduled at their soonest convenience at the DUT Chiropractic Day Clinic (DUT CDC).

Upon the participant's arrival at the DUT CDC for their initial consult, they were given a new patient information sheet (for participants who have never been at the CDC) to fill in their details.

The participants were taken to the consultation room where they were given a letter of information (Appendix A) to read and were given a chance to ask any questions of the researcher. They were then asked to sign the informed consent form (Appendix B).

After a full case history (Appendix C), a physical examination (Appendix D and Appendix E), foot and ankle regional examinations (Appendix F) were conducted by the researcher. After this, the researcher stepped out of the room and the research assistant (6th year Chiropractic student) came in to collect baseline measurements (NRS, FFI, DIR, AR, EDM, and STR). The assistant left the consultation room once baseline data was taken.

After the research assistant had completed data capturing the researcher returned to the consultation and sent the participant to the reception to be allocated into either group A or B using the hat method. Once the participant was allocated, the researcher went to the reception to get the group letter of the participant.

The corresponding treatment as per the allocated group was then administered to the participant by the researcher. After the treatment, ice was applied by the researcher on the lateral ligaments of the ankle for 10 minutes. The participants were given verbal and written instructions (Appendix L) on how to store and apply ice at home. All participants were given ice packs and were instructed to apply ice at home for 10 minutes three times per day. The researcher then scheduled the next appointment which was to be within the next two (minimum) to four (maximum) days.

During follow-up appointments at the DUT CDC the participants were re-assessed. Before the interventions, the researcher left the room to allow the research assistant to collect subjective (NRS and FFI) and objective (DIR, AR, EDM and STR) measurements. After this, the research assistant left the consultation room to allow the researcher to administer treatment according to their allocated group. An explanation was given to group B participants on the final follow up that they did not receive a full treatment and why. Therefore, participants who were allocated in group B received a free treatment after the final follow-up appointment.

The participants had 4 visits in two weeks. The same research assistant was used throughout the study at all appointments. The researcher did not know the results taken by the research assistant till the end of the four treatments. Also the research assistant was not aware which treatment each participant received until the end of the four treatments.

A flow diagram of all the procedures is outlined in the Figure 3.1.

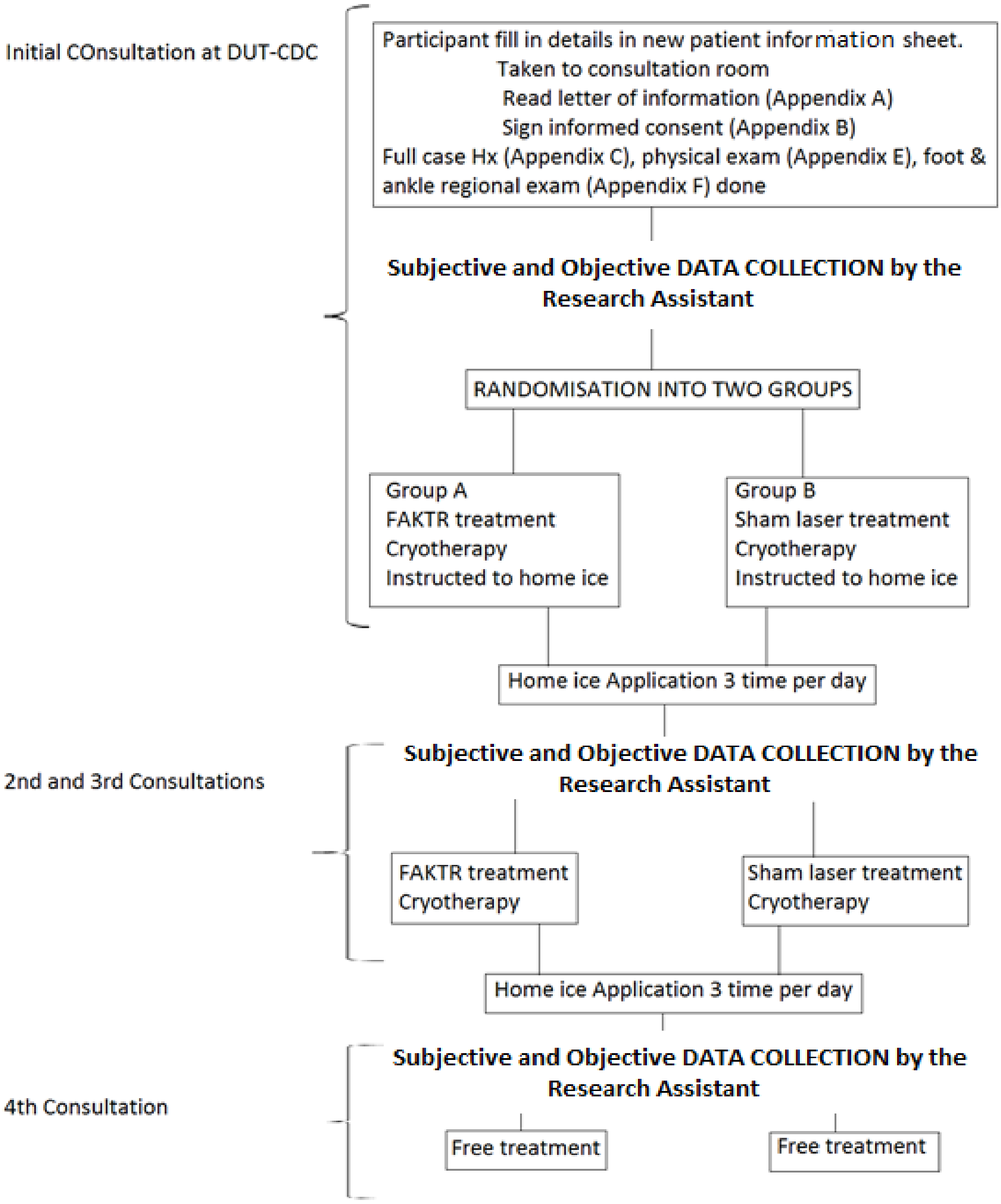

Figure 3.1: Flow diagram of the research procedure

3.8.1 Treatment Groups or Interventions

The study had two treatment groups, Group A and Group B. Group A was the group receiving a myofascial treatment protocol (FAKTR© Concept) and cryotherapy. Group B participants received sham laser and cryotherapy. There were 20 participants in each group.

3.8.1.1 Group A (Myofascial Treatment Protocol, FAKTR© Concept)

During the initial consultation, Group A (The FAKTR© Concept treatment group) participants were positioned in a seated position with zero weight on the ankle. The FAKTR© Concept tool number 4 was placed initially on the ATFL at an angle of 30° to 60° and a downward pressure was applied to the participant's tolerance (should not exceed 6 out of 10 on a NPRS). The FAKTR© Concept tool was then moved in a multidirectional stroking fashion for 30 seconds with the depth of the downward pressure maintained. After this, the same treatment was applied to the PTFL, retinaculum, dorsum of the foot, medial and lateral sides of the foot, along the Achilles tendon, and extending to the anterolateral leg 8 cm to 12 cm above the malleolus. While seated with zero weight, the participant dorsiflexed, plantarflexed, everted and inverted the ankle to determine the position of provocation. Once the position of provocation was established, the participant was treated as above in that position of provocation. Cryotherapy was then applied for 10 minutes after the FAKTR© Concept treatment. The participants were given an ice pack at the end of the initial consultation. Ice therapy was self-administered at home for 10 minutes three times a day for three days. The compliance of the patient was monitored using a treatment diary which was returned to the researcher on the follow-up treatment.

On the second consultation, the participants tried to weight-bear. In the weight-bearing position, the participants dorsiflexed, plantarflexed, everted and inverted the ankle to determine the position of provocation again. Once the position of provocation was established, the participants were then treated in the position. Treatment was applied by pressing down the FAKTR© Concept tool and moving it in multiple directions on the ATFL, PTFL, retinaculum, dorsum of the foot, along the Achilles tendon and on the anterolateral aspect of the leg 8 cm to 12 cm above the malleolus. The participant was then asked to perform a function that provokes the pain (for example walking). Once the functional provocative position was established, the participant was then asked to perform that function that provokes the pain. Treatment was applied as described above while the participant was performing that function. The area was then iced for 10 minutes.

During the third consultation, resistance and proprioception were added. While standing on a wobble board, the participant dorsiflexed, plantarflexed, everted and inverted to determine the position of provocation. Once the provocative position was established, the participant was then treated with the previous FAKTR© Concept protocol. Then, a theraband was tied on the forefoot and was pulled in dorsiflexion, plantarflexion, eversion and inversion to determine the position of provocation. Once that position was established, then the participant was treated with the FAKTR tool using the previous FAKTR protocol described. Cryotherapy was then applied to the area after the FAKTR© Concept treatment to reduce the petechial haemorrhage induced by the FAKTR tools.

The final (4th) consultation was for data collection purposes but however the participants were given a free treatment.

3.8.1.2 Group B (Sham Laser and Cryotherapy)

Group B participants received sham laser and standard cryotherapy treatment. The therapeutic laser machine was turned on but not started. It was then moved 4 mm above the skin surface to eliminate the massage effect of the head of the laser machine on the skin surface. The sham laser was applied to the ATFL, PTFL, calcaneofibular ligament (CFL), retinaculum, the dorsum of the foot, medial and lateral sides of the foot, along the Achilles tendon and extending to the anterolateral leg 8 cm to12 cm above the malleolus.

After sham laser, cryotherapy was applied for 10 minutes and the participants were given a verbal explanation of the correct ice pack preparation and application. This verbal instruction was supplemented by a step wise written instruction. The compliance of the patient was monitored using a treatment diary which was returned to the researcher on the follow-up treatment. Ice therapy was self-administered at home for 10 minutes three times a day for three days. After the initial consultation, the participant was required to come back to the Chiropractic Day Clinic after 3-4 days and then 7-8 days for sham laser and data collection.

3.8.2 Measurements

All measurements were taken by the research assistant prior to the administration of treatments during the initial consultation and at all the follow-up consultations.

3.8.2.1 Subjective Measurements

1. **Numerical Pain Rating Scale (NPRS)** - A 11-point (0 – 10) NPRS was used to structure the measurements of the participants' pain intensity. The NPRS ranges from 0 being "No Pain" to 10 being "Worst Imaginable Pain" (Ferreira-Valente, Pais-Ribeiro and Jensen, 2011). The NPRS measurements are reliable and valid for use in clinical trials (Childs, Piva and Fritz, 2005). The participants were asked to describe the amount of pain they were experiencing on a scale of 0 to 10, where 0 is no pain and 10 is the worst imaginable pain. This was done on all visits. The effectiveness of an intervention was defined by the differences in NPRS values of subsequent visits (Farrar et al 2001).
2. **Foot function index** (Appendix G) – The FFI was used in this study to measure the functional damage to the ankle. The participant was given the FFI questionnaire by the research assistant at each visit. The questionnaire was marked out of a total of 170 and each score was expressed as a percentage. These percentages were then compared to assess the effectiveness of interventions. The function index (FFI) was designed to measure the extent of foot pathology in terms of pain, disability and activity restrictions (Budiman-Mak, Conrad and Roach, 1991). Budiman-Mak, Conrad and Roach (1991) examined the FFI for test-retest reliability and internal consistence. It has been proved that the FFI is a reliable measurement tool for patients with rheumatoid arthritis and it is recommended also as a reliable tool in other foot orthopaedic intervention trials (Ferreira-Valente, Pais-Ribeiro and Jensen, 2011; Saag et al., 1996). The FFI was administered at all visits. The effectiveness of an intervention was measured by the FFI score differences of subsequent visits.

3.8.2.2 Objective Measurements

1. **Algometer** – the algometer used was a handheld unit with a $1cm^2$ application surface. An algometer was used to determine the pressure pain threshold of the participants. This is regularly used as an outcome measure for research studies to document the efficacious nature of the treatment modalities. This instrument was used to measure the pressure (measured by force per square meter, Kg/m^2) a patient could withstand before perceiving pain (Fischer, 1988). The handheld algometer was tested by Kinse, Sands and Stone (2009) for its

validity and reliability and it was considered reliable and valid for testing pressure pain threshold. According to Fischer (1990) the pressure pain threshold is used in clinical practice to determine the hot spot tenderness and diagnosis of myofascial pain syndrome characterised by active trigger points (Ohrbach and Gale, 1989).

The algometer was used according to the following procedure:

- The same algometer (Wagner Pain Test™ Model FPK algometer) was used during the study period for standardisation purposes because sometimes different instruments are calibrated differently. The dial was set at zero and the pressure applied slowly at a constant rate of approximately 1kg/cm^2/s (Fischer, 1988) and participants were told to say when they start to experience pain.
- The researcher palpated the lateral ankle to locate the area of maximum tenderness. This hot spot area was then marked with a pen.
- The 1cm ^{2} round rubber surface of the algometer was applied slowly perpendicular (Fischer, 1988) to the marked hot spot area on the lateral ankle until the participant indicated pain.
- The reading on the algometer was then recorded in Kg/cm^2.
- All this was repeated on subsequent visits and the effectiveness of the intervention in this case was defined by the differences on the readings of subsequent visits.

2. **Digital Inclinometer** – the DIR was used to measure the ankle dorsiflexion range of motion. This instrument was tested by Konor et al. (2012) for its validity and reliability in measuring ankle dorsiflexion range of motion with a reliability coefficient (ICC = 0.96 to 0.99) and a lower standard error or measurement (SEM) compared to the goniometer (ICC = 0.85 to 0.96).

The digital inclinometer was used in the following way:

- The same digital inclinometer was applied throughout the study period for the purpose of standardisation since sometimes different tools may be calibrated differently.
- Ankle dorsiflexion was measured using a weight-bearing lunge that was performed in a standing position with the heel in contact with the floor,

the great toe 10 cm from the wall, and the knee in line with the second toe (Konor et al., 2012). The participants were then asked to lunge forward directing their knees to touch the wall. The foot was then moved slowly away from the wall, 1 cm at a time (Hoch and McKeon, 2011) and the subject repeated the lunge position until they were unable to touch the wall with the knee without the lifting the heel up off the ground. Once the knee was unable to touch the wall, the foot was moved towards the wall in very small increments until the knee was in touch with the wall and the heel in contact with the ground.

- If the participant was unable to touch the wall with the knee during the initial 10 cm start position, the participant was then asked to move the foot towards the wall 1 cm at a time until they could touch the wall with their knee while keeping the heel in contact with the ground.
- The maximum dorsiflexion range of motion the participant could withstand was measured after the participant reached the final lunge position.
- The digital inclinometer was then turned on and placed along (parallel to) the long axis of the tibia. This reading measured the angle in degrees (^{o}) of the tibia relative to the ground.
- The procedure was repeated at subsequent visits and the effectiveness of the intervention in this case was defined by the difference in the readings at subsequent visits.

3. **Figure-of-eight measurement of ankle oedema** – ankle swelling (EDM) was measured using the figure-of-eight method (Figure 3.2). High reliability and validity has been reported using this technique (Rohner-Spengler, Mannion and Babst, 2007).

   A measuring tape was applied to the ankle in the following way according to Rohner-Spengler, Mannion and Babst (2007):

   - All measurements were performed using a one-quarter inch wide plastic tape following a standard written protocol.

- To perform the figure-of-eight manoeuvre of the ankle, the participants were comfortably positioned supine with the ankle off the edge of the table.
- The tape measure was started and held distal to the lateral malleolus and moved medially across the dorsum of the foot, to just distal to the navicular tuberosity.
- Then it was wrapped around the sole of the foot, under the medial arch towards the proximal aspect of the head of the 5th metatarsal.
- From here, the tape measure was drawn across the dorsum of the foot and the anterior tibialis tendon to the distal aspect of the medial malleolus.
- Finally, the tape measure was wrapped around the Achilles tendon back to the lateral malleolus where the measurement started.
- The measurement at the lateral malleolus was recorded on a data collection sheet (Appendix P).
- All this was done on subsequent visits and the effectiveness of the intervention in this case was defined by the differences on the readings of subsequent visits.

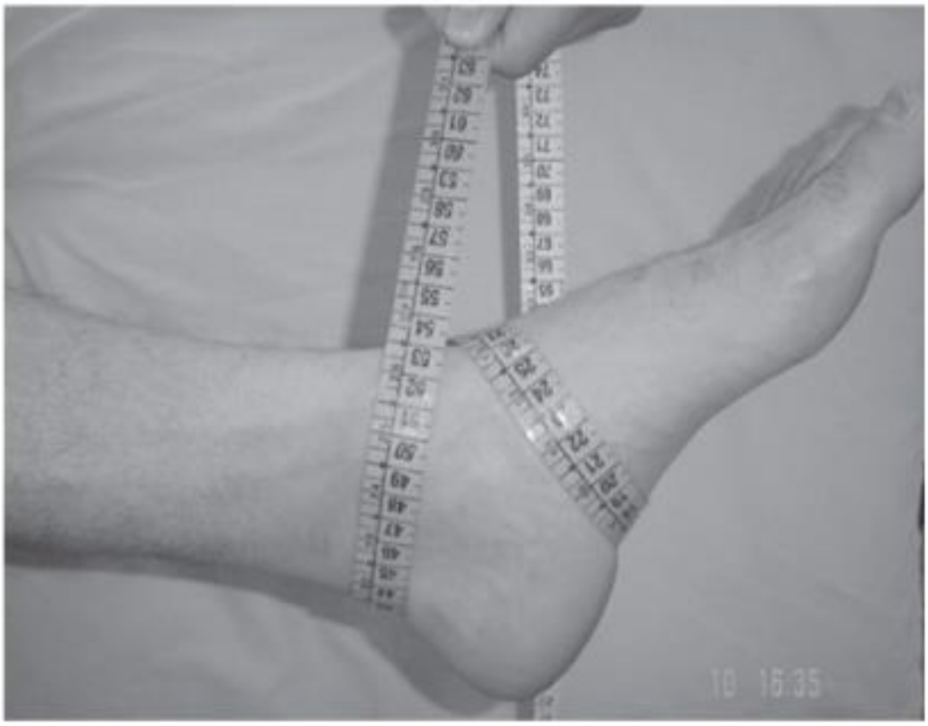

Figure 3.2: Figure-of-eight measurement of oedema

4. **Stork Balance Stand test** – the stability of the ankle was measured using the STR (O'Connell, George and Stork, 1998).

   This test was performed as follows:

   - The participant was asked to stand on both feet bare footed on a non-slip surface.
   - The participant was then asked to place both hands on the hips. Raise the uninvolved leg and place the sole of the uninvolved foot against the medial aspect of the knee of the involved leg.
   - The participant was then asked to raise the heel of the involved leg to balance on the ball of the foot.
   - As the heel was raised off the ground, the stop watch was started.
   - The participant was asked to hold this position for as long as possible.
   - The stop watch was stopped if:

     i. The hand/s came off the hips;
     ii. The involved foot swivelled or hoped in any direction;
     iii. The non-involved foot lost contact with the knee; and
     iv. The heel of the involved foot touched the ground/floor.

- The participant was asked to complete this test three times per consultation. The total time was recorded on the data collection sheet (Appendix P) in seconds and the best out of three was taken.
- All this was repeated on subsequent visits and the effectiveness of the intervention in this case was defined by the differences on the readings of subsequent visits.

3.9 Statistical Analysis

The data was analysed with the assistance of a statistician using the statistical software SPSS version 24.0 (IBM SPSS Inc.). The research statistical aspects included the following: descriptive statistics using frequency and cross-tabulation tables and different types of graphs (including pie charts, bar graphs, etc); inferential statistics using Pearson's and/or Spearman's correlations at a significance level of 0.05 was used, and testing of hypotheses using chi-square tests for nominal data and ordinal data at a level of significance of P = 0.05. The effect of the intervention was assessed using repeated measures ANOVA testing. A significant time x group interaction effect measured the intervention effect. Profile plots were used to visually assess the direction and trend of the intervention effect. This was performed for each outcome separately.

CHAPTER 4 : ANALYSIS AND DISCUSSION OF RESULTS

4.1 Introduction

This chapter presents the results and discussion of the findings obtained in this study. The data collected was analysed with SPSS version 24.0. Descriptive statistics in the form of graphs, cross tabulations and other figures were utilised for the presentation of the quantitative data that was collected. Inferential techniques were used, including the Mann Whitney test interpreted in terms of a p-value of < 0.05.

This chapter combines results and analysis with discussion of results.

The study had two treatment groups, Group A and Group B. Group A was the group receiving a myofascial treatment protocol (FAKTR© Concept) and cryotherapy. Group B participants were the control group and received sham laser and cryotherapy. The General Linear Model was used to determine the significance of the interactions between treatment periods for each variable for each group.

4.2 Objective One

To determine the relative effectiveness of a myofascial treatment protocol combined with cryotherapy in the treatment of acute and or subacute ankle inversion grade I or II sprains in terms of subjective and objective measurements.

4.2.1 Subjective Outcome Measures Group A

4.2.1.1 Numerical Pain Rating Scale (NRS) Group A

Table 4.1 shows descriptive statistics for the NRS analysis.

Table 4.1: Descriptive statistics table for NRS analysis of Group A

Group A		Initial Consult	Consultation 2	Consultation 3	Final Consult
Treatment	N	20	20	20	20
	Mean	6.35	3.65	1.55	0.65
	Std. Deviation	0.81	0.81	0.69	0.75
	Minimum	5.00	2.00	1.00	0.00
	Maximum	8.00	6.00	3.00	3.00
	Range	3.00	4.00	2.00	3.00

As can be seen from the results in Table 4.1, the mean NRS in the FAKTR© Concept treatment group on the initial consultation was 6.35, on consultation two was 3.65, on consult three was 1.55 and last consult was 0.65. Therefore, the average improvement between consultation one and the final (fourth) consult was 5.7. There was a 2.7 improvement between the initial and the second consultation, a 2.1 improvement between consultation two and consultation three and lastly there was a 0.9 improvement between the third and final consultation. This shows that there was a big jump (from 6.35 to 3.65) between the first and second consultations. The FAKTR© Concept had a cumulative effect over time.

Table 4.2 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.2: Tests of within-subjects effects table for NRS Group A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
NRS	Sphericity Assumed	385.200	3	128.400	647.681	0.000	0.972	1943.044	1.000
	Greenhouse-Geisser	385.200	2.245	171.619	647.681	0.000	0.972	1453.725	1.000
	Huynh-Feldt	385.200	2.560	150.483	647.681	0.000	0.972	1657.913	1.000
	Lower bound	385.200	1.000	385.200	647.681	0.000	0.972	647.681	1.000
Error (NRS)	Sphericity Assumed	11.300	57	0.198					
	Greenhouse-Geisser	11.300	42.646	0.265					
	Huynh-Feldt	11.300	48.636	0.232					
	Lower bound	11.300	19.000	0.595					

Table 4.2 shows the F value for the NRS, its associated significance level and effect size ("Partial Eta Squared"). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores for NRS were statistically significantly different ($F(2.245, 11.300) = 647.681$, $p < 0.0005$). This means that there was an overall significant difference between the means of the NRS.

Table 4.2 shows whether there was an overall significant difference in means, however it does not highlight where those differences occurred. The Pairwise Comparison in Table 4.3 presents the results of the Bonferroni post hoc test, which shows which specific means differed.

Table 4.3: Pairwise comparisons table for NRS Group A

(I) NRS		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	2.700*	0.128	0.000	2.324	3.076
	Consult 3	4.800*	0.186	0.000	4.251	5.349
	Final Consult	5.700*	0.147	0.000	5.268	6.132
Consult 2	Initial Consult	-2.700*	0.128	0.000	-3.076	-2.324
	Consult 3	2.100*	0.143	0.000	1.678	2.522
	Final Consult	3.000*	0.103	0.000	2.698	3.302
Consult 3	Initial Consult	-4.800*	0.186	0.000	-5.349	-4.251
	Consult 2	-2.100*	0.143	0.000	-2.522	-1.678
	Final Consult	.900*	0.124	0.000	0.536	1.264
Final Consult	Initial Consult	-5.700*	0.147	0.000	-6.132	-5.268
	Consult 2	-3.000*	0.103	0.000	-3.302	-2.698
	Consult 3	-.900*	0.124	0.000	-1.264	-0.536

Table 4.3 gives the significance level for differences between the individual measurement points (consultations). It shows that there was a significant difference in NRS between the 4 consultations ($p < 0.0005$). From the "mean difference (I-J)", the NRS value was significantly reduced. The FAKTR© Concept treatment group showed statistically significant results between all the four intervals with the p-value < 0.05.

4.2.1.1.1 Discussion of Results for NPRS Group A

The FAKTR© Concept treatment group showed statistically significant ($p < 0.05$) improvement in subjective pain (NRS) over the duration of the study (Table 4.2). There was also statistically significant ($p < 0.05$) improvement in subjective pain (NRS) between all successive follow-up consultations (Table 4.3).

The improvement in subjective pain can be attributed to the Gate Control inhibition described by Melzack and Wall (1965). The mechanism by which the FAKTR treatment works induces local anaesthesia; as the FAKTR© Concept tool is applied over the skin it increases afferent stimulation of the large proprioceptor fibres which results in the inhibition of small fibre nociceptors decreasing nociceptive transmission, so ultimately decreasing the perception of pain levels.

The FAKTR© Concept treatment also breaks down scar tissue and induces active hyperaemia thereby recruiting more fibroblasts to the area aiding in inflammation and allowing healing and tissue remodelling to begin (Carey-Loghmani, 2003). Fibroblasts are cells found in the connective tissue that are responsible for the production of collagen and extracellular matrix (Looney et al, 2011). Therefore, by recruiting more fibroblasts to the area and aiding inflammation, the FAKTR© Concept treatment allows the injury to progress to the final stages of healing. This will ultimately improve the participant's perception of pain.

4.2.1.2 Foot Function Index (FFI) Group A

Table 4.4 shows the descriptive statistics of the FFI analysis.

Table 4.4: Descriptive statistics table for FFI Group A

Group A		Initial Consult	Consultation 2	Consultation 3	Final Consult
Treatment	N	20	20	20	20
	Mean	49.40	31.70	18.05	7.95
	Std. Deviation	13.97	12.86	9.33	5.87
	Minimum	21.00	12.00	5.00	2.00
	Maximum	83.00	68.00	35.00	22.00
	Range	62.00	56.00	30.00	20.00

Figure 4.4 shows that the mean FFI score on the initial consult was 49.40, second consult 31.70, third consult 18.05 and on the fourth consult it was 7.95. The average improvement between the initial consultation and the last consult was 41.45. There was a 17.7 improvement between the initial and the second consultation, a 13.65 improvement between the second and third consultation and a 10.1 improvement between the third and the final consultations. The was also a jump between the first and the second consultations.

Figure 4.5 shows the Test of Within-Subjects Effects for FFI Group A.

Table 4.5: Tests of within-subjects factors effects table for FFI Group A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
FFI	Sphericity Assumed	19333.050	3	6444.350	146.787	0.000	0.885	440.362	1.000
	Greenhouse-Geisser	19333.050	2.189	8830.717	146.787	0.000	0.885	321.361	1.000
	Huynh-Feldt	19333.050	2.486	7777.793	146.787	0.000	0.885	364.865	1.000
	Lower bound	19333.050	1.000	193333.050	146.787	0.000	0.885	146.787	1.000
Error (FFI)	Sphericity Assumed	2502.450	57	43.903					
	Greenhouse-Geisser	2502.450	41.597	60.160					
	Huynh-Feldt	2502.450	47.228	52.987					
	Lower bound	2502.450	19.000	131.708					

Table 4.5 shows the F value for the FFI, its associated significance level and effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the means for FFI were statistically significantly different ($F(2.189, 2502.450)=146.787$, $p < 0.005$). This means that there was an overall significant improvement in the foot function at a significance level $p < 0.05$.

Table 4.6 shows the significance level for the differences between the individual consultation measurements.

Table 4.6: Pairwise comparisons table for FFI Group A

Measure:

(I) FFI		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	17.700*	1.838	0.000	12.288	23.112
	Consult 3	31.350*	2.359	0.000	24.406	38.294
	Final Consult	41.450*	2.458	0.000	34.215	48.685
Consult 2	Initial Consult	-17.700*	1.838	0.000	-23.112	-12.288
	Consult 3	13.650*	1.903	0.000	8.047	19.253
	Final Consult	23.750*	2.376	0.000	16.754	30.746
Consult 3	Initial Consult	-31.350*	2.359	0.000	-38.294	-24.406
	Consult 2	-13.650*	1.903	0.000	-19.253	-8.047
	Final Consult	10.100*	1.445	0.000	5.845	14.355
Final Consult	Initial Consult	-41.450*	2.458	0.000	-48.685	-34.215
	Consult 2	-23.750*	2.376	0.000	-30.746	-16.754
	Consult 3	-10.100*	1.445	0.000	-14.355	-5.845

In terms of the FFI readings presented in Table 4.6 (the FAKTR© Concept treatment group), there was a statistically significant difference in the FFI reading between all the four consultations. ($p < 0.0005$). From the "mean difference (I-J)" column we can see that the FFI value was significantly reduced at this time point.

4.2.1.2.1 Discussion of Results of Foot Function Index (FFI) Group A

The FFI scores for the FAKTR© Concept treatment group showed statistically significant ($p < 0.05$) improvement over the study period (Table 4.5). The mean scores between successive follow-up consultations also showed statistically significant improvements (Table 4.6).

The functional improvement of the ankle joint can be attributed to the breakdown of scar tissue by the FAKTR© Concept instrument as it is applied in a multidirectional stroking technique over the involved area. The application of the FAKTR© Concept instrument over the involved areas during functional movement patterns restores normal collagen alignment. With the recruitment of fibroblasts there is repair and regeneration of damaged collagen with normal alignment (Gulick, 2014). This result in less pain during functional movement patterns.

According to Perle (2003), Hammer (2003b) and Hammer and Pfefer (2005), IASTM induces controlled microtrauma, hyperaemia, reduces tissue viscosity through accumulation of friction related heat (Markovic, 2015), induces inflammation, and increases fibroblast recruitment and activation which stimulates the body's reparative system. Induced microtrauma, inflammation and fibroblast recruitment are essential healing processes. Therefore, the FAKTR© Concept treatment facilitates healing to progress to its later stages. This explains a significant improvement in functional pain observed in Tables 4.5 and 4.6.

A more significant improvement was noted between the first and the second consultations. This is possibly because there was a greater loss of function present at the initial consultation which was significantly improved by the second consultation to the extent that there was only minimal additional function needed to return to normal function. Between the third and the final consultations the functional loss was almost completely rectified.

4.2.2 Objective Outcome Measures Group A

4.2.2.1 Digital Inclinometer Reading (DIR) Group A

Table 4.7 shows the descriptive statistics of the DIR analysis.

Table 4.7: Descriptive statistics table for DIR Group A

Group A		Initial Consult	Consultation 2	Consultation 3	Final Consult
Treatment	N	20	20	20	20
	Mean (O)	62.80	59.80	58.75	58.40
	Std. Deviation	4.58	3.41	3.04	2.93
	Minimum	54.00	52.00	52.00	52.00
	Maximum	69.00	65.00	65.00	64.00
	Range	15.00	13.00	13.00	12.00

The mean DIR of the FAKTR© Concept treatment group on the initial consultation was 62.80°, second consult 59.80°, third consult 58.75° and on the fourth consult it was 58.40° (Table 4.7). The average improvement between the initial consultation and the fourth consultation was 4.40°. The average improvement between the initial and second consultation was 3°, between the second and third consultation was 1.05° and between the third and the final consultation was 0.35°. Between the initial and second consultations, there was a big jump of 3° from 62.80° to 59.80°. The FAKTR concept had a cumulative effect across the four consultations.

Figure 4.8 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.8: Tests of within-subjects factors effects table for DIR Group A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
DIR	Sphericity Assumed	239.737	3	79.912	31.962	0.000	0.627	95.887	1.000
	Greenhouse-Geisser	239.737	1.271	188.565	31.962	0.000	0.627	40.636	1.000
	Huynh-Feldt	239.737	1.321	181.419	31.962	0.000	0.627	42.237	1.000
	Lower bound	239.737	1.000	239.737	31.962	0.000	0.627	31.962	1.000
Error (DIR)	Sphericity Assumed	142.513	57	2.500					
	Greenhouse-Geisser	142.513	24.156	5.900					
	Huynh-Feldt	142.513	25.108	5.676					
	Lower bound	142.513	19.000	7.501					

Table 4.8 shows the F value for the DIR, its associated significance level and the effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores for DIR showed a statistically significant difference ($F(1.271, 142.513)=31.962$, $p < 0.005$). The tests of within-subjects' effects Table 4.8 shows that there was an overall significant improvement in the FAKTR treatment group in terms of the DIR.

Table 4.9 shows the significance level for the differences between the individual consultation measurements.

Table 4.9: Pairwise comparison table for DIR Group A

Measure:

(I) DIR		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	3.000*	0.616	0.001	1.188	4.812
	Consult 3	4.050*	0.701	0.000	1.985	6.115
	Final Consult	4.400*	0.690	0.000	2.369	6.431
Consult 2	Initial Consult	-3.000*	0.616	0.001	-4.812	-1.188
	Consult 3	1.050*	0.246	0.002	0.327	1.773
	Final Consult	1.400*	0.275	0.000	0.590	2.210
Consult 3	Initial Consult	-4.050*	0.701	0.000	-6.115	-1.985
	Consult 2	-1.050*	0.246	0.002	-1.773	-0.327
	Final Consult	0.350	0.131	0.092	-0.037	0.737
Final Consult	Initial Consult	-4.400*	0.690	0.000	-6.431	-2.369
	Consult 2	-1.400*	0.275	0.000	-2.210	-0.590
	Consult 3	-0.350	0.131	0.092	-0.737	0.037

The significance levels are highlighted in Table 4.9 There was a statistically significant difference between all the means of the first three consultations at a significance level, p-value < 0.05. It is only between the consultation 3 and the final consultation where the DIR showed no statistically significant difference, $p = 0.092$. From the mean difference (I-J) it was evident that the DIR was significantly increasing.

4.2.2.1.1 Discussion of Results for Digital Inclinometer Group A

The DIR scores for the FAKTR© Concept treatment group showed statistically significant ($p < 0.05$) improvement over the duration of the study (Table 4.8). The differences between the means of successive follow-up consultations was statistically significant ($p < 0.05$) between all, except for between the third consultation and the final consultation which showed a p-value of 0.092 (Table 4.9).

According to Strunk, Pfefer and Dube (2014), IASTM breaks down myofascial restrictions and improves the overall range of motion. The FAKTR© Concept treatment is also an IASTM concept that utilises stainless steel instruments to break-down myofascial restrictions that impair normal range of motion. Therefore, by breaking these myofascial restrictions or scar tissue the pre-injury range of motion is restored.

This is in line with the findings of Markovic (2015) who investigated the acute effects of IASTM versus foam rolling on knee and hip range of motion. Markovic (2015) found that IASTM induced statistically significant improvement in knee and hip range of motion during the study period. However, Vardiman (2015) produced conflicting results when he applied IASTM on ankle plantarflexors and reported no change in ankle dorsiflexion range of motion.

4.2.2.2 Algometer Readings (AR) Group A

Table 4.10 shows the descriptive statistics of the AR analysis.

Table 4.10: Descriptive statistics table for AR Group A

Group A		Initial Consult	Consultation 2	Consultation 3	Final Consult
Treatment	N	20	20	20	20
	Mean (N)	1.47	2.44	3.01	3.72
	Std. Deviation	0.55	0.36	0.41	0.65
	Minimum	0.90	1.80	2.40	2.40
	Maximum	2.80	3.10	3.80	4.90
	Range	1.90	1.30	1.40	2.50

As can be seen from Table 4.10, the mean AR in the treatment group on the initial consultation was 1.47 N, second consult 2.44 N, third consult 3.01 N and on the fourth consult it was 3.72 N (Table 4.14). The average improvement between the initial and the fourth consultation was 2.25 N. The was a 0.97 N average improvement between the first consultation and the second consultation, a 0.57 N improvement between the second and the third consultation and a 0.71 N improvement between the third and the final consultation. Again, there was a big jump between the first and the second consultations.

4.5.2.1 Tests of Within-Subjects Effects for AR Group A

Figure 4.11 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.11: Tests of within-subjects effects table for AR Group A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
AR	Sphericity Assumed	54.187	3	18.062	117.952	0.000	0.861	353.856	1.000
	Greenhouse-Geisser	54.187	1.856	29.194	117.952	0.000	0.861	218.932	1.000
	Huynh-Feldt	54.187	2.049	26.450	117.952	0.000	0.861	241.645	1.000
	Lower bound	54.187	1.000	54.187	117.952	0.000	0.861	117.952	1.000
Error (AR)	Sphericity Assumed	8.729	57	0.153					
	Greenhouse-Geisser	8.729	35.266	0.248					
	Huynh-Feldt	8.729	38.925	0.224					
	Lower bound	8.729	19.000	40.459					

Table 4.11 highlights the F value for the algometer reading (AR), its associated significance level and the effect size (Partial Eta Squared). When using ANOVA with repeated measures together with a Greenhouse-Giesser correction, the mean scores for the AR of the FAKTR treatment group showed statistically significant difference ($F(1.865, 8.729) = 117.952$, $p < 0.005$). This shows that there was an overall significant difference between the means of the initial and the final consultations at a significance level p-value < 0.05.

Table 4.12 above shows the significant level for the difference between each consultation measurements.

Table 4.12: Pairwise comparison table for AR Group A

Measure:

(I) AR		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial consult	Consult 2	-.965*	0.093	0.000	-1.238	-0.692
	Consult 3	-1.535*	0.133	0.000	-1.925	-1.145
	Final Consult	-2.250*	0.170	0.000	-2.749	-1.751
Consult 2	Initial Consult	.965*	0.093	0.000	0.692	1.238
	Consult 3	-.570*	0.088	0.000	-0.828	-0.312
	Final Consult	-1.285*	0.138	0.000	-1.691	-0.879
Consult 3	Initial Consult	1.535*	0.133	0.000	1.145	1.925
	Consult 2	.570*	0.088	0.000	0.312	0.828
	Final Consult	-.715*	0.101	0.000	-1.013	-0.417
Final Consult	Initial Consult	2.250*	0.170	0.000	1.751	2.749
	Consult 2	1.285*	0.138	0.000	0.879	1.691
	Consult 3	.715*	0.101	0.000	0.417	1.013

Table 4.12 shows the significance level for the difference between each consultation measurements. Algometer readings (AR) showed statistically significant differences between all four successive consultations as can be shown in Table 4.12 with a significance p-value < 0.05. From the "mean difference (I-J)" column we can see that the AR value was significantly increased at this time point.

4.2.2.2.1 Discussion of Results for Algometer Readings Group A

Algometer reading scores for the FAKTR© Concept treatment group showed statistically significant ($p < 0.05$) improvements over the duration of the study period (Table 4.11). The mean AR scores between individual consultations were also statistically significant across all four consultations (Table 4.12).

The FAKTR© Concept tool induces neural effects by creating a state of touch-induced analgesia (Looney et al., 2011), which increase afferent inputs and local anaesthesia due to the Gate Control Theory of pain inhibition postulated by Melzack and Wall (1965). The FAKTR© Concept treatment accelerates the healing process by its mechanism of action in recruiting fibroblasts which are responsible for the synthesis of extracellular matrix and regeneration of damaged collagen. The breakdown of scar tissue and promotion of a normal collage alignment restores the pre-injury tissue strength. With successive treatments there was progressive healing. The improvement of pain threshold indicates resolution of inflammation at the tendinous insertion (Hammer, 2003). This ultimately increases the tissues' tolerance to pressure thereby improving the pain pressure threshold noted in this study.

4.2.2.3 Oedema Measurements (EDM) Group A

Table 4.13 shows the descriptive statistics of the EDM analysis.

Table 4.13: Descriptive statistics table for EDM Group A

Group A (FAKTR Concept)		Initial Consult	Consultation 2	Consultation 3	Final Consult
Treatment	N	20	20	20	20
	Mean (cm)	55.44	55.11	54.83	54.78
	Std. Deviation	4.17	4.44	4.52	4.50
	Minimum	45.00	44.00	43.00	43.00
	Maximum	61.00	61.00	60.90	60.80
	Range	16.00	17.00	17.90	17.80

As can be seen from Table 4.13, the mean EDM for the FAKTR© Concept treatment group on the initial consultation was 55.44 cm, second consult 55.11 cm, third consult 54.83 cm and the fourth consult 54.78 cm. The average improvement between the initial consultation and the fourth consultation was 0.66 cm. The average improvement between the first and second consultation was 0.33 cm, between the second and the third consultation the average improvement was 0.28 cm and lastly the average improvement between the third and the final consultation was 0.05 cm. A huge improvement was noted between the first and the second consultations. The effect of the FAKTR concept was cumulative.

Figure 4.14 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.14: Tests of within-subjects effects table for EDM Group A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
EDM	Sphericity Assumed	5.439	3	1.813	19.528	0.000	0.507	58.583	1.000
	Greenhouse-Geisser	5.439	1.666	3.265	19.528	0.000	0.507	32.525	0.999
	Huynh-Feldt	5.439	1.806	3.011	19.528	0.000	0.507	35.273	1.000
	Lower bound	5.493	1.000	5.439	19.528	0.000	0.507	19.528	0.987
Error (EDM)	Sphericity Assumed	5.292	57	0.093					
	Greenhouse-Geisser	5.292	31.646	0.167					
	Huynh-Feldt	5.292	34.320	0.154					
	Lower bound	5.292	19.000	0.279					

Table 4.14 shows the F value for the oedema measurements (EDM), its associated significance level and the effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the EDM means for the FAKTR© Concept treatment group were statistically significantly different ($F(1.666, 5.292) = 19.528$, $p < 0.005$). These results show that there was an overall statistically significant difference or improvement in terms of the EDM analysis at a significance level $p < 0.05$.

Table 4.15 shows the significance level between the individual consultation measurements.

Table 4.15: Pairwise comparisons table for EDM Group A

Measure:

(I) EDM		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	.330*	0.089	0.009	0.069	0.591
	Consult 3	.605*	0.121	0.000	0.247	0.963
	Final Consult	.655*	0.121	0.000	0.300	1.010
Consult 2	Initial Consult	-.330*	0.089	0.009	-0.591	-0.069
	Consult 3	0.275	0.094	0.051	-0.001	0.551
	Final Consult	.325*	0.095	0.017	0.046	0.604
Consult 3	Initial Consult	-.605*	0.121	0.000	-0.963	-0.247
	Consult 2	-0.275	0.094	0.051	-0.551	0.001
	Final Consult	0.050	0.028	0.517	-0.031	0.131
Final Consult	Initial Consult	-.655*	0.121	0.000	-1.010	-0.300
	Consult 2	-.325*	0.095	0.017	-0.604	-0.046
	Consult 3	-0.050	0.028	0.517	-0.131	0.031

As can be seen from Table 4.15, oedema measurements showed significant differences ($p < 0.05$) between most intervals (highlighted in Table 4.15). Between consultation 2 and 3 (p-value = 0.051) and between consultation 3 and the final consultation (p-value = 0.517) there was, however no statistically significant difference ($p > 0.005$)

4.2.2.3.1 Discussion of Results for Oedema Measurements

The oedema measurement mean scores for the FAKTR© Concept treatment group showed statistically significant ($p < 0.05$) improvement over the duration of the study. However, between some successive follow-up treatments (between 2nd and 3rd consultations and between the 3rd and final consultation) the differences in mean scores were not statistically significant (i.e. $p > 0.05$).

The FAKTR© Concept treatment uses the mocking stroke which is an oedema reduction method specifically designed to push oedema up the leg. According to Markovic (2015), IASTM reduces tissue viscosity resulting in improved fluid movement, including increased blood flow and lymphatic circulation thereby minimising the buildup of fluids or oedema in the ankle joint. This minimises oedema formation.

Table 4.15 shows that there were significant differences between individual consultation measurements except for between the 2nd and 3rd and between the 3rd and the final consultation. This may be attributed to the fact that most of the oedema is pushed up during the initial consultation using the mocking stroke in addition to the cumulative effect of the FAKTR© Concept explained above. This shows that the FAKTR Concept is effective to improvement of oedema. These findings were in line with the findings of Meyer (2010) which showed a significant improvement in oedema reduction two minutes after treatment using IASTM techniques.

4.2.2.4 Stork Balance Stand Test (STR) for Group A

Table 4.16 shows the descriptive statistics of the STR analysis.

Table 4.16: Descriptive statistics table for STR Group A

Group A		Initial Consult	Consultation 2	Consultation 3	Final Consult
Treatment	N	20	20	20	20
	Mean (sec)	2.50	3.15	3.95	4.75
	Std. Deviation	0.83	0.67	0.89	1.07
	Minimum	1.00	2.00	2.00	3.00
	Maximum	4.00	4.00	5.00	6.00
	Range	3.00	2.00	3.00	3.00

The mean STR for the FAKTR© Concept treatment group on the initial consultation was 2.50 sec, second consult 3.15 sec, third consult 3.95 sec and lastly the fourth consult 4.75 sec (Table 4.16). The average improvement between the initial consultation and the fourth consultation was 2.25 sec. There was a 0.65 sec improvement between the initial and the second consultations, an 0.80 sec improvement between the second and the third consultations and lastly there was a 0.80 sec improvement between the third and the final consultations. Huge improvements were noted between the second and third and between the third and the final consultations. This is mainly because the FAKTR© Concept has a cumulative effect and balance was getting better and better over time.

Table 4.17 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.17: Tests of within-subjects effects table for STR Group A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
STR	Sphericity Assumed	57.138	3	19.046	76.926	0.000	0.802	230.777	1.000
	Greenhouse-Geisser	57.138	2.389	23.916	76.926	0.000	0.802	183.784	1.000
	Huynh-Feldt	57.138	2.756	20.731	76.926	0.000	0.802	212.019	1.000
	Lower bound	57.138	1.000	57.138	76.926	0.000	0.802	76.926	1.000
Error (STR)	Sphericity Assumed	14.113	57	0.248					
	Greenhouse-Geisser	14.113	45.393	0.311					
	Huynh-Feldt	14.113	52.367	0.269					
	Lower bound	14.113	19.000	0.743					

Table 4.17 shows the F value for the stork balance stand test (STR) of the FAKTR treatment group, its associated significance level and the effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the STR mean scores were statistically significantly different ($F(2.389, 14.113) = 76.926$, $p < 0.005$). This means that there was an overall statistically significant difference between the means of the initial and the final STR measurements at a significance level p-value < 0.05.

Table 4.18 shows the significant level for the differences between each consultation measurements.

Table 4.18: Pairwise comparison table for STR Group A

Measure:

(I) STR		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	-.650*	0.131	0.001	-1.037	-0.263
	Consult 3	-1.450*	0.153	0.000	-1.902	-0.998
	Final Consult	-2.250*	0.190	0.000	-2.810	-1.690
Consult 2	Initial Consult	.650*	0.131	0.001	0.263	1.037
	Consult 3	-.800*	0.138	0.000	-1.205	-0.395
	Final Consult	-1.600*	0.184	0.000	-2.140	-1.060
Consult 3	Initial Consult	1.450*	0.153	0.000	0.998	1.902
	Consult 2	.800*	0.138	0.000	0.395	1.205
	Final Consult	-.800*	0.138	0.000	-1.205	-0.395
Final Consult	Initial Consult	2.250*	0.190	0.000	1.690	2.810
	Consult 2	1.600*	0.184	0.000	1.060	2.140
	Consult 3	.800*	0.138	0.000	0.395	1.205

As can be seen from Table 4.18, there was a statistically significant difference between all the four intervals of the stork balance stand test (STR). From the “mean difference (I-J)” column the STR value was significantly increased at this time point.

4.2.2.4.1 Discussion of Results for Stork Balance Stand Test Group A

The STR score for the FAKTR© Concept treatment group showed statistically significant ($p < 0.05$) improvement over the duration of the study period (Table 4.17). Also, between the successive follow-up consultations of all four consultations, there were statistically significant differences in the means (Table 4.18).

The mechanism by which the FAKTR© Concept works addresses balance by treating the participant in a provocative proprioceptive position on a stability pad or on a wobble board. This re-educates proprioceptive nerve endings (Gulick, 2014) and stimulates afferent inputs. There is a dense network of sensory and proprioceptive nerves on the epiligament close to the ligament bony insertion (Bray, 1995). These then get re-educated and ultimately improves balance in the involved ankle joint complex.

The improvement noted between the first and the second consultation was smaller than what was observed between the remaining consultations. This is mainly because of the cumulative effect of the treatment with progressive healing improvements overtime time. There was a 0.80 second difference between consultation two and also between consultation three and the final consultation. The reason for no change between these two successive consultations could be because the ankle had gained its full normal stability already therefore there was no improvement to be expected. This shows that the FAKTR© Concept was effective mainly during the acute phase of the injury to restore balance of the ankle.

4.2.3 Conclusions on Objective One Group A

For Objective One, it was found that the myofascial treatment protocol (FAKTR© Concept) combined with cryotherapy was effective in the treatment of acute and/or subacute inversion grade I or II ankle sprains in terms of subjective (NPRS and FFI) and objective measurements (EDM, DIR, AR f STR).

4.3 Objective Two

To determine the relative effectiveness of cryotherapy and sham laser in the treatment of acute and or subacute ankle grade I or II inversion sprains in terms of subjective and objective measurements.

4.3.1 Subjective Measurements Group B

4.3.1.1 Numerical Pain Rating Scale (NRS) Group B

Table 4.19 gives the descriptive statistics of the NRS of Group B, the control group.

Table 4.19: Descriptive statistics table for NPRS Group B

Group B		Initial Consult	Consultation 2	Consultation 3	Final Consult
Control	N	20	20	20	20
	Mean	6.00	5.15	4.50	4.25
	Std. Deviation	1.03	0.99	0.76	0.79
	Minimum	4.00	4.00	3.00	3.00
	Maximum	8.00	7.00	6.00	6.00
	Range	4.00	3.00	3.00	3.00

The mean NRS for the sham laser group on the initial consultation was 6.00, on second consult was 5.16, on third consult was 4.50 and on the fourth consult it was 4.25 (Table 4.19). The average improvement between the first and the fourth consult was 1.75. There was a 0.85 improvement between the initial and the second consultation, a 0.65 improvement between the second and the third consultation and lastly there was a 0.25 improvement between the third and the final consultation. There was a significant decrease (from 6.00 to 5.15) between the initial and the second consultation. The sham treatment showed improvement in subjective pain between some individual consultations and between some (third and final consultation) successive consultation the difference between the means was not statistically significant.

Table 4.20 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.20: Tests of within-subjects effects table Group B

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
NRS	Sphericity Assumed	36.650	3	12.217	70.695	0.000	0.788	212.086	1.000
	Greenhouse-Geisser	36.650	2.786	13.154	70.695	0.000	0.788	196.972	1.000
	Huynh-Feldt	36.650	3.000	12.217	70.695	0.000	0.788	212.086	1.000
	Lower bound	36.650	1.000	36.650	70.695	0.000	0.788	70.695	1.000
Error (NRS)	Sphericity Assumed	9.850	57	0.173					
	Greenhouse-Geisser	9.850	52.938	0.186					
	Huynh-Feldt	9.850	52.000	0.173					
	Lower bound	9.850	19.000	0.518					

Table 4.20 shows the F value for the NRS of the sham laser group, its associated significance level and the effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores for the NRS of the sham laser (control) group were statistically significantly different (F (2.786, 9.850) = 70.695, p < 0.05). The table of tests within-subject effects show if there was an overall significant change on the measures of a variable. Table 4.20 shows that there was an overall significant change on the NRS values at a significance level p < 0.05.

Table 4.21 shows the significant level for the differences between each consultation measurements.

Table 4.21: Pairwise comparisons table Group B

(I) NRS		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	.850*	0.109	0.000	0.528	1.172
	Consult 3	1.500*	0.136	0.000	1.100	1.900
	Final Consult	1.750*	0.123	0.000	1.388	2.112
Consult 2	Initial Consult	-.850*	0.109	0.000	-1.172	-0.528
	Consult 3	.650*	0.131	0.001	0.263	1.037
	Final Consult	.900*	0.143	0.000	0.478	1.322
Consult 3	Initial Consult	-1.500*	0.136	0.000	-1.900	-1.100
	Consult 2	-.650*	0.131	0.001	-1.037	-0.263
	Final Consult	0.250	0.143	0.577	-0.170	0.670
Final Consult	Initial Consult	-1.750*	0.123	0.000	-2.112	-1.388
	Consult 2	-.900*	0.143	0.000	-1.322	-0.478
	Consult 3	-0.250	0.143	0.577	-0.670	0.170

Table 4.21 shows that between the third and the final consultation there was no statistically significant difference of means. However, all the other successive consultations showed statistically significant improvement in subjective pain measurement at a significance level p-value < 0.05. From the mean difference (I-J) column, the NRS of the control group was significantly reduced.

4.3.1.1.1 Discussion of Results for NRS: Sham Laser Group

The sham laser (control) group showed statistically significant improvement ($p < 0.05$) in subjective pain over the duration of the study (Table 4.20). There was also a statistically significant improvement between individual consultations except for between the third and final consultation (Table 4.21).

The observed subjective pain improvement in the sham laser (control) group can be validated in literature as cryotherapy has been shown to reduce nerve conduction velocity, thereby inducing local analgesic effects that gives pain relief on acute soft tissue injuries (Algafly and George, 2007). According to Bleakley et al. (2007), cryotherapy is more effective in decreasing pain during the acute phase of the injury (immediately after application to 1-week post-injury). This could be the reason for the observed insignificant (p-value = 0.577) improvement between the third and the final consultation which occurred in the second week of the study.

Knight (1989) reports that by decreasing tissue temperature, cryotherapy can reduce metabolism, minimising inflammatory response and aid recovery thereby diminishing pain sensation. During the acute phase of the injury, cryotherapy reduces tissue metabolic rate, minimises secondary hypoxic damage and the extent of tissue injury (Bleakley, McDonough and MacAuley, 2004). Therefore, by reducing tissue metabolism and minimising secondary hypoxic injury and the extent of tissue damage, cryotherapy allows the injury to progress to the next stages of healing without any complications.

The improvement in subjective pain measurements can also be attributed to the power of the placebo effect which could have influenced the results in a positive manner.

4.3.1.2 Foot Function Index (FFI)

Table 4.22 shows the descriptive statistics of the FFI analysis of Group B, the control group.

Table 4.22: Descriptive statistics table Group B

Group B		Initial Consult	Consultation 2	Consultation 3	Final Consult
Control	N	20	20	20	20
	Mean	48.84	39.58	36.95	31.95
	Std. Deviation	10.11	12.69	13.64	10.35
	Minimum	27.00	10.00	9.00	11.00
	Maximum	65.00	64.00	59.00	48.00
	Range	38.00	54.00	50.00	37.00

The mean FFI score of the control group for the initial consultation was 48.84, second consult 39.58, for the third consult was 36.95 and on the fourth consult it was 31.95 (Table 4.22). The average improvement between the initial consultation and the fourth consultation was 16.89%. There was a 9.26 point improvement between the initial and the second consultation, a 2.63 point improvement between the second and the third consultation and finally a 5.00 point improvement between the third and the final consultation.

Table 4.23 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.23: Tests of within-subjects effects table Group B

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
FFI	Sphericity Assumed	2863.724	3	954.575	17.240	0.000	0.489	51.719	1.000
	Greenhouse-Geisser	2863.724	1.922	1490.086	17.240	0.000	0.489	33.132	0.999
	Huynh-Feldt	2863.724	2.147	1334.003	17.240	0.000	0.489	37.009	1.000
	Lower bound	2863.724	1.000	2863.724	17.240	0.001	0.489	17.240	0.975
Error (FFI)	Sphericity Assumed	2990.026	57	55.371					
	Greenhouse-Geisser	2990.026	34.593	86.434					
	Huynh-Feldt	2990.026	38.641	77.380					
	Lower bound	2990.026	19.000	166.113					

Table 4.23 shows the F value for the FFI of the sham laser (control) group, its associated significance level and effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores for the FFI of the control group were statistically significantly different ($F (1.922, 2990.026) = 17.240, p < 0.05$). This shows that there was an overall significant difference between the means for all measurement points.

Table 4.24 shows the significance level of the difference between consultation measurements.

Table 4.24: Pairwise comparison table Group B

Measure:

(I) FFI		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	9.263*	2.934	0.033	0.571	17.955
	Consult 3	11.895*	3.196	0.009	2.425	21.364
	Final Consult	16.895*	2.461	0.000	9.603	24.187
Consult 2	Initial Consult	-9.263*	2.934	0.033	-17.955	-0.571
	Consult 3	2.632	1.489	0.565	-1.780	7.044
	Final Consult	7.632*	2.057	0.010	1.539	13.725
Consult 3	Initial Consult	-11.895*	3.196	0.009	-21.364	-2.425
	Consult 2	-2.632	1.489	0.565	-7.044	1.780
	Final Consult	5.000	1.909	0.104	-0.655	10.655
Final Consult	Initial Consult	-16.895*	2.461	0.000	-24.187	-9.603
	Consult 2	-7.632*	2.057	0.010	-13.725	-1.539
	Consult 3	-5.000	1.909	0.104	-10.655	0.655

The Pairwise comparison (Table 4.24) shows the significance level between the means of the individual consultation measurements of the FFI for the control group. The FFI reading showed a statistically significantly difference in improvement between the means of most of the successive consultation measurements except between consultation 2 and 3 (p-value = 0.565) and between consultation 3 and 4 (p-value = 0.104). From the mean difference (I-J) column, the FFI values were significantly reduced.

4.3.1.2.1 Discussion of Results for FFI: Sham Laser Group

The mean FFI scores for the sham laser (control) group showed statistically significant improvement over the study period (Table 4.23). However, between some individual consultation the mean differences were not statistically significant (between consultation 2 and 3, and between consultation 3 and the final consultation) as shown in Table 4.24.

The significant improvement in subjective pain during daily activities (FFI) observed in Tables 4.23 and 4.24 can be explained in terms of the cryotherapy mechanism in decreasing nerve conduction velocity thereby inducing local analgesic effects which in turn decrease the perception of pain by the participant.

Meyer-Marcotty et al. (2011) compared standard cryotherapy application with compression using cryo/cuff after wrist arthroscopy and reported that compression with the cryo/cuff group produced a significant improvement in pain (VAS) compared to the standard cryotherapy treatment group. This could explain why there was a significant difference between the mean FFI scores of the third and the final consultation. Standard cryotherapy application alone is not effective to improve the functional outcome of the ankle sprain. Bleakley et al. (2007) compared standard cryotherapy application to cryokinetics (application of ice combined with exercise) and found that cryokinetic is more effective than the standard application alone in the improvement of pain and functional outcome.

Therefore, standard cryotherapy application alone in the treatment of ankle sprains can be outperformed by any functional treatment or a combination of ice and functional treatment.

4.3.2 Objective Outcomes Group B

4.3.2.1 Digital Inclinometer Reading (DIR) Group B

The descriptive statistics of the DIR are presented in Table 4.25.

Table 4.25: Descriptive statistics table Group B

Group B		Initial Consult	Consultation 2	Consultation 3	Final Consult
Control	N	20	20	20	20
	Mean (^{O})	61.80	60.95	60.60	60.35
	Std. Deviation	5.04	5.15	4.92	4.28
	Minimum	57.00	55.00	55.00	55.00
	Maximum	76.00	75.00	75.00	70.00
	Range	19.00	20.00	20.00	15.00

The mean DIR on the initial consultation was 61.80°, second consult 60.95°, third consult 60.60° and on the fourth consult it was 60.35° (Table 4.25). The average improvement between the initial consultation and the fourth consultation was 1.45°. There was a 0.85° improvement between the initial and the second consultations, a 0.35° improvement between the second and the third consultation and between the third and the final consultation there was a 0.25° average improvement in ankle dorsiflexion range of motion.

Table 4.26 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.26: Tests of within-subjects effects table Group B

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
DIR	Sphericity Assumed	24.050	3	8.017	12.711	0.000	0.401	38.132	1.000
	Greenhouse-Geisser	24.050	2.406	9.997	12.711	0.000	0.401	30.579	0.998
	Huynh-Feldt	24.050	2.779	8.654	12.711	0.000	0.401	35.324	0.999
	Lower bound	24.050	1.000	24.050	12.711	0.002	0.401	12.711	0.922
Error (DIR)	Sphericity Assumed	35.950	57	0.631					
	Greenhouse-Geisser	35.950	45.710	0.786					
	Huynh-Feldt	35.950	52.802	0.681					
	Lower bound	35.950	19.000	1.892					

Table 4.26 shows the F value of the digital DIR for the control group, its associated significance level and its effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores for DIR for the control group were statistically significantly different ($F(2.406, 35.950) = 12.711$, $p < 0.05$). The DIR analysis showed that there was an overall significant difference between all the means at different measurement points.

Table 4.27 shows the significance level for the difference between consultation measurements.

Table 4.27: Pairwise comparison table Group B

Measure:

(I) DIR		Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	.850*	0.182	0.001	0.315	1.385
	Consult 3	1.200*	0.225	0.000	0.538	1.862
	Final Consult	1.450*	0.303	0.001	0.557	2.343
Consult 2	Initial Consult	-.850*	0.182	0.001	-1.385	-0.315
	Consult 3	0.350	0.209	0.659	-0.264	0.964
	Final Consult	0.600	0.275	0.253	-0.210	1.410
Consult 3	Initial Consult	-1.200*	0.225	0.000	-1.862	-0.538
	Consult 2	-0.350	0.209	0.659	-0.964	0.264
	Final Consult	0.250	0.289	1.000	-0.601	1.101
Final Consult	Initial Consult	-1.450*	0.303	0.001	-2.343	-0.557
	Consult 2	-0.600	0.275	0.253	-1.410	0.210
	Consult 3	-0.250	0.289	1.000	-1.101	0.601

Table 4.27 highlights the significance level between the mean scores of successive consultations. Digital inclinometer readings showed statistically significant difference in mean scores between certain consultations (p-value < 0.05). The significant levels are highlighted in Table 4.27 above. From the mean difference (I-J) column, the DIR value was statistically reduced.

4.3.2.1.1 Discussion of Results for DIR Group B

There was an overall statistically significant improvement ($p < 0.05$) in the objective ankle dorsiflexion range of motion during the study period (Table 4.26). However, the mean DIR scores between consultation 2 and 3, between consultation 2 and the final consultation and between the consultation 3 and the final consultation were not statistically significant, i.e. $p > 0.05$ (Table 4.27).

Cryotherapy is believed to improve joint range of motion by providing pain relief (Knight et al., 2001), reducing muscle tension, and inhibiting muscle spasm (Lin, 2003). Cryotherapy alone is less effective in the improvement of function. In line with this study, Hayden (1964) reported that cold and motion (cryokinetic) is more beneficial in improving joint range of motion than cryotherapy alone. Also, cryotherapy is more effective immediately after application up to 1-week post injury (Bleakley, McDonough and MacAuley, 2004). This explains why the mean DIR scores of the last consultations were not statistically significantly different compared to the mean differences of the initial and the second consultation.

4.3.2.2 Algometer Readings (AR) Group B

The descriptive statistics of the AR are given in Table 4.28.

Table 4.28: Descriptive statistics table Group B

Group B		Initial Consult	Consultation 2	Consultation 3	Final Consult
Control	N	20	20	20	20
	Mean (N)	1.71	2.09	3.52	2.40
	Std. Deviation	0.59	0.54	5.78	0.36
	Minimum	0.30	1.10	1.10	1.60
	Maximum	2.60	3.10	28.00	3.20
	Range	2.30	2.00	26.90	1.60

The mean AR of the control group on the initial consultation was 1.71 N, second consult 2.09 N, third consult was 3.52 N and on the fourth consult it was 2.4 N (Table 4.28). The average improvement between the initial and the fourth consultation was 0.69 N. There was a 0.38 N improvement between the initial consultation and the second consultation, a 1.43 N improvement between the second and the third consultation and lastly there was a -1.12 N improvement between the third and the final consultation. The AR scores were not consistent as the mean value of the third consultation increases more than of the normal range of standard deviation of 5.78 N.

Table 4.29 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.29: Tests of within-subjects effects table Group B

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
AR	Sphericity Assumed	36.387	3	12.129	1.476	0.231	0.072	4.427	0.370
	Greenhouse-Geisser	36.387	1.018	35.729	1.476	0.240	0.072	1.503	0.213
	Huynh-Feldt	36.387	1.021	35.621	1.476	0.240	0.072	1.507	0.213
	Lower bound	36.387	1.000	36.387	1.476	0.239	0.072	1.476	0.211
Error (AR)	Sphericity Assumed	468.499	57	8.219					
	Greenhouse-Geisser	468.499	19.349	24.213					
	Huynh-Feldt	468.499	19.408	24.139					
	Lower bound	468.499	19.000	24.658					

Table 4.29 shows the F value for the AR of the control group, its associated significance level and effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores for the AR of the control group were not statistically significantly different ($F (1.018, 468.499) = 1.476$, $p > 0.05$). Table 4.29 above shows that there was no statistically significant difference between all the means at all intervals.

Table 4.30 shows the significant level of difference between consultation measurements.

Table 4.30: Pairwise comparison table Group B

(I) AR	(J) AR	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	-.385*	0.121	0.029	-0.741	-0.029
	Consult 3	-1.810	1.305	1.000	-5.651	2.031
	Final Consult	-.695*	0.130	0.000	-1.079	-0.311
Consult 2	Initial Consult	.385*	0.121	0.029	0.029	0.741
	Consult 3	-1.425	1.258	1.000	-5.127	2.277
	Final Consult	-.310*	0.074	0.003	-0.527	-0.093
Consult 3	Initial Consult	1.810	1.305	1.000	-2.031	5.651
	Consult 2	1.425	1.258	1.000	-2.277	5.127
	Final Consult	1.115	1.269	1.000	-2.622	4.852
Final Consult	Initial Consult	.695*	0.130	0.000	0.311	1.079
	Consult 2	.310*	0.074	0.003	0.093	0.527
	Consult 3	-1.115	1.269	1.000	-4.852	2.622

The pairwise comparison table in Table 4.30 shows the significance level between the successive consultations. All the highlighted figures in Table 4.30 show the statistically significant improvement in the pain pressure threshold over the duration of the study. Most of the AR in the control group were not statistically significant between successive consultations (levels that are not highlighted in the Table 4.30 above). Between interval 1 and 2 (p-value = 0.029), 1 and 4 (p-value < 0.05) and 2 and 4 (p-value = 0.003) there was a significant difference with a p-value < 0.05. From the mean difference (I-J) column, the AR values were not significantly reduced.

4.3.2.2.1 Discussion of Results for AR Group B

The mean scores of the AR (pain pressure threshold) over the duration of the study period were not statistically significantly different (Table 4.29). However, the mean AR scores between some individual consultation were statistically significantly different (Table 4.30).

The slight improvement in objective pain pressure threshold observed in the control (sham laser) group of this study can be explained in terms of the mechanism of action of cryotherapy which is more effective during the acute phase of the injury (Bleakley, McDonough and MacAuley, 2004). The findings of this study conflict with the results of the study with Algafly and George (2007) which reported a statistically significant improvement in the pain pressure threshold after ice application. According to Algafly and George (2007) and Bleakley, McDonough and MacAuley (2004), the application of ice reduces nerve conduction velocity and decrease tissue excitability with the pain transmitting fibres more affected, A-delta fibres (Cameron, 1999). Similarly, Hatem (2006) produced conflicting results to this study regarding the effect of cryotherapy versus placebo, finding a statistically significant improvement in the pain pressure threshold in the cryotherapy group as compared to the placebo group.

4.3.2.3 Oedema Measurements (EDM) Group B

The descriptive statistics of the EDM analysis is provided in Table 4.31.

Table 4.31: Descriptive statistics table Group B

Group B		Initial Consult	Consultation 2	Consultation 3	Final Consult
Control	N	20	20	20	20
	Mean (cm)	54.08	54.08	54.83	54.13
	Std. Deviation	13.78	13.56	13.36	13.36
	Minimum	0.00	1.00	2.00	2.00
	Maximum	72.00	72.00	72.00	72.00
	Range	72.00	71.00	70.00	70.00

The mean EDM for the control group on the initial consultation was 54.08 cm, second consult 54.08 cm, third consult 54.83 cm and on the fourth consult it was 54.13 cm (Table 4.31). The average improvement between the initial consultation and the fourth consultation was -0.05 cm. There was a 0.00 cm improvement between the initial and the second consultation, a 0.75 cm increase in oedema between the second and the third consultation, and between the third and the final consultation there was a 0.70 cm decrease in oedema. These findings of this study were unexpected and conflict with the results of other studies which demonstrates that ice application is effective in the improvement of oedema. However, there was an overall 0.05 cm increase in oedema over the duration of the study.

Table 4.32 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.32: Tests of within-subjects effects table Group B

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
EDM	Sphericity Assumed	0.050	3	0.017	0.275	0.843	0.014	0.286	0.100
	Greenhouse-Geisser	0.050	1.082	0.046	0.275	0.624	0.014	0.298	0.080
	Huynh-Feldt	0.050	1.096	0.046	0.275	0.627	0.014	0.302	0.080
	Lower bound	0.050	1.000	0.050	0.275	0.606	0.014	0.275	0.079
Error (EDM)	Sphericity Assumed	3.450	57	0.061					
	Greenhouse-Geisser	3.450	20.554	0.168					
	Huynh-Feldt	3.450	20.822	0.166					
	Lower bound	3.450	19.000	0.182					

Table 4.32 above shows the F value for the oedema measurements of the sham laser (control) group, its associated significance level and the effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores of the AR were not statistically significantly different ($F(1.082, 3.450) = 0.275$, $p > 0.05$). The tests of within-subject's effects Table 4.32 above shows that there is no significant difference between all the means at all measurement points.

Table 4.33 shows the significance level of difference between consultation measurements.

Table 4.33: Pairwise comparison table Group B

Measure:

(I) EDM		Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	0.000	0.073	1.000	-0.214	0.214
	Consult 3	-0.050	0.114	1.000	-0.386	0.286
	Final Consult	-0.050	0.114	1.000	-0.386	0.286
Consult 2	Initial Consult	0.000	0.073	1.000	-0.214	0.214
	Consult 3	-0.050	0.050	1.000	-0.197	0.097
	Final Consult	-0.050	0.050	1.000	-0.197	0.097
Consult 3	Initial Consult	0.050	0.114	1.000	-0.286	0.386
	Consult 2	0.050	0.050	1.000	-0.097	0.197
	Final Consult	0.000	0.000		0.000	0.000
Final Consult	Initial Consult	0.050	0.114	1.000	-0.286	0.386
	Consult 2	0.050	0.050	1.000	-0.097	0.197
	Consult 3	0.000	0.000		0.000	0.000

The pairwise comparison table (Table 4.33) demonstrates the significance levels between the individual consultations. Oedema measurements between all consultations in the control group did not demonstrate any significant difference between the mean scores across all four consultations (p-value > 0.05). From the mean difference (I-J) column, there was no change in the EDM values.

4.3.2.3.1 Discussion of Results for EDM Group B

The oedema measurement mean scores for the sham laser (control) group were not statistically significantly different over the duration of the study period (Table 4.32). The oedema measurements means scores did not demonstrate any significance between any of the individual consultation mean measurements (Table 4.33).

The results of this study conflict with the findings of several studies (for example, Karunakara, Lephart and Pinciverio, 1999). There was worsening of the ankle oedema over the study period. This increase in oedema in the sham laser group can be attributed to the mistake that was made in the stepwise written instruction for home ice application. In the methodology section and in the literature review it is recommended that ice application should not be more that 10 minutes but on the written instruction, participants were instructed (by mistake) to apply ice for 20 minutes at a time. Brown and Hahn (2009) in their case report also reported that prolonged cryotherapy application can result in vessel dilation, increased extra-cellular hemorrhage and limb threatening conditions. Cryotherapy has been shown to reduce swelling by cold induced vasoconstriction and by decreasing blood vessel permeability, thereby minimising haemorrhage (Karunakara, Lephart and Pinciverio, 1999).

According to Meeusen and Lievens (1986), when the physiological processes after cryotherapy application are examined in clinical trials, some of the outcomes differ from the expectations. The slight increase in swelling in this study may be attributed to cold induced damage to superficial lymph vessels (Meeusen and Lievens, 1986). Lymphatic vessel damage can result in leakage of the lymph fluid that can ultimately accumulate around the ankle joint (Khoshnevis, Craik and Diller; 2015).

4.3.2.4 Stork Balance Stand Test (STR) Group B

Table 4.34 gives the descriptive statistics of the STR analysis.

Table 4.34: Descriptive statistics table Group B

Group B		Initial Consult	Consultation 2	Consultation 3	Final Consult
Control	N	20	20	20	20
	Mean (sec)	7.20	7.00	6.90	6.60
	Std. Deviation	18.00	15.50	14.03	12.01
	Minimum	1.00	2.00	2.00	2.00
	Maximum	82.00	71.00	63.00	55.00
	Range	81.00	69.00	61.00	53.00

The mean scores of the DIR in the sham treatment group on the initial consultation was 7.20 sec, the second consultation 7.00 sec, the third consultation 6.90 sec and lastly on the final consultation was 6.60 sec. Therefore, the average improvement between the initial and the final consultation was 0.60 sec. There was a 0.20 sec improvement between the initial and the second consultation, a 0.10 sec between the second and third consultation and between the third and the final consultation there was a 0.30 sec improvement.

Table 4.35 shows if there was an overall significant difference between the means at the different measurement points.

Table 4.35: Tests of within-subjects effects table Group B

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
STR	Sphericity Assumed	3.750	3	1.250	0.168	0.918	0.009	0.503	0.079
	Greenhouse-Geisser	3.750	1.089	3.443	0.168	0.708	0.009	0.183	0.068
	Huynh-Feldt	3.750	1.104	3.395	0.168	0.711	0.009	0.185	0.068
	Lower bound	3.750	1.000	3.750	0.168	0.687	0.009	0.168	0.068
Error (STR)	Sphericity Assumed	424.750	57	7.452					
	Greenhouse-Geisser	424.750	20.693	20.526					
	Huynh-Feldt	424.750	20.985	20.240					
	Lower bound	424.750	19.000	22.355					

Table 4.35 shows the F value for the stork balance stand test (STR) of the sham laser (control) group, its associated significance level and its effect size (Partial Eta Squared). When using ANOVA with repeated measures with a Greenhouse-Giesser correction, the mean scores of STR of the control group were not statistically significantly different (F (1.089, 424.750) = 0.168, p > 0.05). Table 4.47 shows that there was no significant difference between all the means at all intervals. Cryotherapy and sham laser was not effective in improving balance and stability of the ankle.

Table 4.36 shows the significance levels between the individual consultations.

Table 4.36: Pairwise comparison test Group B

Measure:

(I) STR		Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
Initial Consult	Consult 2	0.200	0.579	1.000	-1.503	1.903
	Consult 3	0.300	1.016	1.000	-2.691	3.291
	Final Consult	0.600	1.394	1.000	-3.505	4.705
Consult 2	Initial Consult	-0.200	0.579	1.000	-1.903	1.503
	Consult 3	0.100	0.497	1.000	-1.363	1.563
	Final Consult	0.400	0.832	1.000	-2.048	2.848
Consult 3	Initial Consult	-0.300	1.016	1.000	-3.291	2.691
	Consult 2	-0.100	0.497	1.000	-1.563	1.363
	Final Consult	0.300	0.471	1.000	-1.086	1.686
Final Consult	Initial Consult	-0.600	1.394	1.000	-4.705	3.505
	Consult 2	-0.400	0.832	1.000	-2.848	2.048
	Consult 3	-0.300	0.471	1.000	-1.686	1.086

The mean difference (I-J) value increased between all the four interventions, but it was however not significant at a significant level p-value < 0.05. From the mean difference (I-J) column, the STR value were not significantly improved.

4.3.2.5 Discussion of Results for STR Group B

The mean scores of the STR for the sham laser (control) group were not statistically significantly different at the significance level p-value < 0.05 (Table 4.35). There was no significance demonstrated between any of the individual mean STR scores of the sham laser (control) group during the duration of the study (Table 4.36). The STR measures balance and proprioception of the ankle joint.

The effect of cryotherapy on balance and proprioception has been poorly investigated over the years. However, a few studies have been conducted to determine the effectiveness of cryotherapy on balance and joint position sense with conflicting results. A systematic review by Costello and Donnelly (2010) showed that four studies found cryotherapy to have zero effect on proprioception, while three other studies found that proprioception was decreased after cryotherapy application.

Khanmohammadi, Someh and Ghafarinejad (2011) investigated the effect of cryotherapy on normal ankle joint position sense at the middle range of dorsiflexion and plantarflexion (actively and passively), and found no significant difference in joint position sense at middle range dorsiflexion and plantarflexion (actively and passively) before and after cryotherapy application. Therefore, the results of this study are in line with the findings of other studies.

4.3.3 Conclusion of Objective Two Group B

It was found that sham laser combined with cryotherapy was effective in the treatment of acute and/or subacute inversion grade I or II ankle sprains in terms of subjective measurements (NPRS and FFI). In terms of the objective measurements (EDM, DIR, AR and STR) sham laser combined with cryotherapy was found to be not effective in treating acute and/or subacute ankle grade I or II inversion sprains.

4.4 Objective 3: Comparison of the FAKTR© Concept and Sham laser Groups

The results below look at the mean trends over treatment periods for the various variables.

4.4.1 Numerical Pain Rating Scale (NRS) Comparison

Table 4.37: Mean trends over treatment periods for the variable NRS

	Initial Consult	Consultation 2	Consultation 3	Final Consult
FAKTR Treatment Group	6.35	3.65	1.55	0.65
Sham Laser Group	6.00	5.15	4.50	4.25
Mann Whitney p-value	0.314	0.000	0.000	0.000

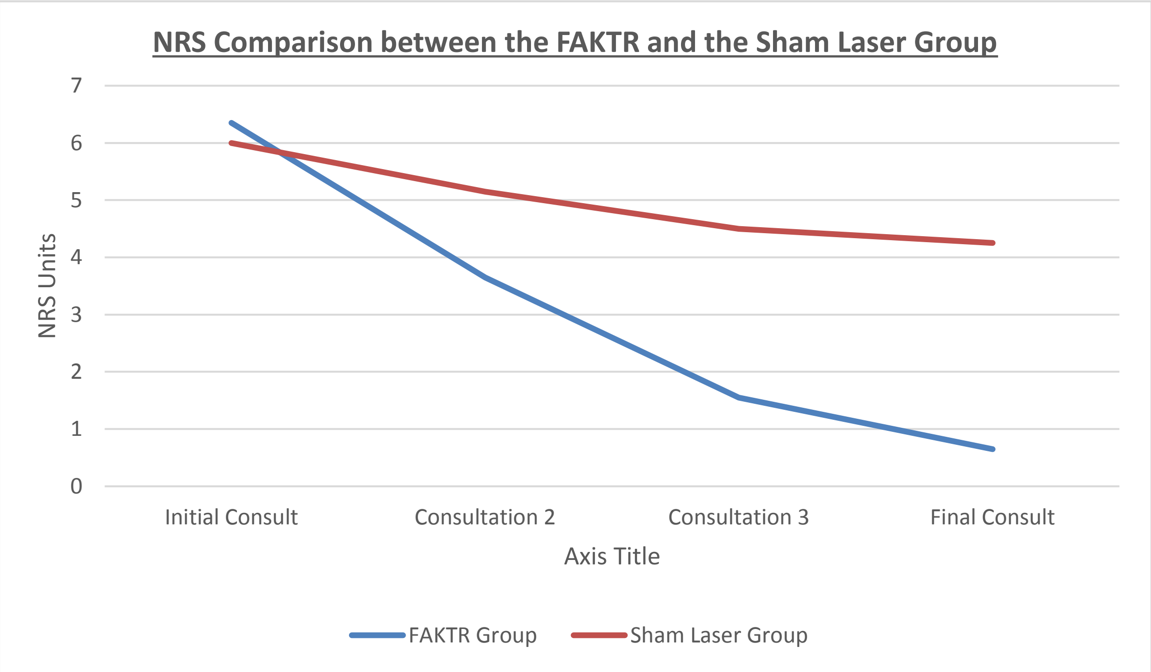

Figure 4.1: Mean trends over treatment periods for the variable NRS

4.4.1.1 Analysis of Results NRS

As can be seen from Table 4.37, the NRS readings are similar at the initial consultation (6.35 for the FAKTR© Concept treatment group and 6.00 for the sham laser group) with differences appearing for the remaining consultations. The sham laser group values are higher than the FAKTR© Concept treatment group. The differences increase over time, developing significant differences (p-value < 0.05).

As can be seen from Figure 4.1, the mean NRS scores for both groups were similar at baseline. At the end of the study there was a statistically significant difference between the NRS mean scores with the FAKTR© Concept treatment group showing more improvement compared to the sham laser (control) group.

4.4.1.2 Discussion of Results NRS

The FAKTR© Concept treatment group outperformed the control group because of its mechanism of action in breaking down scar tissue/ myofascial restrictions, inducing hyperaemia with the recruitment of fibroblasts which are responsible for the synthesis of extracellular matrix and repair of damaged collagen fibrils, which in turn speeds up the healing process (Gulick, 2014). This will ultimately lower the perception of pain by the participant.

Similarly, Looney et al. (2011) had similar findings when he investigated the effectiveness of IASTM (non-FAKTR© Concept) on participants presenting with plantar fasciitis. There was a statistically significant improvement in pain using the NRS as compared to the control group which showed no statistically significant or clinically relevant improvement in terms of the subjective pain measurement

However, Gulick (2014) had conflicting results when investigating the effect of IASTM (non-FAKTR© Concept) versus placebo on myofascial trigger points of the upper back. The IASTM did not outperform the placebo; both trigger points showed improvements on pressure sensitivity with the algometer post intervention.

The significant difference in the mean scores of the NRS between the FAKTR© Concept treatment and the sham laser groups can also be attributed to the control group not receiving any extra treatment. The FAKTR© Concept treatment had multiple effects which contributed to the observed out-performance.

Both groups received cryotherapy, therefore the FAKTR© Concept treatment outperformed sham laser. This means that FAKTR© Concept treatment was more effective in the treatment of acute and or subacute grade I or II inversion ankle sprains during the study period than the sham laser treatment.

4.4.2 Digital Inclinometer Reading (DIR) Comparison

Table 4.38: Mean trends over treatment periods for the variable DIR

	Initial Consult	Consultation 2	Consultation 3	Final Consult
FAKTR Treatment Group	62.80	59.80	58.75	58.40
Sham Laser Group	61.80	60.95	60.60	60.35
Mann Whitney p-value	0.369	0.862	0.355	0.242

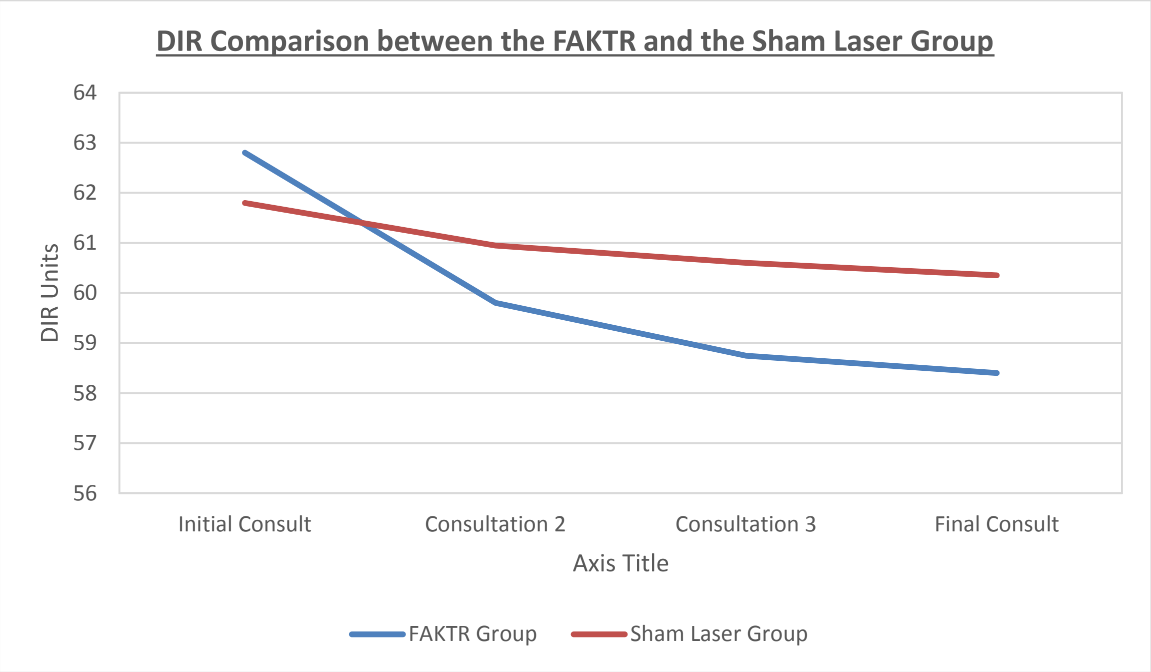

Figure 4.2: Mean trends over treatment periods for the variable DIR

4.4.2.1 Analysis of Results DIR

The patterns observed are similar to those of the NRS findings, however the differences are not significant for any treatment period. All of the p-values > 0.05. The DIR measurements of both the sham laser treatment group and the FAKTR© Concept treatment group were slightly different (62.80º for the FAKTR © Concept treatment group and 61.80 for the sham laser group) at the initial consultation with the FAKTR© Concept treatment group slightly above the sham laser group. However, at the end of the study period the mean DIR score for the FAKTR© Concept treatment group was lower than for the sham laser (control) group. The mean differences between the two groups were not statistically significant (p-value = 0.242) over the duration of the study.

4.4.2.2 Discussion of Results DIR

The reason for these results can be because FAKTR© Concept treatment breaks down scar tissue, post injury fibrous adhesions and myofascial restrictions (Hammer and Pfefer, 2005. This can ultimately result in improved range of motion. The FAKTR concept has multiple effects that can collectively result in improved range of motion. According to Knight et al. (2001), cryotherapy improves range of motion by providing pain relief, inhibiting muscle spasm and reducing muscle tension. This can be the reason for the observed improved range of motion in the sham laser (control) group.

Both groups received cryotherapy, and there was improvement in ankle dorsiflexion range of motion observed in both groups. However, the FAKTR© Concept treatment outperformed the sham laser even though there was no significant difference between the mean DIR scores between both groups at the final consultation.

4.4.3 Algometer Reading (AR) Comparison

Table 4.39: Mean trends over treatment periods for the variable AR

	Initial Consult	Consultation 2	Consultation 3	Final Consult
FAKTR Treatment Group	1.47	2.44	3.01	3.72
Sham Laser Group	1.71	2.09	3.52	2.40
Mann Whitney p-value	0.114	0.068	0.000	0.000

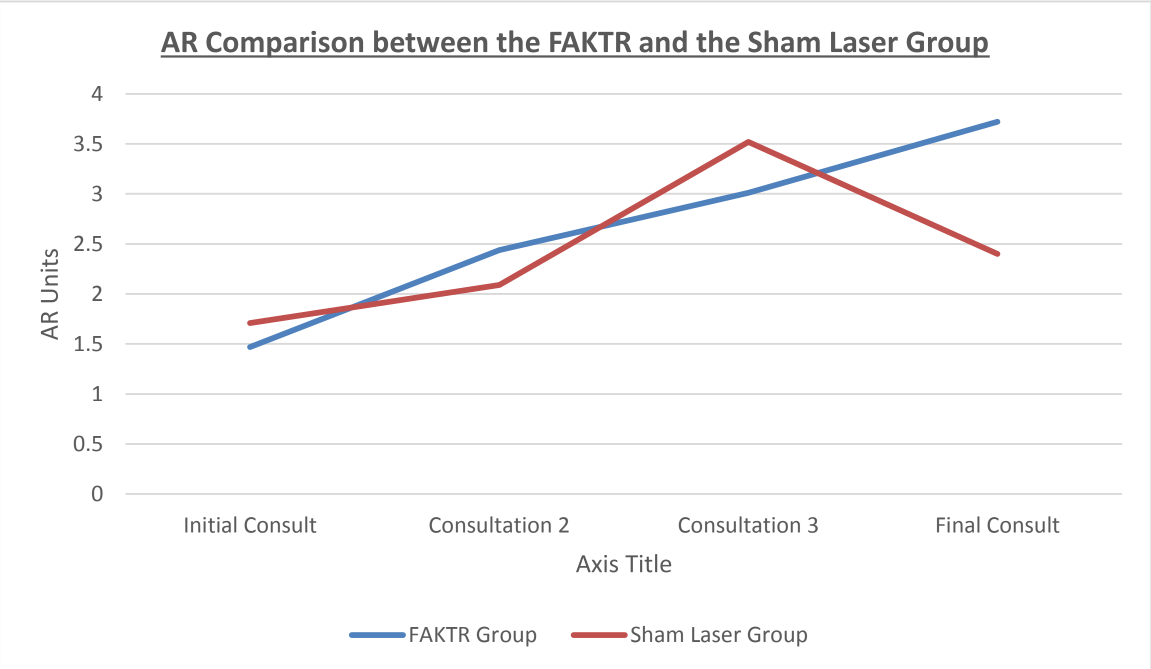

Figure 4.3: Mean trends over treatment periods for the variable AR

4.4.3.1 Analysis of Results AR

Table 4.39 and Figure 4.3 show that the readings are similar at the baseline with significant differences appearing for the last two consultations. Changes only started to occur at remaining consultations with the FAKTR© Concept treatment group showing a significant improvement (p-value < 0.05) as compared to the sham laser group at the final consultation. The sham laser treatment group values are higher than the FAKTR© Concept treatment group for consultation 3 and lower for the final consultation. Both the FAKTR© Concept treatment group and the sham laser groups had similar baseline algometry measurements (1.47 N for the FAKTR© Concept treatment group and 1.71 N for the sham laser group) (Figure 4.3). The difference between these two groups was only significant (p-value < 0.05) between the last two consultations, which were the third and the fourth consultations.

4.4.3.2 Discussion of Results AR

The results can be attributed to cryotherapy having temporary analgesic effects, but it is not effective for a prolonged period of time or for subacute or chronic injuries (Bleakley et al, 2010). The FAKTR© Concept has long term effects and is also effective on subacute and chronic injuries, facilitating healing of chronically degenerated soft tissues, therefore FAKTR© Concept treatment can have a healing effect on the injury, even after the effects of cryotherapy are finished. The AR were taken on the most tender area of ankle sprain and as time progressed along with the progression of treatment there was progressive healing, hence a noted improvement of pain threshold (Gulick, 2014).

Both groups received cryotherapy. The FAKTR© Concept treatment outperformed the sham laser with a mean difference of 1.32 N which was statistically significant (p-value < 0.05) at the final consultation. This means that the FAKTR© Concept treatment was more effective than sham laser in the treatment of acute and or subacute grade I or II inversion ankle sprains in terms of AR (pain pressure threshold).

4.4.4 Oedema Measurements (EDM) Comparison

Table 4.40: Mean trends over treatment periods for the variable EDM

	Initial Consult	Consultation 2	Consultation 3	Final Consult
FAKTR Treatment Group	55.44	55.11	54.83	54.78
Sham Laser Group	54.08	54.08	54.13	54.13
Mann Whitney p-value	0.862	0.738	0.620	0.602

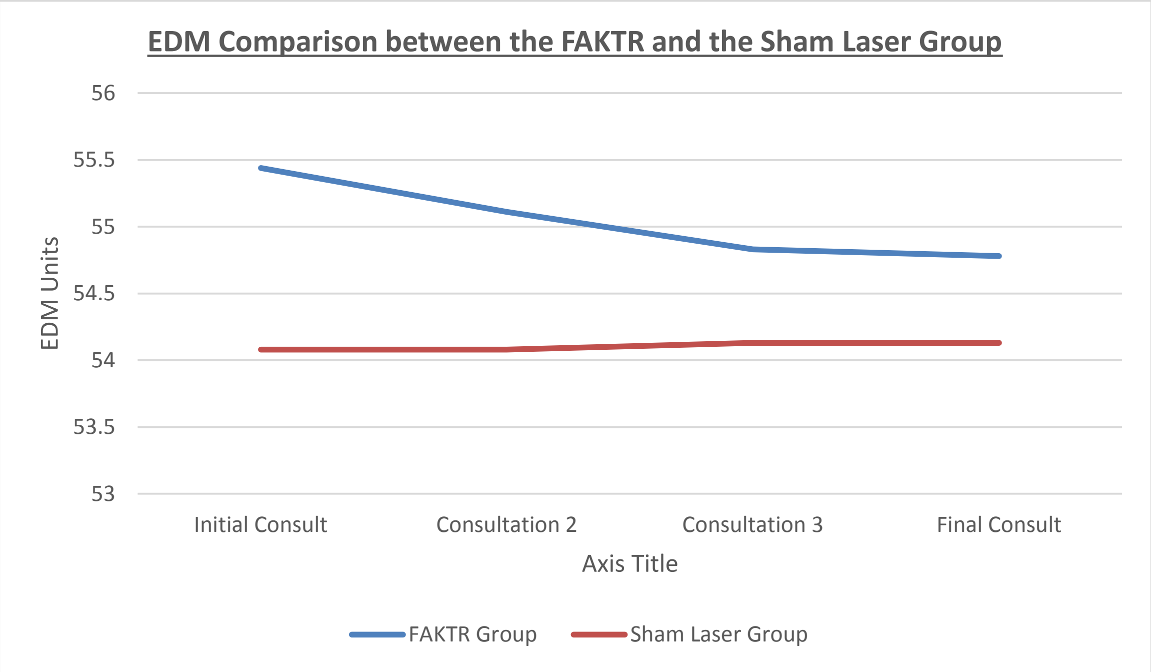

Figure 4.4: Mean trends over treatment periods for the variable EDM

4.4.4.1 Analysis of Results EDM

As can be seen from Table 4.40 and Figure 4.4, the values for all consultations are higher for the FAKTR© Concept treatment group than those for the sham laser group, but it can be shown from the pattern of the graph that the treatment group was getting better as compared to the control group with almost constant values. However, the differences were not statistically significant between all the consultations.

4.4.4.2 Discussion of Results EDM

The amount of ankle swelling/oedema was significantly improved in the FAKTR© Concept treatment group, whereas in the sham laser (control) group there was a slight worsening of the oedema, measured using the figure-of-eight maneuver.

Cryotherapy is used mainly to minimise pain and inflammation during the acute phase of the injury (Bleakley, 2008. FAKTR© Concept treatment is very effective in oedema reduction as it utilises the mocking stroking technique designed to push oedema up (Doerr, 2010). Instrument assisted soft tissue mobilisation has been postulated to reduce tissue viscosity, thereby improving blood flow and lymphatic circulation (Markovic, 2015). All this works in favour of reducing oedema around the ankle joint.

However, there was no initial or expected oedema improvement in the sham laser group. The worsening of oedema in the sham laser group may be attributed to the cold induced damage of lymphatic vessels which can result in the leakage of the lymphatic fluid that will accumulate around the ankle joint and may aggravate the swelling (Meeusen and Lievens, 1986).

Both groups received cryotherapy. The FAKTR treatment outperformed the sham laser with a mean improvement of 0.66 cm (decrease in swelling) as compared to the sham laser that had a slight worsening of 0.05 cm (increase in swelling). This means that the FAKTR© Concept treatment was more effective than sham laser in the treatment of acute and or subacute grade I or II inversion ankle sprains in terms of objective oedema measurements.

4.4.5 Stork Balance Stand Test (STR) Comparison

Table 4.41: Mean trends over treatment periods for the variable STR

	Initial Consult	Consultation 2	Consultation 3	Final Consult
FAKTR Treatment Group	2.50	3.15	3.95	4.75
Sham Laser Group	7.20	7.00	6.90	6.60
Mann Whitney p-value	0.862	0.369	0.004	0.001

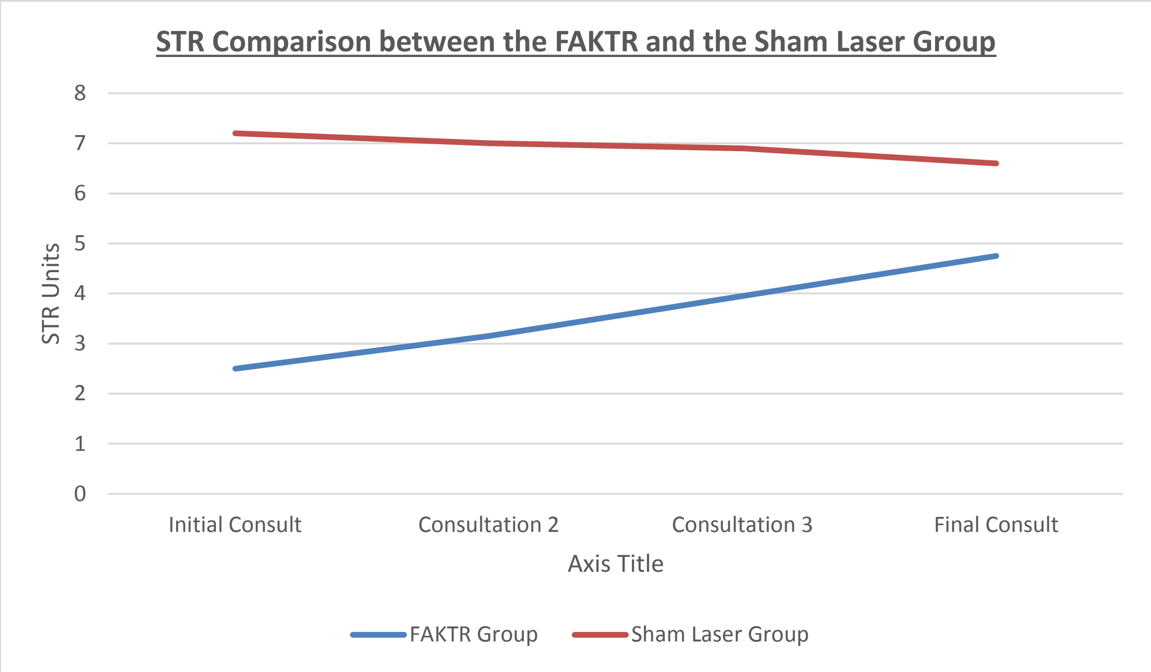

Figure 4.5: Mean trends over treatment periods for the variable STR

4.4.5.1 Analysis of Results STR

The baseline STR mean scores were completely different with a mean of 2.50 seconds for the FAKTR treatment group and 7.20 seconds for the sham laser group. However, there was improvement observed in the FAKTR© Concept treatment group. From Figure 4.5 it is evident that sham laser group showed no improvement, and that the participants' balance/proprioception was reduced. The STR measurements were only statistically significant between the last two consultations (Table 4.41). The values for all measurement periods were higher for the control group than the FAKTR© treatment group.

4.4.5.2 Discussion of Results STR

The differences between the mean STR scores between the two study groups were statistically significant over the duration of the study.

The FAKTR© Concept treatment group outperformed the sham laser (control) group in the terms of improvement in balance. The FAKTR© Concept addresses proprioception during treatment when the participant is placed on a wobble board or a stability pad to provoke pain while treatment is being applied. As the FAKTR© Concept instrument is applied over the skin surface it stimulates or re-educates a dense network of sensory and proprioceptive nerve endings (Gulick, 2014) on the epiligament (Bray, 1995). This in turn improves balance and proprioceptive function of the ankle joint.

Cryotherapy has not been found to be effective on balance and proprioception (Costello and Donnelly; 2010). Some studies have shown that cryotherapy reduces proprioception (Surenkok et al., 2008), and some studies have shown that cryotherapy has no effect on proprioception (Wassinger et al., 2007; Dover and Powers, 2004).

Both groups received cryotherapy but the FAKTR© Concept treatment outperformed the sham laser. This means that the FAKTR© treatment was more effective in the treatment of sub-acute and acute ankle sprains during the study period than the sham laser treatment.

4.4.6 Foot Function Index (FFI) Comparison

Table 4.42: Mean trends over treatment periods for the variable FFI

	Initial Consult	Consultation 2	Consultation 3	Final Consult
FAKTR© Treatment Group	49.40	31.70	18.05	7.95
Sham Laser Group	48.84	39.58	36.95	31.95
Mann Whitney p-value	0.945	0.054	0.000	0.000

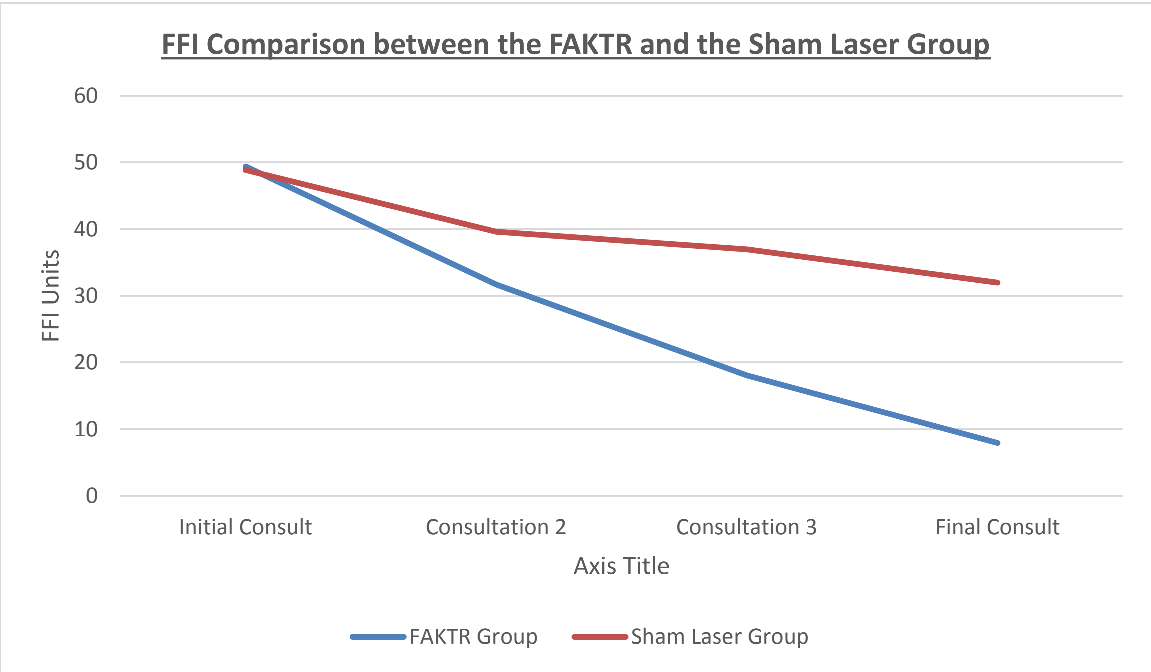

Figure 4.6: Mean trends over treatment periods for the variable FFI

4.4.6.1 Analysis of Results FFI

Both groups had similar baseline FFI scores with differences appearing between the remaining consultations (Table 4.42 and Figure 4.6). When compared together, the FAKTR© Concept treatment group had a more statistically and clinically significant difference as compared to the sham laser treatment group. However, the difference between the two groups was only significant between the last two consultations with the p-value < 0.05.

4.4.6.2 Discussion of Results FFI

The glide of fascia and soft tissue during the FAKTR© Concept treatment improves functional movements (Myer, 2001). The functional improvement is also due to the breakdown of scar tissue and the repair and regeneration of damaged collagen (Gulick, 2014). According to Perle (2003), Hammer (2003b) and Hammer and Pfefer (2005), IASTM treatments induce controlled microtrauma, hyperemia, and inflammation; reduce tissue viscosity through accumulation of friction related heat (Markovic, 2015); and increase fibroblast recruitment and activation, which stimulates the body's reparative system. These multiple effects of the FAKTR© Concept treatment improve function, therefore can be expected to improve FFI.

Cryotherapy alone is less effective in improving function. Cryotherapy is sometimes combined with exercise (cryokinetic) or stretch (cryostretch) when addressing function (Knight, 1989). This could be the reason why it was outperformed by an active functional treatment (FAKTR© Concept) in this study.

4.4.7 Conclusion for Objective Three

For Objective Three, it was found that the addition of a myofascial treatment protocol (FAKTR© Concept) combined with cryotherapy was more effective in the treatment of acute and/or sub-acute grade I or II inversion ankle sprains in terms of subjective (NPRS and FFI) and objective (DIR, AR, EDM and STR) measurements, than cryotherapy alone.

CHAPTER 5 : CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusion

Both groups (control group and the FAKTR© treatment group) showed clinical improvements during the study period in terms of the subjective measurements although there was greater improvement in the FAKTR© Concept treatment group as compared to the control group. The FAKTR© treatment group showed statistically significant improvements during the study period. Intra-group analysis of the NPRS and FFI values showed a statistically significant improvement in the FAKTR© treatment group. Intra-group analysis of NPRS and FFI values in the control group were not statistically significant. However, inter-group analysis of both the NPRS and FFI showed statistically significant differences. Therefore, the myofascial treatment protocol combined with cryotherapy was more effective than sham laser combined with cryotherapy in terms of the study subjective measurements (NPRS and FFI values).

There was no improvement whatsoever in the control group with regards to ankle stability and swelling. However, the FAKTR© treatment group demonstrated statistically significant improvements in terms of the objective measurements of the study (EDM, DIR, AR and STR). Inter-group analysis of the DIR and EDM showed no statistically significant difference between all the treatment periods. The AR and STR measurements showed statistically significant differences between the two groups only on the last two consultations. In conclusion, the FAKTR© protocol combined with cryotherapy was more effective than sham laser combined with cryotherapy in the treatment of sub-acute and acute ankle inversion sprains.

In terms of the hypothesis of the study, the Null hypothesis which stated that there will be no significant difference between the two groups was dismissed. The Alternative Hypothesis which stated that there will be a significant difference between the two groups was accepted.

Therefore, the incorporation of the FAKTR treatment protocol in the management of patients with ankle sprains is suggested by this study to be of beneficial effects as it gives a complete package of treatment in addressing all symptoms of an ankle sprain.

5.2 Recommendations

- It is difficult to generalise the results of this study as the sample size was small. Forty participants were recruited, 20 in each group. A larger sample size would have strengthened the results of this study.
- A future study could include another group with no treatment to rule out the natural history of acute ankle sprains.
- It would have been better if post-treatment data was also gathered to assess the immediate effects of the treatment protocol.
- Future studies could look at long term effects of the treatment protocols, say at a three-month follow-up.
- The FFI questionnaire should be translated to local languages, for example IsiZulu, to cater for those who do not understand the English language.

5.3 Limitations

- A mistake that was made on the stepwise written instruction, instructing participants to apply ice for 20 minutes at a time where as in the methodology section and in the literature review its advised that ice application should not be more than 10 minutes. This discrepancy could have skewed the results especially the increased oedema noted in the group B participants.
- The participants also could have used other forms of home treatment while others are not for example compression bandages, elevation, rest even though they have been instructed not to use any form of medication to relieve the pain. This also could influence the results.

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Appendices

APPENDIX A: LETTER OF INFORMATION

APPENDIX A

LETTER OF INFORMATION

Dear Participant: Welcome to my research project. Thank you for taking the time to consider participating in my study.

I am a Chiropractic student completing my Master's Degree at the Durban University of Technology.

Title of the Research Study: The effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in the treatment of acute ankle sprains

Principal Investigator/s/researcher: Morris Kahere, B. Tech: Chiropractic

Co-Investigator/s/supervisor: Dr G. Matkovich, M. Tech: Chiropractic

Brief Introduction and Purpose of the Study:

Ankle injuries are one of the most commonly occurring sports complaints, with ankle sprain being the most common injury. An ankle sprain is an injury that occurs when you roll, twist or turn your ankle in an awkward way. This can stretch or tear the tough band of tissue (ligaments) that help to hold your ankle bones together. Ligaments help to stabilise joints, preventing excessive movement. A sprained ankle occurs when ligaments are forced beyond their normal range of motion. Most ankle sprains involve injuries to the outer side of the ankle.

People use various methods to manage ankle sprains with ice and functional treatment being the most recommended ones. Poorly managed ankle sprains increase the chances of recurrence. Recurrent ankle sprains are very common and the greatest predisposition of a recurrent ankle sprain is the history of at least one ankle sprain, which ultimately results in chronic ankle instability (CAI). Chronic ankle instability is characterised by recurring giving way of the outside (lateral) of the ankle. Repetitive sprains are also linked to increased risk of wear and tear at the ankle. The purpose of this study is to determine the effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in the treatment of acute ankle sprain.

Outline of procedure:

You will be required to have a case history, physical examination and ankle and foot regional examination done at the DUT Chiropractic Day Clinic. The examination will confirm your eligibility to participate in the study. Once accepted you will be required to sign the letter of informed consent. You will be expected to attend another three visits within two weeks. The study consists of two treatment groups (an active and a control treatment group), one group receiving a myofascial treatment protocol combined with cryotherapy and the other group receiving cryotherapy and detuned laser. Therefore there will be a fifty percent chance that you will fall into either of the groups. The schedule of attendance shall be as outlined below:

Consultation 1 (day 1)

- assessed for eligibility
- randomisation
- subjective and objective measurements
- treatment

Day 2-3 -: 3 times home self-ice pack application per day for 10 minutes

Consultation 2 (day 4-6)

- measurements
- treatment

Consultation 3 (day 7-10)

- measurement s
- treatment

Consultation 4 (day 11-15)

- measurements

Risks or Discomforts to the Participant: You may feel transient discomfort during the treatment sessions as you will be treated in a position of provocation. This however will be transient.

Benefits: You may directly benefit as you could have an improvement in your symptoms, according to the study hypothesis. The results of this study will be published in the form of a dissertation and kept at the DUT Library.

Reason/s why the Participant May Be Withdrawn from the Study: You may withdraw from the study at any time should you wish to do so. Reasons for withdrawal from this study may include sickness, injury or any other unforeseen circumstances. Should you not attend the follow-up session you will be withdrawn from the study. Should you choose not to attend there will be no adverse consequences to you.

Remuneration: There will be no remuneration for participating in the study.

Costs of the Study: The participant will not need to cover any costs incurred in the conduction of the study.

Confidentiality: All personal information will be kept confidential by use of a coding system for the analysis and reporting of information. Information will be stored in the DUT Chiropractic Day Clinic for 5 years, after which it will be shredded.

Research-related Injury: The research will be non-invasive and there is no risk of injury to participants. The DUT Chiropractic Day Clinic protocol will be followed and injury would also need to be reported to the Institutional Research Ethics Committee. So please make sure you will let me know of such problems.

Persons to Contact in the Event of Any Problems or Queries:
Please contact: Dr. N de Busser: 031-373 2094 (Research supervisor) Morris Kahere: 083 615 3446 (Researcher) Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F.Otieno on 031 373 2382 or dvctip@dut.ac.za.
Your participation is highly appreciated and essential to the growth of research in chiropractic and sport.

APPENDIX B: CONSENT

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, ____________ (name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: ___________,
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

____________________ __________ ______ _______________________

Full Name of Participant **Date** **Time** **Signature/Right Thumbprint**

I, ______________ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_________________ __________ ___________________

Full Name of Researcher **Date** **Signature**

_________________ __________ ___________________

Full Name of Witness (If applicable) **Date** **Signature**

_________________ __________ ___________________

Full Name of Legal Guardian (If applicable) Date **Signature**

APPENDIX C: CHIROPRACTIC DAY CLINIC CASE HISTORY

DUT DURBAN UNIVERSITY OF TECHNOLOGY | DEPARTMENT OF CHIROPRACTIC AND SOMATOLOGY

CHIROPRACTIC PROGRAMME

CHIROPRACTIC DAY CLINIC CASE HISTORY

Patient:____ Date: ____________

File #: ____________________ Age: ____________

Sex: ____________ ________________________________

________________________________ Signature ________________________
Occupation:

Student:

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature:

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

CASE STATUS:

PTT: Signature: Date:
CONDITIONAL: Reason for Conditional:
Signature: Date:
Conditions met in Visit No: Signed into PTT: Date:
Case Summary signed off: Date:

Student's Case History:

1. **Source of History:**

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

3. **Present Illness:**

	Complaint 1(principle complaint)	Complaint 2 (additional or secondary complaint)

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

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

Allergies

Immunizations

Screening Tests incl. x-rays

Environmental Hazards (Home, School, Work)

Exercise and Leisure

Sleep Patterns

Diet

Current Medication

Analgesics/week:

Other (please list):

Tobacco Alcohol Social Drugs

7. Immediate Family Medical History:

Age of all family members Health of all family members Cause of Death of any family members

	Noted	Family member		Noted	Family member
Alcoholism			Headaches		
Anaemia			Heart Disease		
Arthritis			Kidney Disease		
CA			Mental Illness		
DM			Stroke		
Drug Addiction			Thyroid Disease		
Epilepsy			TB		
Other (list)					

8. Psychosocial history:

Home Situation and daily life Important experiences Religious Beliefs

9. Review of Systems (please highlight with an asterisk those areas that are a problem for the patient and require further investigation)

General

Skin

Head

Eyes

Ears

Nose/Sinuses

Mouth/Throat

Neck

Breasts

Respiratory

Cardiac

Gastro-intestinal

Urinary

Genital

Vascular

Musculoskeletal

Neurologic

Haematological

Endocrine

Psychiatric

APPENDIX D: PHYSICAL EXAMINATION

CHIROPRACTIC PROGRAMME

Chiropractic DAY CLINIC

PHYSICAL EXAMINATION

Patient:____File#:__________ Date:_____

Clinician:____________________________Signature: __________________________

Student:____________________________Signature: __________________________

VITALS

Pulse rate:

Respiratory rate:

Blood pressure: R L Medication if hypertensive:

Temperature:

Height:

Weight: Any change Y/N If Yes: how much gain/loss

Over what period

GENERAL EXAMINATION

General Impression:

Skin:

Jaundice:

Pallor:

Clubbing:

Cyanosis (Central/Peripheral):

Oedema:

Lymph nodes - Head and neck:

- Axillary:
- Epitrochlear:
- Inguinal:

Urinalysis:

CARDIOVASCULAR EXAMINATION

1) Is this patient in **Cardiac Failure**?
2) Does this patient have signs of **Infective Endocarditic**?
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).

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 bilateral:

- Adventitious sounds (crackles, wheezes, crepitations)
- Pleural frictional rub:
- Vocal resonance - Whispering pectoriloquy:
- Bronchophony:
- Egophony:

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:

G.U.T EXAMINATION

External genitalia**:**

Hernias:

Masses:

Discharges:

NEUROLOGICAL EXAMINATION

Gait and Posture - Abnormalities in gait:

- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Romberg’s 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:

- Kernig's 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:

Rinne's = L: R:

Weber's lateralisation:

Vestibular function - Nystagmus:

- Romberg's:

- Wallenberg's:

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:

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 E: PHYSICAL EXAMINAITON SENIOR

DUT DURBAN UNIVERSITY OF TECHNOLOGY

DEPARTMENT OF CHIROPRACTIC AND SOMATOLOGY

CHIROPRACTIC PROGRAMME

PHYSICAL EXAMINATION:

SENIOR

Patient Name: File no: Date:

Student: Signature:

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

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

SYSTEM SPECIFIC EXAMINATION:
CARDIOVASCULAR EXAMINATION
RESPIRATORY EXAMINATION
ABDOMINAL EXAMINATION
NEUROLOGICAL EXAMINATION
COMMENTS
Clinician: Signature:

APPENDIX F: FOOT AND ANKLE REGIONAL EXAMINATION

CHIROPRACTIC PROGRAMME

FOOT AND ANKLE

REGIONAL EXAMINATION

Patient: _______ _________File no: _Date:________________________

Student: _______ _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

Weight bearing: **R** **L** ***Non weight bearing:*** **R** **L**

Plantar flexion			50°		
Dorsiflexion			20°		
Supination					
Pronation					
Toe dorsiflexion			40° (mtp)		
Toe dorsiflexion			40° (mtp)		
		Big toe plantar flexion (mtp) 45°			
		Big toe plantar flexion (mtp) 45°			
		Toe abduction + adduction			
		5° first ray dorsiflexion			
		5° first ray plantar flexion			

Passive movement motion palpation (Passive ROM quality, ROM overpressure, joint play)	**R**	**L**		**R**	**L**
Ankle joint: *Plantarflexion*			Subtalar joint: *Varus*		
Dorsiflexion			*Valgus*		
Talocrural: *Long axis distraction*			Midtarsal:*A-P glide*		
First ray: *Dorsiflexion*			*P-A glide*		
Plantarflexion			*rotation*		
Circumduction of forefoot on fixed rearfoot			Intermetatarsal glide		
			Tarso metatarsal joints: *A-P*		
Interphalangeal joints: *L-A dist*			Metatarsophalangeal dorsiflexion (with associated plantar flexion of each toe)		
A-P glide					
lat and med glide					
rotation					

Resisted Isometric	**R**	**L**		**R**	**L**

Movements

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

Neurological

	R	L
Dermatomes		
Myotomes		
Reflexes		
Balance/proprioception		

Special tests

	R	L
Anterior drawer test		
Talar tilt		
Thompson test		
Homan sign		
Tinel's sign		
Test for rigid/flexible flatfoot		
Kleiger test (med. deltoid)		

Alignment

	R	L
Heel to ground		
Feiss line		
Tibial torsion		
Heel to leg (subtalar neutral)		
Subtalar neutral position:		
Forefoot to heel (subtalar & Midtarsal neutral)		
First ray alignment		
Digital deformities		
Digital deformity flexible		

Palpation

	R	L
Anteriorly		
Medial malleoli		

Med tarsal bones, tibial (post) artery		
Lat. malleolus, 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 G: FOOT FUNCTION INDEX

Foot Function Index

Section 1: To be completed by patient Name:__________________________ Age:____ Date:________ Occupation: _________________________ Number of days of foot pain:_____________

Section 2: To be completed by patient

This questionnaire has been designed to give your therapist information as to how your foot pain has affected your ability to manage in everyday life.

For the following questions, we would like you to score each question on a scale from 0 (no pain) to 10 (worst pain imaginable) that best describes your foot **over the past WEEK**.

Please read each question and place a number from 0-10 in the corresponding box. **No Pain** 0 1 2 3 4 5 6 7 8 9 10 **Worst Pain Imaginable**

1. In the morning upon taking your first step?
2. When walking?
3. When standing?
4. How is your pain at the end of the day?
5. How severe is your pain at its worst?

Answer all of the following questions related to your pain and activities **over the past WEEK**, how much difficulty did you have? ***Disability Scale*** ***No Difficulty*** 0 1 2 3 4 5 6 7 8 9 10 ***So Difficult unable to do***

6. When walking in the house?
7. When walking outside?
8. When walking four blocks?
9. When climbing stairs?
10. When descending stairs?
11. When standing tip toe?
12. When getting up from a chair?
13. When climbing curbs?

14. When running or fast walking?

Answer all the following questions related to your pain and activities **over the past WEEK**. How much of thetime did you: ***Disability Scale:***   ***None of the time*** 0 1 2 3 4 5 6 7 8 9 10 ***All of the time***

15. Use an assistive device (cane, walker, crutches,etc) indoors?
16. Use an assistive device (cane, walker, crutches,etc) outdoors?
17. Limit physical activities?

Section 3: To be completed by physical therapist/provider SCORE:______/170 x100= _____%   **(SEM 5, MDC 7)**   **SCORE**: **Initial_____ Subsequent_____ Subsequent_____ Discharge_____**

APPENDIX H: WEST POINT ANKLE SPRAIN GRADING SYSTEM

West Point Ankle Sprain Grading System

Criterion	Grade 1	Grade 2	Grade 3
Location of tenderness	ATFL	ATFL, CFL	ATFL, CFL, PTFL
Oedema, Ecchymosis	Slight	Moderate	diffuse
Weight bearing ability	Full or partial	Diffuse without crutches	Impossible without Significant pain
Ligament damage	Stretched	Partial tear	Complete tear
Instability	None	None or slight	Definite

APPENDIX I: LETTER OF AUTHORISATION FROM THE FAKTR© CO-FOUNDER

To whom it may concern:

Durban University of Technology
Faculty of Health Science
Institutional Research Ethics Committee (IREC)
P.O. BOX 1334, Durban 4000
Tel: 031 373 2102
Fax: 031 202 3632

From: Thomas E. Hyde, DC - Co-founder Functional and Kinetic Treatment with Rehab (FAKTR)

Date: March 11, 2014

RE: Morris Kahere/FAKTR

I, Thomas E. Hyde (co-founder FAKTR) hereby grant Morris Kahere the permission to pursue a study, or studies utilizing the Concepts of FAKTR (myofascial treatment protocol). I feel honoured that Morris has chosen our Concept for his research project. I carry malpractice insurance through NCMIC here in the US. Since its inception there have never been any claims filed against FAKTR. The FAKTR tools are made of 316-L surgical grade stainless steel with zero cutting edges. The edges are prepared at such an angle as not to disrupt the skin in any way. Should you have any additional questions, please do not hesitate to contact me. I am excited to see his results and to be of assistance as needed. I would also like to offer my greatest thanks to DUT for this opportunity.

Respectfully,

Thomas E. Hyde, DC, DACBSP, CSTI, FRCCSS (Hon), ICSSD, ART®, GT®, FAKTR™
Asheville,NC28803
828-505-3452
828-505-2997fax
tomhyde444@gmail.com
www.tomhydedc.com

TOM HYDE,DC

APPENDIX J: MEMORANDUM – PERMISSION TO USE THE CLINIC

MEMORANDUM

To : Prof Puckree
Chair: RHDC

Prof Adam
Chair: IREC

From : Dr Charmaine Korporaal
Clinic Director: Chiropractic Day Clinic: Chiropractic and Somatology

Date : 09.03.2014

Re : Request for permission to use the Chiropractic Day Clinic for research purposes

---

Permission is hereby granted to:

Mr Morris Kahere (Student Number: 21143420)

Research title: The effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in the treatment of acute ankle sprains.

It is noted that Mr. Kahere is currently a B.Tech: Chiropractic student, therefore he would require registration as an M.Tech: Chiropractic student to access and therefore conduct his research. Therefore it is requested that Mr. Kahere submit a copy of his RHDC / IREC approved proposal along with proof of his M.Tech: Chiropractic registration to the Clinic Administrators before he starts with his research in order that any special procedures with regards to his research can be implemented prior to the commencement of him seeing patients.

Thank you for your time.

Kind regards

[redacted]

Dr Charmaine Korporaal
Clinic Director: Chiropractic Day Clinic: Chiropractic and Somatology
Cc: Mrs. Pat van den Berg: Chiropractic Day Clinic
Dr L O'Connor: Research co-ordinator
Dr N de Busser: Research supervisor

APPENDIX K: MEMORANDUM OF UNDERSTANDING

Durban University of Technology

Memorandum of understanding between:

The RESEARCH INSTITUTION'-Durban University of Technology (this includes the respective research student and research supervisor, Department of Chiropractic). The Faculty of Health Sciences Research Committee, The Institutional Research Committee and any other related DUT employees.

AND

The 'Cofounder'-Myofascial treatment protocol(including all members, employees, associates)

This Memorandum of Understanding pertains to the following research project and must be read in conjunction with:

APPENDIX A-Detailed Research Proposal (PG4a)

APPENDIX B-Durban University of Technology Research Committee Research Ethics Policy and Guidelines

Title of the study:

The effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in the treatment of acute ankle sprains.

Research Student: Morris Kahere-Student No: 21143420

Research Supervisor: Dr N. de Busser (Dept. Chiropractic and Somatology-Durban University of Technology)

This study is a Master's Mini Dissertation conducted in partial compliance with the Master's Degree in Technology in the Department of Chiropractic-Faculty of Health Sciences-Durban University of Technology. This study will obtain ethical approval from the Faculty of Health Sciences Research & Ethics Committee (FRC) of Durban University of Technology.

Section 1-Funding of the study and financial commitment

1.1 A research allowance of R5000.00 has been awarded by the Dept. Post-graduate Development & Support –The details of the funds approved are described in Section A of the Research Proposal (PG4a) attached.

1.2 The ‘COFOUNDER’-will donate (free of charge) the respective experimental tools in quantities sufficient to meet the requirements described in the research proposal PG4a attached.

1.3 The ‘COFOUNDER’-acknowledges that THE RESEARCH INSTITUTION’ will have no financial obligations or commitments to the ‘COFOUNDER’ what so ever as a result of conducting this study.

1.4 The ’COFOUNDER’-(with the exception of Section 1.2) may not award or incentivize the study or its related parties in any manner what so ever, nor remunerate, award or offer any financial or other donation or gift to any of those involved with the study.

<u>Section 2-Academic processes and outcome</u>

2.1 The FRC has approved the above mentioned Research Supervisor who in conjunction with the Research Student are the sole contributors to the academic content, procedures, results and findings of the study based on the prescribed data analysis in the research proposal, barring amendments required by the approved research examiners appointed by the RESEARCH INSTITUTION.

2.2 The ‘COFOUNDER’ acknowledges that the findings upon completion of the study (as determined by the Research Student and Research Supervisors and according to the protocol stated in the attached research proposal) will be final and non-negotiable.
The ‘COFOUNDER’-acknowledges further that it has no authority over the outcome of this study and may not influence the findings or the reporting thereof in any matter.

2.3 Any modification or deviation from the approved research proposal, must be applied for in writing, endorsed by both the Research Student & Supervisors and Head of Department before serving before the FRC/IREC, the final say therein will be determined by the FRC/IREC.

2.4 The ‘COFOUNDER’-acknowledges that it may not influence or make any change to the approved research protocol/proposal.

<u>Section 3-Publication of findings</u>

3.1 The findings and outcome of the above mentioned study remain the intellectual property of the ‘RESEARCH INSTITITION’ indefinitely. The study will be published in the format of a hard bound dissertation which will be placed in the DUT library.

3.2 Publication of the findings of this study in a journal or other scholarly medium will be a discretion of the Research student and /or Research Supervisors who will determine the appropriate medium and place of publication as well as content of the publication. Authorship of any scholarly output originating from this study of the Research Student and Research Supervisors and other collaborators appointed by the Research Student and/or the Research Supervisors. Such scholarly publication must include the names of the Researcher and the Research Supervisor as well as the ‘RESEACH INSTITUTION’.

3.3 Any reference what so ever to the findings of this study if quoted or mentioned in any format must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the ‘RESEARCH INSTITITION’.

3.4 Any reference what so ever to any secondary publication arising from this original study must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the ‘RESEARCH INSTITUTION’

3.5 The ‘COFOUNDER’-may make reference to the outcome of this study in the prescribed manner mentioned in section 3.3 and 3.4 undertaking 3.1 and 3.2.

Section 4-Indemnity

4.1 The Research Student, the Research Supervisor and the research facilities and its staff are duly covered by the ‘RESEARCH INSTITUTION’ insurance policy pertaining to public liability, injury or harm which may occur as a result of conducting this study.

4.2 The ’COFOUNDER’-undertakes to indemnify the ‘RESEARCH INSTITUTION’ with regard to any outcome, incidents, injury or harm which occurs as a result of the conduction of this study including the results of the study and publication thereof. The possible side-effects include but are not limited to: treatment may be mildly uncomfortable, cause petecchae, bruising or transient minimal pain and discomfort.

Section 5

5.1 Ethical clearance of the proposed study will be granted by the DUT IREC (such ethical clearance become invalid should there be any deviation from the approved research methodology described in the research proposal attached).

5.2 The ‘COFOUNDER’ undertakes to abide by the DUT Research Committee Research Ethics Policy and Guidelines (APPENDIX B).

5.3 In addition to 5.2 the ‘COFOUNDER’ should note and refer to**Section 1.4,2 & 3** of this document.

I ____Thomas E. Hyde________________________ (**name of representative of the 'COFOUNDER')** hereby in my official capacity as representative of FAKTR© hereby agree to abide by the regulations stated in this memorandum of understanding between the 'COFOUNDER' and the 'RESEARCH INSTITUTI[redacted]

____ __31 March 2015________________

Signature of official representative of the 'COFOUNDER' Date

I **Mr. Morris Kahere** hereby in my capacity as **the research student** hereby agree to abide by the regulations in this memorandum of understanding between the 'COFOUNDER' and the 'RESEARCH INSTITUTION'

____ __________________

Signature of research Student Date

APPENDIX L: STEPWISE WRITTEN INSTRUCTION OF THE CORRECT STORAGE AND APPLICATION OF ICE

<u>Stepwise written instruction of the correct storage and application of ice</u>

1. Keep ice pack in the freezer
2. Apply ice pack to the ankle with sleeve on the ice pack for 20 minutes
3. Remove sleeve from ice pack and return ice pack to freezer

APPENDIX M: ADVERT

Have you recently injured, rolled, twisted or turned on your ankle in an awkward way?

Are you between the ages of **18-40** years?

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

Should you qualify for the study, you will receive **FREE TREAMENT**
This will include an assessment and treatment

For more information, please contact

Morris Kahere

(031)373 2205 or (031)373 2512 or 083 615 3446

APPENDIX N: EMAIL COMMUNICATION WITH THE STATISTICIAN

Email communication with the statistician

7/31/14

Morris Kahere <mrrskhr@gmail.com>

to Tonya

Hi Tonya :)

I hope this finds you well! This is Morris again, now I do not know what to write on data analysis, how the data is going to be analysed for my research? May you please assist me in this regard.

My utmost respect

Tonya Esterhuizen <tonya.esterhuizen7@gmail.com> 7/31/14

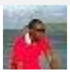
to me

Dear Morris

Please send me the latest draft of your research proposal.

Thanks

Tonya



Morris Kahere <mrrskhr@gmail.com>

7/31/14

to Tonya

Hi Tonya

Kindly receive the attached pg4a&b document below.

Many thanks, hey!

Attachments area

Preview attachment MORRIS KAHERE-pg4ab.docx

MORRIS KAHERE-pg4ab.docx

Tonya Esterhuizen **<tonya.esterhuizen7@gmail.com>**

8/4/14

to me

HI Morris

I have added the stats section to the relevant part in the protocol, see attached.

Regards

Tonya

Attachments area

Preview attachment MORRIS KAHERE-pg4abTE.docx

MORRIS KAHERE-pg4abTE.docx

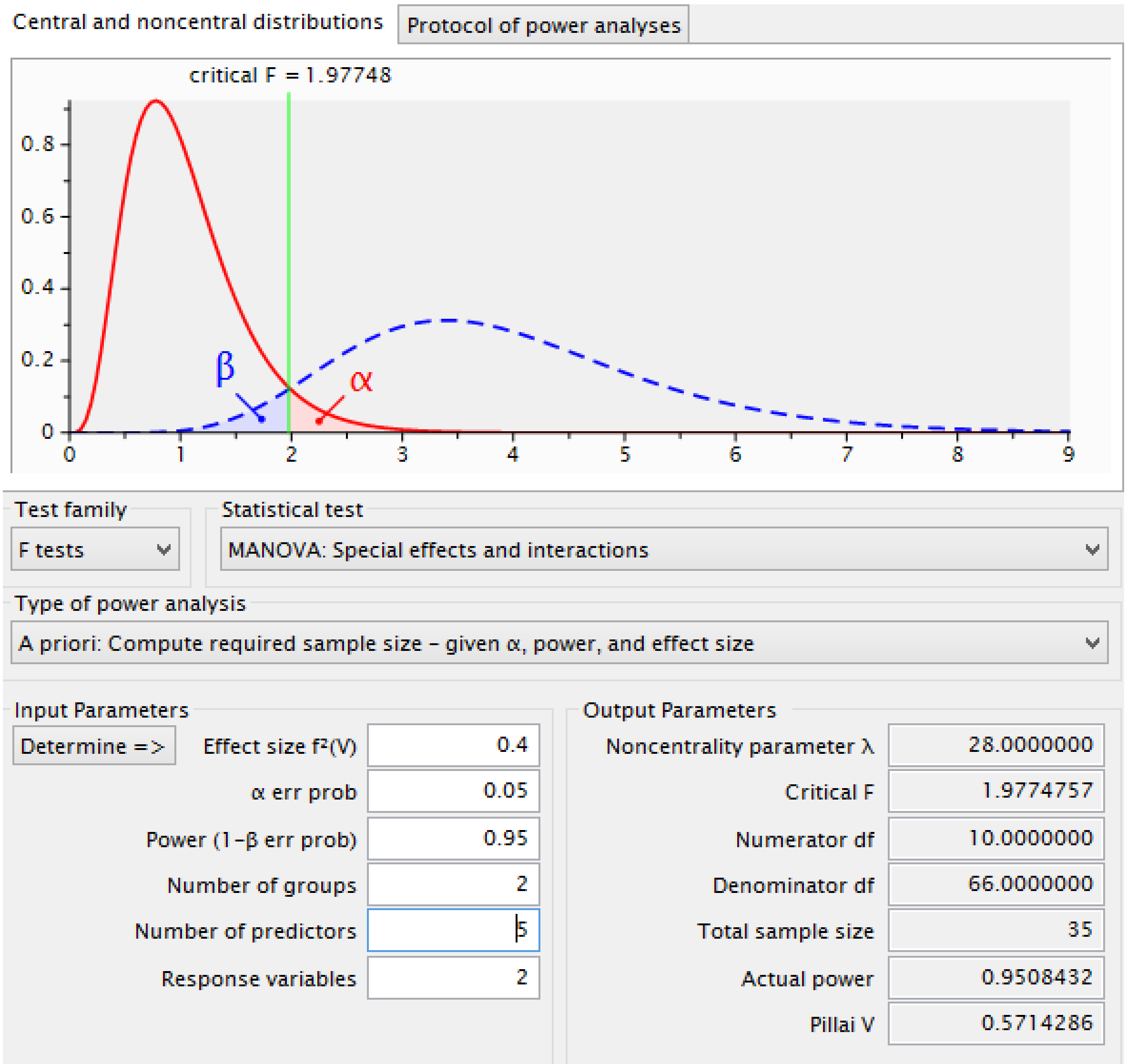
APPENDIX O: EMAIL FROM DEEPAK SINGH

Deepak Singh <singhd@dut.ac.za> Feb 11

to me

Hi Morris

Please see the Power calculation below.



For an above average effect size, the total sample size for 2 groups is 35. (This can be broken up into 2 groups. I would aim for slightly more. Say 40) However, this is limited to a small number of predictors and response variables.

As there are numerous fixed factors inn your study, this will do.

Best wishes

Deepak Singh

Appendix P

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site
Gate 8, Ritson Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2900
Fax: 031 373 2407
Email: lavishad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

19 August 2015

IREC Reference Number: **REC 53/15**

Mr M Kahare
Corner 4th Street and Central Avenue
Office of the President and the Cabinet
10th Floor Compensation Building
Causeway
Harare

Dear Mr Kahare

The effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in the treatment of acute ankle sprain

I am pleased to inform you that Full Approval has been granted to your proposal REC 53/15.

The Proposal has been allocated the following Ethical Clearance number **IREC 080/15**. Please use this number in all communication with this office.

Approval has been granted for a period of two years, before the expiry of which you are required to apply for safety monitoring and annual recertification. Please use the Safety Monitoring and Annual Recertification Report form which can be found in the Standard Operating Procedures [SOP's] of the IREC. This form must be submitted to the IREC at least 3 months before the ethics approval for the study expires.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's.

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Kindly submit the letter from the NHREC providing evidence of registration as a clinical trial to the IREC office.

Yours Sincerely

[redacted]

Professor J K Adam
Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY

2015 -08- 19

INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

Appendix Q

Institutional Research Ethics Committee
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Room MS 49, Mansfield School Site
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Tel: 031 373 2900
Fax: 031 373 2407
Email: lavishad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

9 May 2016

Mr M Kahare
Corner 4th Street and Central Avenue
Office of the President and the Cabinet
10th Floor Compensation Building
Causeway
Harare

Dear Mr Kahare

Application for Amendment of Approved Research Proposal

The effectiveness of a myofascial treatment protocol combined with cryotherapy compared to cryotherapy alone in treatment of acute and subacute ankle sprain

I am pleased to inform you that your application to include an emollient oil during treatment has been Approved.

Yours Sincerely

Professor J K Adam
Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY

2016 -05- 09

INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA