

The relative effectiveness of Piroxicam versus  
Protease administration in the treatment of Acute  
Grade 1 and 2 Ankle Inversion Sprains.

by  
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A dissertation submitted to the Faculty of Health in partial compliance with the  
requirements for a Master's Degree in Technology: Chiropractic at Technikon Natal.

I, Simon Gray Bellingham do hereby declare that this dissertation represents my own  
work in both conception and execution.

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## DEDICATION

I dedicate this work to two families:

The Bellingham family who supported me unconditionally throughout my life and  
studies.

The Goldberg family (Ann, Jenifer and Flora) for adopting me. I do not believe  
that I would have endured living in a city for seven years without the help of  
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## ABSTRACT

The purpose of this study was to evaluate Piroxicam versus Protease administration, in terms of subjective and objective clinical findings, in order to determine the effectiveness of each approach in the treatment of grade 1 and 2 acute ankle inversion sprains.

The study was a prospective, randomized, double blinded, controlled study. The study involved 30 subjects, 15 in each group which were selected from the general population. One group received Protease and strapping while the other group two received Piroxicam and strapping. Patients received 3 treatments over a period of one week.

Patients in the Protease group received 1200mg (3 x 400mg) of Protease daily before meals for seven days. Patients in the Piroxicam group received 40mg (2 x 20mg) of Piroxicam for the first two days, and then 20mg (1 x 20mg) for the following five days, administered with meals.

All patients were taught how to apply an elastic crepe bandage to the ankle, which was to be used at all times, except during bathing for the duration of the study.

Subjective assessment was by means of the Short-form McGill Pain Questionnaire and the Numerical Pain Rating Scale-101. Objective measurements used in this study were the following: the use of an extremity range of motion goniometer, assessment of tenderness by means of an algometer and assessment of swelling by means of foot volumetry. Assessments were taken on all of the consultations for all subjective and objective measures.

Statistical analysis was completed under the supervision of Kavanal N. Thomas (Research Statistician) at Technikon Natal, at a 5% level of significance. The non-parametric Wilcoxon signed rank tests were used to analyze data within each group. The non-parametric Mann-Whitney unpaired U tests were used to analyze the data between each group.

In terms of patients' subjective response to treatment, both groups showed a significant overall decrease in pain perception (NRS-101 and Short-form McGill Pain Questionnaire).

In terms of objective findings both groups showed a significant overall increase in pressure pain threshold (algometric readings), ankle dorsiflexion range of motion (goniometer readings) and decrease in the amount of swelling in foot (volumetry readings).

There was no significant difference between the two groups in terms of subjective and objective findings.

It was concluded that both treatment protocols were equally effective in the treatment of symptoms and signs found in acute grade 1 or 2 ankle inversion sprains. This study therefore supports the use of Proteases in the treatment of symptoms and signs found in acute grade 1 or 2 ankle inversion sprains in preference to Piroxicam to avoid the negative side effects of non steroidal anti-inflammatory medication.

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## **ABBREVIATIONS USED IN CHAPTER FOUR**

CONSULT - Consultation

GONIOMET - Goniometer

McGill - Short-form McGill Pain Questionnaire

NRS- Numerical Pain Rating Scale-101

P-VALUE- Level of significance

-VE RANKS - Negative Ranks

+VE RANKS - Positive Ranks

## CHAPTER ONE: INTRODUCTION

### 1.1 THE PROBLEM AND ITS SETTING

The ankle joint is formed by the tibia, fibula and talus, the dome of the talus fitting into the mortice formed by the tibia and fibula (Mack, 1982). The lateral ligaments are damaged by excessive inversion accompanied by plantar flexion or medial rotation. Common mechanisms of injury include uneven surfaces, landing from a jump, stepping or landing on an opponents' foot, changing direction or decelerating (Reid, 1992: 220-221).

Ankle sprains occur frequently in the general population and are a common sports injury. Garrick and Requa (1988) reported that of 16,754 total injuries seen in a centre for sports' medicine (U.S.A.) 9.5% involved the ankle with 50.4% of these injuries being sprains. During an investigation by Garrick (1977) of 2840 participants in 14 sports the overall injury rate for all sports was 41 % with the rate of occurrence of ankle injuries being 5.7%. Of these ankle injuries 85% were sprains.

In a study by Fallet *et al.* (1998) of 639 acute ankle injuries the most common soft tissue injuries involved the lateral ankle ligaments and these comprised 83.7% of all soft tissue injuries and 71.7% of the total injuries evaluated.

Treatment of ankle sprains is determined by the grade of ankle sprain with grade three ankle sprains being referred for casting and grade one and two ankle sprains being treated in the acute phase by rest, ice, compression, elevation and Non Steroidal Anti-inflammatory (NSAID) medication (Reid, 1992: 239,242).

Failure to evaluate, diagnose and adequately treat the ankle sprain may result in continued pain, instability and decreased function eventually resulting in ankle morbidity (Kuwada, 1995).

### 1.2 STATEMENT OF THE PROBLEM

The purpose of this randomised double blinded controlled study is to evaluate Piroxicam versus Protease administration, in terms of subjective and objective clinical findings, in order to determine the effectiveness of each approach in the treatment of grade 1 and 2 acute ankle inversion sprains.

### 1.3 NEED FOR A SOLUTION TO THE PROBLEM

Piroxicam is an oxycam derivative that possesses anti-inflammatory, analgesic and antipyretic activity. Piroxicam is an effective anti-inflammatory with potency equivalent to that of indomethacin (well known NSAID). Piroxicam is better tolerated than aspirin (well known NSAID) and indomethacin over prolonged treatment periods. The principal advantage of Piroxicam is that it has a long half life, allowing the administration of a single daily dose which enables patients to be more compliant (Insel, 1990: 668-669). Slatyer *et al.* (1997) in a randomized controlled trial of Piroxicam in the management of acute ankle sprains found that the treatment group had less pain, were able to resume training more rapidly and were found to have increased exercise endurance on resumption of activity when compared to the placebo group. The study concluded that NSAID's should form an integral part of the treatment of ankle sprains. Although NSAID'S have been found to be effective in the treatment of ankle sprains they do have numerous adverse side effects and special precautions in the case of Piroxicam these include: peptic ulceration, gastro-intestinal bleeding, edema, changes in liver function parameters in patients taking anti-coagulation medication, blood urea and nitrogen elevation in patients with renal dysfunction, prolonged bleeding, dermal hypersensitivity reactions, decreases in haemoglobin and haematocrit, thrombocytopenia and non-thrombocytopenic purpura, aplastic anaemia, leucopenia, eosinophilia, broncho spasm, central nervous system effects and increased plasma lithium levels (APPENDIX D).

Proteases defined as proteolytic enzymes are integral in living organisms. They fulfill a large range of regulatory and functional roles in almost every cellular process including repair and healing. After the advent of Proteases becoming available commercially it was a logical step to administer Proteases from an exogenous source to accelerate and enhance healing. Calendre *et al.* (1991) in a placebo controlled trial in which 190 patients with ankle sprains were studied found oral Streptokinase Streptodornase (bacterial derived protease) to effectively ameliorate the inflammatory symptoms associated with ankle sprains as compared to placebo. Braumuller (1990) studied the effects of Wobenzym (a mixture of Pancreatin, Papain, Bromelain, Trypsin and Chymotrypsin) on ankle sprains in 44 patients in a randomized, placebo controlled, double blinded study. The Protease group exhibited less swelling, less pain, more flexion of the ankle joint, and quicker return to work and training than the placebo group. Thus in each of these studies on Protease supplementation for ankle sprains, significant anti-inflammatory effects were found, these translated into significant benefits in outcome of therapy ie. quicker recovery.

The author could not locate any published studies comparing the use of Proteases and Piroxicam in the treatment of inflammatory symptoms and signs found in acute grade 1 and 2 ankle sprains.

## 1.4 BENEFITS OF THE STUDY

If Proteases are found to be equally or more effective than non steroidal anti-inflammatory medication, in terms of controlling inflammation, and speeding up recovery, it would be recommended by the author that Proteases be used in preference to non steroidal anti-inflammatory medication to avoid possible negative side effects. This treatment approach could be extended to other conditions in which inflammation hampers recovery.

## CHAPTER TWO: LITERATURE REVIEW

### 2.1 INTRODUCTION

Regardless of whose statistics one reads, ankle sprains are a major problem. According to Kuwada (1995), they` affect all people especially athletes who are likely to sprain an ankle at some stage in their athletic career. It is estimated that 20% to 25% of all time loss-injuries in running and jumping sports are a result of ankle injuries (Mack 1982).

In a study by Garrick (1977), it was determined that 85% of ankle injuries were sprains of which the lateral ankle ligaments are most frequently injured. In a more recent study by Fallet *et al.* (1998), of 639 acute ankle injuries the most common soft tissue injuries involved the lateral ankle ligaments and these comprised 83.7% of all soft tissue injuries and 71.7% of the total injuries evaluated.

The lateral ligaments are damaged by excessive inversion accompanied by either plantar flexion or rotation (Reid, 1992: 220), hence the common name for this type of injury is either lateral ankle sprain or ankle inversion sprain.

Treatment of acute ankle sprains is determined by the severity of the sprain with grade three ankle sprains being referred for casting (Reid, 1992 : 242) and grade one and two ankle sprains being treated with rest, ice, compression, elevation and immobilization. When inflammatory symptoms are prominent, therapy with Non Steroidal Anti-inflammatory medication (NSAIDs) is considered (Reid, 1992: 239), however very few medical alternatives to NSAIDs were found in the literature reviewed.

### 2.2 EPIDEMIOLOGY

Ankle injuries are the most common musculoskeletal complaint in the emergency room, and make up a large portion of private office practice Boruta *et al.* (1990). According to Reid (1992 : 215), ankle injuries may constitute up to 12% of the emergency room load in many centers.

Undoubtably the majority of ankle injuries are sprains. During an investigation by Garrick (1977) of 2840 participants in 14 sports the overall injury rate for all sports was 41 % with the rate of occurrence of ankle injuries being 5.7%. Of these ankle injuries 85% were sprains. Garrick and Requa (1988) reported that of



16,754 total injuries seen in a centre for sports' medicine (U.S.A.) 9.5% involved the ankle with 50.4% of these injuries being sprains.

In a study by Fallet et al. (1998) of 639 acute ankle injuries the most common soft tissue injuries involved the lateral ankle ligaments and these comprised 83.7% of all soft tissue injuries and 71.7% of the total injuries evaluated.

In the afore mentioned study by Fallet et al. (1998), it was found that the age of patients with ankle sprains ranged from 4 to 85 years old, with the average age being 34 years.

According to Garrick (1977), in the afore mentioned epidemiological survey of ankle sprains, women and men appear to be equally affected.

In an epidemiological survey conducted by Yeng Mphil et al. (1994), involving 380 athletes with sprained ankles, it was recorded that injury to the dominant ankle was 2.4 times higher than injury to the non-dominant side.

Of the athletes involved in the afore mentioned study by Yeng Mphil et al. (1994), the prevalence of ankle sprains in various sports was determined -:

- 25% running \ jumping sports
- 20% racquet sports
- 19% ball games
- 14% soccer
- 6% fencing
- 16% other.

According to Mack (1982), ankle injuries constitute 20% to 25% of the total time lost due to injuries in running and jumping sports. In basketball they comprise more than 50% of major injuries and in soccer and volleyball more than 25% (Reid 1992 :215).

A prospective study done on 639 patients with acute ankle injuries it was found that many patients had multiple-component injuries however 71.7% of the injuries evaluated involved the lateral ligaments. The anterior talofibular, posterior talofibular and calcaneofibular ligaments were solely injured in 16.5%, 1.6% and 0.7% times respectively; however combined injury to more than one ligament appeared to be the most common form of injury. The most common pattern was combined injury to the anterior talofibular and calcaneofibular ligaments, occurring in 34.2% of the patients. All three lateral ligaments were involved 31.3% of the time (Fallet et al. 1998).

## 2.3 ANATOMY AND BIOMECHANICS

### THE DISTAL TIBIOFIBULAR JOINT

This is a type of fibrous joint (syndesmosis) in which the intervening fibrous connective tissue forms an interosseous membrane (Dorlands Medical Dictionary 1988 : 1629). It is located between the inferior ends of the tibia and fibular. Although this joint is anatomically distinct from the ankle joint, it functions almost exclusively to serve this joint. The function of the talocrural or ankle joint is dependant on the tibiofibular mortise. The tibia and fibular would be unable to grasp and hold the distal joint segment if these bones were able to separate. The analogous mortise of a wrench which for obvious reasons could not perform properly if the two pincers kept moving apart every time force was applied (Norkin and Levangie 1992 :383).

#### **Articular Surfaces of the Distal Tibiofibular Joint**

A rough, convex, triangular facet on the inferior medial surface of the fibular articulates with the distal tibia via an appropriately shaped facet.

#### **Stability of the Distal Tibiofibular Joint**

Much of the strength of the ankle joint is dependant on the union of the tibia and fibular; this union is maintained by the following ligaments:

*Interosseous Ligament* : This ligament is continuous with the interosseous membrane which lies superiorly. It consists of a strong band that lies between the tibia and fibula attaching at the medial border of the distal fibula and at the fibular notch on the tibia.

*Anterior and Posterior Tibiofibular Ligament* : these ligaments attach at the fibular notch on the tibia and extend to the anterior and posterior fibular borders.

*Transverse Tibiofibular Ligament* : This ligament is made up of the inferior deep fibers of the of the posterior tibiofibular ligament.

#### **Blood Supply of the Distal Tibiofibular Joint**

The articular arteries are derived from the perforating branch of the fibular \ peroneal artery and the medial malleolar branches of the anterior and posterior tibial arteries.

#### **Nerve Supply of the Distal Tibiofibular Joint**

The articular innervation is derived from the deep fibular \ peroneal, tibial and saphenous nerves (Moore 1992 :487).

### **Movement of the Distal Talofibular Joint**

Very little movement occurs due to the strong interosseous ligaments. The joint does provide a measure of elasticity to accommodate the talus during dorsiflexion of the foot (Moore 1992 : 487).

## **THE ANKLE JOINT**

The ankle joint is regarded as a hinge type of synovial joint which by definition only allows movement in one plane, as the hinge of a door (Dorlands Medical Dictionary 1988 : 691). It is located between the inferior ends of the tibia and fibula and the superior aspect of the talus (Moore 1992 : 487).

### **The Articular Surface of the Ankle Joint**

The tibia and fibula form a deep socket into which the trochlea of the talus fits. The three sided socket is formed by both malleoli on either side and the inferior aspect of the tibia. The socket has a number of facets for articulation with the talus. The fibula has an articular facet on its medial aspect that faces medially and articulates with the lateral surface of the talus. The tibia articulates with the talus with its inferior surface and with the lateral surfaces of its medial malleolus. The superior articular facet of the talus is called the trochlea because of its pulley like shape. It is wider anteriorly and convex from anterior to posterior and slightly concave from medial to lateral (Moore 1992 : 488).

### **Articular capsule**

The capsule is fibrous and is thin anteriorly and posteriorly, laterally it is supported by the collateral ligaments. Superiorly it attaches to the articular borders of the tibia and the malleoli, inferiorly it attaches to the talus close to the superior articular surface, except anterior inferiorly where it attaches to the dorsum of the neck of the talus. The fibrous capsule is strengthened medially by the deltoid ligaments and laterally by the lateral ligaments.

The articular capsule is lined by the synovium which may at times project superiorly for a short distance into the tibiofibular ligament. The articular cavity is superficial on either side of tendo-calcaneus therefore when there is inflammation in the joint swelling is visible at this location (Moore 1992: 488).

### **Lateral ligamentous structures**

- *anterior talofibular ligament* : this ligament runs obliquely from the anterior portion of the lateral malleolus to the anterior portion of the talus, insertion is just superior to the lateral articular facet. This ligament often occurs as a thickening

in the capsule as opposed to a discrete structure.

- *calcaneofibular ligament*: this ligament arises at the apex of the lateral malleolus and runs inferiorly and posteriorly to insert into the prominence on the lateral portion of the calcaneus. This is a discrete ligament and the strongest of the lateral ligaments.

- posterior talofibular ligament: this ligament runs from the posterior medial aspect of the fibula to the posterior surface of the talus, inserting into the prominence just distal to the articular surface. This ligament is intra-articular and has no independent stabilizing function, playing only a support role in lateral ankle stability.

### **Medial ligamentous structures (The Deltoid Ligament)**

- deltoid ligament: this consists of deep and superficial fibers.

The superficial fibers of the deltoid ligament diverge from the medial malleolus distally and extend anteriorly to the neck of the tarsal navicular (*tibionavicular ligament*) and posteriorly along the medial aspect of the os calcis to the sustentaculum tali (*tibiocalcaneal ligament*).

The deep fibers (*anterior and posterior talotibial ligaments*), originate at the medial malleolus and insert anteriorly along the neck of the talus and posteriorly on the posterior medial tubercle of the talus. Functionally the ligaments making up the deltoid ligament are considered as a single structure (Nicholas and Hershman 1995 : 423).

The deltoid ligament is extremely strong, and when powerful eversion does occur, an avulsion fracture of the distal tibia will often occur (Moore 1992 : 490).

When the medial ligaments are involved there is more chance of an associated malleolar fracture or damage to the interosseous membrane (Reid 1992 : 217).

### **The stability of the ankle joint**

The lateral malleolus projects down below the level of the subtalar joint and considerably lower than that of the medial malleolus, as a result of this there is greater bony stability on the lateral side of the ankle than on the medial side. The deltoid ligament is considered the strongest ligament in the ankle which is necessary due to the decreased bony protection medially (Mack, 1982).

During weight bearing the fibula moves slightly lateral and inferior resulting in a deep and supportive mortise joint. With physiological loading, the mortise formed by the articular surfaces accounts for 30% of the stability in rotation and 100% of inversion and eversion stability (Stormont et al. 1985).

The anterior tibiofibular ligament and the deltoid ligament limit internal rotation .

External rotation is primarily limited by the calcaneofibular ligament (Reid 1992 : 216 -217).

In normal circumstances the bony configuration secures most physiological motion in the fully weight-bearing position however in the plantar flexed position, in the unloaded ankle and at the extremes of traumatically induced motion the lateral ligaments assume a greater role (Reid 1992 : 218). It is therefore important to discuss the stability of the ankle joint at dorsi flexion and plantar flexion as it varies quite considerably in these two positions.

*Dorsi flexion* : The ankle joint is best supported in this position as a result of the following:

- strong ligaments
- several tendons that cross the joint which are bound tightly by retinaculum
- because the talus is wedge shaped anteriorly it fills the mortise joint as it moves posteriorly into dorsi flexion, allowing the malleoli to grip the talus tightly and preventing all but the slightest movement.

*Plantar flexion* : The joint is relatively unstable in this position because the wedge shaped talus moves anteriorly leaving the narrow posterior portion of the talus in the mortise joint resulting in a greater amount of free play. The elasticity of the ligaments between the tibia and fibula does result in a certain degree of closure between the tibia and fibula however not enough to permit the same tight fit as in the dorsi flexed position. Hence there is some side to side movement that occurs in fully plantar flexed position. The wedge shaped talus still prevents posterior displacement of the foot during sudden jumps and stops in the plantar flexed position (Moore 1992 : 488).

For obvious reasons medial and lateral ligament complexes assume a greater role in this position.

There are important musculotendinous structures related to the medial and lateral ligament structures which significantly add to the stability of the ankle joint. The medial stabilizers of this joint are the tibialis posterior, the flexor digitorum communis and the flexor hallucis longus; these muscles originate in the posterior compartment of the leg and pass posterior and inferior to the medial malleolus. The lateral stabilizers are the peroneus longus and brevis muscles; these muscles originate in the lateral compartment of the leg and pass inferior to the lateral malleolus (Mack 1982 : 79).

The peroneus brevis muscle tends to prevent over inversion of the foot, thus aiding the ligaments in preventing serious inversion injuries to the ankle joint. (Moore 1992 : 490).

### **Blood Supply of the Ankle Joint**

This is supplied from malleolar branches of the anterior tibial and peroneal arteries.

### **Nerve Supply of the Ankle Joint**

Innervation is derived from the deep peroneal \ fibular nerve and the tibial nerve (Moore 1992 : 490).

### **Movement of the Ankle Joint**

The movement which occurs at the ankle joint is dorsi flexion and plantar flexion through a maximum range of 90 degrees ( dorsi flexion 30 degrees, plantar flexion 50 degrees). In the normal standing position the foot makes a right angle with the leg, this is the neutral position of the ankle joint (Palastanga, Field and Soames 1990: 538).

The ankle permits 20 degrees dorsi flexion and 50 degrees plantar flexion (Magee 1992:468).

Movement of the ankle takes place about a transverse axis which is level with the tip of the lateral malleolus and slightly below the level of the medial malleolus. The axis is strictly speaking not horizontal due to the anatomical location of the fibula and tibial malleoli. The axis slopes slightly inferiorly and laterally. Because of the obliquity of the joint axis there is a slight movement resembling inversion on full plantar flexion and eversion on full dorsi flexion however this is not true inversion \ eversion movement (Palastanga, Field and Soames 1990: 538) (ankle inversion \ eversion occurs at the subtalar joint).

The muscles responsible for plantar flexion of the foot, at the ankle joint are the gastrocnemius, soleus, plantaris, flexor digitorum longus, flexor hallucis longus, tibialis posterior and peroneal muscles. These muscles are all innervated by the tibial nerve except peroneus longus and brevis which are innervated by the superficial peroneal nerve.

The muscles responsible for dorsi flexion are the tibialis anterior, extensor digitorum longus, extensor hallucis longus and peroneus tertius. These muscles are all innervated by the deep peroneal nerve (Magee 1992 : 475 ).

## **2.4 MECHANISMS OF INJURY AND PATHOMECHANICS**

For reasons already discussed the ankle is least stable against inversion, especially in the unloaded and \ or plantar flexed position. If excessive forces are applied in these circumstances, injury to the lateral ligaments is likely to ensue.

According to Reid (1992 : 221), the lateral ligaments are most likely to be injured in the following circumstances:

- Landing from a jump
- Stepping or landing on an opponents foot
- Changing direction
- Decelerating
- Uneven surfaces

There are many factors which may contribute towards the likelihood of developing a sprain. In an evaluation of one hundred ankle injuries in ballet dancers, Hamilton (1982), stated that predisposing factors to ankle sprains could be the following:

- Fatigue especially when attempting new steps
- Cavus feet
- Previous injury
- Peroneal tendon weakness

Other predisposing factors according to Reid (1992), were the following:

- Low profile boots
- Narrow, long, shoe studs
- Generalized ligament laxity
- Varus heel
- Tight Achilles tendon
- Tarsal coalition

According to Mack (1982 : 79), when inversion at the ankle is initiated, the ankle loses the bony stability that it had in the neutral position. If inversion increases, the medial malleolus may lose its stabilizing function and serve as a fulcrum for further inversion. If the everting muscles (peroneal muscles) are not strong enough, it is possible that the tensile strength of the ligament is exceeded and injury to the ligament results.

The peroneus brevis muscle tends to prevent over inversion of the foot, thus aiding the lateral ligaments in preventing serious inversion injuries to the ankle joint. Violent inversion can result in avulsion of the tuberosity of the fifth metatarsal bone, into which the peroneus brevis inserts (Moore 1992 : 490).

In the unstable plantar flexed position the anterior talofibular ligament is almost perpendicular to the supporting surface and parallel to the long axis of the tibia. In this position it provides maximum protection against pathological inversion in the ankle joint (Reid 1992: 218). Hence it is the most likely ligament to be damaged in the plantar flexed position when forces exceed the strength of this ligament. The calcaneofibular ligament is perpendicular to the supporting surface in the neutral position however this is a more stable position especially in the supported foot and as a result this ligament is less frequently injured. This is clearly demonstrated in a study by Fallet *et al.* (1998), where of 547 patients

studied with lateral ligament injury, 16.5% involved the anterior talofibular ligament on its own as opposed to 0.7% of injuries involving solely the calcaneofibular ligament. In most situations more than one ligament is injured at a time the most common pattern of injury (34.2%), was to both the anterior talofibular and calcaneofibular ligaments. Injury to all three lateral ligaments occurred 31.3% of the time. According to Reid (1992), the posterior talofibular ligament is moderately stressed in the stable dorsi flexed position and is subsequently rarely injured on its own.

## 2.5 PROPRIOCEPTION

Proprioception is defined by Lephart and Fu (1995) as a specialized variation of the sensory modality of touch that encompasses the sensations of joint movement (kinesthesia) and joint position (joint position sense).

Proprioception is essential for proper joint function in sports, and daily activities. It modulates muscle function and initiates reflex stabilization (Lephart and Fu, 1995).

Proprioceptive deficits after ankle injury seem to be frequently evident and may be considered as one of the reasons for resulting functional instability (Jerhosch and Bischof, 1996). Their study included 14 healthy volunteers and 16 athletes with ankle instability, proprioceptive function of the ankle was found to be normal in all the control group whereas in the test group there was a highly significant difference in tests between injured and non injured ankles.

## 2.6 DIAGNOSIS AND GRADING OF ANKLE INVERSION SPRAINS

If the ankle has no obvious deformity the best opportunity to accurately evaluate it is shortly after the injury. After the patient has relaxed and initial pain has decreased a period referred to by some as the "golden period" begins. This period is characterized by no swelling, no guarding, and substantial decrease in initial pain, all of which facilitate a fruitful physical exam (Reid 1992: 222), (Thomas et al. 1998).



**A thorough case history** will on most occasions give one the correct diagnosis. Important questions to ask are:

- How did it happen (inversion, eversion, plantar flexion, etc)
- Where does it hurt
- Did the intensity of pain prevent you from continuing to play (ruptured ligament, fracture)
- Were you able to bear weight (fracture, severity of injury)
- have you injured this ankle before (to identify recurrent sprain) (Thomas et al. 1998).

According to Singer et al. (1995), other important questions include:

- Was there an audible "pop"
- Time of onset of swelling
- Location of swelling.

**Physical examination** should include both ankles as the uninjured ankle will provide a useful reference point.

*Careful assessment* of the areas of swelling and the maximum areas of tenderness may help decide which of the ligaments are affected. When viewing the ankle from behind, one is able to determine whether definition of the Achilles tendon is lost. Lost definition on either side of the tendon immediately after injury is an indication of bleeding into the joint capsule which may indicate contusion of the joint surfaces. Inadequate therapy following injury can result in late development of edema around the tendon which does not have the same implications in terms of assessing severity. Excessive deformity should raise suspicion of ankle fracture, diastasis or dislocation (Reid 1992 : 222-223). The anterior talofibular ligament and the deep fibers of the deltoid ligament blend with the joint capsule therefore injury to these structures may result in joint effusion. Within a day there is usually diffuse ecchymosis in the region of the injury (Hertling and Kessler, 1996: 421).

*Palpation* over the site of the lesion is likely to be tender with swelling and elevated skin temperature. It is also likely that there will be diffuse tenderness in the presence of marked swelling (Hertling and Kessler, 1996: 421). The author usually performs a neurological and vascular examination at this time.

*Active, passive and resisted range of motion tests should be performed.*

In the acute stage active movements can often only be performed with difficulty and the examiner must exercise judgement in requesting the patient to perform these movements to avoid undue discomfort or stress to the part.

Passive movements and joint-play movements are key objective tests. If the ankle mortise joint capsule has been stressed, with a subsequent articular effusion, the ankle movements will be limited in a capsular pattern; plantar flexion will be slightly more limited than dorsi flexion. Mild to moderate sprains should produce pain on those movements that stress the ligament and an associated muscle-spasm end feel. Acute ruptures often demonstrate hyper mobility however protective a muscle spasm can give false positives.

Resisted movements should be strong and painless. When peroneal tendons have been strained in conjunction to an inversion sprain, resistance to eversion is strong and painful (Hertling and Kessler, 1996: 421).

*Special tests* for determining if there has been damage to the lateral ligament complex includes anterior draw test and talar tilt. Anterior draw test is used to assess the status of the anterior talofibular ligament while talar tilt can be adapted to test both anterior talofibular and calcaneofibular ligaments. Other orthopaedic tests should be performed to rule out other injuries, these include:

- Kleigers test (determine status of the deltoid ligament)
- Thomson's test (determine status of Achilles tendon)(Magee 1992:479-482)
- External rotation test (determine status of interosseous ligament)(Alonso *et al.* 1998).
- Homan's test (determine presence of deep venous thrombosis)
- Balance/proprioception (determine status of proprioception)
- Tinel's sign (determine status of the anterior tibial branch of the deep peroneal nerve and posterior tibial nerve)(Magee 1992:479-482).

**The decision to radiograph the ankle** for possible fractures should be based upon Ottawa ankle rules. These rules have been shown to be 100% sensitive for fractures, allowing the physician to reduce the number of unnecessary radiographs in patients with ankle injuries. According to these rules ankle radiographs are only necessary if there is pain in the region of the malleolus and one or both of the following:

- bone tenderness along the posterior edge or tip of either malleolus
- inability to bear weight either immediately or on consultation (take a few steps).

Foot radiographs need only be taken if there is midfoot pain and any of the following:

- bone tenderness at the base of the fifth metatarsal
- bone tenderness at the navicular
- inability to bear weight either immediately or on consultation (take a few steps).

These rules remain secondary to clinical judgement and obviously need not apply to patients with visible deformity. The Ottawa rules should not be applied to intoxicated patients, patients with head injuries, patients with diminished sensory perception in the lower limbs, patients with multiple painful injuries and pregnant patients. These rules have not been tested on patients under the age of 18 years (Steill *et al.* 1993).

**Grading of ankle sprains** is done in order to more accurately assess various aspects of the inversion sprain such as treatment approach, prognosis etc. The most accurate classification system found by the author was that of Reid, (1992:226) and was hence used for this study (table 2.1).

TABLE 2.1 CLASSIFICATION OF ANKLE SPRAINS

SEVERITY	PATHOLOGY	SIGNS AND SYMPTOMS	DISABILITY
Grade 1 - mild	Mild stretch No instability Single ligament involved Usually anterior talofibular ligament	No hemorrhage Minimal swelling Point tenderness No anterior drawer No varus laxity	No or little limp Minimal functional loss Difficulty hopping
Grade 2 - moderate	Large spectrum of injury Mild to moderate instability Complete tear of ant talofibular ligament or Partial tear of ant talofibular plus calcaneofibular ligaments	Some hemorrhage Localized swelling Margins of Achilles tendon less defined May be anterior drawer No varus laxity	Limp with walk Inability to toe raise Inability to hop Unable to run
Grade 3 - severe	Significant instability Complete tear of anterior capsule, talofibular ligament and associated tear of anterior talofibular and calcaneofibular ligaments	Diffuse swelling both sides of Achilles tendon, early hemorrhage May be tenderness medially and laterally Positive anterior drawer Positive varus laxity	Unable to bear weight fully Significant pain inhibition Initially almost complete loss of range of motion

## 2.7 ASSOCIATED INJURIES AND DIFFERENTIAL DIAGNOSIS

In a prospective study of 639 ankle injuries presenting as sprains by Fallat et al. (1998), it was found that there were 92 cases of avulsion or compression fracture in the foot or ankle. The remaining 547 patients had soft tissue injuries of which the majority had inversion sprains (469 patients). Many patients had other associated injuries including: 92 cases of avulsion or compression fracture in the foot or ankle, 180 cases of damage to the ankle joint capsule, 111 cases of involvement to extensor digitorum brevis, 83 cases of peroneal tendon involvement, 67 cases involving Achilles tendon, 41 cases on calcaneo-cuboid involvement, 31 cases of syndesmosis injuries and 80 patients were found to have neuritis. From these findings Fallat et al. concluded that there are more components to the sprained ankle than injury to the lateral ligaments and hence suggested that this condition be more appropriately termed "sprained ankle syndrome". Without considering the components of the syndrome incomplete diagnosis may be made, resulting in suboptimal or inappropriate treatment. This may result in incomplete healing, recurrent injury or chronic pain and edema.

### 2.7.1 EVERSION \ DELTOID LIGAMENT SPRAINS

In the afore mentioned study by Fallat et al. (1998), in which 639 people with acute ankle injuries were assessed only 19 people were primarily diagnosed with eversion sprains. According to Singer et al. (1995 : 424), the most common injury results when the fixed, weight bearing, pronated foot receives a blow on the lateral aspect. The amount of force required to tear the deltoid ligament often results in simultaneous injury to other structures.

The signs and symptoms are similar to those of inversion sprains except they occur over the medial side of the ankle. The special test used to diagnose this condition is Kleiger test (Magee 1992 :481-482).

### 2.7.2 SYNDESMOSIS SPRAIN

According to Hopkinson et al. (1990), and injury to the syndesmosis especially the anterior tibiofibular ligament occurs frequently. Since it is difficult to prove incomplete injury the true incidence is presently a matter of speculation. Injury to syndesmosis may be considered the worst type of sprain due to prolonged

recovery times which may be twice as long as the recovery from a grade three ankle sprain.

This type of sprain is best detected using the external rotation test. Squeeze test, anterior palpation test and dorsi flexion-compression tests were found to be less reliable than the former test. Alonso et al. (1998).

### 2.7.3 BIFURCATE LIGAMENT (calcaneocuboid and calcaneonavicular ligaments)

Injury to this ligament occurs with forced plantar flexion or dorsi flexion or direct trauma.

This injury is associated with up to 19% of ankle inversion sprains. There may be an associated avulsion of the anterior process of the calcaneus.

These sprains are often mistaken for lateral ankle sprains because the pain and swelling situated near the lateral malleolus. The point of maximal tenderness is midway between the tuberosity of the fifth metatarsal and the tip of the lateral malleolus. Injury will often produce pain for many months (Alonso et al. 1998).

### 2.7.4 ACHILLES TENDON RUPTURE

Rupture occurs with rapid plantar flexion at an area of poor circulation 2 to 6 centimeters above the os calcis. At the time of injury patients will feel a sharp pain in the Achilles and often state that it sounded like someone shot them (Alonso et al. 1998).

The special test to diagnose this condition is Thomson's test (Magee 1992:482).

### 2.7.5 ACHILLES TENDINITIS

According to Fallat et al. (1998), 12.2% of the 547 patients with soft tissue trauma to the ankle had with Achilles tendinitis.

Achilles tendinitis presents with pain over the posterior heel, calcaneus, and sometimes up the Achilles tendon into the calf. Achilles tendinitis may be

associated with posterior calcaneal hyperostosis, infratendinous bursitis or supratendinous bursitis (Brantingham et al. 1998).

### 2.7.6 PERONEAL TENDON SUBLUXATION

The condition occasionally occurs spontaneously owing to anatomic variation of the posterior fibular sulcus and surrounding collagen, however the precipitating event is usually an ankle sprain.

The athlete may complain of pain, swelling, or a sensation of "popping" or "snapping" around the lateral malleolus. On examination there is tenderness on palpation of the peroneal sheath posterior to the fibular malleolus, with prominence of the sheath demonstrated by resisted dorsi flexion and eversion (Reid 1992 : 254).

### 2.7.7 PERONEAL TENDINITIS

According to Fallat et al. (1998), 15.2% of the 547 patients with soft tissue trauma to the ankle had with Achilles tendinitis. Sammarco and Cooper (1998 : 338), stated that peroneal tendinitis may be caused by acute inversion injury resulting in inflammation at the lateral malleolus .

Patients present with pain and swelling posterior to the lateral malleolus. On examination there is swelling and tenderness along the tendon and pain on resisted eversion. There may be associated subluxating peroneal tendons, hind foot stiffness or peroneal spasm ( Sammarco and Cooper 1998 : 338).

### 2.7.8 EXTENSOR DIGITORUM BREVIS STRAIN

In the afore mentioned study by Fallat et al. (1998), extensor digitorum brevis strains were common occurring in 111 patients of the 639 patients evaluated. Of the 111 patients 32 patients were given the primary diagnosis of extensor digitorum brevis strain.

## 2.7.9 NERVE INJURIES

According to Nitz et al. (1985), 10% of patients with grade two sprains and 80% of patients with grade three sprains had changes compatible with denervation. Although most lesions are subclinical permanent footdrop and chronic instability may result in rare cases.

The peroneal nerve moves 5 to 8mm during inversion. With forced inversion the resultant traction is associated with a compression effect of the peroneus longus muscle covering the nerve and pushing it against the bone. This effect is magnified by associated plantar flexion (Nitz et al. 1985). According to Clavel et al. (1986), peroneal nerve entrapment may also occur due to a blow to the lateral ankle. In both instances injury results from traction or haematoma. Occasionally there is late onset of paralysis due to an intra neural haematoma however this is usually preceded by intense neuritic pain (Reid 1992 : 253).

Tarsal tunnel syndrome is a compressive neuropathy to the posterior tibial nerve or its terminal branches (medial calcaneal, medial plantar and lateral plantar). This occurs in the fibro-osseous canal formed by the laciniate ligament (flexor retinaculum) and posterior border of the medial malleolus. Amongst other causes trauma is a known aetiological factor. Many believe that this condition may result from poorly treated ankle inversion sprains (Brantingham 1999).

## 2.7.10 FRACTURES

According to Reid (1992 : 226), the following fractures may be incorrectly diagnosed as a sprain:

- Malleolar fracture of fibular or tibia
- Fibular shaft \ Maisonneuve fracture
- Talar neck fracture
- Fifth metatarsal base at peroneus brevis insertion
- Cuboid at attachment of bifurcate ligament
- Osteochondral fracture of talar dome
- Calcaneal anterior process

The most common of these fractures are fifth metatarsal fractures, cracks or avulsion fractures of the fibular malleolus and osteochondral lesions of the talar dome (Reid 1992 : 224).

## 2.8 TREATMENT OF THE ACUTE ANKLE INVERSION SPRAIN

The goals of treatment are to obtain the quickest return to pre-injury level and to maintain a stable ankle joint with full range of motion. Parker *et al.* (1997), stated that treatment of the acute ankle inversion sprain has varied according to the severity of the injury with conservative methods predominantly used for grades one and two, and operative treatment considered for grade three. Conservative therapy includes the use of rest, ice, compression, elevation and drug therapy. According to Reid (1992 : 228 - 231), edema and effusion play a central role in the degree of initial pain, the ability to progress weight bearing, the rate of restoration of normal range of motion, and the duration of chronic aching and disability. Effective treatment of this problem is important for ensuring the maximal return to function in minimal time, therefore a well planned and executed therapy possibly enhanced by judicious use of non steroidal anti-inflammatory drugs (NSAID's) is essential in the acute stage.

### 2.8.1 REST AND EXERCISE

The extent to which a patient must rest should be based on data gained from an examination that reflects the nature and extent of the pathological process as well as etiological considerations. Knowledge of the healing response of musculoskeletal tissues and of their response to various stress condition must also be applied. Too little exercise results in loss of extensibility whereas too much exercise results in inadequate healing, the appropriate compromise is difficult to judge (Hertling and Kessler 1996 : 136). For the first few hours minimal weight bearing is encouraged with elevation at every opportunity however even at this initial stage of injury it is recommended that the patient use a towel etc. to pull the ankle into the neutral position or into dorsi flexion. The key to relieving pain is to decrease effusion and edema and maintain dorsi flexion. Maintenance of dorsi flexion is important in order to enable comfortable weight-bearing and to prevent heel cord tightening (Reid 1992 : 239). Garrick and Schelkun (1997), stated that return to full activity can take anywhere between three days to six weeks depending on how comfortable the patient feels with the movement and how quickly he or she regains muscular strength. According to Reid (1992 : 239), resisted work should not begin until the patient can support at least 50% of their body weight on the injured ankle, this may be judged by pushing on a scale.



## 2.8.2 CRYOTHERAPY

Ice is applied to decrease blood flow and reduce capillary hydrostatic pressure, thereby decreasing extravasation of blood and fluid (Hertling and Kessler 1996 : 422).

Ice should be applied for the acute phase of inflammation which may last several days. The ice can be applied for as much as 20 minutes every hour initially to prevent excess swelling. The best manner in which to apply ice is with an ice-pack because one is then able to keep the leg in the elevated position. Ice whirlpools can be used instead of an ice-pack however this is not ideal because the foot is in the dependant position which can promote edema (Reid 1992 : 239). In a randomized controlled study of 34 patients with grade two ankle inversion sprains by Wilkerson and Horn-Kingery (1993), three different ice and taping protocols were applied. The conclusions drawn from this study were that the ideal ice treatment in the acute stage is two applications of ice per day at 20 to 30 minutes per application. Application of cold for longer than this typical protocol has not shown to be of any benefit.

## 2.8.3 COMPRESSION AND TAPING

Increased external pressure to the area will minimize capillary leakage by reducing the volume of the tissue spaces. This can be done by appropriate application of an elastic bandage with a horseshoe pad below the malleolus (Hertling and Kessler 1996 : 422).

In the afore mentioned study by Wilkerson and Horn-Kingery (1993), it was found that subjects who received focal compression to the soft tissues around the periphery of the fibular malleolus recover higher levels of ankle function earlier than those who receive a more uniform mode of eternal compression.

Role of ankle taping is as follows:

- Immediate post injury support and edema control
- Protecting the acute sprain between treatments
- Preventing recurrence when returning to activity
- Supporting the chronically functional, unstable ankle
- As a prophylactic measure in the uninjured athlete (Reid 1992 : 233).

According to Hertling and Kessler (1996 : 423), taping is useful providing support to the injured ankle as well as providing proprioceptive feedback to enhance protective reflexes (such as the contraction of peroneal muscles) during weight bearing thereby lessening the chance of overstress to the ankle ligaments.

## 2.8.4 ELEVATION

Elevation reduces capillary hydrostatic pressure thereby minimizing fluid loss to extravascular tissue. Elevation also serves to increase lymphatic and venous return. In the initial stages of injury it is best to keep the leg elevated as much as possible there by minimizing swelling ( Hertling and Kessler 1996 : 422).

## 2.8.5 MANIPULATION

In a single blinded placebo controlled study of thirty patients with sub acute and chronic ankle sprains it was concluded that those patients who received manipulation improved more rapidly than those in the placebo group (Pellows 1999).

In study comparing the effectiveness of manipulation to non steroidal anti-inflammatory drug therapy (Piroxicam) in thirty acute ankle sprain patients, it was found that both groups responded equally well (Coetzer 1999).

From the above studies it would seem appropriate to assess the acute ankle for restricted joint play and manipulate where indicated. According to Hertling and Kessler (1996 : 423), patients with mild acute ankle sprains should be assessed for normal joint play before being discharged from the therapist's care. In the event of lost joint play restricted movements must be restored with passive joint mobilization techniques.

## 2.8.6 DRUG THERAPY

### 2.8.6.1 NON STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID's)

The benefits of well planned and executed therapy may be enhanced by the judicious use of NSAID's (Reid 1992 : 231).

NSAID's form a chemically diverse group which all have the ability to inhibit the cyclo-oxygenase pathway which prevents endoperoxide production. Inhibition of

prostaglandins (a group of endoperoxides), results in most of the therapeutic effect of NSAID's. The therapeutic effect of NSAID's are as follows :

-*Anti-inflammatory action* is caused by prostaglandin inhibition. Prostaglandins produce vasodilation and increase vascular permeability. Because NSAID's do not inhibit other mediators of inflammation, inflammation is attenuated but not stopped.

-*Analgesic action* is exerted both peripherally and centrally, but it is the peripheral actions that predominate. Analgesia is caused again by prostaglandin inhibition. Prostaglandins do not cause pain themselves, but potentiate the pain caused by other mediators of inflammation ( e.g. histamine and bradykinin )(Neal 1992 : 66).

One of the drawbacks of using NSAID's is that side effects are relatively common. The reason for frequent side effects is partly due to the fact that they are often used in high doses for long periods and that they are widely used in the elderly. The main side effects of NSAID's are damage to the gastrointestinal tract mucosa and nephrotoxicity. Other adverse side effects include bronchospasm (especially in asthmatics), skin rashes and other allergies (Neal 1992 : 66).

## PIROXICAM

Piroxicam is a NSAID that belongs to the oxicam group. It's mechanism of action is via reversible competitive inhibition of cyclo-oxygenase (Neal 1992 : 66). The principal advantage of Piroxicam is that it has a long-half life and thus need only be taken once daily thereby ensuring better patient compliance (Insel 1990 : 668).

In a randomized placebo-controlled clinical trial of Piroxicam in the management of acute ankle sprains by Slatyer *et al.* (1997), 364 army recruits were treated. Of the 364 patients, 184 (50,5%) were allocated to the Piroxicam group and the remaining 180 (49,5%) were allocated to the placebo group. It was found that in the treatment group, patients had less pain, were able to resume training more rapidly and were found to have increased exercise endurance on resumption of activity when compared to the placebo group. Patients in the placebo group had less swelling and increased range of motion. The Piroxicam group of patients also demonstrated greater instability when the anterior draw test was applied. It was postulated that the analgesic effect of NSAID's may allow for premature return of patients to normal activity before adequate healing has occurred.

Side effects and special precautions for Piroxicam include: peptic ulceration, gastro-intestinal bleeding, edema, changes in liver function parameters in patients taking anti-coagulation medication, haematuria and nitrogen elevation

in patients with renal dysfunction, prolonged bleeding, dermal hypersensitivity reactions, decreases in haemoglobin and haematacrit, thrombocytopenia and non-thrombocytopenic purpura, aplastic anaemia, leucopenia, eosinophilia, broncho spasm, central nervous system effects and increased plasma lithium levels (Appendix D).

Piroxicam interacts with a wide range of drugs to increase the risk of bleeding and peptic ulcers. Such drugs include oral anticoagulants, corticosteroids, other NSAID's and aspirin. Patients on antihypertensive medication and diuretics should be cautious when taking Piroxicam as it may attenuate the effect of these drugs. Piroxicam may also raise lithium blood levels, a worthwhile consideration for those on lithium therapy (Medical Association of South Africa 1989 : 335).

### 2.8.6.2 PROTEASES

Proteases defined as any enzyme that catalyse the splitting of interior peptide bonds in a protein (Dorlands Medical Dictionary 1988 :1371). Plant extracts with high content of proteolytic enzymes have been used for a long time in traditional medicine. In recent times pancreatic enzymes have been included in enzyme therapy. The therapeutic use of proteolytic enzymes is partly based on scientific studies and is partly empirical (Leipner and Saller 2000). In sports the specific group of enzymes used are the hydrolases which serve largely to inhibit inflammation (Kleine 1990). Proteolytic enzymes have analgesic, anti-inflammatory and edema reducing properties( Klein and Kullich 1999).According to Leipner and Saller (2000), enzyme therapy can reverse the adverse effects caused by radiotherapy and chemotherapy. In some instances there is evidence that, in some types of tumours, survival may be prolonged. The beneficial effect of systemic enzyme therapy seems based on its anti-inflammatory potential. However, the precise mechanism of action of systemic enzyme therapy remains unsolved.

In a double blinded study by Klein and Pabst (1988), 24 subjects were injected on the anterior forearm with 2ml of there own blood thereby inducing an artificial haematoma. The enzymes used were a combination of Pancreatin, Papain, Bromelain, Lipase, Amylase, Trypsin, Chymotrypsin. Tenderness was measured using a tonometer and readings were taken 9 times over a 6 hour period. Individual variance was ruled out by pretesting the pain threshold of each patient 30 minutes before injection and marking this point as 0. The results showed a statistical improvement ( $p < 0.05$ ) in the active group compared to the placebo group as early as 45min after enzyme application. The following year Klein and Pabst used the same experimental design but with different outcome readings on 100 patients(50 in the active group and 50 in the placebo group). The patients

had a constant pressure applied to the haematoma and pain was measured on a pain score. Measurements were taken for up to 14 days. The results revealed that patients in the active group had period tenderness for an average of 3.85 days as opposed to the 6.98 days in the placebo group ( $p < 0.001$ ). The score of tenderness in the active group was 5.66 as opposed to 10.48 in the placebo group ( $p < 0.001$ ). From these two statistically significant readings it was also determined that pain reduction was longer lasting and healing was quicker in the active group. There were no side effects in either of these trials. Klein and Pabst (1990), concluded that systemic enzyme therapy is a highly effective and safe treatment for patients with sports injuries.

In a double-blind study comparing the use of hydrolytic enzyme therapy to placebo in the postoperative treatment of meniscus injuries of 80 patients by Rahn (1990), the results showed a statistical improvement in those patients in the enzyme group compared to the placebo group. The following aspects were shown:

- marked reduction in postoperative edema,
- early functional after-care,
- improved mobility.

Calendre *et al.* (1991) in a placebo controlled trial in which 190 patients with ankle sprains were studied found oral Streptokinase Streptodornase (bacterial derived Protease) to effectively ameliorate the inflammatory symptoms associated with ankle sprains as compared to placebo. Braumuller (1990) studied the effects of a mixture of Proteases (Pancreatin, Papain, Bromelain, Trypsin and Chymotrypsin) on ankle sprains in 44 patients in a randomized, placebo controlled, double blinded study. The Protease group exhibited less swelling, less pain, more flexion of the ankle joint, and quicker return to work and training than the placebo group. Thus in each of these studies on Protease supplementation for ankle sprains, significant anti-inflammatory effects were found, these translated into significant benefits in outcome of therapy ie quicker recovery.

For this study hydrolytic Protease extracts from pineapple (Bromelain) and *Aspergillus Oryza* and *Niger* (Brinolase) were used. Bromelain has been extensively researched and is known for the following properties:

- interference with growth of malignant cells,
- inhibition of platelet aggregation,
- fibrinolytic activity,
- anti-inflammatory action,
- skin debridement.

The mechanism of action of Bromelain affecting these varied biological effects relates in part to its modulation of the arachidonate cascade (Taussig and Batkin 1988). It is not always accurate to extrapolate results from animal studies

however study of the bioavailability of Bromelain in rats after oral administration showed a peak plasma content of 40% one hour after administration (White et al. 1988). Enteric coating of tablets to resist stomach acidity has shown to be helpful in achieving highest serum levels however Bromelain and Brinolase do not require capsules with enteric coating due to the wide range of pH stability (Cilliers 1999)(Howell 1985 : 116). Aspergillus Proteases were recommended for sports medicine. Better results are obtained from enzyme combinations (Cilliers 1999).

In South Africa enzymes can be bought at a reasonable price from most health stores however it is the Bromelain enzymes or the combination of Bromelain and Aspergillus enzymes that appear to be most available.

## **CHAPTER 3: METHODOLOGY**

### **3.1 OBJECTIVES OF THE STUDY**

The objective of this study was to evaluate the relative effectiveness of Piroxicam versus Protease administration in the treatment of Acute Grade 1 and 2 Ankle Inversion Sprains, in terms of objective and subjective findings.

The first objective was to determine the relative effectiveness of Piroxicam versus Protease administration in the treatment of Acute Grade 1 and 2 Ankle Inversion Sprains, in terms of objective measures.

The second objective was to determine the relative effectiveness of Piroxicam versus Protease administration in the treatment of Acute Grade 1 and 2 Ankle Inversion Sprains, in terms of subjective measures.

### **3.2 STUDY DESIGN AND PROTOCOL**

The design was that of a prospective, randomized, double blinded, study. Subjects were informed of the study via local notice boards and newspapers. The study incorporated 30 patients who were accepted according to an inclusion criteria. Patients were randomly assigned to either group. Each group consisted of 15 patients, whom were seen on 3 occasions over a period of 7 days.

#### **3.2.1 STANDARD OF ACCEPTANCE**

At the initial consultation the candidate underwent a case history (Appendix A), physical examination (Appendix B) and ankle regional examination (Appendix C). During this process the patient was screened for Grade one and two ankle inversion sprain. Acceptance of the candidate was dependent on whether or not they met the specific inclusion criteria.

### 3.2.2 INCLUSION AND EXCLUSION CRITERIA

Patients had to be between the age of 15 to 65 years and be diagnosed with acute grade one or two ankle inversion sprain to be included into the study.

Patients will be excluded from the study for the following reasons:

- Patients with an ankle or foot fracture.
- Patients with previous major soft tissue injuries or ankle fractures in the affected ankle.
- Patients with a history of chronic instability in the affected ankle.
- Patients with a history of adverse reactions to NSAID's. (Slatyer *et al.* 1997).
- Patients with contra-indications to Adco-Piroxicam in accordance with Adco Piroxicam Package Insert ie: patients who have hepatic dysfunction and patients who are pregnant (Appendix D). For the purpose of this study patients for whom special precautions are necessary will be further excluded. Special precautions include: history of upper gastrointestinal disease, patients on coumarin type anti-coagulants, patients with renal disease and patients with aspirin sensitivity (Appendix D).

The decision will be based on the case history, questionnaire and the opinion of a medical practitioner. The questionnaire will consist of a set of questions devised by a medical practitioner to detect patients at risk of developing side effects (Appendix E). The patient will also be required to complete an indemnity form (Appendix F) and a declaration stating that they may use Piroxicam (Appendix G). It will be the medical practitioner who decides to include or exclude the patient.

The Ottawa ankle rules (the decision rules for the use of radiography in acute ankle injuries) will be applied and for standardization patients requiring radiographs will be excluded from the study. The Ottawa ankle rules have been found to have 100% sensitivity at the 95% confidence level for detecting ankle fractures (Stiell *et al.* 1994) .

### 3.2.3 INTERVENTION

Subjects found suitable for the study were given a letter of information (Appendix H ) and asked to complete an informed consent form (Appendix I ).

Patients were randomly assigned to one of the two groups each consisting of 15 patients.

All patients received the same management of the ankle sprain with the exception of the trial drugs.



Patients were taught how to apply an elastic crepe bandage to the area, which was used at all times, except during showering for the duration of the study. The bandage was applied with firm pressure from the toes to 6 cm above the malleoli (Slatyer *et al.* 1997).

The nature of the two medications is such that each must be taken in a specific way. Neither medication can be taken in the manner of the other, hence to make it undetectable as to which treatment the patient is getting, each patient received both the Adco-Piroxicam capsules and the Protease capsules. Only one set of capsules contained active ingredients with the other set of capsules containing corn starch. This ensured that the patient was blinded as to which group they belong. The patients were required to bring back the bottle in which the medication was placed to check on patient compliance and to obtain the code.

Throughout the study both the examiner and the patient were blinded as to which treatment group the patient belonged (double blinding).

Adco-Piroxicam capsules were administered using the usual dosage regimen for acute musculo skeletal disorders ie:  
40 mg daily (2 x 20mg) orally for the first 2 days, followed by 20mg (1 x 20 mg) orally for the following 5 days.

Protease capsules were administered using the following dosage regimen:  
1200mg (3 X 400mg) daily before meals for seven days.

Patients were required to attend the clinic 3 times over a period of approximately 1 week. Data was collected on each visit and it was ensured that the patient was adequately strapped.

Patients were asked to abstain from the usage of any other analgesic or anti-inflammatory medication and further asked to abstain from exercise.

### 3.2.4 ETHICAL CONSIDERATIONS

The rights and welfare of the patients were protected:

- informed consent was made (Appendix I)
- the patient was not be coerced into participating in the study
- information was given to the patient in an understandable language
- the research involved no more than minimal risk
- confidentiality was maintained
- participation was voluntary and did not involve financial benefits
- patients were free to withdraw from the study at any stage (Pak and Adams, 1994: 37).

### **3.3 MEASUREMENT AND OBSERVATION**

#### **3.3.1 THE DATA**

The study incorporated both primary and secondary data as mentioned below:

##### **3.3.1.1 PRIMARY DATA**

- Case history (Appendix A)
- Ankle regional examination (Appendix C)
- Numerical Pain Rating Scale 101 (Appendix J)
- Short-form Mc Gill Pain Questionnaire (Appendix K)
- Algometer reading for Pressure-pain Threshold (Appendix L)
- Goniometer reading for dorsi flexion (Appendix L)
- Foot volumetry studies (Appendix L)

##### **3.3.1.2 SECONDARY DATA**

Literature was obtained from journals, text books and the Internet.

#### **3.3.2 METHOD OF MEASUREMENT**

##### **3.3.2.1 SUBJECTIVE MEASUREMENT**

###### **1) THE NUMERICAL PAIN RATING SCALE -101(NRS-101)**

The NRS - 101 consists of asking the patient to rate their perceived level of pain intensity on a numerical scale from 0 to 100, with the 0 representing "no pain" and the 100 representing "pain as bad as it could be". When the NRS - 101 was compared to five other pain intensity scales in a clinical trial by Jensen, Karoly and Braver (1986), it was found to be the most practical index for measuring pain intensity. Its advantages were the following:

- it is simple to administer and score
- oral and written responses may be used
- age doesn't affect the scale.

Upon completion of the questionnaire values recorded for pain at its worst and pain at its least were added together for each consultation and divided by two to get an average the pain intensity for each consultation.

## 2) THE SHORT FORM MCGILL PAIN QUESTIONNAIRE

The short form McGill Pain Questionnaire was derived from the standard McGill Pain Questionnaire for more rapid acquisition of data. Data obtained with the questionnaire provides information on the sensory, affective and overall intensity of pain. The questionnaire consists of 15 representative words (descriptors) which are rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate or 3 = severe (Melzack, 1987). On completion of the questionnaire the points were added to form a final score out of a maximum of 45 points for that consultation.

### 3.3.2.2 OBJECTIVE MEASUREMENT

#### 1) ALGOMETER

Algometer readings were taken to measure changes in pressure-pain threshold. This measurement has been found adequate for quantification of tender spots in soft tissues. It has been found to be particularly useful in assessing treatment results (Fischer, 1987). Nussum and Downes (1998) report reliability of clinical pressure pain algometric measurements.

The algometer used was the force dial manufactured by Wagner Instruments: PO Box 1217, Greenwich CT 06836. The pressure range of the algometer was 11 kg.

The area of tenderness was located through palpation of the lateral ankle area. The footplate was placed over the area of tenderness with the shaft exerting pressure in the direction of the pain produced on palpation. The gauge was turned away from the patient and the pressure was increased at a rate of approximately 1kg/ cm squared / second. The patients were informed to indicate when they first sensed the pain produced by the pressure by saying "yes" (pressure-pain threshold).

Upon the patients' response the instrument was removed and the measurement recorded in kg per square centimeter.

## 2) GONIOMETER

The goniometer was used to measure ankle dorsi flexion which according to Pope et al.(1998), is a strong predictor of ankle injury.

Goniometer readings were taken on each consultation according to the technique tested by Johnson and Gross (1997), in which intra and inter-examiner reliability for maximum ankle dorsi flexion was shown to be high and moderate respectively.

The goniometer used in this study was manufactured by Baseline, Fabrication Enterprise, Inc., Irvington, New York, U.S.A.

The patient was placed in the prone position with the affected side knee extended. One arm of the goniometer was aligned with the fifth metatarsal and the other arm was aligned with the fibula. Zero degrees was taken as that point where the foot was perpendicular to the leg i.e. that point where the ankle was between dorsi flexion and plantar flexion.

## 3) FOOT VOLUMETRY

Volumetry is used to measure the volume differences in feet which are swollen due to ankle sprains. Foot volumetry was done on both feet at all consultations in order to use the unaffected foot as a baseline to which the affected foot is compared.

Volumetry readings were taken on each consultation according to the technique tested by Goldie, Gunterberg and Jacobson (1974).

The apparatus consists of a plastic tank with a built in outlet for spill water. The outlet was an L- formed plastic pipe connected to a rubber tube on the outside of the tank which allowed the water run off to be collected. The patient was instructed to hold his heel close to the side with his calf in contact with the wall in order to obtain the same position for each individual measurement. The volume of water displaced was weighed and the readings were therefor given in milligrams. The reading of the affected foot was subtracted from the reading of the normal foot in order to determine the difference between the two feet; this difference was used for statistical analysis (Goldie, Gunterberg and Jacobson 1974).

### 3.4 THE LOCATION OF DATA

The primary data was obtained from the Short-form McGill Pain Questionnaire, the NRS-101, the algometer readings, the goniometer readings and foot volumetry. Data was collected at all three consults. All consultations took place at the Technikon Natal Chiropractic Day Clinic.

The secondary data was obtained from journals and text books.

### 3.5 STATISTICAL ANALYSIS

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

#### 3.5.1 TREATMENT OF THE DATA

1. The scores for the NRS- 101 were represented as a percentage.
2. The scores for the McGill Short -form Pain Questionnaire were represented as a ratio.
3. The Algometer Pain Threshold readings were represented in kilograms per squared centimeter.
4. The Goniometer Range of Motion readings were represented in degrees.
5. The Foot Volumetry readings were represented in milligrams.
6. Statistical analyses were performed once all the data were collected.

#### 3.5.2 METHODS OF DATA ANALYSIS

The sample size of this group was small (15 per group), therefore non-parametric tests were used in the analysis of data. These tests included the Wilcoxon's Signed Rank Test for intra- group analysis and the Mann Whitney U-

test for inter- group analysis(Portney and Watkins 1993 : 351 - 352).

### **3.5.2.1 COMPARISON BETWEEN RELATED SAMPLES WITHIN EACH GROUP**

The **Wilcoxon Signed Rank Test** was used at a 5% level of significance to determine whether any statistically significant differences occurred within each group.

The one tailed Wilcoxon Signed Rank Test was used to determine whether or not there were any improvements between the first and second consultation and the first and third consultation with respect to the Numerical Pain Rating Scale, McGill Short-form Pain Questionnaire, the goniometer readings, the algometer readings and the volumetry readings.

The two tailed Wilcoxon Signed Rank Test was used to determine whether or not there was any difference between the readings obtained from the normal and the sprained ankle for each consultation with respect to the goniometer and algometer readings.

### **Hypothesis Testing and the Decision Rule for the one tailed Wilcoxon Signed Rank Test**

The null hypothesis ( $H_0$ ) was the same for both groups, it is stated below:

**$H_0$ :** There is no improvement between consultations.

The alternative hypothesis ( $H_a$ ) is the same for both groups and is described below:

**$H_a$ :** There is an improvement between consultations.

### **The Analyzed Data and the P-value**

The **P value** (level of statistical significance) is acquired in order to further interpret the results from data collected once in a spread sheet format. The P value is defined as the probability of obtaining an outcome as or more extreme than that observed in the study if the null hypothesis were true, if the P value is low we might decide to reject the null hypothesis as incorrect (Coggon, 1995:

66). The data was analyzed at the  $\alpha = 0.05$  level and the decision rule was applied as follows:

Reject the null hypothesis if the P-value is  $\leq \alpha$

Accept the null hypothesis if the P-value is  $> \alpha$

The actual P-value for the one tailed Wilcoxon Test in the SPSS statistical package differs from that value reported on the tables and is determined using the following formula:

$$P = \frac{\text{Reported P - value}}{2} \quad \text{if} \quad \begin{cases} \text{Ha is of a form } > \text{ and Z is positive} \\ \text{Ha is of a form } < \text{ and Z is negative} \end{cases}$$

$$P = 1 - \left( \frac{\text{Reported P - value}}{2} \right) \quad \text{if} \quad \begin{cases} \text{Ha is of a form } > \text{ and Z is negative} \\ \text{Ha is of a form } < \text{ and Z is positive} \end{cases}$$

### Hypothesis Testing and the Decision Rule for the two tailed Wilcoxon Signed Rank Test

The null hypothesis ( $H_0$ ) was the same for both groups, it is stated below:

**$H_0$ :** There is no difference between related data within each group for each consultation.

The alternative hypothesis ( $H_a$ ) is the same for both groups and is described below:

**$H_a$ :** There is a difference between related data within each group for each consultation.

### The Analyzed Data and the P-value

The data was analyzed at the  $\alpha = 0.05$  level and the decision rule was applied as follows:

Reject the null hypothesis if the P-value is  $\leq \alpha$

Accept the null hypothesis if the P-value is  $> \alpha$

### 3.5.2.2 COMPARISON BETWEEN THE TWO GROUPS

The **Mann-Whitney Test** was used at a 5% level of significance to determine whether any statistically significant differences occurred between each group for each consultation with respect to the Numerical Pain Rating Scale, McGill Short-form Pain Questionnaire, the goniometer readings, the algometer readings and the volumetry readings.

#### Hypothesis Testing and the Decision Rule

Integrating the data from the two groups required a further null hypothesis and an alternative hypothesis described below:

**H<sub>0</sub>:** There is no difference between the two groups.

**H<sub>a</sub>:** There is a difference between the two groups.

#### The Analyzed Data and the P-value

The data was analyzed at the  $\alpha = 0.05$  level and the decision rule was applied as follows:

Reject the null hypothesis if the P-value is  $\leq \alpha$

Accept the null hypothesis if the P-value is  $> \alpha$



## CHAPTER 4: THE RESULTS

### 4.1 INTRODUCTION

This chapter deals with the results accompanied by relevant interpretations obtained after statistically analyzing the data from the measurement criteria utilized namely:

- the Numerical Pain Rating Scale-101
- the Short-form McGill Pain Questionnaire
- the goniometer readings
- the algometer readings
- foot volumetry.

### 4.2 CRITERIA GOVERNING THE ADMISSIBILITY OF DATA

Data collected from patients who met with the criteria of the study was used. Only responses to the Numerical Pain Rating Scale-101 and Short-form McGill Pain Questionnaire completed under the researchers' supervision were utilized. Similarly, only the algometer readings, goniometer readings and foot volumetry readings taken by the researcher were used.

### 4.3 TABLES OF DEMOGRAPHIC DATA

TABLE 4.1 Age distribution

AGE	PROTEASE GROUP	PIROXICAM GROUP	TOTAL % OF PATIENTS
15-24	10	6	53.3
25-34	4	7	36.7
35-44	1	1	6.7
45-54			
55-65		1	3.3

TABLE 4.2 Gender distribution

GENDER	PROTEASE GROUP	PIROXICAM GROUP	TOTAL % OF PATIENTS
Male	9	10	63.3
Female	6	5	36.6

TABLE 4.3 Race distribution

RACE	PROTEASE GROUP	PIROXICAM GROUP	TOTAL % OF PATIENTS
Caucasian	9	9	60
Asian	1	1	6.7
Black	5	5	33.3

TABLE 4.4 Activity leading to injury

ACTIVITY	PROTEASE GROUP	PIROXICAM GROUP
Hockey	2	1
Soccer	2	2
Rugby	1	2
Netball	2	1
Cricket		1
Running	1	1
Squash	1	
Skateboarding		1
Surfing	1	
Karate	1	
High Heel Shoes	2	2
Other	2	4

## 4.4 TABLES OF STATISTICAL RESULTS

### 4.4.1 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES OF THE PROTEASE GROUP

**TABLE 4.5** Statistical results of the Numerical Rating Scale-101 comparing the first and second visits of the Protease group.

#### WILCOXON SIGNED RANKS TEST

#### RANKS

NRS SCORES FOR CONSULT 2 - NRS SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	13	7.96	103.5
	+VE RANKS	1	1.5	1.5
	TIES	1		
	TOTAL	15		

Negative ranks(-ve ranks) = NRS scores for consultation 2 < NRS scores for consultation 1

Positive ranks (+ve ranks) = NRS scores for consultation 2 > NRS scores for consultation 1

Ties = NRS scores for consultation 2 = NRS scores for consultation 1

**TEST STATISTICS**

	NRS SCORES FOR CONSULT 2 - NRS SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.205</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Numerical Rating Scale-101 indicating an improvement between the first and second visits in the Protease group.

**TABLE 4.6** Statistical results of the Numerical Rating Scale-101 comparing the first and third visits of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

NRS SCORES FOR CONSULT 3 - NRS SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	14	7.5	105
	+VE RANKS	0	0	0
	TIES	1		
	TOTAL	15		

Negative ranks(-ve ranks) = NRS scores for consultation 3 < NRS scores for consultation 1

Positive ranks (+ve ranks) = NRS scores for consultation 3 > NRS scores for consultation 1

Ties = NRS scores for consultation 3 = NRS scores for consultation 1

**TEST STATISTICS**

	NRS SCORES FOR CONSULT 3 - NRS SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.297</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Numerical Rating Scale-101 indicating an improvement between the first and third visits in the Protease group.

**TABLE 4.7** Statistical results of the Short form McGill Pain Questionnaire  
comparing the first and second visits of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

McGILL SCORES FOR CONSULT 2 - McGill SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	13	7.92	103
	+VE RANKS	1	2	2
	TIES	1		
	TOTAL	15		

Negative ranks(-ve ranks) = McGill scores for consultation 2 < McGill scores for consultation 1

Positive ranks (+ve ranks) = McGill scores for consultation 2 > McGill scores for consultation 1

Ties = McGill scores for consultation 2 = McGill scores for consultation 1

**TEST STATISTICS**

	McGILL SCORES FOR CONSULT 2 - McGILL SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.178</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Short form McGill Pain Questionnaire indicating an improvement between the first and second visits in the Protease group.



**TABLE 4.8** Statistical results of the Short form McGill Pain Questionnaire  
comparing the first and third visits of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

McGILL SCORES FOR CONSULT 3 - McGill SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	13	7.96	103.5
	+VE RANKS	1	1.5	1.5
	TIES	1		
	TOTAL	15		

Negative ranks(-ve ranks) = McGill scores for consultation 3 < McGill scores for consultation 1

Positive ranks (+ve ranks) = McGill scores for consultation 3 > McGill scores for consultation 1

Ties = McGill scores for consultation 3 = McGill scores for consultation 1

**TEST STATISTICS**

	McGILL SCORES FOR CONSULT 3 - McGILL SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.21</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Short form McGill Pain Questionnaire indicating an improvement between the first and third visits in the Protease group.

#### 4.4.2 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES OF THE PIROXICAM GROUP

**TABLE 4.9** Statistical results of the Numerical Rating Scale-101 comparing the first and second visits of the Piroxicam group.

##### WILCOXON SIGNED RANKS TEST

RANKS				
NRS SCORES FOR CONSULT 2 - NRS SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	15	8	120
	+VE RANKS	0		
	TIES	0		
	TOTAL	15		

Negative ranks(-ve ranks) = NRS scores for consultation 2 < NRS scores for consultation 1

Positive ranks (+ve ranks) = NRS scores for consultation 2 > NRS scores for consultation 1

Ties = NRS scores for consultation 2 = NRS scores for consultation 1

**TEST STATISTICS**

	NRS SCORES FOR CONSULT 2 - NRS SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.409</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Numerical Rating Scale-101 indicating an improvement between the first and second visits in the Piroxicam group.

**TABLE 4.10** Statistical results of the Numerical Rating Scale-101 comparing the first and third visits of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

NRS SCORES FOR CONSULT 3 - NRS SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	15	8	120
	+VE RANKS	0	0	0
	TIES	0		
	TOTAL	15		

Negative ranks(-ve ranks) = NRS scores for consultation 3 < NRS scores for consultation 1

Positive ranks (+ve ranks) = NRS scores for consultation 3 > NRS scores for consultation 1

Ties = NRS scores for consultation 3 = NRS scores for consultation 1

**TEST STATISTICS**

	NRS SCORES FOR CONSULT 3 - NRS SCORES FOR CONSULT 1
Z - VALUE (based on positive ranks)	-3.411
P - VALUE	0.001

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Numerical Rating Scale-101 indicating an improvement between the first and third visits in the Piroxicam group.

**TABLE 4.11** Statistical results of the Short form McGill Pain Questionnaire  
comparing the first and second visits of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

McGILL SCORES FOR CONSULT 2 - McGill SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	15	8	120
	+VE RANKS	0	0	0
	TIES	0		
	TOTAL	15		

Negative ranks(-ve ranks) = McGill scores for consultation 2 < McGill scores for consultation 1

Positive ranks (+ve ranks) = McGill scores for consultation 2 > McGill scores for consultation 1

Ties = McGill scores for consultation 2 = McGill scores for consultation 1

**TEST STATISTICS**

	McGILL SCORES FOR CONSULT 2 - McGILL SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.413</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Short form McGill Pain Questionnaire indicating an improvement between the first and second visits in the Piroxicam group.



**TABLE 4.12** Statistical results of the Short form McGill Pain Questionnaire  
comparing the first and third visits of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

McGILL SCORES FOR CONSULT 3 - McGill SCORES FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	15	8	120
	+VE RANKS	0	0	0
	TIES	0		
	TOTAL	15		

Negative ranks(-ve ranks) = McGill scores for consultation 3 < McGill scores for consultation 1

Positive ranks (+ve ranks) = McGill scores for consultation 3 > McGill scores for consultation 1

Ties = McGill scores for consultation 3 = McGill scores for consultation 1

**TEST STATISTICS**

	McGILL SCORES FOR CONSULT 3 - McGill SCORES FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.408</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the Short form McGill Pain Questionnaire indicating an improvement between the first and third visits in the Piroxicam group.

### 4.4.3 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES IN THE PROTEASE GROUP

**TABLE 4.13** Statistical results of the algometer threshold readings comparing the sprained ankle to the normal ankle for visit one of the Protease group.

#### WILCOXON SIGNED RANKS TEST

#### RANKS

ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	13	7	91
	+VE RANKS	0	0	0
	TIES	2		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings of sprained ankle for consultation 1 < Algometer readings of normal ankle for consultation 1

Positive ranks (+ve ranks) = Algometer readings of sprained ankle for consultation 1 > Algometer readings of normal ankle for consultation 1

Ties = Algometer readings of sprained ankle for consultation 1 = Algometer readings of normal ankle for consultation 1

**TEST STATISTICS**

	ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.184</b>
<b>P - VALUE</b>	<b>0.001</b>

The null hypothesis was rejected for the algometer threshold readings indicating a difference between the normal and sprained ankle in the Protease group for the first visit.

**TABLE 4.14** Statistical results of the algometer threshold readings comparing the sprained ankle to the normal ankle for visit two of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	11	6	66
	+VE RANKS	0	0	0
	TIES	4		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings of sprained ankle for consultation 2 < Algometer readings of normal ankle for consultation 2

Positive ranks (+ve ranks) = Algometer readings of sprained ankle for consultation 2 > Algometer readings of normal ankle for consultation 2

Ties = Algometer readings of sprained ankle for consultation 2 = Algometer readings of normal ankle for consultation 2

**TEST STATISTICS**

	ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.944</b>
<b>P - VALUE</b>	<b>0.003</b>

The null hypothesis was rejected for the algometer threshold readings indicating a difference between the normal and sprained ankle in the Protease group for the second visit.

**TABLE 4.15** Statistical results of the algometer threshold readings comparing the sprained ankle to the normal ankle for visit three of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	10	5.5	55
	+VE RANKS	0	0	0
	TIES	5		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings of sprained ankle for consultation 3 < Algometer readings of normal ankle for consultation 3

Positive ranks (+ve ranks) = Algometer readings of sprained ankle for consultation 3 > Algometer readings of normal ankle for consultation 3

Ties = Algometer readings of sprained ankle for consultation 3 = Algometer readings of normal ankle for consultation 3

**TEST STATISTICS**

	ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3
Z - VALUE (based on positive ranks)	-2.825
P - VALUE	0.005

The null hypothesis was rejected for the algometer threshold readings indicating a difference between the normal and sprained ankle in the Protease group for the third visit.



**TABLE 4.16** Statistical results of the algometer threshold readings comparing the first and second visit of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR CONSULT 2 - ALGOMETER READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	3	4.5	13.5
	+VE RANKS	10	7.75	77.5
	TIES	2		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings for consultation 2 < Algometer readings for consultation 1

Positive ranks (+ve ranks) = Algometer readings for consultation 2 > Algometer readings for consultation 1

Ties = Algometer readings for consultation 2 = Algometer readings for consultation 1

**TEST STATISTICS**

	ALGOMETER READINGS FOR CONSULT 2 - ALGOMETER READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.238</b>
<b>P - VALUE</b>	<b>0.025</b>

**Actual P - value= 0.0125**

The null hypothesis was rejected for the algometer threshold readings indicating an improvement between the first and second visits in the Protease group.

**TABLE 4.17** Statistical results of the algometer threshold readings comparing the first and third visit of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR CONSULT 3 - ALGOMETER READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	0	0	0
	+VE RANKS	14	7.5	105
	TIES	1		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings for consultation 3 < Algometer readings for consultation 1

Positive ranks (+ve ranks) = Algometer readings for consultation 3 > Algometer readings for consultation 1

Ties = Algometer readings for consultation 3 = Algometer readings for consultation 1

**TEST STATISTICS**

	ALGOMETER READINGS FOR CONSULT 3 - ALGOMETER READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.299</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value= 0.0005**

The null hypothesis was rejected for the algometer threshold readings indicating an improvement between the first and third visits in the Protease group.

**TABLE 4.18** Statistical results of the goniometer readings comparing the sprained ankle to the normal ankle for visit one of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	13	7	91
	+VE RANKS	0	0	0
	TIES	2		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings of sprained ankle for consultation 1 < Goniometer readings of normal ankle for consultation 1

Positive ranks (+ve ranks) = Goniometer readings of sprained ankle for consultation 1 > Goniometer readings of normal ankle for consultation 1

Ties = Goniometer readings of sprained ankle for consultation 1 = Goniometer readings of normal ankle for consultation 1

**TEST STATISTICS**

	GONIOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 1
Z - VALUE (based on positive ranks)	-3.191
P - VALUE	0.001

The null hypothesis was rejected for the goniometer readings indicating a difference between the normal and sprained ankle in the Protease group for the first visit.

**TABLE 4.19** Statistical results of the goniometer readings comparing the sprained ankle to the normal ankle for visit two of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	11	6	66
	+VE RANKS	0	0	0
	TIES	4		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings of sprained ankle for consultation 2 < Goniometer readings of normal ankle for consultation 2

Positive ranks (+ve ranks) = Goniometer readings of sprained ankle for consultation 2 > Goniometer readings of normal ankle for consultation 2

Ties = Goniometer readings of sprained ankle for consultation 2 = Goniometer readings of normal ankle for consultation 2

**TEST STATISTICS**

	GONIOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.952</b>
<b>P - VALUE</b>	<b>0.003</b>

The null hypothesis was rejected for the goniometer readings indicating a difference between the normal and sprained ankle in the Protease group for the second visit.



**TABLE 4.20** Statistical results of the goniometer readings comparing the sprained ankle to the normal ankle for visit three of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	7	4.79	33.5
	+VE RANKS	1	2.5	2.5
	TIES	7		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings of sprained ankle for consultation 3 < Goniometer readings of normal ankle for consultation 3

Positive ranks (+ve ranks) = Goniometer readings of sprained ankle for consultation 3 > Goniometer readings of normal ankle for consultation 3

Ties = Goniometer readings of sprained ankle for consultation 3 = Goniometer readings of normal ankle for consultation 3

**TEST STATISTICS**

	GONIOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.2</b>
<b>P - VALUE</b>	<b>0.028</b>

The null hypothesis was rejected for the goniometer readings indicating a difference between the normal and sprained ankle in the Protease group for the third visit.

**TABLE 4.21** Statistical results of the goniometer readings comparing the first and second visit of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR CONSULT 2 - GONIOMET READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	1	1.5	1.5
	+VE RANKS	9	5.94	53.5
	TIES	5		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings for consultation 2 <

Goniometer readings for consultation 1

Positive ranks (+ve ranks) = Goniometer readings for consultation 2 >

Goniometer readings for consultation 1

Ties = Goniometer readings for consultation 2 =

Goniometer readings for consultation 1

**TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 2 - GONIOMETER READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.666</b>
<b>P - VALUE</b>	<b>0.008</b>

**Actual P - value=0.004**

The null hypothesis was rejected for the goniometer readings indicating an improvement between the first and second visits in the Protease group.

**TABLE 4.22** Statistical results of the goniometer readings comparing the first and third visit of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR CONSULT 3 - GONIOMET READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	0	0	0
	+VE RANKS	13	7	91
	TIES	2		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings for consultation 3 <

Goniometer readings for consultation 1

Positive ranks (+ve ranks) = Goniometer readings for consultation 3 >

Goniometer readings for consultation 1

Ties = Goniometer readings for consultation 3 =

Goniometer readings for consultation 1

**TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 3 - GONIOMETER READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.203</b>
<b>P - VALUE</b>	<b>0.001</b>

**Actual P - value=0.0005**

The null hypothesis was rejected for the goniometer readings indicating an improvement between the first and third visits in the Protease group.

**TABLE 4.23** Statistical results of the foot volumetry readings comparing the first and second visit of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

VOLUMETRY READINGS		N	MEAN RANK	SUM OF RANKS
FOR CONSULT 2 -	-VE RANKS	9	8.56	77
VOLUMETRY	+VE RANKS	6	7.17	43
READINGS	TIES	0		
FOR CONSULT 1	TOTAL	15		

Negative ranks(-ve ranks) = Volumetry readings for consultation 2 < Volumetry readings for consultation 1

Positive ranks (+ve ranks) = Volumetry readings for consultation 2 > Volumetry readings for consultation 1

Ties = Volumetry readings for consultation 2 = Volumetry readings for consultation 1

**TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 2 - VOLUMETRY READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-0.966</b>
<b>P - VALUE</b>	<b>0.334</b>

The null hypothesis was accepted for the foot volumetry readings indicating no improvement between the first and second visits in the Protease group.



**TABLE 4.24** Statistical results of the foot volumetry readings comparing the first and third visit of the Protease group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

VOLUMETRY READINGS FOR CONSULT 3 - VOLUMETRY READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	11	8.73	96
	+VE RANKS	4	6	24
	TIES	0		
	TOTAL	15		

Negative ranks(-ve ranks) = Volumetry readings for consultation 3 < Volumetry readings for consultation 1

Positive ranks (+ve ranks) = Volumetry readings for consultation 3 > Volumetry readings for consultation 1

Ties = Volumetry readings for consultation 3 = Volumetry readings for consultation 1

**TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 3 - VOLUMETRY READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.045</b>
<b>P - VALUE</b>	<b>0.041</b>

**Actual P - value= 0.0205**

The null hypothesis was rejected for the foot volumetry readings indicating an improvement between the first and third visits in the Protease group.

#### 4.4.4 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES IN THE PIROXICAM GROUP

**TABLE 4.25** Statistical results of the algometer threshold readings comparing the sprained ankle to the normal ankle for visit one of the Piroxicam group.

##### WILCOXON SIGNED RANKS TEST

##### RANKS

ALGOMETER READINGS		N	MEAN RANK	SUM OF RANKS
FOR	-VE RANKS	13	7	91
SPRAINED -	+VE RANKS	0	0	0
NORMAL	TIES	2		
ANKLE FOR CONSULT 1	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings of sprained ankle for consultation 1 < Algometer readings of normal ankle for consultation 1

Positive ranks (+ve ranks) = Algometer readings of sprained ankle for consultation 1 > Algometer readings of normal ankle for consultation 1

Ties = Algometer readings of sprained ankle for consultation 1 = Algometer readings of normal ankle for consultation 1

**TEST STATISTICS**

	ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.185</b>
<b>P - VALUE</b>	<b>0.001</b>

The null hypothesis was rejected for the algometer threshold readings indicating a difference between the normal and sprained ankle in the Piroxicam group for the first visit.

**TABLE 4.26** Statistical results of the algometer threshold readings comparing the sprained ankle to the normal ankle for visit two of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	12	6.5	78
	+VE RANKS	0	0	0
	TIES	3		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings of sprained ankle for consultation 2 < Algometer readings of normal ankle for consultation 2

Positive ranks (+ve ranks) = Algometer readings of sprained ankle for consultation 2 > Algometer readings of normal ankle for consultation 2

Ties = Algometer readings of sprained ankle for consultation 2 = Algometer readings of normal ankle for consultation 2

**TEST STATISTICS**

	ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.074</b>
<b>P - VALUE</b>	<b>0.002</b>

The null hypothesis was rejected for the algometer threshold readings indicating a difference between the normal and sprained ankle in the Piroxicam group for the second visit.

**TABLE 4.27** Statistical results of the algometer threshold readings comparing the sprained ankle to the normal ankle for visit three of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	11	7.91	87
	+VE RANKS	2	2	4
	TIES	2		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings of sprained ankle for consultation 3 < Algometer readings of normal ankle for consultation 3

Positive ranks (+ve ranks) = Algometer readings of sprained ankle for consultation 3 > Algometer readings of normal ankle for consultation 3

Ties = Algometer readings of sprained ankle for consultation 3 = Algometer readings of normal ankle for consultation 3

**TEST STATISTICS**

	ALGOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.924</b>
<b>P - VALUE</b>	<b>0.003</b>

The null hypothesis was rejected for the algometer threshold readings indicating a difference between the normal and sprained ankle in the Piroxicam group for the third visit.



**TABLE 4.28** Statistical results of the algometer threshold readings comparing the first and second visit of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR CONSULT 2 - ALGOMETER READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	3	4.17	12.5
	+VE RANKS	10	7.85	78.5
	TIES	2		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings for consultation 2 < Algometer readings for consultation 1

Positive ranks (+ve ranks) = Algometer readings for consultation 2 > Algometer readings for consultation 1

Ties = Algometer readings for consultation 2 = Algometer readings for consultation 1

**TEST STATISTICS**

	ALGOMETER READINGS FOR CONSULT 2 - ALGOMETER READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.308</b>
<b>P - VALUE</b>	<b>0.021</b>

**Actual P - value= 0.0105**

The null hypothesis was rejected for the algometer threshold readings indicating an improvement between the first and second visits in the Piroxicam group.

**TABLE 4.29** Statistical results of the algometer threshold readings comparing the first and third visit of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

ALGOMETER READINGS FOR CONSULT 3 - ALGOMETER READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	2	2	4
	+VE RANKS	12	8.42	101
	TIES	1		
	TOTAL	15		

Negative ranks(-ve ranks) = Algometer readings for consultation 3 < Algometer readings for consultation 1

Positive ranks (+ve ranks) = Algometer readings for consultation 3 > Algometer readings for consultation 1

Ties = Algometer readings for consultation 3 = Algometer readings for consultation 1

**TEST STATISTICS**

	ALGOMETER READINGS FOR CONSULT 3 - ALGOMETER READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-3.046</b>
<b>P - VALUE</b>	<b>0.002</b>

**Actual P - value= 0.001**

The null hypothesis was rejected for the algometer threshold readings indicating an improvement between the first and second visits in the Piroxicam group.

**TABLE 4.30** Statistical results of the goniometer readings comparing the sprained ankle to the normal ankle for visit one of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS		N	MEAN RANK	SUM OF RANKS
FOR	-VE RANKS	11	6	66
SPRAINED -	+VE RANKS	0	0	0
NORMAL	TIES	4		
ANKLE FOR CONSULT 1	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings of sprained ankle for consultation 1 < Goniometer readings of normal ankle for consultation 1

Positive ranks (+ve ranks) = Goniometer readings of sprained ankle for consultation 1 > Goniometer readings of normal ankle for consultation 1

Ties = Goniometer readings of sprained ankle for consultation 1 = Goniometer readings of normal ankle for consultation 1

**TEST STATISTICS**

	GONIOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.938</b>
<b>P - VALUE</b>	<b>0.003</b>

The null hypothesis was rejected for the goniometer readings indicating a difference between the normal and sprained ankle in the Piroxicam group for the first visit.

**TABLE 4.31** Statistical results of the goniometer readings comparing the sprained ankle to the normal ankle for visit two of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	8	4.5	36
	+VE RANKS	0	0	0
	TIES	7		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings of sprained ankle for consultation 2 < Goniometer readings of normal ankle for consultation 2

Positive ranks (+ve ranks) = Goniometer readings of sprained ankle for consultation 2 > Goniometer readings of normal ankle for consultation 2

Ties = Goniometer readings of sprained ankle for consultation 2 = Goniometer readings of normal ankle for consultation 2

**TEST STATISTICS**

	GONIOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 2
Z - VALUE (based on positive ranks)	-2.527
P - VALUE	0.012

The null hypothesis was rejected for the goniometer readings indicating a difference between the normal and sprained ankle in the Piroxicam group for the second visit.



**TABLE 4.32** Statistical results of the goniometer readings comparing the sprained ankle to the normal ankle for visit three of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS		N	MEAN RANK	SUM OF RANKS
FOR	-VE RANKS	6	3.5	21
SPRAINED -	+VE RANKS	0	0	0
NORMAL	TIES	9		
ANKLE FOR CONSULT 3	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings of sprained ankle for consultation 3 < Goniometer readings of normal ankle for consultation 3

Positive ranks (+ve ranks) = Goniometer readings of sprained ankle for consultation 3 > Goniometer readings of normal ankle for consultation 3

Ties = Goniometer readings of sprained ankle for consultation 3 = Goniometer readings of normal ankle for consultation 3

**TEST STATISTICS**

	GONIOMETER READINGS FOR SPRAINED - NORMAL ANKLE FOR CONSULT 3
<b>Z - VALUE</b> (based on positive ranks)	<b>-2.232</b>
<b>P - VALUE</b>	<b>0.026</b>

The null hypothesis was rejected for the goniometer readings indicating a difference between the normal and sprained ankle in the Piroxicam group for the third visit.

**TABLE 4.33** Statistical results of the goniometer readings comparing the first and second visit of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR CONSULT 2 - GONIOMET READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	2	2.5	5
	+VE RANKS	5	4.6	23
	TIES	8		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings for consultation 2 <  
Goniometer readings for consultation 1

Positive ranks (+ve ranks) = Goniometer readings for consultation 2 >  
Goniometer readings for consultation 1

Ties = Goniometer readings for consultation 2 =  
Goniometer readings for consultation 1

**TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 2 - GONIOMETER READINGS FOR CONSULT 1
Z - VALUE (based on positive ranks)	-1.524
P - VALUE	0.128

**Actual P - value= 0.064**

The null hypothesis was accepted for the goniometer readings indicating no improvement between the first and second visits in the Piroxicam group.

**TABLE 4.34** Statistical results of the goniometer readings comparing the first and third visit of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

GONIOMET READINGS FOR CONSULT 3 - GONIOMET READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	0	0	0
	+VE RANKS	10	5.5	55
	TIES	5		
	TOTAL	15		

Negative ranks(-ve ranks) = Goniometer readings for consultation 3 <

Goniometer readings for consultation 1

Positive ranks (+ve ranks) = Goniometer readings for consultation 3 >

Goniometer readings for consultation 1

Ties = Goniometer readings for consultation 3 =

Goniometer readings for consultation 1

**TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 3 - GONIOMETER READINGS FOR CONSULT 1
Z - VALUE (based on positive ranks)	-2.809
P - VALUE	0.005

**Actual P - value= 0.0025**

The null hypothesis was rejected for the goniometer readings indicating a improvement between the first and third visits in the Piroxicam group.

**TABLE 4.35** Statistical results of the foot volumetry readings comparing the first and second visit of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

VOLUMETRY READINGS		N	MEAN RANK	SUM OF RANKS
FOR CONSULT 2 -	-VE RANKS	10	8	80
VOLUMETRY	+VE RANKS	5	8	40
READINGS	TIES	0		
FOR CONSULT 1	TOTAL	15		

Negative ranks(-ve ranks) = Volumetry readings for consultation 2 < Volumetry readings for consultation 1

Positive ranks (+ve ranks) = Volumetry readings for consultation 2 > Volumetry readings for consultation 1

Ties = Volumetry readings for consultation 2 = Volumetry readings for consultation 1

**TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 2 - VOLUMETRY READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-1.136</b>
<b>P - VALUE</b>	<b>0.256</b>

**Actual P - value= 0.128**

The null hypothesis was accepted for the foot volumetry readings indicating no improvement between the first and second visits in the Piroxicam group.



**TABLE 4.36** Statistical results of the foot volumetry readings comparing the first and third visit of the Piroxicam group.

**WILCOXON SIGNED RANKS TEST**

**RANKS**

VOLUMETRY READINGS FOR CONSULT 3 - VOLUMETRY READINGS FOR CONSULT 1		N	MEAN RANK	SUM OF RANKS
	-VE RANKS	11	8.45	93
	+VE RANKS	4	6.75	27
	TIES	0		
	TOTAL	15		

Negative ranks(-ve ranks) = Volumetry readings for consultation 3 < Volumetry readings for consultation 1

Positive ranks (+ve ranks) = Volumetry readings for consultation 3 > Volumetry readings for consultation 1

Ties = Volumetry readings for consultation 3 = Volumetry readings for consultation 1

**TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 3 - VOLUMETRY READINGS FOR CONSULT 1
<b>Z - VALUE</b> (based on positive ranks)	<b>-1.874</b>
<b>P - VALUE</b>	<b>0.061</b>

**Actual P - value= 0.0305**

The null hypothesis was rejected for the foot volumetry indicating an improvement between the first and third visits in the Piroxicam group.

#### 4.4.5 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES FOR THE FIRST VISIT FOR THE PROTEASE AND PIROXICAM GROUPS

**TABLE 4.37** Statistical results of the Numerical Rating Scale-101 comparing the first visit for the Protease and Piroxicam groups.

##### MANN-WHITNEY TEST

##### RANKS

NRS SCORES FOR CONSULT 1	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	12.87	193
	PIROXICAM	15	18.13	272
	TOTAL	30		

##### TEST STATISTICS

	NRS SCORES FOR CONSULT 1
MANN-WHITNEY U	73
WILCOXON W	193
Z - VALUE	-1.648
P - VALUE	0.099

The null hypothesis was accepted for the Numerical Rating Scale-101 indicating no difference between the Protease and Piroxicam groups for consultation one.

**TABLE 4.38** Statistical results of the McGill Pain Questionnaire comparing the first visit for the Protease and Piroxicam groups.

**MANN-WHITNEY TEST**

**RANKS**

McGill SCORES FOR CONSULT 1	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	11.17	167.5
	PIROXICAM	15	19.83	297.5
	TOTAL	30		

**TEST STATISTICS**

	McGill SCORES FOR CONSULT 1
<b>MANN-WHITNEY U</b>	<b>47.5</b>
<b>WILCOXON W</b>	<b>167.5</b>
<b>Z - VALUE</b>	<b>-2.703</b>
<b>P - VALUE</b>	<b>0.007</b>

The null hypothesis was rejected for the McGill Pain Questionnaire indicating a difference between the Protease and Piroxicam groups for consultation one.

#### 4.4.6 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES FOR THE SECOND VISIT FOR THE PROTEASE AND PIROXICAM GROUPS

**TABLE 4.39** Statistical results of the Numerical Rating Scale-101 comparing the second visit for the Protease and Piroxicam groups.

##### MANN-WHITNEY TEST

##### RANKS

NRS SCORES FOR CONSULT 2	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.53	218
	PIROXICAM	15	16.47	247
	TOTAL	30		

##### TEST STATISTICS

	NRS SCORES FOR CONSULT 2
MANN-WHITNEY U	98
WILCOXON W	218
Z - VALUE	-0.606
P - VALUE	0.545

The null hypothesis was accepted for the Numerical Rating Scale-101 indicating no difference between the Protease and Piroxicam groups for consultation two.

**TABLE 4.40** Statistical results of the McGill Pain Questionnaire comparing the second visit for the Protease and Piroxicam groups.

**MANN-WHITNEY TEST**

**RANKS**

McGill SCORES FOR CONSULT 2	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.2	213
	PIROXICAM	15	16.8	252
	TOTAL	30		

**TEST STATISTICS**

	McGill SCORES FOR CONSULT 2
<b>MANN-WHITNEY U</b>	<b>93</b>
<b>WILCOXON W</b>	<b>213</b>
<b>Z - VALUE</b>	<b>-0.816</b>
<b>P - VALUE</b>	<b>0.414</b>

The null hypothesis was accepted for the McGill Pain Questionnaire indicating no difference between the Protease and Piroxicam groups for consultation two.

#### 4.4.7 STATISTICAL RESULTS COMPARING THE SUBJECTIVE MEASURES FOR THE THIRD VISIT FOR THE PROTEASE AND PIROXICAM GROUP

**TABLE 4.41** Statistical results of the Numerical Rating Scale-101 comparing the third visit for the Protease and Piroxicam groups.

##### MANN-WHITNEY TEST

##### RANKS

NRS SCORES FOR CONSULT 3	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	15.7	235.5
	PIROXICAM	15	15.3	229.5
	TOTAL	30		

##### TEST STATISTICS

	NRS SCORES FOR CONSULT 3
MANN-WHITNEY U	109.5
WILCOXON W	229.5
Z - VALUE	-0.126
P - VALUE	0.902

The null hypothesis was accepted for the Numerical Rating Scale-101 indicating no difference between the Protease and Piroxicam groups for consultation three.

**TABLE 4.42** Statistical results of the McGill Pain Questionnaire comparing the third visit for the Protease and Piroxicam groups.

### MANN-WHITNEY TEST

#### RANKS

McGill SCORES FOR CONSULT 3	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.43	216.5
	PIROXICAM	15	16.57	248.5
	TOTAL	30		

### TEST STATISTICS

	McGill SCORES FOR CONSULT 3
MANN-WHITNEY U	96.5
WILCOXON W	216.5
Z - VALUE	-0.688
P - VALUE	0.492

The null hypothesis was accepted for the McGill Pain Questionnaire indicating no difference between the Protease and Piroxicam groups for consultation three.



#### 4.4.8 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES FOR THE FIRST VISIT FOR THE PROTEASE AND PIROXICAM GROUP

**TABLE 4.43** Statistical results of the Algometer Threshold readings comparing the first visit for the Protease and Piroxicam groups.

##### MANN-WHITNEY TEST

##### RANKS

ALGOMETER SCORES FOR CONSULT 1	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14	210
	PIROXICAM	15	17	255
	TOTAL	30		

##### TEST STATISTICS

	ALGOMETER SCORES FOR CONSULT 1
MANN-WHITNEY U	90
WILCOXON W	210
Z - VALUE	-0.961
P - VALUE	0.337

The null hypothesis was accepted for the Algometer Threshold readings indicating no difference between the Protease and Piroxicam groups for consultation one.

**TABLE 4.44** Statistical results of the Goniometer readings comparing the first visit for the Protease and Piroxicam groups.

**MANN-WHITNEY TEST**

**RANKS**

GONIOMET READINGS FOR CONSULT 1	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.07	211
	PIROXICAM	15	16.93	254
	TOTAL	30		

**TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 1
MANN-WHITNEY U	91
WILCOXON W	211
Z - VALUE	-0.902
P - VALUE	0.367

The null hypothesis was accepted for the Goniometer readings indicating no difference between the Protease and Piroxicam groups for consultation one.

**TABLE 4.45** Statistical results of the Foot Volumetry readings comparing the first visit for the Protease and Piroxicam groups.

**MANN-WHITNEY TEST**

**RANKS**

VOLUMETRY READINGS FOR CONSULT 1	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	13.83	207.5
	PIROXICAM	15	17.17	257.5
	TOTAL	30		

**TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 1
<b>MANN-WHITNEY U</b>	<b>87.5</b>
<b>WILCOXON W</b>	<b>207.5</b>
<b>Z - VALUE</b>	<b>-1.037</b>
<b>P - VALUE</b>	<b>0.3</b>

The null hypothesis was accepted for the Foot Volumetry readings indicating no difference between the Protease and Piroxicam groups for consultation one.

#### 4.4.9 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES FOR THE SECOND VISIT FOR THE PROTEASE AND PIROXICAM GROUP

**TABLE 4.46** Statistical results of the Algometer Threshold readings comparing the second visit for the Protease and Piroxicam groups.

##### MANN-WHITNEY TEST

##### RANKS

ALGOMETER SCORES FOR CONSULT 2	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.13	212
	PIROXICAM	15	16.87	253
	TOTAL	30		

##### TEST STATISTICS

	ALGOMETER SCORES FOR CONSULT 2
MANN-WHITNEY U	92
WILCOXON W	212
Z - VALUE	-0.856
P - VALUE	0.392

The null hypothesis was accepted for the Algometer Threshold readings indicating no difference between the Protease and Piroxicam groups for consultation two.

**TABLE 4.47** Statistical results of the Goniometer readings comparing the second visit for the Protease and Piroxicam groups.

**MANN-WHITNEY TEST**

**RANKS**

GONIOMET READINGS FOR CONSULT 2	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.57	218.5
	PIROXICAM	15	16.43	246.5
	TOTAL	30		

**TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 2
MANN-WHITNEY U	98.5
WILCOXON W	218.5
Z - VALUE	-0.592
P - VALUE	0.554

The null hypothesis was accepted for the Goniometer readings indicating no difference between the Protease and Piroxicam groups for consultation two.

**TABLE 4.48** Statistical results of the Foot Volumetry readings comparing the second visit for the Protease and Piroxicam groups.

# **MANN-WHITNEY TEST**

## **RANKS**

VOLUMETRY READINGS FOR CONSULT 2	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	12.73	191
	PIROXICAM	15	18.27	274
	TOTAL	30		

# **TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 2
MANN-WHITNEY U	71
WILCOXON W	191
Z - VALUE	-1.722
P - VALUE	0.085

The null hypothesis was accepted for the Foot Volumetry readings indicating no difference between the Protease and Piroxicam groups for consultation two.

#### 4.4.1 STATISTICAL RESULTS COMPARING THE OBJECTIVE MEASURES FOR THE THIRD VISIT FOR THE PROTEASE AND PIROXICAM GROUP

**TABLE 4.49** Statistical results of the Algometer Threshold readings comparing the third visit for the Protease and Piroxicam groups.

##### MANN-WHITNEY TEST

##### RANKS

ALGOMETER SCORES FOR CONSULT 3	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.5	217.5
	PIROXICAM	15	16.5	247.5
	TOTAL	30		

##### TEST STATISTICS

	ALGOMETER SCORES FOR CONSULT 3
<b>MANN-WHITNEY U</b>	<b>97.5</b>
<b>WILCOXON W</b>	<b>217.5</b>
<b>Z - VALUE</b>	<b>-0.625</b>
<b>P - VALUE</b>	<b>0.532</b>

The null hypothesis was accepted for the Algometer Threshold readings indicating no difference between the Protease and Piroxicam groups for consultation three.

**TABLE 4.50** Statistical results of the Goniometer readings comparing the third visit for the Protease and Piroxicam groups.

# **MANN-WHITNEY TEST**

## **RANKS**

GONIOMETER READINGS FOR CONSULT 3	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	14.83	222.5
	PIROXICAM	15	16.17	242.5
	TOTAL	30		

# **TEST STATISTICS**

	GONIOMETER READINGS FOR CONSULT 3
<b>MANN-WHITNEY U</b>	<b>102.5</b>
<b>WILCOXON W</b>	<b>222.5</b>
<b>Z - VALUE</b>	<b>-0.433</b>
<b>P - VALUE</b>	<b>0.665</b>

The null hypothesis was accepted for the Goniometer readings indicating no difference between the Protease and Piroxicam groups for consultation three.



**TABLE 4.51** Statistical results of the Foot Volumetry readings comparing the third visit for the Protease and Piroxicam groups.

# **MANN-WHITNEY TEST**

## **RANKS**

VOLUMETRY READINGS FOR CONSULT 3	GROUP	N	MEAN RANK	SUM OF RANKS
	PROTEASE	15	13.33	200
	PIROXICAM	15	17.67	265
	TOTAL	30		

# **TEST STATISTICS**

	VOLUMETRY READINGS FOR CONSULT 3
<b>MANN-WHITNEY U</b>	<b>80</b>
<b>WILCOXON W</b>	<b>200</b>
<b>Z - VALUE</b>	<b>-1.348</b>
<b>P - VALUE</b>	<b>0.178</b>

The null hypothesis was accepted for the Foot Volumetry readings indicating no difference between the Protease and Piroxicam groups for consultation three.

## CHAPTER 5: DISCUSSION OF THE RESULTS

### 5.1 INTRODUCTION

This chapter involves the discussion of results after statistical analysis of the data obtained from the subjective and objective tests.

The results are discussed in two parts, that is, the subjective and objective results. Each measurement parameter is discussed and involves intra and inter group comparison.

Evaluation of the intra-group results of the first and third visits (overall measurement interval) gives an indication of the effectiveness of the treatment regime. The comparison of the first and second visits (first measurement interval) are also evaluated to give an indication of any residual benefits of the treatment. In the case of the algometer and goniometer readings evaluation of the results between the normal and sprained ankle at each consultation gives an indication of the difference between the patient's ankles at the start of the treatment period. Any increase or decrease in this difference during the treatment period will give a further indication of the effectiveness of the treatment regime.

Evaluation of inter-group results of the first consultation will reveal any variance in the subjective and objective findings between the two groups presenting at the

start of the study. The assessment and evaluation of the data from the second consultation will reveal any difference in the rate of improvement between the groups. The comparison of the data collected at the third consultation will indicate the effectiveness of the treatment at the conclusion of the study.

## **5.2 INTRA-GROUP COMPARISON**

### **5.2.1 SUBJECTIVE DATA**

The subjective data is comprised of the results from the Numerical Pain Rating Scale and the McGill Short-form Pain Questionnaire.

The statistical data can be found in tables 4.5, 4.6, 4.9, and 4.10.

#### **5.2.1.1 NUMERICAL PAIN RATING SCALE**

Statistical analysis revealed that both the Protease and the Piroxicam groups showed significant improvements between treatment one and treatment two, and between treatment one and the final treatment. This indicates that the treatments in both groups were effective in reducing the percentage of pain intensity.

### 5.2.1.2 MCGILL SHORT-FORM PAIN QUESTIONNAIRE

Statistical analysis revealed that both the Protease and the Piroxicam groups showed significant improvements between treatment one and treatment two, and between treatment one and the final treatment. This indicates that the treatments in both groups were effective in reducing the quality and intensity of pain.

### 5.2.2 OBJECTIVE DATA

The objective data is comprised of the results from the algometer, goniometer and foot volumetry readings.

The statistical data can be found in tables 4.13 to 4.36.

#### 5.2.2.1 ALGOMETER READINGS

Statistical analysis revealed that in both the Protease and the Piroxicam groups there was a difference between the normal and sprained ankle on the first, second and third consultations with regards to pain threshold. This indicates that the sprained ankle in both groups had a lower pain threshold throughout the treatment period compared to the normal ankle.

Statistical analysis revealed that both the Protease and the Piroxicam groups showed significant improvements between treatment one and treatment two, and between treatment one and the final treatment. This indicates that the treatments in both groups were effective in increasing the pain threshold.

In summary, it is indicated that the treatments in both groups were effective in increasing the pain threshold however there remained a difference in pain threshold between the sprained and the normal ankle throughout the treatment period.

#### 5.2.2.2 GONIOMETER READINGS

Statistical analysis revealed that in both the Protease and the Piroxicam groups there was a difference between the normal and sprained ankle on the first, second and third consultations with regards to ankle dorsi flexion. This indicates that the sprained ankle in both groups had less dorsi flexion throughout the treatment period compared to the normal ankle.

Statistical analysis revealed that in the Protease group there was improvement between treatment one and treatment two, and between treatment one and the final treatment with regards to ankle dorsi flexion. This indicates that the treatment was effective in increasing the ankle dorsi flexion.

Statistical analysis revealed that in the Piroxicam group there was no improvement between treatment one and treatment two however there was an improvement between treatment one and the final treatment with regards to ankle dorsi flexion. This indicates that the treatment was effective in increasing the ankle dorsi flexion.

In summary, it is indicated that the treatments in both groups were effective in increasing the ankle dorsi flexion however there remained a difference in ankle dorsi flexion between the sprained and the normal ankle throughout the treatment period.

#### 5.2.2.3 FOOT VOLUMETRY READINGS

Statistical analysis revealed that both the Protease and the Piroxicam groups showed no improvement between treatment one and treatment two however there was an improvement between treatment one and the final treatment with regards in the swelling of the foot. This indicates that the treatments in both groups were effective in reducing the swelling of the foot.

## **5.3 INTER-GROUP COMPARISON**

### **5.3.1 SUBJECTIVE DATA**

The subjective data is comprised of the results from the Numerical Pain Rating Scale and the McGill Short-form Pain Questionnaire.

The statistical data can be found in tables 4.37 to 4.42.

#### **5.3.1.1 NUMERICAL PAIN RATING SCALE**

Statistical analysis of the Numerical Pain Rating Scale revealed no significant difference between the two groups at any period of time throughout the study. This suggests that both treatment approaches were equally effective in reducing the percentage of pain intensity.

#### **5.3.1.2 MCGILL SHORT-FORM PAIN QUESTIONNAIRE**

Statistical analysis of the McGill Short-form Pain Questionnaire revealed that there was a difference in the quality and intensity of pain between the two groups at the first consultation however there was no difference between the two groups at the second and third consultations. This suggests that both treatment approaches were effective in reducing the percentage of pain intensity.

### **5.3.2 OBJECTIVE DATA**

The objective data is comprised of the results from the algometer, goniometer and foot volumetry readings.

The statistical data can be found in tables 4.43 to 4.51

#### **5.3.2.1 ALGOMETER READINGS**

Statistical analysis of the algometer readings revealed no significant difference between the two groups at any period of time throughout the study. This suggests that both treatment approaches were equally effective in increasing the pain threshold.

#### **5.3.2.2 GONIOMETER READINGS**

Statistical analysis of the goniometer readings revealed no significant difference between the two groups at any period of time throughout the study. This suggests that both treatment approaches were equally effective in increasing ankle dorsi flexion.



### **5.3.2.3 FOOT VOLUMETRY READINGS**

Statistical analysis of the foot volumetry readings revealed no significant difference between the two groups at any period of time throughout the study. This suggests that both treatment approaches were equally effective in reducing the swelling in the foot.

## **5.4 PROBLEMS ENCOUNTERED WITH THE DATA**

### **5.4.1 THE SUBJECTIVE DATA**

Both the Numerical Pain Rating Scale 101 and the Short-form McGill Pain Questionnaire were chosen for this study in order to have two subjective measurements on pain. The examiner felt that the correlation between the results of these two questionnaires suggests that there was no problems with this data.

### **5.4.2 THE OBJECTIVE DATA**

The examiner felt that although the same point was used to take the algometer readings certain factors could affect the outcome namely direction of pressure applied through the shaft of the algometer, skin slack and the emotional state of the patient.

The examiner encountered no problems with the goniometer readings.

The examiner felt that when using foot volumetry as a reading it was almost impossible to rule out many of the factors which may affect swelling either unilaterally or bilaterally. Those factors which affect both feet would have been negated as the reading in each instance was the difference between the normal and affected side. Those factors which affect one of the feet would have swayed the results i.e. a tight shoe worn on the unaffected foot.

## CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

### 6.1 CONCLUSION

The study consisted of 30 patients diagnosed with acute grade 1 or 2 ankle inversion sprains. The patients were randomly allocated into two groups .

Patients were required to attend the clinic 3 times over a period of approximately 1 week. Data was collected on all three visits. All patients received the same management of the ankle sprain with the exception of the trial drugs. Patients were taught how to apply an elastic crepe bandage to the area, which was used at all times for the duration of the study. One group received Protease and one group received Piroxicam.

The results indicated that both groups were effective overall in decreasing the patient's pain perception (NRS-101) and (McGill) however no differences were found between the groups for these subjective measures.

For those objective measurements the results indicate that both groups were effective overall in increasing the pressure pain threshold, increasing the ankle dorsi flexion and decreasing the swelling in the foot. Over the treatment period the pressure pain threshold and ankle dorsi flexion did not recover to the point where values between the normal and affected ankle were equal (due to the nature of the readings this could only be established for the pressure pain

threshold and ankle dorsi flexion). No differences were found between the groups for objective measures.

It was concluded that both treatment protocols were equally effective in the treatment of symptoms and signs found in acute grade 1 or 2 ankle inversion sprains. This study therefore supports the use of Proteases in the treatment of symptoms and signs found in acute grade 1 or 2 ankle inversion sprains in preference to Piroxicam to avoid the negative side effects of non steroidal anti-inflammatory medication.

This treatment may be enhanced by the prescription of appropriate exercises and avoidance of aggravating factors and by the employment of other treatment regimes.

This study may be used as a foundation for further studies comparing the use of Proteases to non steroidal anti-inflammatory medication in the same or other chiropractic conditions.

## 6.2 RECOMMENDATIONS

The following recommendations are made for future studies:

### **Financial Freedom:**

If the researcher was in a position to enjoy financial freedom, then a larger sample size could be seen and allowances could be made for the purchase of more sensitive testing equipment.

### **Sample Size and Statistical Analysis:**

A larger sample size could be selected and parametric statistical analysis should be used to improve the validity of the research.

### **Randomization:**

Stratified randomization procedures could be used, taking into account factors such as age, gender and grade of sprain. These factors could aid in making the sample more linear in distribution and therefore produce more valid trial conclusions.

### **Data measurement:**

Significant changes may be detected with more advanced technology that is more accurate and sensitive or specific, thereby possibly allowing more accurate results and more significant findings.

**Follow up consultation:**

The inclusion of a follow up consultation a few weeks after the completion of the study to assess medium term effects of treatment would increase the information provided by the study.

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

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

**FOR CLINICIAN'S USE ONLY**

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

**Case History:**

**Examination:**

Previous: \_\_\_\_\_

Current: \_\_\_\_\_

**X-Ray Studies:**

Previous: \_\_\_\_\_

Current: \_\_\_\_\_

**Clinical Path. lab:**

Previous: \_\_\_\_\_

Current: \_\_\_\_\_

**Case Status:**

PTT: \_\_\_\_\_ Conditional: \_\_\_\_\_ Signed Off: \_\_\_\_\_ Final Sign out: \_\_\_\_\_

Recommendations: \_\_\_\_\_

**Intern's Case History**

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



3. Present Illness:

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

4. Other Complaints:

5. Past Medical History:

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

6. Current health status and life-style:

- ▶ Allergies
- ▶ Immunizations
- ▶ Screening Tests
- ▶ Environmental Hazards (Home, School, Work)
- ▶ Safety Measures (seat belts, condoms)
- ▶ Exercise and Leisure
- ▶ Sleep Patterns
- ▶ Diet
- ▶ Current Medication
- ▶ Tobacco
- ▶ Alcohol
- ▶ Social Drugs

7. Immediate Family Medical History:

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

8. Psychosocial history:

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

9. Review of Systems:

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

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

## PHYSICAL EXAMINATION

Patient: \_\_\_\_\_ File#: \_\_\_\_\_ Date: \_\_\_\_\_  
Clinician: \_\_\_\_\_ Signature: \_\_\_\_\_  
Intern: \_\_\_\_\_ Signature: \_\_\_\_\_

1. VITALS

Pulse rate:

Respiratory rate:

Blood pressure: R L

Temperature:

Height:

Weight:

2. GENERAL EXAMINATION

General Impression:

Skin:

Jaundice:

Pallor:

Clubbing:

Cyanosis (Central/Peripheral):

Oedema:

Lymph nodes - Head and neck:  
- Axillary:  
- Epitrochlear:  
- Inguinal:

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

Pulses:      - General Impression:  
              - Radio-femoral delay:  
              - Carotid:  
              - Radial:

- Dorsalis pedis:  
- Posterior tibial:  
- Popliteal:  
- Femoral:

Percussion:      - borders of heart

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

#### 4.      RESPIRATORY EXAMINATION

1) Is this patient in Respiratory Distress ?

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

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

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

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

#### 5.      ABDOMINAL EXAMINATION

1) Is this patient in Liver Failure ?

Inspection    - Shape:  
                  - Scars:  
                  - Hernias:

Palpation      - Superficial:  
                  - Deep = Organomegally:



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

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

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

### **Sensory System:**

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

### **Cerebellar function:**

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

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

8. SPINAL EXAMINATION:(See Regional examination)

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

9. BREAST EXAMINATION:

Summon female chaperon.

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

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



**Foot and ankle regional examination**

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

**Observation**

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

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

**Active movements**

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

**Resisted Isometric movements:**

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

**Passive movement motion palpation**

(Passive ROM quality, ROM overpressure, joint play)

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

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

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

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

### Special tests

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

### Alignment

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

### Palpation

#### *Anteriorly*

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

#### *Posteriorly*

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

#### *Plantarily*

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

SCHEDULING STATUS:

S3

PROPRIETARY NAME  
(and dosage form):**ADCO-PIROXICAM 10 mg Capsules**  
**ADCO-PIROXICAM 20 mg Capsules****COMPOSITION:**

Each ADCO-PIROXICAM 10 mg Capsule contains 10 mg piroxicam.  
Each ADCO-PIROXICAM 20 mg Capsule contains 20 mg piroxicam.

**PHARMACOLOGICAL CLASSIFICATION:**

A. 3.1. Antirheumatics (Anti-inflammatory agents)

**PHARMACOLOGICAL ACTION:**

ADCO-PIROXICAM has analgesic, anti-inflammatory and antipyretic properties, and is used in the treatment of rheumatoid arthritis and other rheumatic disorders. Piroxicam acts as an inhibitor of prostaglandin biosynthesis.

ADCO-PIROXICAM is completely absorbed after oral administration: peak concentrations in plasma occur within two to four hours. Neither food nor antacids alter the rate or extent of absorption.

After absorption, piroxicam is extensively (99%) bound to plasma proteins, and has a long plasma half-life of approximately thirty-five to forty-five hours. At steady state, (eg. after seven to ten days) concentrations of piroxicam in plasma and synovial fluid are approximately equal.

Piroxicam is metabolised in the liver by hydroxylation of the pyridyl ring of the piroxicam side chain followed by conjugation with glucuronic acid and urinary elimination. Less than 10% of the drug is excreted in the urine unchanged.

**INDICATIONS:**

ADCO-PIROXICAM is indicated for a variety of conditions requiring anti-inflammatory and/or analgesic activity, such as rheumatoid arthritis, osteo-arthritis (arthrosis, degenerative joint disease), ankylosing spondylitis, acute musculoskeletal disorders and acute gout.

**CONTRA-INDICATIONS:**

ADCO-PIROXICAM should not be used in those patients who have previously shown a hypersensitivity to the drug; patients who have hepatic dysfunction; and patients who are pregnant. ADCO-PIROXICAM should be used with caution in patients with a history of gastrointestinal haemorrhage, ulcers or aspirin sensitivity.

**WARNINGS:****Use during pregnancy:**

The safety of ADCO-PIROXICAM use during pregnancy or during lactation has not yet been established. ADCO-PIROXICAM inhibits prostaglandin synthesis and release by an effect on prostaglandin biosynthetase. This effect has been associated with an increased incidence of dystocia and delayed parturition in pregnant animals when drug administration was continued into late pregnancy.

**Use in children:**

ADCO-PIROXICAM is not recommended for children.

**DOSAGE AND DIRECTIONS FOR USE:**

**Rheumatoid arthritis, osteo-arthritis (arthrosis, degenerative joint disease), ankylosing spondylitis:**

The usual daily dose for the relief of signs and symptoms of rheumatoid arthritis or osteo-arthritis is 20 mg given in single or divided doses. Since steady state concentrations in plasma are not reached for seven to ten days, maximal therapeutic responses should not be expected for two weeks. Long-term administration of doses higher than 30 mg carries an increased risk of gastrointestinal side-effects.

**Acute musculoskeletal disorders:**

Therapy should be initiated with 40 mg daily for the first two days, given in single or divided doses. For the remainder of the seven to fourteen day treatment period, the dose should be reduced to 20 mg daily.

**Acute Gout:**

Therapy should be initiated by a single oral dose of 40 mg followed on the next four to six days by 40 mg given in a single or divided daily dosage. ADCO-PIROXICAM is not indicated for the long-term management of gout.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Gastrointestinal symptoms are the most commonly encountered side-effects. Long-term administration of doses higher than 30 mg daily carries an increased risk of gastrointestinal side-effects.

Peptic ulceration and gastrointestinal bleeding have been reported with ADCO-PIROXICAM. Drug administration should be closely supervised in patients with a history of upper gastrointestinal disease.

Other than the gastrointestinal symptoms, oedema, mainly ankle oedema, has been reported. Routine ophthalmoscopy and slit-lamp examination have revealed no evidence of ocular changes.

ADCO-PIROXICAM should not be used in patients on coumarin-type anticoagulants. Changes in different liver function parameters have been observed. Some patients may develop increased serum transaminase levels during treatment with ADCO-PIROXICAM.

Care should be exercised with the use of ADCO-PIROXICAM in patients with renal dysfunction. Blood urea nitrogen elevation has been observed in some patients. These elevations are not progressive over the course of treatment with ADCO-PIROXICAM, a plateau being reached which returns to or towards baseline levels if treatment is stopped. The rise in blood urea nitrogen is not associated with elevations in serum creatinine.

ADCO-PIROXICAM decreases platelet aggregation and prolongs bleeding time. This effect should be kept in mind.

Dermal hypersensitivity reactions, usually in the form of skin rash, have been reported. Stevens-Johnson syndrome may develop.

Decreases in haemoglobin and haematocrit, independent of gastrointestinal bleeding, have occurred. Thrombocytopenia and non-thrombocytopenic purpura (Henoch-Schönlein), aplastic anaemia, leucopenia and eosinophilia have been reported, and constitute indications for immediate withdrawal of ADCO-PIROXICAM.

It should be assumed that ADCO-PIROXICAM will precipitate bronchoconstriction in those patients who are hypersensitive to aspirin. Central nervous system effects such as dizziness, headache, somnolence and vertigo have been reported. ADCO-PIROXICAM increases plasma lithium levels.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

In the event of overdosage with ADCO-PIROXICAM, supportive and symptomatic therapy is indicated.

**IDENTIFICATION:**

ADCO-PIROXICAM 10 mg Capsules : Opaque maroon/opaque grey capsules.

ADCO-PIROXICAM 20 mg Capsules : Opaque maroon/opaque maroon capsules.

**PRESENTATION:**

ADCO-PIROXICAM 10 mg Capsules : Securitainers of 60 capsules.

ADCO-PIROXICAM 20 mg Capsules : Securitainers of 30 capsules.

**STORAGE INSTRUCTIONS:**

Store below 25 °C. Protect from light. Keep out of reach of children.

**REGISTRATION NUMBERS:**

ADCO-PIROXICAM 10 mg Capsules : U/3.1/195

ADCO-PIROXICAM 20 mg Capsules : U/3.1/196

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

**Adcock Ingram Limited**

Adcock Ingram Park

17 Harrison Avenue, Bryanston Ext. 77

Private Bag X69, Bryanston, 2021

ZIMBABWE ONLY:  
10 mg : 96/3.1/3081  
PP 10

**DR D.R. MOODLEY**

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**PATIENT PROFILE AND DRUG INFORMATION SCREENING FOR PROSPECTIVE STUDIES  
INVOLVING ANTI-INFLAMMATORY DRUGS AT TECHNIKON NATAL CHIROPRACTIC  
DEPARTMENT**

**QUESTIONNAIRE :**

1. Have you had any reaction, allergic or otherwise to any inflammatory drug, or drug used in the management of pain or musculo-skeletal disorders (e.g. Aspirin, Disprin, Voltaren, Feldene) ?  
  
YES    \_\_\_\_\_  
NO     \_\_\_\_\_
2. Have you ever had any disorder of the liver, biliary tract or pancreas ?  
  
YES    \_\_\_\_\_  
NO     \_\_\_\_\_
3. Have you ever suffered with recurrent heartburn, peptic ulcers, bleeding disorders, including the vomiting of blood or passage of blood rectally or otherwise ?  
  
YES    \_\_\_\_\_  
NO     \_\_\_\_\_
4. Are you currently taking Warfarin, Aspirin, other anticoagulants or anti-inflammatory agents or any other drug at all, whether allopathic, herbal or otherwise, including steroid based agents ?  
  
YES    \_\_\_\_\_  
NO     \_\_\_\_\_
5. Have you ever suffered any dysfunction of the kidneys, bladder or urinary system ?  
  
YES    \_\_\_\_\_  
NO     \_\_\_\_\_
6. Have you ever suffered from any medical condition not disclosed above  
  
YES    \_\_\_\_\_  
NO     \_\_\_\_\_

DETAILS \_\_\_\_\_

7. Have you had any surgery previously ?

YES \_\_\_\_\_

NO \_\_\_\_\_

DETAILS \_\_\_\_\_

8. Have you received a blood transfusion in the last 5 years ?

YES \_\_\_\_\_

NO \_\_\_\_\_

REASON \_\_\_\_\_

9. Have you had endoscopy, radiographs or other investigations done to you ?

YES \_\_\_\_\_

NO \_\_\_\_\_

DETAILS \_\_\_\_\_

10. Are you asthmatic, or do you suffer with chronic disease of the lungs or respiratory system ?

YES \_\_\_\_\_

NO \_\_\_\_\_

11. Have you been diagnosed with any psychiatric disorder including depression, manic depression, or are you on anti-psychotic medication or Lithium therapy

YES \_\_\_\_\_

NO \_\_\_\_\_

**FEMALE PATIENTS:**

1. Are you pregnant now ?

YES \_\_\_\_\_

NO \_\_\_\_\_

2. State the onset date of your last period \_\_\_\_\_

3. Are your periods regular ? \_\_\_\_\_

**THE ABOVE DETAILS ARE TRUE TO THE BEST OF MY ABILITY.**

Patient \_\_\_\_\_

I.D. \_\_\_\_\_

Parent if under 21 \_\_\_\_\_

I.D. \_\_\_\_\_

## INDEMNITY

**WHERE THE FOLLOWING REQUIRE SIGNATURES, IT WILL BE THAT OF THE PATIENT IF OVER 21 YEARS OF AGE, OR BY THE PATIENT AND PARENT IF UNDER 21 YEARS**

1. While every effort has been made to screen the patient for possible drug interactions or effects, the research team cannot be held responsible for ad hoc reactions that may develop. While all patients may be protected by common laws, it is also imperative that the patient specifically indemnifies the research team, including Doctor D.R. Moodley and Technikon Natal against prospective legal action.  
\_\_\_\_\_
2. Telephonic or other consultations are a necessary part of the research. The patient acknowledges this and makes no claim against default in such cases  
\_\_\_\_\_
3. Any consultation or special investigation deemed necessary by the research team will be followed by the patient concerned, failing which the patient is freely entitled to be excluded from the study. This clause does not revoke the constitutional rights of the patient in terms of freedom of will.  
\_\_\_\_\_
4. I am prepared to undertake emergency or other treatment at a government hospital should the need arise. Private or attached costs will not be borne by Technikon Natal, Dr Moodley or any member of the research team.  
\_\_\_\_\_

**SIDE EFFECTS OF ANTI- INFLAMMATORY DRUGS :**

1. Gastro-intestinal symptoms including heartburn, acid reflex, indigestion, nausea, vomiting, bleeding, peptic ulcers.
2. Oedema (swelling of body) especially at ankles.
3. Transcient hepatitis
4. Transcient renal dysfunction
5. Skin and allergic reactions including urticaria and angiooedema
6. Blood disorders e.g. anaemia, decreased platelets, decreased white blood cells
7. Wheeze related to broncho constriction
8. Dizziness and headaches

**\*\*I have been advised of all the above side-effects that can occur in a small minority of patients**

\_\_\_\_\_

**\*\*I will inform the research team should any of the above side-effects develop**

**PATIENT:** \_\_\_\_\_

**PARENT :** \_\_\_\_\_

**DATE :** \_\_\_\_\_

DECLARATION :

I PARTAKE OF MY OWN FREE WILL IN THIS STUDY, HAVING BEEN DIAGNOSED WITH

\_\_\_\_\_

AND MAY USE THE FOLLOWING DRUG

\_\_\_\_\_

DOSAGE

\_\_\_\_\_

PATIENT : \_\_\_\_\_

PARENT : \_\_\_\_\_

RESEARCH STUDENT : \_\_\_\_\_

CLINICAL SUPERVISOR : \_\_\_\_\_

MEDICAL DOCTOR : \_\_\_\_\_

DATE : \_\_\_\_\_

## APPENDIX H

Dear participant,

Welcome to this research study. You have been selected to participate in a clinical trial comparing two forms of medication for ankle sprains.

The aim of the study is to compare the effectiveness of two treatment approaches in the management of ankle sprains. Your co-operation in this study will enable the chiropractic profession to design a more effective treatment plan for patients with your condition.

There are two treatment groups, each consists of 15 people and you will be allocated to one of these groups. Members of both groups will receive active treatment. Participants in the same group will receive identical treatment.

You will be required to attend the clinic 3 times over a period of 7 days. During the study you will not be able to receive any other form of treatment (chiropractic or otherwise) for your ankle sprain and you are further asked to refrain from any new or unaccustomed activities.

Treatment is free of charge and will be performed under the supervision of a qualified chiropractor.

Thank you for your interest and support.

Simon Bellingham.  
6<sup>th</sup> year Chiropractic Resident.



**INFORMED CONSENT FORM**  
( To be completed by patient / guardian )

Date : \_\_\_\_\_

Title of research project : The relative effectiveness of Piroxicam versus Protease administration in the treatment of Acute Grade 1 and 2 Ankel Inversion sprains.

Name of supervisor : Dr. Horace White

Name of research student : Simon Bellingham

Please circle the appropriate answer

YES NO

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

If you have answered no to any of the above, please obtain the necessary information before signing

Please Print in block letters:

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

Parent /Guardian Name: \_\_\_\_\_ Signature: \_\_\_\_\_

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

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

Numerical Rating Scale - 101 Questionnaire

Date: \_\_\_\_\_

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

File number: \_\_\_\_\_

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

Please write only the number.

\_\_\_\_\_

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

Please write only the number.

\_\_\_\_\_

**Short-form McGill Pain Questionnaire (SF-MPQ)**

Ronald Melzack (1984)

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

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

	NONE 0	MILD 1	MODERATE 2	SEVERE 3
THROBBING				
SHOOTING				
STABBING				
SHARP				
CRAMPING				
GNAWING				
HOT-BURNING				
ACHING				
HEAVY				
TENDER				
SPLITTING				
TIRING-EXHAUSTING				
SICKENING				
FEARFUL				
PUNISHING-CRUEL				

# APPENDIX L

NAME: \_\_\_\_\_

GONIOMETER READINGS	
LEFT	RIGHT
DATE:	
DATE:	
DATE:	

VOLUMETRY READINGS	
LEFT	RIGHT
DATE:	
DATE:	
DATE:	

ALGOMETER READINGS	
LEFT	RIGHT
DATE:	
DATE:	
DATE:	