THE EFFICACY OF A LOCAL ACTION TRANSCUTANEOUS FLURBIPROFEN PATCH, IN THE TREATMENT OF LATERAL EPICONDYLITIS.

By

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I, Daryl Bruce Somerset Oehley, do hereby declare that this dissertation represents my own work in both conception and execution.

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DEDICATION

This dissertation is dedicated to my beloved parents and family.

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ABSTRACT

The purpose of this study was to determine the relative efficacy of topical flurbiprofen in the form of a local action transcutaneous patch (LAT), in the treatment of lateral epicondylitis.

The design was a, double blinded, randomised, placebo study, in which forty patients were selected from the general population. The patients were randomly and equally divided into an experimental and control group. The experimental group received the flurbiprofen LAT (TransAct®) patches and the control group received the placebo patches. All the patients underwent a medical history, physical and elbow regional examination, which allowed for the diagnosis of lateral epicondylitis.

All participants in the study received two patches every 24 hours, changing the patch 12 hourly, over a period of seven days. With each patient being seen three times over the seven day period. Objective and subjective measurements were taken at the initial (first) and last (third) visits respectively. The objective data consisted of goniometer readings, for wrist flexion and extension range of motion, and grip strength dynamometer readings of the affected arm, in both the 90º and 180º elbow positions. The subjective data was collected using the McGill Short-form Pain Questionnaire and the Numerical Pain Rating Scale 101.

The data was gathered at the relevant consultations and was then statistically analysed, using a 95% (α = 0.05) confidence level. The inter-group analysis was performed using the Mann-Whitney U-test and the intra-group analysis was performed using the Wilcoxon's signed rank test.

Intra-group statistical analysis revealed statistically significant subjective (McGill Pain Questionnaire and NRS 101) improvement, in the patient's perception of pain within both groups, between the first and third visits.

There was a statistically significant objective (Grip Strength and Wrist Range of Motion) improvement between the first and third visits, with regards to grip strength 180º, in the placebo group, and wrist flexion range of motion in the flurbiprofen LAT (TransAct®) group.

Inter-group statistical analysis revealed, no improvement between the two groups, for both the subjective and objective measurements, between first and third visits.

The results of the study seem to suggest that the flurbiprofen LAT (TransAct®) patches, were no more effective than the placebo patches, in the treatment of lateral epicondylitis.

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TABLE OF CONTENTS

CHAPTER 4

LIST OF APPENDIXES

LIST OF TABLES

LIST OF FIGURES

COMPARISONS USING BAR CHARTS

CHAPTER ONE

1.0 INTRODUCTION

1.1 THE PROBLEM AND ITS SETTING

Tennis elbow, carpenter's elbow, dentist's elbow, tiller's elbow in yachtsmen, potato picker's plight and politician's paw, (Hyde and Gengenbach, 1997) are just a few of the many synonyms used to describe lateral epicondylitis.

Lateral epicondylitis is the most common overuse injury of the elbow, with an incidence of between 1%-3% of all adults (Sharat and Maffulli, 1997). This condition is characterised by pain and acute tenderness over the lateral side of the elbow, usually related to the common extensor tendon of the forearm (Thomson, Skinner and Piercy, 1991). The majority of cases are believed to be caused by an overuse syndrome, related to excessive wrist extension (Brunker and Khan, 1993) often seen in activities such as; carpentry, pruning shrubs and racquet sports (Hertling and Kessler, 1990). This excessive wrist extension results in tearing of the musculotendinous junction of the forearm extensor muscles (Hyde and Gengenbach, 1997).

To date there has been inconsistent evidence as to the effectiveness of conservative treatment (Sevier and Wilson, 1999, Brunker and Khan, 1993). A well managed non–surgical treatment regimen should be used initially for all patients suffering from lateral epicondylitis (Jobe and Ciccotti, 1994).

It has been suggested that the best results are usually obtained by using a combination of different treatment protocols, such as rest, ice, non-steroidal anti-inflammatory drugs and corticosteroid injections (Jobe and Ciccotti, 1994, Brunker and Khan, 1993).

Although modalities such as such as rest, ice, non-steroidal anti-inflammatory drugs and corticosteroid injections have been investigated to some degree, further research is still needed to determine which method is more effective in treating lateral epicondylitis (Sevier and Wilson, 1999, Jobe and Ciccotti, 1994).

Oral non-steroidal anti-inflammatory drugs are commonly used in the treatment of musculoskeletal injuries and soft tissue rheumatism (Poul et al. 1993, Burgos et al. 2001). One such oral non-steroidal anti-inflammatory drug is flurbiprofen which is a widely used, well established, propionic acid derived oral non-steroidal anti-inflammatory drug, which has anti-inflammatory, analgesic and anti-pyretic properties. However, due to the systemic iatrogenic side effects caused by long term use of these oral non-steroidal anti-inflammatory drugs such as nausea, diarrhoea, peripheral oedema, haemorrhage, renal failure and gastro-intestinal ulceration (MIMS, 2000), an alternate route of administration had to be sought to limit these side effects. One such alternative has been the development of the local action transcutaneous patch containing a non-steroidal anti-inflammatory drug (Poul et al. 1993, Burgos et al. 2001). The flurbiprofen LAT patch traded as TransAct®, is one example of a LAT patch containing a non-steroidal anti-inflammatory drug. Flurbiprofen LAT is a 40mg topical formulation of flurbiprofen and peppermint oil (Taburet et al, 1995), which is supplied as a non-woven polyester patch supporting a self adhesive formulation of flurbiprofen, which has a sustained flurbiprofen release for a period of twelve hours (Ritchie et al. 1995).

Several studies have been done to support the efficacy and tolerability of flurbiprofen LAT patches in the treatment of soft tissue rheumatism and acute soft tissue trauma (Ritchie et al. 1995).

In a randomised double blinded, parallel group study by Poul et al. (1993) comparing flurbiprofen LAT patch with an identical non-medicated control in the treatment of soft tissue rheumatism, one hundred and four patients were treated twelve hourly with either flurbiprofen LAT patches or a non-medicated (but identical) control patch over a fourteen day period. Only twenty-four percent of the study sample had either medial or lateral epicondylitis, with the remainder comprised of other soft tissue injuries. The results revealed a statistically significant difference in favour of the flurbiprofen LAT group at both seven days ($p = 0.02$) and fourteen days ($p = 0.009$).

Local action transcutaneous patches have not been fully investigated in the treatment of lateral epicondylitis. However, with lateral epicondylitis being a soft tissue lesion (Hyde and Gengenbach, 1997) the flurbiprofen LAT patch will provide a local concentration of flurbiprofen in the area of the lesion, in turn providing a reduced concentration of plasma flurbiprofen, thereby reducing the incidence of systemic side effects (Sugawara, 1990). There are however, no studies available that determine the efficacy of topical flurbiprofen in the treatment of lateral epicondylitis.

1.2 THE STATEMENT OF THE PROBLEM

The purpose of this study is to evaluate the relative efficacy of topical flurbiprofen in the form of a local action transcutaneous patch, in terms of subjective and objective clinical findings for the treatment of lateral epicondylitis.

1.2.1 Subproblem One

The first sub-problem of this study was to determine the efficacy of a local action transcutaneous flurbiprofen patch, in the treatment of lateral epicondylitis, in terms of subjective clinical findings.

1.2.2 Subproblem Two

The second sub-problem of this study was to determine the efficacy of a local action transcutaneous flurbiprofen patch, in the treatment of lateral epicondylitis, in terms of objective clinical findings.

1.3 HYPOTHESIS

1.3.1 Hypothesis One

It is hypothesised that local action transcutaneous flurbiprofen patches will be more effective than the placebo patches in the management of lateral epicondylitis, in terms of subjective clinical findings.

1.3.2 Hypothesis Two

It is hypothesised that local action transcutaneous flurbiprofen patches will be more effective than the placebo patches in the management of lateral epicondylitis, in terms of objective clinical findings.

1.4 BENEFITS OF THE STUDY

The aim of this research study was to see how effective local action transcutaneous flurbiprofen patches were in the treatment of lateral epicondylitis.

This may provide valuable knowledge as to the effectiveness of this method of anti-inflammatory use, for the treatment of this complicated and difficult soft tissue injury. The benefits of these local action transcutaneous patches to the patients, may lie in the higher concentrations of anti-inflammatory in the underlying soft tissues and the lower concentration of anti-inflammatory in the systemic circulation, in turn decreasing the systemic iatrogenic side effects caused by long term use of oral non-steroidal anti-inflammatory drugs.

This research study may provide a foundation for further studies and investigations into the effectiveness of this mode of anti-inflammatory administration, for lateral epicondylitis and many other soft tissue injuries.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 INTRODUCTION TO LATERAL EPICONDYLITIS

The term “Tennis elbow” was first used over a century ago to describe a condition commonly seen in English lawn tennis players (Viola, 1998), however it is far from unique to this group of people. It is also seen in fishermen, golfers, and violinists, amongst others (Ollivierre and Nirschl, 1996). This condition is commonly characterised by pain and acute tenderness over the lateral side of the elbow, which is usually related to the common extensor tendon of the forearm (Thomson, Skinner and Piercy, 1991).

2.2 INCIDENCE

Lateral epicondylitis affects about 1-3% of the adult population (Sharat and Maffulli, 1997) and is seldomly observed in patients under the age of 30 (Viola, 1998). This condition occurs mostly between the ages of 40–60 years, with a peak incidence in the early forties, and an equal incident rate between males and females (Viola, 1998 and Sharat and Maffulli, 1997). In studies by Shaik (2000) and Roodt (2001) the average age of patients were found to be in the forties, which is consistent with the findings by Sharat and Maffulli (1997). Tennis elbow is found to be far less common in the black population as compared to that of the white population. Lateral epicondylitis is six times more common than medial epicondylitis and right-sided epicondylitis was found to be twice as common, as that of left sided epicondylitis (Viola 1998).

2.3 AETIOLOGY AND PATHOLOGY

The precise aetiology of this condition is unknown, but the syndrome, often described as a combination of degenerative changes (Ernst, 1992) and excessive eccentric loading of the forearm extensor muscles, usually due to repetitive gripping and twisting motions, beyond the adaptive capacity of the forearm extensor musculature, leading to tears occurring in the tendons of the extensor muscles, with the extensor carpi radialis brevis (ECRB) being the most common. These tears usually occur where the ECRB tendon inserts into the bone via sharpey's fibres, at the junction of the hyaline cartilage and calcified cartilage at the lateral epicondyle (Hyde and Gengenbach, 1997, Sharat and Maffulli, 1997 and Field and Savoie, 1998).

These patients can be categorised into two different groups, a younger group with a sport-related injury and an older group with an overuse or work related injury, with the second being a lot more difficult to treat. This could be due to alterations in collagen content, lipid and ground substance, that occurs with increasing age, which leads to the tendons losing their elasticity (Viola, 1998).

According to Coonrad and Hooper (1973) who conducted a study on the course, natural history, conservative and surgical management of medial and lateral epicondylitis, of the 1000 patients involved in the study; 39 had to be treated surgically, because they had failed to respond to conservative care. The following findings were observed during the surgery; 28 patients demonstrated tears in either the extensor or flexor tendon. 22 had tears to the superficial portion, 6 were deep (with the superficial portion of the tendon intact) and four had extensive avulsion of the extensor or flexor origin. In 11 patients actual tears were not demonstrated, but in 9 of these scar tissue replacement could be seen and in the other 2 patients only minute calcareous deposits were noted, both macroscopically and microscopically.

In the 28 patients where gross tears were seen, microscopic studies were done on the torn margins, which revealed, “round cell infiltration, scattered foci of fine calcification and scar tissue with marginal areas of cystic degeneration”, but in some cases fibrinoid degeneration was found to be present. In the 9 patients with no visible lesions, scar tissue was found in the aponeurosis adjacent to the epicondyle (Coonrad and Hooper, 1973).

These findings indicate that there was some degree of inflammatory reaction occurring, and that anti-inflammatory treatment for lateral epicondylitis should be of benefit.

2.4 DIAGNOSIS

Tennis elbow characteristically presents as pain and acute tenderness over the lateral side of the elbow (Thomson, Skinner and Piercy, 1991) and may radiate distally to the elbow (Jackson, 1997). Patients often complain of an ache over the area of the lateral epicondyle, which is often associated with a weak grip, and even some degree of morning stiffness (Field and Savoie, 1998, Sharat and Maffulli, 1997).

The pain associated with lateral epicondylitis may be gradual or acute in presentation (Sharat and Maffulli, 1997), but usually occurs within 24-72 hours of a provocative activity (Jackson, 1997). Activities such as sports, especially with over head arm motions or activities requiring excessive wrist extension (Field and Savoie, 1998). This is consistent with studies by Shaik (2000) and Haswell (2002) who found sporting activities to be the most popular cause of injury, with racquet sports being the dominant. This pain is usually aggravated by; shaking hands, turning door handles, shaving with an electric razor and even lifting a teapot, and can progress to the stage that the pain becomes so intense, that these individuals are unable to perform normal daily activities (Kamien, 1990).

Pain can be reproduced over the lateral epicondyle by using the following orthopaedic tests:

- **Palpation of the lateral epicondyle**:

To reveal palpatory tenderness, this test is self explanatory (Sharat and Maffulli, 1997).

- **Resisted wrist extension (Thomsen test)**:

The shoulder is flexed to 60º, the elbow extended, the forearm pronated and the wrist extended about 30º. Pressure is applied to the dorsum of the second and third metacarpals in the direction of wrist flexion and ulnar deviation, to stress the extensor carpi radialis brevis and longus muscles. A positive test is pain in the area of the extensor carpi radialis brevis and longus muscle attachments to the elbow (Sharat and Maffulli, 1997).

- **Resisted middle finger extension (Maudsley's test):**

The resisted middle finger extension test is performed by the patient extending the middle finger (third digit) of the hand, distal to the proximal interphalangeal joint, against resistance form the examiner. This will stress the extensor digitorum muscle and tendon. Pain over the lateral epicondyle of the humerus is a positive for this test (Magee, 1997).

- **Cozen's Test:**

The examiner rests their thumb over the lateral epicondyle, while stabilising the elbow joint. The patient is then asked to make a fist, pronate the forearm, radially deviate and extend the wrist, against resistance from the examiner. A positive sign for this test is a sudden severe pain in the area of the lateral epicondyle (Magee, 1997).

- **Mills' test:**

While palpating the lateral epicondyle, the examiner pronates the patient's forearm, flexes the wrist fully, and extends the elbow. A positive test is indicated by pain over the lateral epicondyle of the humerus. This manoeuvre may put stress on the radial nerve, and may cause symptoms similar to tennis elbow, if there is compression of the radial nerve (Magee, 1997).

2.5 DIFFERENTIAL DIAGNOSIS

There are conditions other than tennis elbow that could complicate the diagnosis or lead to a misdiagnosis of tennis elbow. These conditions often present with similar signs and symptoms to that of tennis elbow.

Radial Tunnel Syndrome

Radial Tunnel Syndrome is a condition resulting from compression of the radial nerve, at any point along the path between the supinator muscle and the radial head. The pain usually presents as aching in the extensor-supinator muscle mass in the proximal forearm (Field and Savoie, 1998).

This condition is usually differentiated from tennis elbow primarily on the character and location of the pain, with the maximal tenderness being localised to the area adjacent to the lateral epicondyle in tennis elbow (Field and Savoie, 1998).

Synovial Fringe Entrapment

This is a painful condition which results due to radio-humeral joint compression. Accessory anteroposterior motion may be decreased between the radial head and the capitulum (Thomson, Skinner and Piercy, 1991).

Bursitis

A radiohumeral bursa is not a common anatomical finding. This condition usually presents as a pea sized swelling and localised tenderness in the region, slightly anterior and distal to the lateral epicondyle, with maximal pain over the anterolateral aspect of the radial head (Kamien, 1990).

Arthritis

Arthritis of the radio-humeral and radio-ulnar joints usually presents with pain on active and passive elbow motion. Loss of extension and stiffness are common complaints (Viola, 1998). Symptoms are often made worse when a load placed in the hand or the arm is used in one position for a prolonged period of time, such as holding a telephone (Thomson, Skinner and Piercy, 1991).

Osteochondritis Dissecans

Osteochondritis dissecans is usually seen in a younger group of patients, than those that usually present with tennis elbow. This condition usually has an insidious onset of diffuse elbow pain, decreased range of motion, crepitation and intermittent locking of the elbow (Field and Savoie, 1998).

Lateral Ligament Strain

Lateral ligament strains of the elbow usually present with pain, when an adduction force is applied to the forearm, with the elbow in extension and the forearm in supination (Thomson, Skinner and Piercy, 1991).

Muscular Strain

Extensor carpi radialis longus muscular strains, usually present with palpatory tenderness over the lateral supra-condylar ridge of the elbow (Thomson, Skinner and Piercy, 1991).

Posterolateral Plicas

Posterolateral plicas when symptomatic usually produce symptoms over the posterolateral aspect of the elbow, with associated complaints of catching, snapping and popping. These lesions are usually palpated in the posterolateral gutter of the elbow (Field and Savoie, 1998).

Cervical Nerve Root Entrapment

In addition to the elbow pain, the patient may present with pain or tenderness over the area of C4,5,6 especially on the side of the symptomatic elbow. Range of motion of the neck may be reduced and may even reproduce or exacerbate the symptoms when tested (Thomson, Skinner and Piercy, 1991).

Myofascial Trigger Points

Myofascial trigger points usually present as pain over the lateral epicondyle and may refer down to the wrist and hand. This is commonly due to a composite pain pattern that is referred from the supinator, extensor carpi radialis longus and the extensor digitorum muscles (Travell, Simons and Simons, 1999).

It is important to note that tennis elbow doesn’t usually present with visible swelling, however if this is the presentation; arthritic synovitis, infection, trauma and tumours should be ruled out (Viola, 1998).

2.6 TREATMENT

According to Sharat and Maffulli (1997) there is a large success rate in patients with tennis elbow, managed with conservative care. Conservative care should include pain relief, cessation of bleeding, controlling inflammation, promoting healing, rehabilitation and prevention of recurrence (Viola, 1998). In a study done by Coonrad and Hooper (1973) in a series of one thousand patients, they found an 82-93% success rate in patients with non-surgical management. It therefore suggests the importance of a well managed conservative approach, before considering referral for surgery (Sharat and Maffulli, 1997).

The following are just a few of the many different types of treatment available to patients suffering with tennis elbow.

2.6.1 Rest and Activity Modification

Initially, any activity that may cause pain or discomfort to the patient should be eliminated. Literature mentions, that complete rest is important for recovery. This can be achieved by using a posterior moulded cast or splint. The affected arm should be splinted with the elbow in flexion, the forearm in supination and wrist in extension, to allow for complete relaxation of the forearm extensor muscles (Sharat and Maffulli, 1997).

Avoidance of activities such as overhead arm movement in certain sports (Field and Savoie, 1998), as well as any activity that leads to pain, for as long as the acute pain persists, or until the provocative activities becomes tolerable (Jackson, 1997).

2.6.2 Cryotherapy

Ice is indicated especially in the acute phase of the condition. This is done by applying crushed ice or a frozen gel pack directly to the soft tissue over the lateral epicondyle (Sharat and Maffulli, 1997) for a period of 10-15 minutes, four to six times a day (Jackson, 1997). The ice is used to decrease oedema, haemorrhage and control any inflammation, associated with tears occurring in the extensor muscles of the forearm (Sharat and Maffulli, 1997).

2.6.3 Therapeutic Ultrasound

Ultrasound involves a series of electrical and mechanical phenomena that lead to a thermal and mechanical effect on both the superficial and deep levels of cells (Viola, 1998).

Thermal effects of ultrasound on the tissues are:

1) Increase extensibility of collagen tissue

2) Decrease joint stiffness

3) Increase pain threshold

4) Reduce muscle spasm

5) Assist in mobilising inflammatory infiltrates, oedema and excudates

6) Increase blood flow

7) Increase local metabolism

8) Increase nerve conduction velocity (Viola, 1998)

In a randomised controlled study by Lundeberg, Abrahamsson and Haker (1988), to investigate the effects of continuous ultrasound, placebo ultrasound and rest in the treatment of epicondylalgia. Ninety-nine patients, were allocated into three equal groups of thirty-three. Group one received continuous ultrasound (Frequency of 1.0MHz, Intensity of 1.0Wcm^{-2} for 10 minutes); group two received placebo ultrasound and group three received rest. The results revealed that there was no significant difference in recovery of patients when comparing patients receiving continuous ultrasound compared to placebo ultrasound. But there was a significant difference ($p<0.01$) in pain alleviation when comparing continuous ultrasound to rest.

Similar results were found in a randomised controlled study done by Haker and Lundeberg (1991) on forty-four patients, to determine the effect of pulsed ultrasound in the treatment on lateral epicondylalgia; patients were treated two to three times a week for ten visits, with each treatment lasting ten minutes. The study revealed that pulsed ultrasound had no significant difference over placebo in terms of subjective and objective outcomes.

These studies concluded that ultrasound, whether pulsed or continuous, was no more effective than placebo, in reducing pain, inflammation and scar tissue formation in patients with lateral epicondylitis.

2.6.4 Laser

Laser is an acronym for light amplification by stimulated emission of radiation. The proposed effects of laser include acceleration of collagen synthesis, increase vascularisation, and reduced pain and inflammation. These effects are subtle and occur primarily at cellular level (Viola, 1998).

Mixed results have been found in studies done thus far. In a randomised clinical trial done by Lundeberg, Abrahamsson and Haker (1987) to compare the effect of laser versus placebo laser in the treatment of tennis elbow, fifty-seven patients suffering from tennis elbow were placed into three groups.

Group A received placebo laser, Group B received infrared Gallium-Arsenide laser radiation and group C received Helium-Neon radiation. The results revealed that laser had no significant improvement over placebo in the treatment of tennis elbow.

In a more recent, double-blinded, randomised, controlled study by Vasseljen et al. (1992), to determine the effect of low level laser versus placebo in the treatment of tennis elbow, the results were some what different to those found by Lundeberg, Abrahamsson and Haker (1987). Thirty patients were divided into two groups, the one group received laser and the other group received placebo laser over a period of eight treatments. The findings revealed a significant improvement in the laser group over the placebo group, in terms of the visual analog scale and grip strength, at a four week follow-up.

These studies revealed that more research is needed to determine whether laser is an effective method of decreasing inflammation, pain and scar tissue formation in patients with lateral epicondylitis.

2.6.5 Cross Friction Massage

Transverse friction massage has been deemed helpful in the management of tennis elbow (Viola, 1998). Its function is to produce a reactive hyperaemia around the scar which softens the scar (Kamien, 1990) allowing the two surfaces of the muscle joined together by the scar tissue to be pulled apart, and the rest of the tendon to take up the strain. This eventually leads to the fresh tear being bridged by new fibrous tissue, which is not under tension (Cyriax and Cyriax, 1993). This technique should be done for five to ten minutes over a period of three to four days (Thomson, Skinner and Piercy, 1991).

In a randomised, control study by Shaik (2000) to determine the effectiveness of cross friction massage and Mills' manipulation versus cross friction alone, for a sample size of fifteen, there was no statistically significant difference between the two groups. Both groups did however, have a significant intra-group improvement in both subjective and objective measurements over the six treatments, but not between the sixth treatment and the one month follow-up. This could possibly suggest that Mills manipulation and cross friction are of value, in the short term relief of patients symptoms, but are not as effective in the long term management of lateral epicondylitis.

2.6.6 Manipulation

A reduction in joint play motion of the radiocapitellar and superior radio – ulnar joints is commonly found in patients suffering from chronic lateral epicondylitis, however, other restrictions in elbow accessory motion may be noted. In this case a low – amplitude, high – velocity manipulation is essential and may require several manipulations to restore full accessory motion of the elbow (Hyde and Gengenbach, 1997). According to Viola (1998) Mill's manipulation could be considered as an alternative form of treatment before performing surgery.

However, in a recent placebo controlled study by Roodt (2001), to determine the efficacy of manipulation of the elbow joint in patients suffering from lateral epicondylitis, there was no statistically significant improvement of manipulation over placebo in the treatment of lateral epicondylitis. This could possibly be due to lateral epicondylitis being of a soft tissue origin and not directly joint related (Sharat and Maffulli, 1997), that manipulation of the elbow was found to have little or no benefit to the patients.

2.6.7 Counter Force Bracing

Counterforce bracing has been used to decrease the overload forces on the common extensor tendon (Viola, 1998; Brunker and Khan, 1993). This occurs by distributing the muscular contraction forces to the surrounding tissues and to the brace itself (Field and Savoie, 1998), in turn relieving the tension on the tear in the extensor tendon (Viola, 1998).

This has been shown to occur by Snyder-Mackler and Elper (1989), in a study on ten normal patients without lateral epicondylitis. They compared electromyography (EMG) reading at 80% of maximum voluntary isometric contraction of extensor carpi radialis brevis (ECRB) and extensor digitorum communis (EDC) with a standard band, an aircast band and with no band. The results revealed a statistically significant decrease in the EMG readings in the extensor muscles, proximal to the band, when using the aircast band, compared to that of the standard tennis elbow band and control values (no band). Unfortunately there are limitations to the interpretation of these results, due to factors such as the small sample size and the fact that this study was performed on asymptomatic normal patients.

2.6.8 Trigger Point Therapy

Myofascial trigger points in the brachioradialis, suprinator and the extensor muscles of the forearm may be responsible for the symptoms of lateral epicondylitis (Rachlin, 1994).

“A myofascial trigger point, is a hyperirritable spot, usually within a taut band of skeletal muscle or in the fascia, that is painful on compression and can give rise to characteristic referred pain, tenderness and autonomic phenomena” (Travell, Simons and Simons, 1999). These trigger points can be inactivated by ischaemic compression, dry needling, spray and stretch, injection and corrective actions (Viola, 1998).

In a recent study by Haswell (2002) to determine the effectiveness of dry needling compared to sham placebo needles in patients suffering with lateral epicondylitis; dry needling of myofascial trigger points in the forearm extensor muscles was found to be statistically significant in reducing the patients pain perception compared to that of the sham placebo needles.

This could indicate that not all the pain associated with tennis elbow is due to the changes occurring in the tendon, but a combination of the tendon tear and a myofascial pain pattern, from the myofascial trigger points in the forearm muscles.

2.6.9 Surgery

Surgery should only be considered after a failed, twelve month period of conservative care, due to tennis elbow being a self-limiting condition (Brunker and Khan, 1993, Kamien, 1990). Surgery might be considered earlier in highly competitive athletes with symptoms that are severely reducing their level of participation (Field and Savoie, 1998).

The most common surgical techniques for tennis elbow are listed below (Viola, 1998).

1) Excision of part of the extensor origin, together with excision of the orbicular ligament.

2) Total release of the extensor musculature from the lateral epicondyle.

3) Distal tendon lengthening of the affected muscle

4) Denervation

In a study to determine the effectiveness of surgical treatment for lateral epicondylitis by Nirschl and Pettrone (1979). Eighty-eight patients under went surgery to the extensor carpi radialis brevis (ECRB); the surgery consisted of open excision of the identified lesion and repair. The results revealed an excellent result in sixty-six elbows, a good result in nine, fair in eleven and failure in two. However there was an overall improvement of 97.7 per cent over the preoperative status, and in 85.2 per cent of the cases the patients were able to return to full activities including sport.

2.6.10 Corticosteroid Injections

Corticosteroid injections are the mainstay of treating tennis elbow (Price et al. 1991). These injections are generally reserved for non-competitive individuals with pain significant enough to impede daily living. However corticosteroid injections should be used sparingly in competitive athletes (Field and Savoie, 1998) due to the side effects associated with their long term use. These side effects include subcutaneous fat atrophy, skin pigmentation, tendon rupture, cartilage damage and infections (Viola, 1998).

There remains no overall agreement as to the correct dose, route of administration, or which steroid preparation to use (Sharat and Maffulli, 1997). However literature does recommend no more than three injections within a year (Field and Savoie, 1998). Commonly used steroids are; betamethasone sodium phosphate (Field and Savoie, 1998), hydrocortisone and triamcinolone, which are usually mixed with 2ml 1% lignocaine (Price et al. 1991).

In a comparative study conducted by Price et al. (1991) comparing local injections of lignocaine, hydrocortisone and triamcinolone in the treatment of tennis elbow; a 2ml 1% lignocaine injection was compared with either a 25mg hydrocortisone or 10mg triamcinolone injection made up to 2ml with 1% lignocaine. Within the first 8 weeks, pain relief was greater with the triamcinolone compared to the hydrocortisone.

These differences however were not statistically significant. The response to both the steroid preparations was significantly better than for the lignocaine. At 24 weeks, the degree of improvement was similar for all three groups, but many patients still had pain and relapse was common. Six months after the injections the corticosteroid treatment appeared to be no more effective than lignocaine in the treatment of lateral epicondylitis.

2.6.11 Non-Steroidal Anti-Inflammatory Drugs

Oral non-steroidal anti-inflammatory drugs are commonly used in the treatment of musculoskeletal injuries and soft tissue rheumatism (Poul et al. 1993, Burgos et al. 2001). In a study by Kivi (1982), eighty-eight patients were treated conservatively for tennis elbow, forty-seven were treated with local corticosteroid and anaesthetic injections, twenty with methylprednisolone injections and the last group of twenty-one with wrist immobilisation in combination with oral indomethacin. The results concluded that oral non-steroidal anti-inflammatory drugs are as effective as steroid injections in treating tennis elbow.

Although in a recent, randomised trial of local corticosteroid injections and naproxen for the treatment of lateral epicondylitis; it was found that at 4 weeks, 92% of the patients receiving corticosteroid injections had improved, compared to 57% of the patients taking oral naproxen and 28% in the placebo groups respectively. This meant that local corticosteroid injections had a clear clinical advantage over a two week course of oral naproxen, at 4 weeks (Hay et al. 1999). However within a 12 months period, the study reflected that most of the patients had improved, irrespective of the initial treatment. Both these studies indicate that corticosteroid injections and oral non-steroidal anti-inflammatory drugs are effective in decreasing symptoms.

A major drawback to the use of corticosteroid injections and oral non-steroidal anti-inflammatory drugs are the side effects associated with their use.

Hay et al. (1999) recorded that two patients experienced local skin atrophy at six months and one at twelve months, in those patients receiving the corticosteroid injection. Four patients had to discontinue the oral naproxen due to gastro-intestinal side effects; and one patient had an allergic reaction to the naproxen. Other common side effects caused by oral non-steroidal anti-inflammatory drugs are nausea, diarrhoea, peripheral oedema, haemorrhage, renal failure and gastro-intestinal ulceration (MIMS, 2000).

To limit the systemic side effects caused by long term use of oral non-steroidal anti-inflammatory drugs, alternative modes of applications were sought (Taburet, 1995). One such alternative has been the development of the local action transcutaneous patch containing a non-steroidal anti-inflammatory drug (Poul et al. 1993, Burgos et al. 2001).

One type of non-steroidal anti-inflammatory patch was researched by Taburet et al. (1995) in a study comparing the pharmacokinetics of oral flurbiprofen and a locally acting transcutaneous flurbiprofen patch in healthy volunteers. Results revealed that the plasma concentration of a single topical application of 40mg flurbiprofen was equivalent to less than 1% of the value observed after a single oral administration of a 50mg flurbiprofen tablet. Flurbiprofen local action transcutaneous (LAT) penetrates slowly and in small quantities into the systemic circulation. Therefore sustained local tissue concentrations and limited systemic penetration of flurbiprofen delivered by flurbiprofen LAT patches, may lead to improved systemic tolerability, relative to the oral preparation.

Martens (1997) in a randomised, parallel-group study, researched the efficacy and tolerability of oral diclofenac and flurbiprofen LAT patches, in the treatment of soft tissue rheumatism. The study found that transcutaneous flurbiprofen was significantly superior to oral diclofenac sodium in terms of efficacy and tolerability. The only adverse effects of the flurbiprofen LAT patch were mild skin irritation at the site of application, compared to gastrointestinal side effects suffered by patients in the diclofenac group.

In a double-blinded, comparative study of local action transcutaneous flurbiprofen (Flurbiprofen LAT) versus piketoprofen cream in the treatment of extra-articular rheumatism, by Burgos et al. (2001), 129 patients were randomly divided into two groups, one receiving 40mg flurbiprofen LAT patch twice daily and the other receiving 1.8% piketoprofen cream (equivalent to 36mg) three times daily for 14 days. The study concluded that flurbiprofen LAT was effective, well tolerated, and an attractive treatment option for extra-articular rheumatism.

Flurbiprofen is a propionic acid derived non-steroidal anti-inflammatory drug (Martens, 1997), which has a low molecular weight, making it particularly suited to pass through the epidermis and achieve efficient skin and tissue penetration. Flurbiprofen also has the right balance of hydrophillic and lipophyllic properties to maintain high levels locally in the target tissues. Its hydrophillic quality allows for penetration through the epidermis and its lipophyllic quality allow for penetration through the stratum corneum (Costa, 2000).

The flurbiprofen LAT patch (TransAct®) is a 40mg topical formulation of flurbiprofen and peppermint oil, available locally as a 10 cm x 14cm non-woven polyester medicated adhesive patch (Ritchie et al. 1995, Taburet, 1995). These flurbiprofen LAT patches (TransAct®) are prepared by forming an ointment, in which the flurbiprofen is dissolved in peppermint oil and evenly distributed in an oil and water emulsion, in an acrylic moisturised base, which is designed to have a sustained flurbiprofen release for a period of twelve hours (Ritchie et al. 1995; Costa, 2000).

Very few controlled clinical trials are available, to determine the effectiveness of topical non-steroidal anti-inflammatory drugs in the treatment of tennis elbow (Ernst, 1992).

In a randomised, double blinded, placebo, cross–over study, to determine the effectiveness of topical diclofenac in the treatment of chronic lateral epicondylitis; fourteen patients were treated using a pluronic lecithin liposomal organo–gel (PLO) over the affected elbow, three times daily for one week, followed by a one week “washout” period with no gel and a third week of using a second PLO gel. Both the gels were identical except only one PLO gel contained the 2% diclofenac. The results revealed a significant improvement in pain (P=0.007) and wrist extension strength (P=0.03), with the diclofenac PLO (Burnham et al. 1998).

Although studies have shown topical non-steroidal anti-inflammatory drugs to be effective in treating lateral epicondylitis, there are no studies available to determine the effectiveness of flurbiprofen LAT (TransAct®), in the treatment and overall management of lateral epicondylitis.

CHAPTER THREE

3.0 MATERIAL AND METHODS

3.1 INTRODUCTION

This chapter outlines the basic procedure utilised to carry out this research study. Which includes the study design, subject selection criteria, inclusion and exclusion criteria and the interventions the patients will receive. Material and methods used for data collection as well statistical procedures for data evaluation will also be discussed.

3.2 THE STUDY DESIGN

This study was deigned as a randomised double-blinded placebo study. Randomisation was selected to try prevent biases in the sample, while a double blind design was used to reduce biases of the researcher. A placebo was used as a control to determine the efficacy of the experimental local action transcutaneous (LAT) patch.

3.3 THE OBJECTIVES OF THE STUDY

The objective of this study was to determine the effectiveness of topical flurbiprofen in the form of a local action transcutaneous (LAT) patch compared with a placebo patch, and to identify the effectiveness of each treatment protocol, (intra-group analysis) in terms of subjective an objective measurements. An inter-group analysis was performed to determine if either of these treatment interventions were more effective than the other.

3.4 THE STUDY SAMPLE

This study was limited to patients between the ages of twenty-one to sixty (Thomson, Skinner and Piercy, 1991 and Shaik 2000).

Advertisements requesting participation in the clinical trial involving chiropractic treatment of elbow pain were placed on the notice boards at the Durban Institute of Technology, local universities, local sports clubs and in local newspapers. No other restrictions in terms of race, sex, income bracket, occupation or area of residence were placed when selecting the study sample.

The individuals who responded to the advertisements were telephonically interviewed to explain the conditions of the study. The telephonic interview was also used as a screening process to assess whether the patients were suffering from lateral elbow pain. Following the telephonic interview, patients were scheduled for an initial contact screening appointment to assess whether they comply with at least one or more of the inclusion criteria, before being accepted into the study.

Patients with lateral elbow pain that presented at the chiropractic day clinic were also considered for the study.

3.4.1 The Inclusion Criteria

The following criteria were used to determine which patients should be included into the study:

- Tenderness with palpation over the lateral epicondyle (Sharat and Maffulli, 1997).

- Pain which is gradual in onset and presenting after activity. The pain usually occurs in the area of the lateral epicondyle, and may continue down the dorsal aspect of the forearm over the wrist extensor muscles down to as far as the wrist (Thomson, Skinner and Piercy, 1991).

- Pain produced by tapping over the lateral epicondyle of the elbow (Travell, Simons and Simons,1999).

- Pain with limited wrist flexion when the elbow is extended and forearm pronated (Travell, Simons and Simons, 1999).

- Pain over the lateral epicondyle with resisted wrist extension (Sharat and Maffulli, 1997).

- Painful resisted wrist abduction and supination (Hyde and Gengenbach, 1997).

- Resisted finger extension especially the third finger (Hyde and Gengenbach, 1997).

3.4.2 The Exclusion Criteria

Patients presenting with any of the following, were excluded from the study:

- Avulsion fractures of the lateral epicondyle (Hyde and Gengenbach, 1997).

- Any tumours of the involved extremity.

- Bleeding disorders.

- Systemic arthritic disorders e.g. rheumatoid arthritis or osteoarthritis, etc.

- Neurological disorder e.g. nerve root impingement (Meridel and Gatterman, 1990).

- Pregnant and breast feeding females, due to the safety of flurbiprofen LAT (Transact®) not been well established (MIMS, 2000) during pregnancy and lactation.

- A known hypersensitivity to flurbiprofen or peppermint oil.

- Broken or fragile skin, dermatoses and infection at the application site.

- Active peptic ulceration.

- Severe hepatic insufficiency.

- Severe renal insufficiency.

- Gastro – intestinal haemorrhage (MIMS, 2000).

- Any participant who has used any local action transcutaneous patch containing a non-steroidal anti-inflammatory drug in the past six months (Koes et al. 1995).

3.4.3. Washout Period

Any participant who is on any oral non-steroidal anti-inflammatory drug will be required to participate in a three day washout period prior to entering the study (Poul et al. 1993).

3.4.4 Allocation of Subjects

Once the subjects were accepted to participate in the study, they were made aware of the details of the study in writing. Following this the patient were asked to complete and sign an informed consent form (Appendix B).

At this stage the patients were also made aware that during the course of the study, they were not to engage in any other form of treatment for lateral epicondylitis and were free to withdraw from the study at any time without reason. Thereafter, an initial consultation was scheduled for the prospective participant. At the initial consultation a patient history (Appendix C) was taken, a relevant physical examination (Appendix D) and elbow regional examination (Appendix E) was conducted.

During the orthopaedic elbow regional examination, specific tests were used to diagnose lateral epicondylitis. These specific tests were used to identify the clinical lesion in the area of the lateral epicondyle, common extensor muscles and the conjoined tendon of the extensor muscles of the forearm. These tests included the Thomsen test or resisted wrist extension (Sharat and Maffulli, 1997 and Magee, 1997), Mills test (Magee, 1997), and Cozen's test (Magee, 1997). Resisted third finger extension was also used to diagnose lateral epicondylitis because of the extensor digitorum originating from the common extensor tendon, but specifically it is used to differentiate between a tear in the extensor carpi radialis longus and the extensor digitorum communis (Hammer, 1991 and Magee, 1997).

For the purpose of this study, at least one or more of these tests had to be positive in order to diagnose the patient as having lateral epicondylitis. Positive tests were noted for each patient to determine which tests most commonly produce positive findings in patients with lateral epicondylitis (Appendix I).

Forty patients were selected for this study. Random allocation of patients was utilised to separate the patients into two equal groups of twenty patients each. The "A" group were those who received a placebo patch, whilst group "B" were those who received the flurbiprofen LAT (TransAct ®) patch.

Once the patients had been placed into their respective groups, they were advised on how to apply the patches, how long to wear the patches, the best time to change the patches and the side effects that might develop with the use of these patches. The directions were general for both groups and were not specific for each type of patch, due to the researcher being blinded to the study.

Instructions on patch application (Appendix K)

1. Wipe the skin over lying the elbow joint clean.

2. Remove one patch from the sachet and ensure that the sachet is securely re-closed.

3. Remove the peel off liner and apply adhesive side to the skin.

4. When applying the patch, stretch the patch gently to prevent the surface from wrinkling.

5. It is recommended that bathing should be arranged to coincide with routine changing of the patch.

6. Do not wet patch. Remove before bathing.

7. Replace every 12 hours.

8. Use only one patch at a time. (Boots Healthcare package insert 2000).

Had any of the patients developed any of the following side effects during the treatment period, they would have been excluded from the study.

- Bronchospasm.

- Anaphylactic reactions.

- Angioedema.

- Gastro-intestinal ulceration.

- Any of the systemic side effects that may develop due to prolonged use.

- Any other hypersensitivity type reactions such as numbness, itching, redness or tingling in the area of application (MIMS, 2000).

3.4.5 Blinding

A double blinding procedure was chosen for this study. With both the patient and the researcher being blinded from knowing which research group the patient had been placed into.

The researcher questioned (Appendix J) all the patients on the precautions and contra-indications to the use of the flurbiprofen LAT (TransAct®) patches as laid out by MIMS (2000), prior to the patients being placed into a specific treatment group. The researcher then discussed each patient's individual findings with a registered pharmacist to ensure their safety to the drug application. The flurbiprofen LAT (TransAct®) patches were then dispensed to the patient, under supervision of the registered pharmacist. Thereafter the patient was instructed by the researcher on how to correctly apply the patches to their elbow (Appendix K).

Conforming to the procedure of a double blinded study an independent person placed the patient into a research group. The patient placement was done by asking the patients to draw a letter out of a bag. There were forty small pieces of paper placed in a bag, marked with either the letter “A” or the letter “B”. Once the patient had drawn a letter from the bag, an independent person issued them with a pre-packed packet of patches, according to which letter was chosen by the patient.

An independent person took note of the patient’s name and the group in which the patient was placed, and only made this information available to the researcher once that patient had completed the study. Once the patient had been given their patches, an independent person (clinician) then applied the first patch to the patient, at the clinic, to ensure that there was no confusion on how to apply the patch.

3.4.6 Placebo

The patients participating in this study were blinded from knowing which treatment they were receiving by covering both patches in the same low allergy self adhesive Hypafix dressing, so that both patches looked identical. The placebo patch contained peppermint oil, so that the placebo patch smelt identical to the peppermint oil contained within the flurbiprofen LAT (TransAct®) patch. The placebo patches were also be made up of a piece of gauze (Melolin®) on the underside of the patch to give the patch a similar height to that of the Hypafix covered flurbiprofen LAT (TransAct®) patch.

3.5 INTERVENTION

Group “A” was treated with the placebo patch. The placebo patch was a pre-prepared patch made of the Hypafix dressing with a thin layer of gauze underneath (Melolin®) containing peppermint oil. Each patient received two placebo patches every 24 hours, changing the patch 12 hourly, over a period of seven days (Poul et al. 1993).

Group “B” was treated with a 40mg flurbiprofen LAT (TransAct®) patch covered with the Hypafix dressing. Each patient received two TransAct® patches every 24 hours, changing the patch twelve hourly, over a period of seven days (Poul et al. 1993).

Each patient was seen three times over a period of seven days. This included an initial visit, a mid-week visit and on the last day of treatment. The initial consultation was scheduled in the morning and in the late afternoon. This allowed the patient to sleep through the night without having to change the patch, thus allowing for better patient compliance.

Patients were asked to remove the patch a few minutes prior to the follow-up consultation, to prevent the unblinding of the researcher. Following the consultation the patients were asked to replace the patch as soon as possible after leaving the clinic.

The patients were given eight patches initially to last them until their second visit, followed by another six at the second visit to last them until the one week final visit.

Patients were allowed to apply a bandage to the elbow, to prevent the patch from coming off.

3.6 THE DATA

The data in this study consists of primary and secondary data

3.6.1 The Primary Data

The objective measurements for this study were:

- Wrist flexion and extension range of motion which was obtained by using a goniometer (Appendix F).

- Grip strength of the involved elbow was assessed; using a hand held dynamometer to obtain the readings. Two grip strength readings were taken on the symptomatic side, one with elbow at ninety degree flexion and the other with the elbow straight at one hundred and eighty degrees (Appendix F).

The subjective measurements for this study were:

- The Numerical Pain Rating Scale 101 which was used to subjectively determine the patients response to the treatment in terms of their perception of pain intensity (Appendix G).

- The McGill Pain Questionnaire which was designed to provide a quantitative measure of clinical pain (Appendix H) (Melzack, 1975).

3.6.2 The Secondary Data

The secondary data was obtained from journal articles, textbooks and any literature related to lateral epicondylitis. The data included the incidence, symptoms, diagnostic criteria and related information on past and current treatment and management protocols for this condition. Flurbiprofen LAT (TransAct®) patches were extensively researched to determine their efficacy in the treatment of soft tissue injuries and their benefit in the management of lateral epicondylitis.

3.7 METHOD OF MEASUREMENT

3.7.1 Subjective Measurements

The subjective measurements consisted of the Numerical Rating Scale 101 (Appendix G) and the short-form McGill Pain Questionnaire (Appendix H).

3.7.1.1 Short-Form McGill Pain Questionnaire

The McGill Pain Questionnaire was designed to provide a quantitative measure of clinical pain, which could be used statistically (Melzack, 1975). It is one of the most widely used measuring tests for pain, providing valuable information on the sensory, affective and evaluative dimension of the pain experienced (Melzack, 1987). The questionnaire consists of fifteen types of descriptive words, which are rated on an intensity scale: 0 = none, 1 = mild, 2 = moderate and 3 = severe, giving a score out of forty-five (Appendix H).

3.7.1.2 Numerical Rating Scale 101

The Numerical Pain Rating Scale was used to subjectively determine the patients' response to the treatment, in terms of their perception of pain intensity (Jensen et al. 1986).

The patients' perception of pain was recorded on a numerical scale from 1 to 100. 0 being "no pain" and 100 being the "worst pain". The patients were asked to indicate their perception of pain intensity when it is most intense and least intense. The average of these two figures indicated the average pain experienced by the patient (Appendix G). Jensen et al. (1986) found the NRS-101 to be simple, effective and the recommended choice of measuring clinical pain intensity.

3.7.2 Objective Measurements

The objective measurements consisted of wrist range of motion (goniometer) readings and grip strength dynamometer readings.

3.7.2.1 Goniometer Readings

Goniometer readings were taken to assess the degrees of wrist flexion and extension ranges of motion, on the side of the symptomatic elbow only (Appendix F). In a study done by Solveborn and Olerud (1996), it was found that wrist and elbow range of motion was limited in patients suffering from lateral epicondylitis. Goniometer readings taken for passive and active wrist and elbow range of motion, were found to be reliable and of high measurement precision (Solveborn and Olerud, 1996).

3.7.2.2 Grip Strength Dynamometer Readings

Grip strength was assessed using a hand held dynamometer to obtain the readings. Two grip strength readings were taken on the symptomatic side, one with the elbow at ninety degree flexion and the other with the elbow straight at a one hundred and eighty degrees (Appendix F).

De Smet and Fabry (1997) found that there was a marked reduction in grip force on the pathological side, as well as a considerable difference in grip force on the symptomatic side, when the readings were taken with a straight elbow as compared to when they were taken with the elbow at ninety degree flexion. This reduction in grip force was significant on the pathological side but not on the normal control side.

3.8 STATISTICAL ANALYSIS

3.8.1 <u>The Sample Size of the Study</u>

Forty patients took part in the study. Group A consisted of 20 patients receiving the placebo patches. Group B consisted of 20 patients receiving the flurbiprofen LAT (TransAct®) patches (n_1=20, n_2 =20).

All data analyses was done in consultation with trained research statistician. Data was captured onto a spreadsheet and the SPSS© software package was used for statistical analyses (SPSS Inc. 1999).

Four measurements were statistically analysed. These included NRS-101, McGill pain questionnaire, wrist range of motion and grip strength readings. For each of these, readings were taken at the first visit and third visit respectively (one week follow-up).

Wrist range of motion readings were taken in flexion and extension, and grip strength readings were taken at 90 degrees flexion and 180 degrees, of the symptomatic arm only.

Wrist range of motion (goniometer readings), NRS-101 and grip strength dynamometer readings were the continuous variables, while the McGill pain questionnaires were the categorical variables.

3.8.2 Inter-Group Comparisons (Fluriprofen LAT Group versus Placebo Group)

The Mann-Whitney U-test, a non-parametric test, was used to compare the flurbiprofen LAT (TransAct®) group and the placebo group, with regards to the NRS-101, McGill Pain Questionnaire, Grip Strength readings and Goniometer reading.

The above test was used to determine whether any statistically significant difference existed between the fluriprofen LAT (TransAct®) group and placebo group at the 1^{st} and 3^{rd} visits, for each variable at $\alpha = 0.05$ level of significance.

Hypothesis Testing:

The null hypothesis (Ho) states that there was no difference in pain levels, with regards to the pain questionnaires, and no difference in wrist range of motion and grip strength between groups. The alternative hypothesis (H1) states that there was a difference in pain levels, with regards to the pain questionnaires, and a difference in wrist range of motion and grip strength between groups.

- H_0: There was no difference between groups
- H_1: There was a difference between groups
- α = 0.05 Level of significance.

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

3.8.3 Intra-Group Comparisons (Fluriprofen LAT Group versus Placebo Group)

Wilcoxon's signed rank, a non-parametric test, was used to compare the results of the related samples within the flurbiprofen LAT (TransAct®) group and within the placebo group, with regards to the NRS-101, McGill Pain Questionnaire, Grip Strength readings and Goniometer reading.

The above test was used to determine whether any significant difference existed between related samples, within the flurbiprofen LAT (TransAct®) patches and within the placebo groups at the 1st and 3rd visits, for each variable at α = 0.05 level of significance.

Hypothesis Testing:

The null hypothesis (Ho) states that there was no difference in pain levels, with regards to the pain questionnaires, and no difference in wrist range of motion and grip strength between groups. The alternative hypothesis (H1) states that there was a difference in pain levels, with regards to the pain questionnaires, and a difference in wrist range of motion and grip strength between groups.

- H_0: There was no difference between groups
- H_1: There was a difference between groups
- α = 0.05 Level of significance.

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

3.9 SUMMARY

Forty patients suffering from lateral epicondylitis were selected to participate in this study. Twenty patients were randomly allocated into the fluriprofen LAT (TransAct®) group and twenty into the placebo group. Each patient was assessed, in terms of objective and subjective clinical findings and all the necessary data was obtained for statistical analysis.

CHAPTER FOUR

4.0 THE RESULTS

4.1 INTRODUCTION

This chapter concerns itself with the results obtained, after statistical analysis of the data, from the measurement criteria as discussed in chapter 3. The data is presented in tabular form with relevant comments and interpretation in order to accept or reject the null hypothesis.

4.2 THE HYPOTHESIS

Wilcoxon's signed rank test was used to compare the results of the related samples within the flurbiprofen LAT (TransAct®) group and within the placebo group, with regard to the NRS-101, McGill Pain Questionnaire, grip strength and goniometer readings. The null hypothesis (Ho) states that there was no difference in pain levels, with regard to the pain questionnaires, and no difference in wrist range of motion and grip strength between groups. The alternative hypothesis (H1) states that there was a difference in pain levels, with regard to the pain questionnaires, and a difference in wrist range of motion and grip strength between groups.

The Mann-Whitney U-test was used to compare the fluriprofen LAT (TransAct®) group and placebo group, with regard to the NRS-101, McGill Pain Questionnaire, Grip strength and goniometer readings. The null hypothesis (Ho) states that there was no difference in pain levels, with regards to the pain questionnaires, and no difference in wrist range of motion and grip strength between groups.

The alternative hypothesis (H1) states that there was a difference in pain levels, with regard to the pain questionnaires, and a difference in wrist range of motion and grip strength between groups.

4.3 ANALYSED DATA

The data was analysed at $\alpha = 0.05$ level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

4.4 DEMOGRAPHIC DATA

Table 4.4.1 **RACE DISTRIBUTION**

RACE	NUMBER OF PATIENTS GROUP A	NUMBER OF PATIENTS GROUP B	OVERALL/ PERCENTAGE
WHITE	16	17	33 (83%)
INDIAN	3	3	6 (15%)
BLACK	0	0	0 (0%)
COLOURED	1	0	1 (2%)

Table 4.4.2 **AGE DISTRIBUTION**

AGE INTERVALS (YEARS)	NUMBER OF PATIENTS GROUP A	NUMBER OF PATIENTS GROUP B	OVERALL/ PERCENTAGE
21-30	1	0	1
31-40	7	4	11
41-50	9	8	17
51-60	3	8	11
Average Age	**(42.4)** Min Age: 30 Max Age: 55	**(47.9)** Min Age: 37 Max Age:57	**(45.2)** Min Age: 30 Max Age: 57

Table 4.4.3 **GENDER DISTRIBUTION**

GENDER	NUMBER OF PATIENTS GROUP A	NUMBER OF PATIENTS GROUP B	OVERALL/ PERCENTAGE
Male	13	16	29 (72%)
Female	7	4	11(28%)

Table 4.4.4 **CAUSE OF INJURY**

CAUSE OF INJURY		NUMBER OF PATIENTS
Racquet Sports:	Tennis	7 (17.5%)
	Squash	4 (10%)
Other Sports:	Golf	3 (7.5%)
	Jet Ski	1 (2.5%)
	Motor Bike	1 (2.5%)
	Ten Pin Bowling	1 (2.5%)
	Drumming	1 (2.5%)
Non-Sporting Activities:	Insidious	7 (17.5%)
	Lifting Something Heavy	5 (12.5%)
	Work with Hands	2 (5%)
	Computer Mouse	1 (2.5%)
	Rolling Pin	1 (2.5%)
	Hammering	1 (2.5%)
	Guitar	1 (2.5%)
	Sanding	1 (2.5%)
	Bumped Elbow	1 (2.5%)
	Garden Work	1 (2.5%)
	Cutting Glass	1 (2.5%)

Table 4.4.5 **OCCUPATION OF PATIENTS**

GROUP A	NUMBER OF PATIENTS
Self-Employed	5 (25%)
Technician	2 (10%)
Clerk	1 (5%)
Sales Director	1 (5%)
Accountant	1 (5%)
Boat Repairs	1 (5%)
Artisan	1 (5%)
Life Assurance	1 (5%)
Design Engineer	1 (5%)
Sales Representative	1 (5%)
Computer Consultant	1 (5%)
Station Commander	1 (5%)
Financial Manager	1 (5%)
Journalist	1 (5%)
Reimburse-ment Officer	1 (5%)

GROUP B	NUMBER OF PATIENTS
Manager	4 (20%)
Self-Employed	3 (15%)
Sales Representative	3 (15%)
Deputy Director	1 (5%)
Clothing Manufacture	1 (5%)
House wife	1 (5%)
Computer Analyst	1 (5%)
Retired	1 (5%)
Fitter and Turner	1 (5%)
Electrician	1 (5%)
Transport Director	1 (5%)
Shelving and Racking	1 (5%)
Unemployed	1 (5%)

Table 4.4.6.1. **TOTAL NUMBER OF TESTS POSITIVE IN GROUP A (PLACEBO)**

Tests Positive per Visit	**Visit 1**	**Visit 2**	**Visit 3**	**Average**
Resisted wrist extension	13	14	11	(12.67)
Mills test	16	13	12	(13.67)
Cozen's test	11	9	7	(9.0)
Resisted third finger extension	6	5	5	(5.33)
Total Tests Positive	**46**	**41**	**35**	

Table 4.4.6.2. **TOTAL NUMBER OF TESTS POSITIVE AT VISIT 1 IN GROUP A (PLACEBO)**

Tests Positive per Visit	Visit 1	Percentage Positive Tests
Resisted wrist Extension	13	(28%)
Mills test	16	(35%)
Cozen's test	11	(24%)
Resisted third finger extension	6	(13%)
Total Positive	**46**	**(100%)**

Table 4.4.6.3. **TOTAL NUMBER OF TESTS POSITIVE AT VISIT 2 IN GROUP A (PLACEBO)**

Tests Positive per Visit	Visit 2	Percentage Positive Tests
Resisted wrist Extension	14	(34%)
Mills test	13	(32%)
Cozen's test	9	(22%)
Resisted third finger extension	5	(12%)
Total Positive	**41**	**(100%)**

Table 4.4.6.4. **TOTAL NUMBER OF TESTS POSITIVE AT VISIT 3 IN GROUP A (PLACEBO)**

Tests Positive per Visit	Visit 3	Percentage Positive Tests
Resisted wrist Extension	11	(32%)
Mills test	12	(34%)
Cozen's test	7	(20%)
Resisted third finger extension	5	(14%)
Total Positive	**35**	**(100%)**

Table 4.4.6.5 **TOTAL NUMBER OF TESTS POSITIVE IN GROUP B (TRANSACT®)**

Tests Positive per Visit	**Visit 1**	**Visit 2**	**Visit 3**	**Average**
Resisted wrist extension	18	14	11	(14.33)
Mills test	16	13	6	(11.67)
Cozen's test	12	7	3	(7.33)
Resisted third finger extension	14	7	6	(9.0)
Total Tests Positive	**60**	**41**	**26**	

Table 4.4.6.6. **TOTAL NUMBER OF TESTS POSITIVE AT VISIT 1 IN GROUP B (TRANSACT®)**

Tests Positive per Visit	Visit 1	Percentage Positive Tests
Resisted wrist Extension	18	(30%)
Mills test	16	(27%)
Cozen's test	12	(20%)
Resisted third finger extension	14	(23%)
Total Positive	**60**	**(100%)**

Table 4.4.6.7. **TOTAL NUMBER OF TESTS POSITIVE AT VISIT 2 IN GROUP B (TRANSACT®)**

Tests Positive per Visit	Visit 2	Percentage Positive Tests
Resisted wrist Extension	14	(34%)
Mills test	13	(32%)
Cozen's test	7	(17%)
Resisted third finger extension	7	(17%)
Total Positive	**41**	**(100%)**

Table 4.4.6.8. **TOTAL NUMBER OF TESTS POSITIVE AT VISIT 3 IN GROUP B (TRANSACT®)**

Tests Positive per Visit	Visit 3	Percentage Positive Tests
Resisted wrist extension	11	(42%)
Mills test	6	(23%)
Cozen's test	3	(12%)
Resisted third finger extension	6	(23%)
Total Positive	**26**	**(100%)**

4.5 THE NON-PARAMETRIC WILCOXON SIGNED RANK TESTS

4.5.1 Results of the Wilcoxon Signed Rank Test for Continuous Variables

Table 4.5.1 Results of the Wilcoxon signed rank test for Grip Strength (Elbow at 180º) for both Group A and Group B

The data was analysed at $\alpha = 0.05$ level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Grip Strength 180 Degrees	Mean Rank	Standard Deviation	P values (Treatment 1and3)
Grip 1 Placebo	4.10	13.42	0.002
Grip 3 Placebo	12.63	15.58	
Grip 1 TransAct®	8.42	12.07	0.073
Grip 3 TransAct®	10.73	9.28	

The null hypothesis was rejected for the Grip Strength 180º placebo group (group A), indicating that at ($\propto$) = 0.05 level of significance there was a statistically significant improvement between consultations. The null hypothesis was accepted for the Grip Strength 180º TransAct® group (Group B), indicating that at ($\propto$) = 0.05 level of significance there was no improvement between consultations.

Table 4.5.2 Results of the Wilcoxon signed rank test for Grip Strength (Elbow at 90º) for both Group A and Group B

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Grip Strength 90 Degrees	Mean Rank	Standard Deviation	P values (Treatment 1and3)
Grip 1 Placebo	6.88	12.44	0.500
Grip 3 Placebo	10.13	13.25	
Grip 1 TransAct®	8.17	10.27	0.063
Grip 3 TransAct®	10.85	8.30	

For both Grip Strength 90º groups the null hypothesis was accepted, indicating that at ($\propto$) = 0.05 level of significance there was no improvement between consultations.

Table 4.5.3 Results of the Wilcoxon signed rank test for Wrist Range of Motion (Flexion at the wrist) for both Group A and Group B

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Goniometer Flexion	Mean Rank	Standard Deviation	P values (Treatment 1and3)
Flex 1 Placebo	5.17	11.09	0.113
Flex 3 Placebo	6.31	9.60	
Flex 1 TransAct®	6.50	7.04	0.004
Flex 3 TransAct®	8.79	6.23	

The null hypothesis was accepted for the Wrist Flexion placebo group (Group A), indicating that at ($\propto$) = 0.05 level of significance there was no improvement between consultations. The null hypothesis was rejected for the for Wrist Flexion TransAct® group (Group B), indicating that at ($\propto$) = 0.05 level of significance there was a statistically significant improvement between consultations.

Table 4.5.4 Results of the Wilcoxon signed rank test for Wrist Range of Motion (Extension at the wrist) for both Group A and Group B

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Goniometer Extension	Mean Rank	Standard Deviation	P values (Treatment 1and3)
Ext 1 Placebo	4.67	11.59	0.162
Ext 3 Placebo	5.86	10.84	
Ext 1 TransAct®	7.83	11.98	0.067
Ext 3 TransAct®	7.41	11.41	

For both Wrist Extension groups the null hypothesis was accepted, indicating that at ($\propto$) = 0.05 level of significance there was no improvement between consultations.

Table 4.5.5 Results of the Wilcoxon signed rank test for the Numerical Rating Scale-101 for both Group A and Group B

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

NRS Scale	Mean Rank	Standard Deviation	P values (Treatment 1and3)
NRS 1 Placebo	8.04	13.47	0.006
NRS 3 Placebo	4.25	15.75	
NRS 1 TransAct®	8.77	13.83	0.001
NRS 3 TransAct®	4.50	16.13	

For both NRS–101 groups the null hypothesis was rejected, indicating that at ($\propto$) = 0.05 level of significance there was a statistically significant improvement between consultations.

4.6 THE NON-PARAMETRIC WILCOXON SIGNED RANK TESTS

4.6.1 Results of the Wilcoxon Signed Rank Test for Categorical Variables

Table 4.6.1 Results of the Wilcoxon signed rank test for the McGill for both Group A and Group B

The data was analysed at $\alpha = 0.05$ level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:
For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

McGill	Mean Rank	Standard Deviation	P values (Treatment 1and3)
McGill 1 Placebo	7.38	7.97	0.006
McGill 3 Placebo	9.00	5.17	
McGill 1 TransAct®	8.92	6.44	0.001
McGill 3 TransAct®	2.00	7.18	

For both McGill groups the null hypothesis was rejected, indicating that at $(\propto) = 0.05$ level of significance there was a statistically significant improvement between consultations.

4.7 THE NON-PARAMETRIC MANN-WHITNEY UNPAIRED TESTS:

4.7.1 Results of Mann-Whitney Test Comparing the Continuous Variables Between Group A and Group B

Table 4.7.1 Results of Mann-Whitney test comparing the continuous variables between Group A and Group B for Grip Strength (180º)

The data was analysed at $\alpha = 0.05$ level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Grip Strength 180º		Mean Rank	Standard Deviation	p-value
Treatment 1	Placebo	18.63	12.71	0.310
	TransAct®	22.38		
Treatment 3	Placebo	19.15	12.67	0.464
	TransAct®	21.85		

The null hypothesis was accepted for Grip Strength 180º, indicating that at $\alpha = 0.05$ level of significance there was no difference between the two groups at treatment 1 and treatment 3.

Table 4.7.2 Results of Mann-Whitney test comparing the continuous variables between Group A and Group B for Grip Strength (90º)

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Grip Strength 90º		Mean Rank	Standard Deviation	p-value
Treatment 1	Placebo	18.80	11.32	0.357
	TransAct®	22.20		
Treatment 3	Placebo	17.85	11.07	0.151
	TransAct®	23.15		

The null hypothesis was accepted for Grip Strength 90º, indicating that at α = 0.05 level of significance there was no difference between the two groups at treatment 1 and treatment 3.

Table 4.7.3 Results of Mann-Whitney test comparing the continuous variables between Group A and Group B for Wrist Range of Motion (Flexion)

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Goniometer Flexion		Mean Rank	Standard Deviation	p-value
Treatment 1	Placebo	21.02	9.18	0.773
	TransAct®	19.98		
Treatment 3	Placebo	19.40	8.07	0.542
	TransAct®	21.60		

The null hypothesis was accepted for Wrist Flexion, indicating that at α = 0.05 level of significance there was no difference between the two groups at treatment 1 and treatment 3.

Table 4.7.4 Results of Mann-Whitney test comparing the continuous variables between Group A and Group B for Wrist Range of Motion (Extension)

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

Goniometer Extension		Mean Rank	Standard Deviation	p-value
Treatment 1	Placebo	21.83	11.71	0.468
	TransAct®	19.17		
Treatment 3	Placebo	21.45	11.02	0.602
	TransAct®	19.55		

The null hypothesis was accepted for Wrist Extension, indicating that at $\alpha = 0.05$ level of significance there was no difference between the two groups at treatment 1 and treatment 3.

Table 4.7.5 Results of Mann-Whitney test comparing the continuous variables between Group A and Group B for the Numerical Rating Scale

The data was analysed at $\alpha = 0.05$ level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

NRS Scale		Mean Rank	Standard Deviation	p-value
Treatment 1	Placebo	21.58	13.53	0.559
	TransAct®	19.42		
Treatment 3	Placebo	22.85	16.11	0.203
	TransAct®	18.15		

The null hypothesis was accepted for NRS - 101, indicating that at α = 0.05 level of significance there was no difference between the two groups at treatment 1 and treatment 3.

4.8 THE NON-PARAMETRIC MANN-WHITNEY UNPAIRED TESTS:

4.8.1 Results of Mann-Whitney Test Comparing the Categorical Variables Between Group A and Group B

Table 4.8.1 Results of Mann-Whitney test comparing the categorical variables between Group A and Group B for McGill

The data was analysed at α = 0.05 level of significance.

- H_0: There was no difference between groups
- H_1: There was a difference between groups

Decision Rule:

For a two-tailed test:

- Reject H_0 at α level of significance if $p < \alpha$.
- Do not reject H_0 at α level of significance if $p \geq \alpha$.

McGill		Mean Rank	Standard Deviation	p-value
Treatment 1	Placebo	22.40	6.19	0.578
	TransAct®	18.60		
Treatment 3	Placebo	19.48	7.15	0.302
	TransAct®	21.52		

The null hypothesis was accepted for McGill, indicating that at α = 0.05 level of significance there was no difference between the two groups at treatment 1 and treatment 3.

4.9 <u>COMPARISONS USING BAR CHARTS</u>

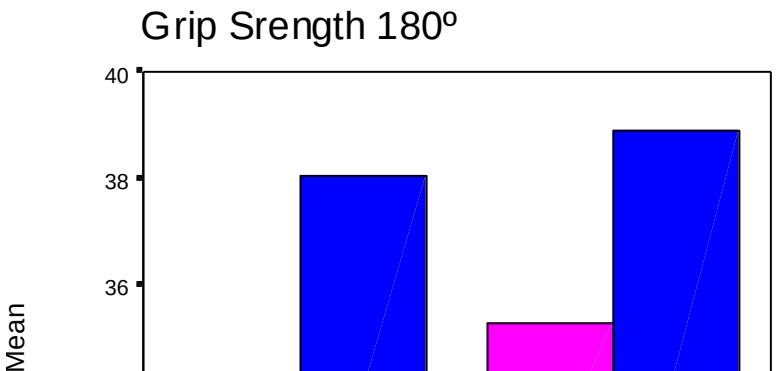

Figure 1 Mean Grip Strength 180º (Comparing Visit 1 to Visit 3.)

This figure indicates the changes in the mean grip strength (elbow at 180º) values over the period of evaluation.

GS1 - Grip strength evaluation mean at treatment 1

GS3 - Grip strength evaluation mean at treatment 3

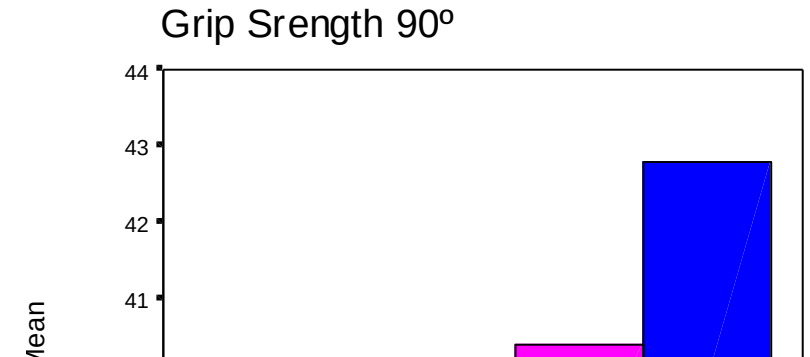

Figure 2 Mean Grip Strength 90º (Comparing Visit 1 to Visit 3).

This figure indicates the changes in the mean grip strength (elbow at 90º) values over the period of evaluation.

GS1 - Grip strength evaluation mean at treatment 1

GS3 - Grip strength evaluation mean at treatment 3

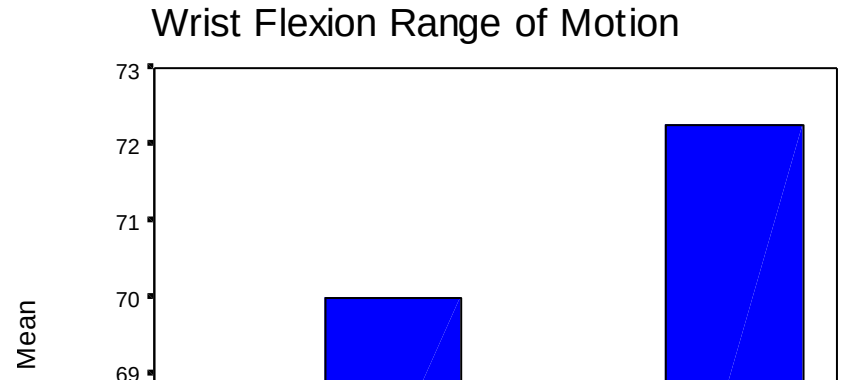

Figure 3 Mean Wrist Range of Motion (Flexion) (Comparing Visit 1 to Visit 3).

This figure indicates the changes in the wrist range of motion (Flexion) values over the period of evaluation.

Flex 1 - Wrist flexion range of motion evaluation mean at treatment 1

Flex 3 - Wrist flexion range of motion evaluation mean at treatment 3

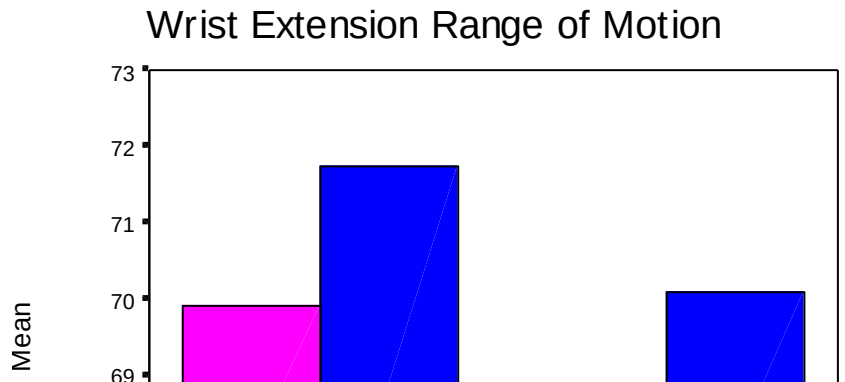

Figure 4 Mean Wrist Range of Motion (Extension) (Comparing Visit 1 to Visit 3).

This figure indicates the changes in the wrist range of motion (Extension) values over the period of evaluation.

Ext 1 - Wrist flexion range of motion evaluation mean at treatment 1

Ext 3 - Wrist flexion range of motion evaluation mean at treatment 3

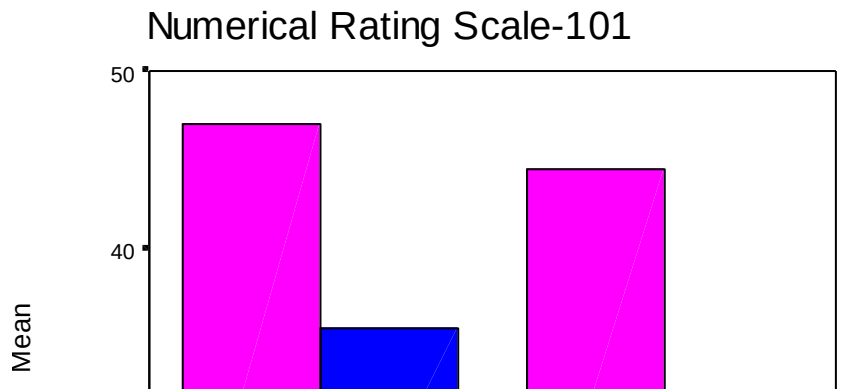

Figure 5 Mean Numerical Rating Scale 101 (Comparing Visit 1 to Visit 3).

This figure indicates the changes in the NRS 101 values over the period of evaluation.

NRS 1 - NRS 101 evaluation mean at treatment 1

NRS 3 - NRS 101 evaluation mean at treatment 3

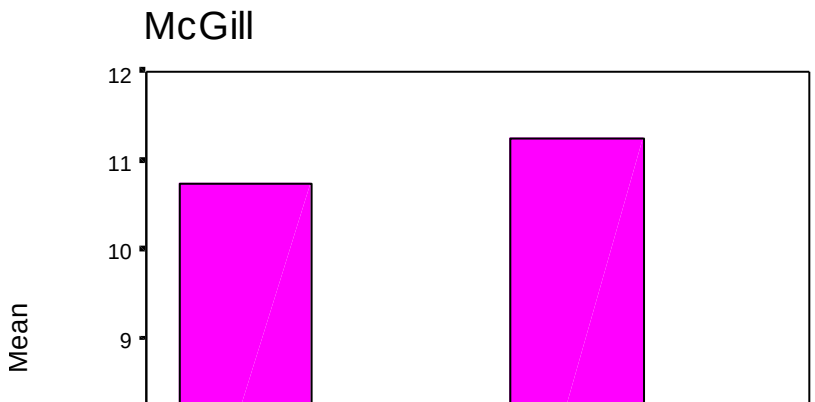

Figure 6 Mean McGill Pain Questionnaire (Comparing Visit 1 to Visit 3).

This figure indicates the changes in the McGill Pain Questionnaire values over the period of evaluation.

McGill 1 - McGill Pain Questionnaire evaluation mean at treatment 1

McGill 3 - McGill Pain Questionnaire evaluation mean at treatment 3

CHAPTER FIVE

5.0 DISCUSSION OF RESULTS

5.1 INTRODUCTION

This chapter deals with a discussion of the subjective and objective clinical data gathered from the Numerical Rating Scale-101, McGill pain questionnaire, grip strength readings and goniometer readings for wrist range of motion.

5.2 DEMOGRAPHIC DATA

Tables 4.4.1 to 4.4.3 provide a breakdown of the racial, age and gender demographics of the study. The average age of patients in group A was 42.4 years of age, in group B the average age was 47.9 and the overall age for the study was 45.2 years. Similar results were found by Shaik (2000) with an overall average age of 40.8, and Roodt (2001) who found much the same, with an overall average age of 47. This is consistent with the finding by Sharat and Maffulli (1997), that the most common age group incidence of lateral epicondylitis is between 40 and 60 years. This falls more into the non-sporting or older age group, with these injuries often being related to overuse or occupational causes and are a lot more difficult to treat (Viola, 1998).

Viola (1998) stated that there is similar incidence rate of lateral epicondylitis in males and females. Of the forty patients participating in the study, 29 (72%) were male and 11 (28%) were female. These findings indicate a large male dominance as opposed to those found in studies by Shaik (2000) and Haswell (2002), who found a slightly more female dominant incidence. This large male predominance could be due to there being a higher male population than female population at the sports clubs, where the majority of the advertising was done.

This could also have been influenced by the male population being involved in more manual occupations than that of the female population, with 25% of the causes in this study being related to manual labour.

Table 4.4.1 provides a breakdown of racial distribution of patients in this study. Of the forty patients in the study 33 (83%) were white, 6 (15%) were indian and 1(2%) coloured. There were no black patients in this study, which is consistent with the study by Viola (1998), which found tennis elbow to be far less common in the black population than that of the white population.

Shaik (2000) and Haswell (2002) argued, that these figures could have been influenced by the methods of advertising, the location of the chiropractic day clinic and the lack of awareness of chiropractic management of lateral epicondylitis in the disadvantaged communities of South Africa.

Table 4.4.4, reflects the cause of injury among the patients in this study. The results revealed that racquet sports, which is believed to be one of the major contributors to the development of tennis elbow (Field and Savoie, 1998), made up 27.5% of the cause of lateral epicondylitis. But 17.5 percent of the patients had not played any racquet sports or had any apparent causative factors for the development of their symptoms. The following made up a large percentage of the remaining causative factors in this study: golf (7.5%), lifting heavy objects (12.5%) and occupations involving heavy/manual labour (12.5%).

In other studies, sporting activities seem to be the most popular cause of injury, with racquet sports being the dominant (Shaik, 2000 and Haswell, 2002). This possibly results from the chronic repetitive overuse of the forearm extensor muscles, commonly associated with racquet sports. Lifting or carrying heavy objects was another cause common to previous studies. This mechanism of injury, which is commonly related to occupations involving manual labour, probably resulted from excessive eccentric loading of the forearm extensor muscles (Shaik, 2000 and Haswell, 2002).

Tables 4.4.6.1 to 4.4.6.8 indicate the most common positive orthopaedic tests during the study. In group A, at the initial consultation, Mills test was found to be the most common positive test (35%), with the resisted wrist extension test being the most common positive test at the second consultation (34%) and Mills test at third consultation respectively (34%).

At the initial consultation, resisted wrist extension test was found to be the most common positive test (30%) in group B. The resisted wrist extension test was also found to be the most common positive test at the second (34%) and third (42%) consultations respectively.

In a study by Haswell (2002), Mills test was found to be the most common positive orthopaedic test. From these findings it could be concluded that due to their higher frequency, resisted wrist extension test and Mills test should be the tests of choice when conducting any orthopaedic examination for lateral epicondylitis.

There was an overall decline in positive tests reflected in both groups, with 46 positive tests at the initial visit as compared to 35 a week later in group A and 60 at the initial visit as compared to 26 a week later in group B. The large drop in positive tests for group B, could be due to this being the active treatment group.

5.3 SUB PROBLEM ONE

The first sub-problem of this study was to determine the efficacy of a local action transcutaneous flurbiprofen patch, in the treatment of lateral epicondylitis, in terms of subjective clinical findings.

5.3.1 Inter- Group Comparison

5.3.1.1 Subjective Data

These results are located in tables 4.7.5 and 4.8.1. Statistical analysis revealed that a difference was not noted between the placebo group (group A) and the local action transcutaneous flurbiprofen group (group B) at the first and third visit, with regards to the Numerical Rating Scale-101 and the McGill Pain Questionnaire.

- **The Numerical Rating Scale (Table 4.7.5)**

A comparison between both the local action transcutaneous flurbiprofen group (group B) and placebo group (group A) revealed no difference (p=0.559) at the initial consultation, which means that both groups had similar levels of pain perception at the initial consultation. A comparison at the third consultation also revealed no difference (p=0.559) between the two groups.

The null hypothesis, which states that there was no difference between groups, was therefore accepted. This means that both treatments were equally effective in reducing the patients perception of pain intensity.

- **The McGill Pain Questionnaire (Table 4.8.1)**

A comparison between both the local action transcutaneous flurbiprofen group (group B) and placebo group (group A) revealed no difference (p=0.578) at the initial consultation, which means that both groups had similar levels of pain perception at the initial consultation. A comparison at the third consultation also revealed no difference (p=0.302) between the two groups.

The null hypothesis, which states that there was no difference between groups, was therefore accepted. This means that both treatments were equally effective in reducing the patients perception of pain.

5.3.2 Intra-Group Comparison

5.3.2.1 Subjective Data

These results are located in tables 4.5.5 and 4.6.1. Statistical analysis revealed that there was a statistically significant difference, with regard to the variables in both the placebo group (group A) and the local action transcutaneous flurbiprofen group (group B). This improvement was noted between the first and third visit, with regards to the Numerical Rating Scale-101 and the McGill Pain Questionnaire.

- **The Numerical Rating Scale (Table 4.5.5)**

A statistically significant difference was noted, in both the placebo group (group A) ($p=0.006$) and the local action transcutaneous flurbiprofen group (group B) ($p=0.001$) between the first and third visit, with regard to the Numerical Rating Scale-101.

The alternative hypothesis, which states that there was a statistically significant difference between the first and third visit, with regard to the variables being tested, was therefore accepted. This means that both the placebo group and the local action transcutaneous flurbiprofen group both improved, in terms of the patients perception of pain intensity, between the initial and final consultation. This was probably due to the patients being constantly aware of the patch (proprioceptive effect) and in turn avoiding any activities that would have aggravated their symptoms, therefore allowing the forearm extensor muscles a chance to rest.

- **The McGill Pain Questionnaire (Table 4.6.1)**

A statistically significant difference was noted, in both the placebo group (group A) (p=0.006) and the local action transcutaneous flurbiprofen group (group B) (p=0.001) between the first and third visit, with regard to the McGill Pain Questionnaire.

The alternative hypothesis was therefore accepted. This means that both the placebo group and the local action transcutaneous flurbiprofen group both improved, in terms of the patients perception of pain, between the initial and final consultation. The patients may have been constantly aware of the patch on their arm, which in turn may have lead them to avoid any activities that could have aggravated their symptoms, therefore allowing the forearm extensor muscles a chance to rest.

5.4 SUB PROBLEM TWO

The second sub-problem of this study was to determine the efficacy of a local action transcutaneous flurbiprofen patch in the treatment of lateral epicondylitis, in terms of objective clinical findings.

5.4.1 Inter- Group Comparison

5.4.1.1 Objective Data

These results are located in tables 4.7.1 to 4.7.4. Statistical analysis revealed that a difference was not noted between the placebo group (group A) and the local action transcutaneous flurbiprofen group (group B) at the first and third visit, with regard to the grip strength and the wrist range of motion.

- **Grip Strength Reading (Table 4.7.1. and 4.7.2.)**

Both the local action transcutaneous flurbiprofen group (group B) and placebo group (group A) had similar levels of grip strength at the initial consultation, which is indicated by the absence of a difference at both the 90º (p=0.357) and 180º (p=0.310) elbow positions. A comparison at the third consultation also revealed no difference between the two groups for grip strength at both the 90º (p=0.151) and 180º (p=0.464) elbow positions.

The null hypothesis was therefore accepted, which means that both treatments were equally effective in improving the patients grip strength.

- **Wrist Range of Motion (Table 4.7.3 and 4.7.4)**

A comparison between both the local action transcutaneous flurbiprofen group (group B) and placebo group (group A) revealed no difference at the initial consultation; which means that both groups had similar wrist range of motion, for both wrist flexion (p=0.773) and wrist extension (p=0.468), at the initial consultation. A comparison at the third consultation also revealed no difference between the two groups for both wrist flexion (p=0.542) and extension (p=0.602).

The null hypothesis was therefore accepted. This means that both treatments were equally effective in improving the patients wrist extension and flexion ranges of motion.

5.4.2 Intra-Group Comparison

5.4.1.2 Objective Data

These results are located in tables 4.5.1 and 4.5.4. Statistical analysis revealed that there was a statistically significant difference, between the first and third visit, with regards to grip strength 180º in the placebo group

(group A), and wrist flexion range of motion in the local action transcutaneous flurbiprofen group (group B). No difference was noted between the first and third visit with regard to the remaining variables in both groups.

- **Grip Strength Reading (Table 4.5.1. and 4.5.2.)**

In the placebo group (group A) a statistically significant difference (p=0.002) was noted between the first and third visit with regard to grip strength 180º. No difference (p=0.500) was noted, between the first and third visit with regard grip strength 90º.

In the local action transcutaneous flurbiprofen group (group B) no difference was noted between the first and third visit with regard to both grip strength 180º (p=0.073) and grip strength 90º (p=0.063).

The null hypothesis, which states that there was no difference between the first and third visit, with regard to the variables being tested, was therefore accepted. However in group A, grip strength 180º, the alternative hypothesis was accepted. This means that patients in the placebo group (group A) improved, in terms of grip strength at 180º, between the initial and final consultation. This was probably due to the patients being constantly aware of the patch and in turn avoiding any activities that would have aggravated their symptoms, therefore allowing the forearm extensor muscles a chance to rest. These results could have been influenced by the placebo patch having greater adhesive properties than that of the active patch, and therefore having a greater proprioceptive effect on the patient.

- **Wrist Range of Motion (Table 4.5.3 and 4.5.4)**

In the placebo group (group A) no difference was noted between the first and third visit with regard to both wrist flexion (p=0.113) and extension (p=0.162) ranges of motion.

In the local action transcutaneous flurbiprofen group (group B) a statistically significant difference (p=0.004) was noted between the first and third visit with regard wrist flexion range of motion. A difference was not noted between the first and third visit (p=0.067), with regard to wrist extension range of motion.

The null hypothesis, which states that there was no difference between the first and third visit, with regard to the variables being tested, was therefore accepted. However in group B, wrist flexion, the alternative hypothesis was accepted. This means that patients in the local action transcutaneous flurbiprofen group (group B) improved, in terms of wrist flexion range of motion, between the initial and final consultation. This could have resulted from patients initially being hesitant to flex their wrist to maximal range of motion due to pain. But due to a decrease in inflammation, pain intensity and relaxation of the forearm extensor muscles following the treatment, the patients were possibly more comfortable with flexing their wrists further, indicating a clinically significant improvement in the local action transcutaneous flurbiprofen (TransAct®) group.

5.5 CONCLUSION OF ABOVE DATA

From the above data it can be concluded that both the local action transcutaneous flurbiprofen patches and the placebo patches are equally effective in the treatment of lateral epicondylitis.

Inter – group comparisons revealed that both groups improved, in terms of the patients' grip strength, wrist range of motion and perception of pain.

Intra – group comparisons revealed that both the placebo and local action transcutaneous flurbiprofen improved the patients' perception of pain between the two consultations. The placebo proved to be effective in improving the patients grip strength at 180º, between the initial consultation and the follow-up a week later.

The local action transcutaneous flurbiprofen group had greater wrist flexion range of motion at the end of the one week treatment, compared to the readings taken at the initial visit.

5.6 STUDY LIMITATIONS

5.6.1 Problems with Demographics

When comparing the demographics of this study, it can be seen that there is a definite male dominance in this study, which could have impacted on the outcomes of the study, by not giving a true reflection of the equal gender incidence of lateral epicondylitis in the general population. The age distribution between the groups could have played a role, especially due to the flurbiprofen LAT (TransAct®) group being on average 5.5 years older than that of the placebo group. According to Viola (1998) an older group of patients can be more difficult to treat than that of a younger group. This is because the older group usually has a more chronic overuse or work related injury, combined with alterations in the collagen content, lipid and ground substance that occurs with increasing age, leading to the tendons losing their adaptive capabilities.

5.6.2 Problems with the Subjective Data

This study was a double-blinded study, in which both the patient and researcher were blinded from knowing which group the patient had been placed, which may have lead to difficulties in completing the questionnaires. The possible reasons for this could have been that patients wanted to please or impress the researcher when answering the questionnaires – the “Hawthorne” effect (Mouton, 1996).

Another problem was that patients expressed some degree of difficulty in defining and quantifying their pain within the parameters of the questionnaires.

It could therefore be beneficial that alternative subjective questionnaires be sort for future studies, to prevent this problem from re-occurring.

5.6.3 Problems with the Objective Data

It was found that some patients squeezed the dynamometer as they attempted to get the grip comfortable in their hands. The researcher had to be aware of this and make sure the dial was on zero before the patient was instructed to squeeze. Some patients did express some difficulty in getting the dynamometer comfortable in their grip and experienced some discomfort to their hand, when squeezing the dynamometer. This could have allowed for an error to occur in the readings, due the discomfort in their hand, thereby limiting their ability to squeeze the dynamometer to the maximum force.

Another problem experienced was that patients, in order to prevent hurting their elbow, didn't always squeeze to maximal contraction. This was more commonly observed at the third visit (second set of readings) where patients knew what to experience from the previous visit, and probably didn't want to re-injure or exacerbate their symptoms at the elbow.

It was found that grip strength taken, especially at 180º, was often extremely painful in patients with severe lateral epicondylitis, and often caused exacerbation of symptoms or a post testing ache.

5.6.4 Problems with the Patches

Although every effort was made to ensure that the patients administered the patches correctly, this may not have been the case, as the onus was left to the patients to change their patches every twelve hours and to use all fourteen patches over the week. The only patch that was administered by someone other than the patient was the first patch, which was administered by an independent person (clinician) at the initial consultation.

The unfortunate problem was that the independent person (clinician) was not always the same person, and changed according to the consulting clinician on duty for that day. This inconsistency may have lead to different patch placement, and might have affected the results of the study, by not keeping the area of anti-inflammatory penetration constant.

It was found that the flurbiprofen LAT (TransAct®) group had great difficulty in keeping the patch stuck to their elbow due to the poor adhesive properties of the patch across a movable joint. Patients in this group had to use a bandage of some sort, wrapped around the elbow to keep the patch on. The placebo patches seemed to stick quite well, as patients in this group didn't express much dissatisfaction.

There were no complaints of adverse effects caused by the flurbiprofen LAT (TransAct®) patches during the study. However, two patients in the placebo group complained about skin reactions from the Hypafix dressing covering the placebo patches. These skin reactions presented as an elevated red area on the skin in the area where the Hypafix was stuck to the skin.

There was a general consensus amongst the patients in both groups, that the patches where too large for the elbow. Many expressed that by the end of the week changing the patches every twelve hours had became tiresome. The flurbiprofen LAT (TransAct®) group had complained that the peppermint smell from the patches had become overwhelming at times. These problems could have led to a lack of compliance amongst patients, thereby possibly affecting the results of the study.

CHAPTER SIX

6.0 RECOMMENDATIONS AND CONCLUSION

6.1 RECOMMENDATIONS

Should this study be repeated, the following are recommended by the researcher:

- **Sample Size**

A larger sample size should be selected, so that a more accurate statistical conclusion could be drawn from the derived information. This may allow for a more accurate representation of the population, in terms of age, race, racial discrimination and occupation.

A larger sample size was initially selected for this study, but due to the low incidence rate of lateral epicondylitis in the general adult population, limitations on only seeing patients in the early mornings and late afternoons, due to the twelve hour treatment time of the LAT (TransAct®) patch and time constraints, the sample size was reduced from thirty to twenty.

- **Follow-up study**

A follow-up reassessment should be set up after one month, six months or even a year, to establish the long term benefits of flurbiprofen LAT (TransAct®) patches.

- **Further Research**

Further studies into the effectiveness of flurbiprofen LAT (TransAct®) patches could be more effectively conducted by performing a longer treatment protocol, possibly over a two week period.

This treatment was found to be effective in treating soft tissue rheumatism (Poul et al. 1993), and could prove to be more effective for the treatment of lateral epicondylitis. A longer treatment protocol would further strengthen the available research on the long term side effects of flurbiprofen LAT (TransAct®) patches.

It would be recommended in further studies, that patients limit their activity with the affected elbow, over the treatment period. The reason for this is that, it was often found that patients were improving over the treatment period, but would deteriorate when the elbow was overused, this could have possibly affected the results of the study. These effects could be determined by further research, into the effectiveness of flurbiprofen LAT (TransAct®) patches versus rest in the treatment of lateral epicondylitis.

- **Blinding**

This study was conducted as a double blinded study, with both the researcher and the patient being blinded to the treatment the patient was receiving. A limitation of the blinding procedure was that different clinicians were involved in administering the patients first patch at the initial consultation. The clinician should be kept constant for further studies, as this consistency would strengthen the study by eliminating further variables.

- **Accuracy of Measurements**

The instrumentation used, particularly the goniometer, should be more sensitive to small changes in the range of motion between treatments, this may be obtained by using a digital inclinometer. The goniometer should be able to ensure that the neutral position of the wrist is kept constant before readings are taken.

The grip strength dynamometer grip should be made more comfortable for the patients' hand, therefore allowing the patient to squeeze the dynamometer to maximum force without experiencing any discomfort.

6.2 CONCLUSION

This double blinded placebo study to determine the relative efficacy of topical flurbiprofen in the form of a local action transcutaneous patch, in the treatment of lateral epicondylitis, revealed that the flurbiprofen LAT (TransAct®) patches were no more effective than the placebo patches in the treatment of tennis elbow.

Further research is needed into lateral epicondylitis, firstly to determine the aetiology and pathological process involved in the development of lateral epicondylitis, and secondly to determine to what degree the inflammatory reaction occurs and at what stage in the course of the condition is the inflammation at its worst. This information is vital for anti-inflammatory management and research, in patients suffering from this painful and difficult condition.

Although the results of this study were not significant, certain patients found the flurbiprofen LAT (TransAct®) patches to be effective in reducing their symptoms, whilst others found the flurbiprofen LAT (TransAct®) patches to have no effect on their symptoms at all. Thus, further research is strongly recommended to assess whether the flurbiprofen LAT (TransAct®) patches are effective, and at what stage in the management of lateral epicondylitis they might be effective.

The proprioceptive effect of these patches seemed to have a definite effect on this study, especially in the grip strength 180º placebo group in which there was a statistically significant intra-group improvement ($p=0.002$) between visits without any difference in the flurbiprofen LAT (TransAct®) group.

Patients in both groups were constantly aware of the patches on their elbows, which could possibly have lead them to avoiding any activities that would have aggravated their symptoms.

Research into the proprioceptive effect in treating lateral epicondylitis needs to be furthered, especially considering that counterforce bracing is believed to be of some benefit in the treatment of lateral epicondylitis, though its not known how much of this is due to the proprioceptive effect of the band.

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