

**THE CLINICAL EFFECTIVENESS OF THERAPEUTIC EXERCISES ALONE AND
IN COMBINATION WITH ORTHOTIC BRACING IN THE TREATMENT OF
LATERAL EPICONDYLALGIA.**

By

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A dissertation submitted in partial compliance with the requirements for the

Master's Degree in Technology: Chiropractic

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I, Megan Flanders, do declare that this dissertation is representative of my own work
in both conception and execution (except where acknowledgements indicate to the
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DECLARATION

I, Megan Flanders, declare that this is my own, unaided work. It is being submitted as partial fulfilment for the Master's degree in Technology, in the programme of Chiropractic, at the Durban University of Technology. It has not been submitted before for any degree or examination in any other Technikon or University.

Megan Flanders

On this day the ____ of the month of _____ 2011.

DEDICATIONS

To my parents, Dave and Judy Flanders, who have always been there to support, encourage and love me in whatever I do, and whom have supported me and made my studying possible.

To the rest of my family, particularly my Grandmother, Eilleen Flanders, and my late Grandfather, Dennis Flanders, who have been pillars of strength, love and support in my life.

To God, whom through all things are possible.

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To Dr. Praveena Maharaj who helped co-supervise this study - thank you too for sacrificing your time to help me complete this thesis. It is much appreciated.

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Abstract

Introduction

Lateral epicondylalgia (L.E) is a common diagnosis in elbow pathology. The aetiology is poorly understood but it is generally accepted to be as a result of repetitive microtrauma, affecting the proximal end of the extensor carpi radialis brevis tendon. Elbow bracing and exercise modification are often utilised by sufferers in order to reduce symptoms. In addition, there have been multiple treatment regimes used in practice to treat L.E, but none has stood out as being more effective than another. Thus, the aim of this study was to investigate the relative clinical effectiveness of therapeutic exercises alone and in combination with orthotic bracing, in terms of subjective and objective clinical findings.

Methods

This stratified, quantitative, prospective clinical trial consisted of two equal groups (n=15) diagnosed with L.E. Group One consisted of a strengthening and stretching programme alone, and Group Two consisted of a combination of the same programme and an orthotic brace. The participants performed the programme daily at home for six weeks, and the brace was worn throughout the day for six weeks. Each participant was assessed before, during and after the programme, in terms of subjective and objective clinical data which was then statistically analysed using SPSS version 18. Repeated measures ANOVA testing was also used to compare the outcomes between the groups over the time points.

Results

Both groups showed significant statistical improvement in terms of all the outcome measures. The groups also showed a clinically significant improvement for all the outcome measures except pressure pain threshold where Group Two showed clinically significant improvement over Group One.

Conclusion

The results show that there was negligible benefit when combining an orthotic brace with therapeutic exercises as opposed to performing the therapeutic exercises alone.

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LIST OF ACRONYMS

ECRB – Extensor Carpi Radialis Brevis

ECRL – Extensor Carpi Radialis Longus

ESWT - Extracorporeal shockwave therapy

L.E – Lateral Epicondylalgia

MRI – Magnetic Resonance Imaging

NPRS – Numerical Pain Rating Scale

PFGS – Pain Free Grip Strength

PPT – Pressure Pain threshold

PRTEE – Patient Rated Tennis Elbow Evaluation

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Chapter One: Introduction

1.1 Introduction

Lateral epicondylalgia (L.E) is also commonly known as tennis elbow or lateral epicondylitis. The latter terms can be misleading as only 5-10% of the cases of L.E are caused by playing tennis, but within the tennis community, 50% of players will suffer from L.E at some point in their life (Hong *et al.*, 2004). The clinical diagnosis is based on local pain anterior or just distal to the lateral epicondyle with palpatory tenderness over this area, especially with resistance to wrist or middle finger extension (Scher *et al.*, 2009).

In this context, L.E is one of the most common lesions of the upper limb (Greenfield and Webster, 2002) and is the most commonly diagnosed injury of the elbow (Hong *et al.*, 2004); it results from repetitive microtrauma and is considered an overuse injury (Greenfield and Webster, 2002). The angiofibrotic dysplasia of L.E most commonly affects the proximal attachment of the extensor carpi radialis brevis (ECRB) tendon (Bishai and Palmer, 2006), but the extensor digitorum communis is also affected in a third of patients (Kraushar and Nirschl, 1999).

Lateral epicondylalgia has a prevalence of 1-3% in the general population and has a peak incidence between 34 and 54 year olds. The onset can be gradual, or brought on suddenly by a traumatic event (Greenfield and Webster, 2002). Lateral epicondylalgia has a natural recovery course of between six months and two years (Struijs *et al.*, 2006); however, chronic cases have been known to persist for up to 8 years (Wood *et al.*, 2006). It seldomly affects people under the age of 30 (Viola, 1998), but when it is seen in young people, it is usually as a result of sporting activities, and when seen in older patients it is generally associated with occupational activities (Hong *et al.*, 2004). The majority of cases (35-64%) are due to occupational stresses (Hong *et al.*, 2004), and L.E is commonly found in golfers, squash players, bricklayers, carpenters, violinists, housewives, dentists, surgeons and anyone else who is involved in repetitive motions, particularly forearm rotation and wrist flexion and extension (Viola, 1998).

Recent literature reports that L.E affects females more frequently (Radpasand *et al.*, 2009), particularly in the military population (Wolf *et al.*, 2010) and that the incidence in females increases to 10% between the ages of 42 and 46 (Olaussen *et al.*, 2009), yet there is also literature stating that L.E affects males and females equally (Johnson *et al.*, 2007). Similarly, L.E has been found more commonly in the dominant arm (Wood *et al.*, 2006; Bjordal *et al.*, 2008; Radpasand *et al.*, 2009), although Greenfield and Webster, (2002) found no association with arm dominance further to the above Stasinopoulos and Stasinopoulos, (2006) reported L.E to be more severe and long standing in females and is more prevalent in the white population as opposed to the black population (Viola, 1998).

Discordant reports concerning the prevalence, aetiology, diagnosis and treatment of L.E date back to 1882 and there is currently still no consensus as to the aetiology, diagnosis and most importantly the most effective treatment protocols (Radpasand *et al.*, 2009). There are multiple publications on L.E but the studies have a large diversity of methods and often result in inconclusive findings. For this reason, there is evidence that suggests the effectiveness of particular treatments, but the optimum treatment for L.E is still unknown (Labelle *et al.*, 1992; Erturk *et al.*, 1997; Struijs, 2001; Vicenzino *et al.*, 2007; Radpasand *et al.*, 2009).

Some of the more common treatment options that L.E sufferers utilize are: stretching and strengthening exercises, ergonomic counselling, education, manipulation, friction massage, steroid injection, orthotic braces and therapeutic ultrasound (Viola, 1998; Greenfield and Webster, 2002; Hong *et al.*, 2004; Peterson *et al.*, 2005; Struijs *et al.*, 2006; Johnson *et al.*, 2007).

Of these, the tennis elbow brace is a common treatment option for L.E (Struijs *et al.*, 2001; Van de Streek *et al.*, 2004; Johnson *et al.*, 2007), as it is perceived to reduce the stress placed on the overloaded extensor tendons (Burton, 1985; Struijs *et al.*, 2004). Despite there being multiple studies, there is no conclusive evidence regarding the relative effectiveness of bracing in the treatment of L.E (Struijs *et al.*, 2001; Hijmans *et al.*, 2004; Johnson *et al.*, 2007). There is, however a general consensus that braces may be helpful, particularly as initial therapy, to assist in performing activities of daily living (Wuori *et al.*, 1998; Struijs *et al.*, 2004). In

addition, braces have many benefits (viz. they are simple to wear) and patients prefer using the brace over other treatments (Dwars *et al.*, 1990).

Conversely, strengthening and stretching exercises are well supported as being an effective treatment option for L.E (Oken *et al.*, 2008), particularly eccentric exercises where even the limited and varied research has shown encouraging results (Malliaris *et al.*, 2008). Despite previous studies concluding that combining physiotherapy as well as strengthening exercises with orthotic bracing was no more effective than the treatments individually (Struijs *et al.*, 2004; Luginbuhl *et al.*, 2008), both strengthening exercises and orthotic bracing show promise as effective treatment options. Therefore, this research aimed to investigate the effectiveness of a particular stretching and strengthening programme (Appendix 6) alone and in combination with an orthotic brace (Appendix 11) in the treatment of L.E.

1.2 Statement of the problem

The aim of this study was to investigate the relative clinical effectiveness of a strengthening and stretching programme alone and in combination with orthotic bracing, in terms of subjective and objective clinical findings, in the treatment of L.E.

1.3 Objectives of the study

1.3.1 Objective One

The first objective was to determine the relative effectiveness of a strengthening and stretching programme versus this programme combined with an orthotic brace, using subjective measures, in the treatment of L.E.

1.3.2 Objective Two

The second objective was to determine the relative effectiveness of a strengthening and stretching programme versus the same programme combined with an orthotic brace, using objective measures, in the treatment of L.E.

1.3.3 Objective Three

The Third objective was to compare the two groups in terms of subjective and objective data.

1.4 Hypothesis and Null Hypothesis

1.4.1 Hypothesis

It was hypothesised that the strengthening and stretching programme of the forearm extensor muscles combined with an orthotic brace, would be equally effective in improving objective and subjective findings in patients with L.E.

1.4.2 Null hypothesis

It was hypothesised that the strengthening and stretching programme of the forearm extensor muscles combined with the orthotic brace would not be as effective as the strengthening and stretching programme alone in improving objective and subjective findings, in patients with L.E.

1.5 Rationale for the study

Vicenzino (2003) stated that therapeutic exercises are the mainstay of treatment for L.E, and eccentric exercises in particular are well supported as being an effective treatment option (Pienimaki *et al.*, 1996; Pienimaki *et al.*, 1998; Svernlov and Adolfsson, 2001; Stasinopoulos *et al.*, 2005; Martinez-Silvestrini *et al.*, 2005; Stasinopoulos and Stasinopoulos, 2006; Croisier *et al.*, 2006; Oken *et al.*, 2008). Subsequent to this it has been found that combining progressive eccentric and concentric training is cheap, convenient and has produced positive long term pain relief (Finestone and Rabinovitch, 2008). This supports literature indicating that strengthening may decrease neovascularisation which is a causative factor in painful tendinopathies (Alfredson *et al.*, 2003; Ohberg and Alfredson, 2004). Despite this positive view towards exercise programmes in the treatment of L.E, Stasinopoulos *et al.*, (2005), suggest further research be conducted into the effectiveness of a

supervised exercise programme, consisting of eccentric exercises and static stretching for L.E.

Additionally, orthotics are commonly used in practice and at home for treating L.E (Johnson *et al.*, 2007). Lateral epicondylalgia has been known to resolve without any form of treatment within eight to twelve months (Oken *et al.*, 2008) and for this reason orthotic braces are often bought by patients without advice or prescription from a health care provider in the hope that the brace will reduce pain whilst the condition runs its natural course (Hijmans *et al.*, 2004). Despite there being literature on the subject, and a general consensus that braces may be helpful (Wuori *et al.*, 1998), no conclusive evidence has been made regarding their relative effectiveness (Struijs *et al.*, 2001; Hijmans *et al.*, 2004; Johnson *et al.*, 2007) and further research is warranted in order to reach a conclusion (Wuori *et al.*, 1998; Struijs *et al.*, 2001; Chan and Gabriel, 2003).

Thus, a study by Luginbuhl *et al.*, (2008) combined a forearm support band and strengthening exercises and compared this to the individual interventions. All three groups produced similar results and therefore no beneficial effect could be identified with any of the interventions. They concluded that the condition would improve with time (Luginbuhl *et al.*, 2008). It should be noted, however, that every patient involved in their study received a cortisone injection prior to the treatment, which may have masked outcomes. Therefore, this current research aimed to contribute to the study by Luginbuhl *et al.*, (2008), by following a similar treatment but was different in that there was no cortisone injection administered to the participants prior to or during the research procedure.

This research may, therefore, provide a clearer conclusion as to the effectiveness of orthotic bracing as an adjunct to stretching and strengthening, as well as adding value to the existing literature concerning stretching and strengthening in the treatment of L.E.

1.6 Benefits of the study

Lateral epicondylalgia affects society as a whole, as it is a painful and debilitating condition that often results in absenteeism from work (Bisset *et al.*, 2005). This absenteeism, therefore, has an impact on the economy, and in the personal life of the patient suffering with this condition because of a constraint on their activities of daily living (Struijs *et al.*, 2006).

1.7 Limitations of the study

One of the limitations to this study was that there were a small number of participants in this clinical trial, thus it is likely that the sample size did not have the required statistical power to measure smaller changes over time. This is because a *priori* power analysis was not completed at the outset of this trial, which would have required significantly more participants than time or budget permitted for this study (Hinton , 2001).

Many studies on treatment options for L.E are flawed and underpowered as a result of small sample sizes which limits the findings (Hong *et al.*, 2004). This was true for this study too, and means that the results obtained serve as an indication, and cannot be assumed true for the population as a whole.

Another limitation was the time frame over which the research took place. It did not allow for long term follow up (over a month, six months or a year) to take place. This means that the long term benefits of this study could not be determined.

1.8 Conclusions

From this chapter it can be seen that there is a necessity to determine the effectiveness of orthotic bracing as an adjunct treatment option in the treatment of L.E. The following chapter, Chapter Two, will discuss the relevant anatomy and review the literature pertaining to L.E and its treatment, specifically therapeutic exercise and orthotic bracing. Chapter Three will discuss the methodology implored in this study, describing the study design and all aspects of how the study was

carried out. Chapter Four illustrates the results obtained from this study. Chapter Five discusses those results and Chapter Six considers any recommendations to future studies and states the conclusion of this study.

Chapter Two: Literature Review

2.1 Introduction

This chapter is a literature review containing information about L.E. The anatomy of the elbow joint as well as the forearm extensor muscles is presented followed by a discussion of L.E in terms of its definition, aetiology, pathophysiology, clinical presentation, differential diagnosis and the common treatment options for L.E. With respect to this research, emphasis will be placed on stretching and strengthening exercises and the use of orthotic bracing in the treatment of this condition.

2.2 Anatomy of the elbow joint and related structures

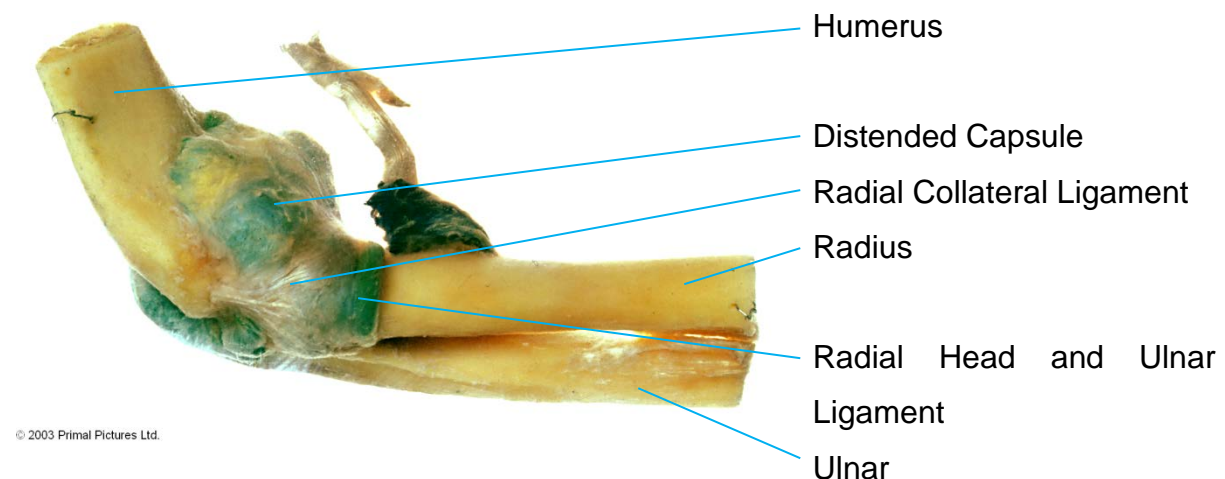


Figure 2.1 Picture depicting the osseous anatomy of the elbow

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The elbow joint is situated at the distal end of the humerus and at the proximal ends of the radius and ulna (Sinnatamby, 2006). It has been described as a hinge type of synovial joint, allowing one plane of motion, flexion and extension (Moore and Dalley, 2006). However, it has also been described as a trochoginglymoid joint, as it actually allows for two types of movements: flexion and extension (the principle

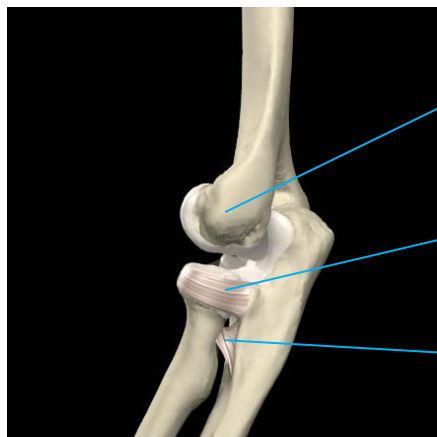
movement of the elbow joint) and rotation (also called pronation and supination) of the forearm (Brabston *et al.*, 2009).

To facilitate these movements, the distal aspect of the humerus consists of the spool shaped trochlea notch on the medial aspect, and the spheroidal capitellum on the lateral aspect (Moore and Dalley, 2006). The capitellum, articulates with the concave surface of the radial head forming what is known as the radiocapitellar joint. This joint bears 60% of the load placed on the elbow when it is in extension, and is also responsible for a large amount of rotation of the forearm. The trochlear, articulates with the greater sigmoid notch of the ulna to form the ulnohumeral joint. This articulation creates a loose type of “hinge” joint that works in conjunction with the medial and lateral collateral ligaments as the primary stabilizers of the elbow joint (Brabston *et al.*, 2009). The articular surfaces of both the radiohumeral and ulnohumeral joints are covered in hyaline cartilage (Moore and Dalley, 2006).

There is also a joint located proximally between the radius and ulna known as the proximal radioulnar joint. This is a type of synovial joint known as a pivot joint which allows for the radial head to articulate with the radial notch of the ulna (Moore and Dalley, 2006). This joint allows for supination and pronation of the forearm to occur smoothly between these two long bones (Sinnatamby, 2006).

The extended ulnar makes an angle of about 170 degrees lateral to the humerus, which is known as the carrying angle. This angle allows the arm to fit into the waist when carried alongside the body. However, when the forearm is held in almost full pronation, the usual working position, the angle between the upper arm and the forearm becomes almost a straight 180 degree angle (Sinnatamby, 2006).

The ligamentous support includes:

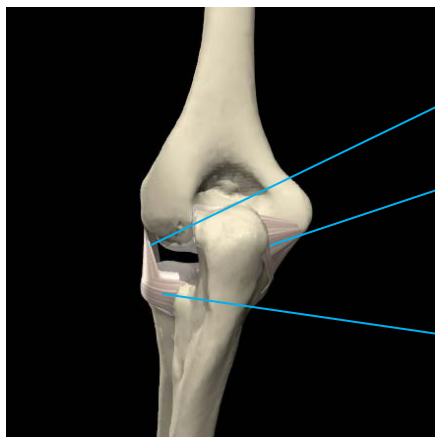


Interactive Shoulder © 2000 Primal Pictures Ltd.

Lateral Epicondyle – point of insertion of the common extensor tendon

Annular Ligament

Quadrate Ligament

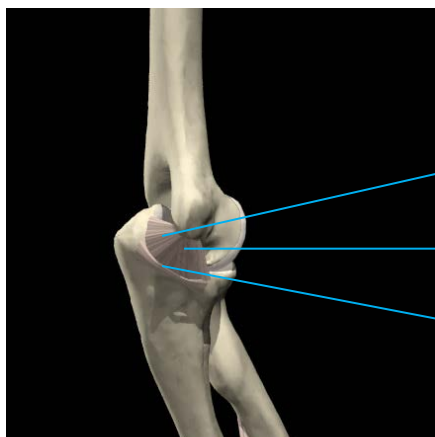


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Lateral radial collateral ligament

Posterior and Oblique fibers of the ulnar collateral ligament

Annular Ligament



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Posterior

Anterior

Oblique

Ulnar Collateral Ligaments

Figure 2.2: Pictures depicting the ligamentous anatomy of the elbow

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The elbow is mainly stabilized through the *ulnohumeral joint*, the *medial ulnar collateral ligament* and the *lateral radial collateral ligament*. The *olecranon*, the posterior aspect of the distal humerus, is also a large stabilizer of the elbow complex; especially when the elbow is in extension and when a valgus force is placed on the elbow joint (Brabston *et al.*, 2009).

The *joint capsule* of the elbow contains an outer fibrous layer lined with an inner synovial membrane. The joint capsule is weakest anteriorly and posteriorly but is strengthened on its medial and lateral sides by the collateral ligaments which are essentially triangular thickenings of the lateral and medial aspects of the fibrous capsule (Moore and Dalley, 2006).

The *lateral collateral ligament* (LCL) is a triangular band (Sinnatamby, 2006) made up of the annular ligament, the radial collateral ligament and the lateral ulnar collateral complex. The *annular ligament* attaches anteriorly and posteriorly to the lesser sigmoid notch (Brabston *et al.*, 2009). It has no attachment to the radius (Sinnatamby, 2006) as it literally just forms a sling around the radial head, holding it in position and allowing the radial head to freely rotate with pronation and supination of the forearm (Moore and Dalley, 2006). The *radial collateral ligament* attaches to the medial aspect of the lateral humeral epicondyle and extends to insert onto the annular ligament (Brabston *et al.*, 2009). The *lateral ulnar collateral ligament* originates on the lateral epicondyle and sends fibers to insert onto the superior crest of the ulna, the radius and the annular ligament (Brabston *et al.*, 2009).

The *medial ulnar collateral ligament* is triangular in shape and is made up of three bands: an *anterior oblique bundle*, a *posterior oblique bundle* and the *transverse ligament*. The medial ulnar collateral ligament originates from the anteroinferior surface of the medial epicondyle and inserts onto the coronoid process and olecranon of the ulnar. The anterior oblique bundle is the strongest of the three bands with the posterior bundle being a fanlike band and the weakest. The oblique band is slender and aids in deepening the socket in which the trochlear of the humerus sits (Moore and Dalley, 2006).

The muscular support includes :

Approximately 17 muscles that cross the elbow and extend to the wrist and hand / or originate from the shoulder complex. These muscles all potentially are able to affect movement of the elbow (Moore and Dalley, 2006).

The extensor muscles of the forearm are found in the posterior (extensor-supinator) compartment of the forearm and are innervated by branches of the radial nerve. The extensor muscles can be divided into a superficial and a deep group.

Within the *superficial group* (Table 2.1) are the extensor carpi ulnaris (ECU), the extensor carpi radialis brevis (ECRB), extensor digiti minimi (EDM) and extensor digitorum (ED), which all attach proximally to the lateral epicondyle through the common extensor tendon. This is significant as the common extensor tendon is affected in L.E. The other two muscles of the superficial extensor group are the brachioradialis and extensor carpi radialis longus (ECRL), which attach proximally to the lateral aspect of the supracondylar ridge of the humerus (Moore and Dalley, 2006).

The *deep group* (Table 2.1) of the extensor muscles consists of abductor pollicis longus (APL), extensor pollicis longus (EPL), extensor pollicis brevis (EPB), extensor indicis (EI) and supinator. It is important to note that the supinator muscle also attaches to the lateral epicondyle of the humerus, the other deep extensor muscles have various attachment points outside of the lateral epicondyle (Moore and Dalley, 2006).

Table 2.1: Muscles of the forearm relevant to L.E

Muscle	Origin	Insertion	Action	Innervation
Extensor carpi radialis brevis (ECRB)	Lateral epicondyle of the humerus	Base of the third metacarpal	Extends and abducts the hand at the wrist	Deep branch of the radial nerve (C7 and C8)
Extensor digiti minimi (EDM)	Lateral epicondyle of the humerus	Extensor expansion of the fifth digit	Extends the fifth digit at the metacarpophalangeal and interphalangeal joints	Posterior interosseous nerve (C7 and C8) as well as the continuation of the deep branch of the radial nerve
Extensor carpi ulnaris (ECU)	Lateral epicondyle of the humerus and the posterior aspect of the ulna	Base of the fifth metacarpal	Extends and adducts the hand at the wrist	Posterior interosseous nerve (C7 and C8) as well as the continuation of the deep branch of the radial nerve
Extensor digitorum	Lateral epicondyle of the humerus	Extensor expansions of the medial four digits	Extends the hand at the wrist and extends the medial four digits at the metacarpophalangeal joints	Posterior interosseous nerve, (C7 and C8) as well as the continuation of the deep branch of the radial nerve
Brachioradialis	Lateral supracondylar ridge of the humerus	Lateral surface of the distal radius	Flexes the forearm	Radial nerve, C5, C6 and C7
Extensor Carpi Radialis Longus (ECRL)	Lateral supracondylar ridge of the humerus	Base of the second metacarpal	Extends and abducts the hand at the wrist	Radial nerve, C6 and C7
Supinator	Lateral epicondyle of the humerus; the radial collateral and annular ligaments; the supinator fossa and the crest of the ulna	The proximal third of the ulna (lateral, posterior and anterior surfaces)	Supinates the forearm	Deep branch of the radial nerve, C5 and C6

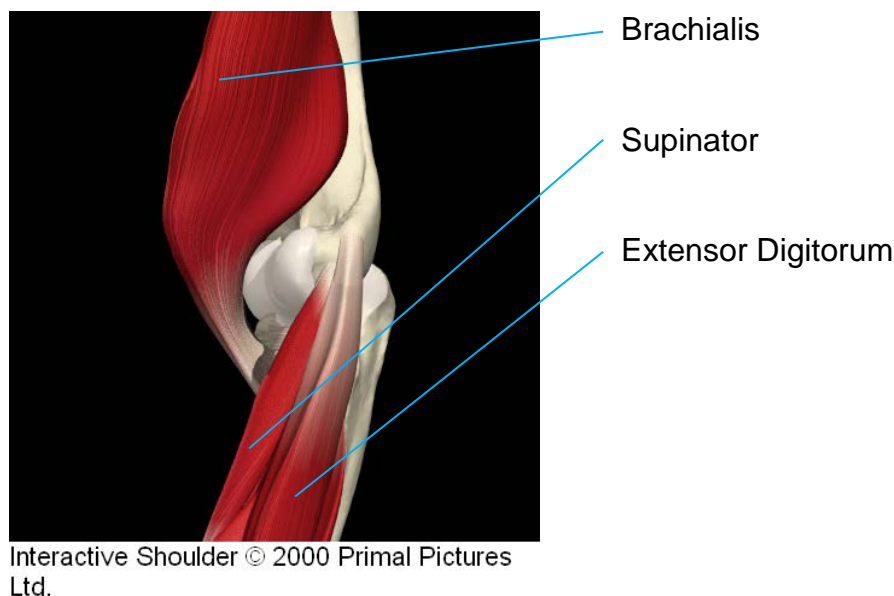
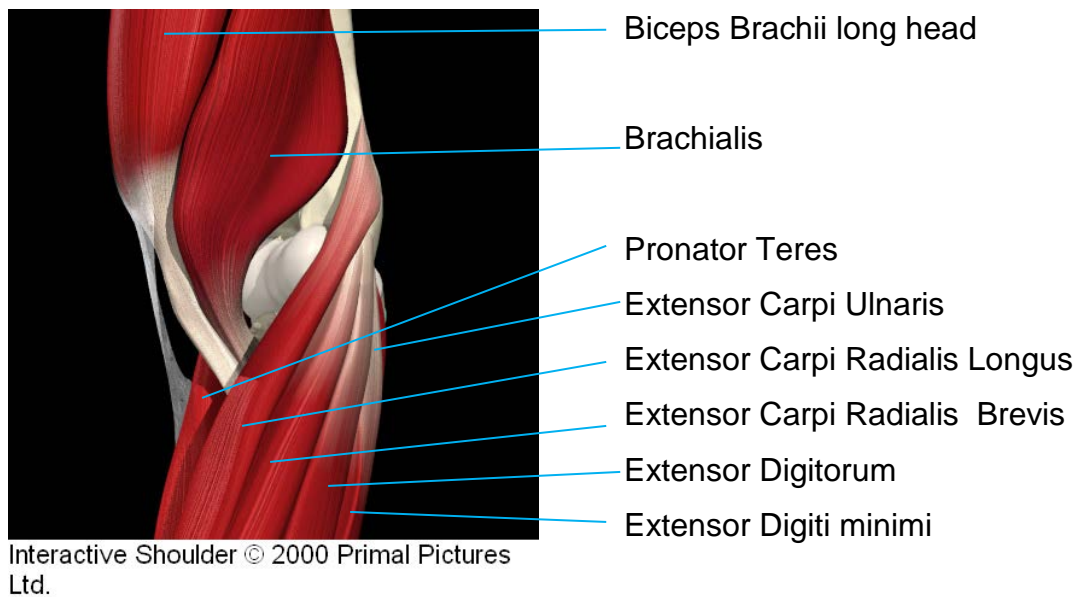


Figure 2.3: Pictures depicting the muscular anatomy of the elbow

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The bony, ligamentous and muscular structures are all maintained by an anastomoses of arteries that supply the elbow joint, however, the brachial artery and its divisions (the radial and ulna arteries) are the principle arterial suppliers (Moore and Dalley, 2006). It is of particular interest to note that the ECRB has been found to have a very vascular tendon superficially, which receives its blood supply via the radial recurrent artery, the posterior branch of the radial collateral artery and the interosseous recurrent artery. The underside, however, has a poor blood supply (Bishai and Palmer, 2006).

The nerve supply is through branches of the musculocutaneous, median, radial and ulnar nerves (Sinnatamby, 2006).

As a result of its structure, the elbow joint is capable of both weight bearing and a smooth range of motion (Moore and Dalley, 1999). The stability for weight bearing of the elbow joint is achieved through the bony articulations as well as muscular, tendinous, ligamentous and capsular supporting components of the elbow (Brabston *et al.*, 2009).

2.3 Lateral Epicondylalgia

2.3.1 Definition

Lateral epicondylalgia (L.E), commonly known as tennis elbow or lateral epicondylitis, is the most commonly diagnosed injury of the elbow (Hong, *et al.*, 2004). Lateral epicondylalgia has been defined as an overuse injury that most commonly affects the extensor carpi radialis brevis (ECRB) origin, resulting from angiofibrotic dysplasia to the proximal part of the tendon (Bishai and Palmer, 2006). Budoff and Nirschl, (2001), describe L.E as an overuse injury of the ECRB tendon resulting from degenerative tendinosis where the damage in the tendon exceeds the ability of the tendon to heal itself.

2.3.2 Aetiology

Although the aetiology of L.E is poorly understood, the most commonly accepted theory is that L.E is an overuse injury as the result of cumulative microtrauma that occurs due to repetitive wrist extension, supination and pronation (Bishai and Palmer, 2006; Scher *et al.*, 2009). Collectively, L.E is thought to be a degenerative (rather than an inflammatory) process that results in histological changes that Nirschl and Pettrone, (1979) termed “angiofibroblastic hyperplasia”. Angiofibroblastic hyperplasia is a description of the changes seen on microscopy, and refers to the abundance of fibroblasts and vascular granulation tissue that is seen in the tendons of the affected muscles in L.E (Nirschl and Pettrone, 1979). Most commonly, it is in the origin of the

ECRB muscle that is affected but the EDC is involved in a third of patients (Kraushar and Nirschl, 1999).

There are usually 3 main areas of involvement in the tendons of the ECRB or EDC (Thomson *et al.*, 1991), which include:

- 1) The tenoperiosteal junction,
- 2) The tendon itself and
- 3) The muscsculotendinous junction.

Additionally, this overuse injury is thought to be associated with motor and muscle dysfunction (Whaley and Baker, 2004), as well as a disordered functioning of the sensory nervous system (pain), which have all been implicated in the aetiology of L.E (Vicenzino, 2003).

The motor dysfunction has been implicated in the aetiology of L.E by Vicenzino (2003), who reported motor control dysfunction. In addition, he reported that the pain that results from L.E is believed to present through the mechanism of secondary hyperalgesia. This occurs due to central sensitization which is a result of disordered neural processing. Secondary hyperalgesia is often found in an area that is away from the injured site, but that is neurologically related to it (Vicenzino, 2003).

The above signs and symptoms have more recently been linked to the lack of vascularity on the underside of the ECRB tendon as there is a poor blood supply, which is thought to result in it being prone to degeneration and partial tears (Bishai and Palmer, 2006). This reduction in the microcirculation of the ECRB has recently been considered a principle factor contributing to the symptoms of L.E (Oskarsson *et al.*, 2009). This theory is supported by Du and Zhao (2009), who found on clinical and anatomic examination that the primary cause of L.E were the pathologic changes found in the origin of the common extensor tendon, which they suggested were secondary to compression of the neurovascular bundle as it passes through the common extensor origin. These reports concur with Oskarsson *et al.*, (2009), who indicate that changes in ECRB muscle tissue in L.E include altered sarcomere length and the appearance of moth eaten fibers, which verify an aberration in vascular supply to the region (Oskarsson *et al.*, 2009).

Thus, it would seem that decreased vascularity of the musculotendinous structures of the ECRB and EDC seem to be the principle association with L.E, however, it is difficult to determine whether the decreased vascularity is a causative agent of L.E or whether it is as a result of the altered motor and muscle dysfunction (and therefore falls in to the category of aggravating the L.E).

2.3.3 Epidemiology

The prevalence of L.E is highest between the ages of 45 and 64 years of age, with it occurring most commonly between the ages of 45 and 54 years (Shiri *et al.*, 2006) but there have been reported incidences of L.E in people as young as 12 years old, and as old as 80 years old (Jobe *et al.*, 1994). Most often (75%) L.E is found in the dominant arm (Wood *et al.*, 2006; Bjordal *et al.*, 2008; Radpasand *et al.*, 2009). Greenfield and Webster, (2002) states that L.E has no association with the dominant arm yet, three studies have indicated that in the majority of reported cases, 75% is in the dominant arm (Wood *et al.*, 2006; Bjordal *et al.*, 2008; Radpasand *et al.*, 2009).

There is also literature stating that L.E affects males and females equally (Greenfield and Webster, 2002). Yet, recent literature reports that L.E affects females twice more than males (Shiri *et al.*, 2006; Radpasand *et al.*, 2009). This would suggest that there are occupational, recreational susceptibilities and / or anatomical variances that may predispose particular groups to differences in presentation of L.E between arm dominances and / or gender predilection. An example is that although tennis is by no means the only cause of L.E, it is estimated that between 10% and 50 % of regular tennis players will suffer from L.E at some point in their lives, and the more time spent playing tennis a week, the higher their chance of developing L.E (Jobe *et al.*, 1994). Additionally, it is generally accepted that specific occupational (Haarh *et al.*, 2003; Shiri *et al.*, 2006) and recreational activities involving repetitive or forceful movements also cause L.E (viz. racquetball, squash, fencing, meat cutting, plumbing, painting, raking and weaving) (Jobe *et al.*, 1994). Looking at these activities it seems to indicate that dependant on the region of a study or the selection criteria; it is possible that the occupations seem to target mainly males, where the recreational activities could have a better gender spread, and thus affect reported statistics (Table 2.2).

Table 2.2 : Table depicting the risk factors and predilection according to gender for L.E

Risk factors	Female	Male
Heavy hand-held tool / handling loads weighing more than five kilograms		Predisposition to male
Large amount of physical strain due to a combination of forceful work, repetition and non-neutral posture of the hands and arms		Predisposition to male
Operating a vibrating tool		Predisposition to male
Low social support at work	Predisposition to female	
Increased age	Equal likelihood	
Longer duration in a strenuous job	Equal likelihood	
Smokers (current and former)	Equal likelihood	
Type-two diabetics	Equal likelihood	
Activities that require a firm hand grip	Equal likelihood	
Jobs requiring repetitive motion of the hand or wrist	Equal likelihood	

Table adapted from Haahr and Anderson (2003) and Shiri *et al.*, (2006).

2.3.4 Clinical presentation and diagnosis of L.E

Despite the pathophysiology of L.E being unclear, it is generally accepted that when the injury is acute it is due to a large tear at the tenoperiosteal junction, and when it is insidious it is due to microtears at the same junction (Viola, 1998).

Lateral epicondylalgia may occur acutely or it may be gradual in onset. When it is gradual in onset the pain usually occurs 24-72 hours after the patient has performed an activity that they are unaccustomed to which involved a significant amount of repetitive motion over a short period of time.

Clinically patients will frequently complain of pain of insidious onset, with no traumatic event associated with it. Patients often describe the pain as being sharp, with tenderness anterior and distal to the lateral epicondyle on palpation (Scher *et al.*, 2009), but the pain is also often described as a burning pain that radiates down into the forearm or up to the shoulder (Viola, 1998). The pain is worse on gripping, extending the elbow, lifting heavy objects and generally with activities of daily living. The pain can be felt at rest in severe cases, and in this instance will restrict movement, particularly at the extremes of flexion and extension of the elbow (Viola,

1998). Conversely when the pain is acute in onset, the patient will generally be able to describe exactly when and how the injury occurred.

A diagnosis of L.E can be made on case history and physical examination alone (Viola, 1998). The three factors that the diagnosis of L.E is generally based on is: 1) the presence of pain locally around the elbow, 2) tenderness on palpation of the lateral epicondyle and 3) an increase in pain on resisted isometric extension of the wrist or middle finger (Shiri *et al.*, 2006).

2.3.5 Differential diagnosis of L.E

The differential diagnosis of L.E is comprehensive (Greenfield and Webster, 2002). If there is any doubt about the diagnosis of L.E, radiographs of the cervical spine, as well as electrodiagnostic or detailed imaging of the elbow may be necessary (Jobe *et al.*, 1994). Ultrasonography is helpful for evaluating joint fluid, ligaments and tendons, with magnetic resonance imaging (MRI) being useful in determining the degree of disease in the tendon and to determine a potential alternate diagnosis (Scher *et al.*, 2009).

Some of the differential diagnoses of L.E are discussed below (Greenfield and Webster, 2002; Viola, 1998; Field and Savoie, 1998):

- Radial nerve entrapment/ Radial tunnel syndrome:

Radial tunnel syndrome occurs when the radial nerve has been compressed at some point along its course between the supinator muscle and the radial head. Paralysis of the radial nerve can result in pain in the lateral elbow. There, however, is often a degree of radial paresthesia and a popping sensation in radial tunnel syndrome that is not present in L.E.

In radial tunnel syndrome there is also often an aching sensation felt in the extensor muscles of the forearm that radiates to the distal arm and forearm. The character of the pain is important to differentiate from L.E, where radial tunnel syndrome pain is more diffuse and found more distally to the pain resulting from

L.E. Although both these conditions have tenderness on palpation, with radial tunnel syndrome the tenderness is felt most distinctly over the radial nerve as opposed to just distal of the lateral epicondyle as in L.E (Viola, 1998; Field and Savoie, 1998). This is generally 6-7 cm distal to the lateral epicondyle over the belly of the brachioradialis muscle in radial nerve entrapment compared to 1-2 cms below the lateral epicondyle in L.E (Mazurek and Shin, 2001). These two conditions have been known to occur simultaneously in up to 5% of cases of L.E. When pain is felt on resisted supination, the radial nerve may be entrapped in the supinator muscle, and when there is pain on resisted long finger extension, it may be trapped in the ECRB muscle (Whaley and Baker, 2004).

- Degenerative arthritis:

Degenerative arthritis of the elbow produces a pain that is less localised and more diffuse than the pain produced in L.E. It generally produces a large amount of stiffness and loss of extension as its main characteristics (Viola, 1998). To differentiate degenerative changes in the radiocapitellar joint from L.E, an axial load is applied to the elbow combined with gentle supination and pronation. This compresses the radiocapitellar joint and will cause pain if there is degeneration of the joint. Radiographs can also be useful to show any degeneration or bony osteophytes that may be present due to degenerative changes in the elbow (Field and Savoie, 1998).

- Infection, trauma, tumour, synovitis, bursitis:

All the above conditions despite having varied aetiologies, all produce a large amount of swelling that is uncommon in L.E (Viola, 1998).

- Entrapment of the posterior interosseous nerve:

There is much debate as to the role and involvement of the posterior interosseous nerve in L.E (Viola, 1998). The posterior interosseous nerve is principally a motor nerve which means that when it is entrapped, weakness

arises in the muscles it supplies, resulting in weakness with extension of the fingers and thumb (usually sparing the supinator muscle). When this weakness is combined with pain at the lateral epicondyle, posterior interosseous nerve entrapment should be suspected (Mazurek and Shin, 2001).

- Osteochondritis dissecans of the radiohumeral joint:

This condition occurs more commonly in adolescent patients, and generally begins as an insidious, diffuse elbow pain with limited range of motion, particularly a loss of full elbow extension, and occasional locking of the elbow. These symptoms are notably different to the localised lateral epicondylar pain, which is more often seen in older patients who are able to achieve a full range of motion (Field and Savoie, 1998).

- Snapping plicae:

Sports that require overhead motions can often cause irritation to the posterolateral capsule of the elbow, leading to thickening of the synovium and the development of symptomatic plicae (Field and Savoie, 1998). This can lead to impingement and repetitive injury and inflammation. Often with plicae there is catching or popping that occurs, unlike in L.E (Field and Savoie, 1998). It is important to palpate the radiocapitellar joint to investigate for the presence of plicae. Another test is to passively flex the elbow whilst the forearm is in either pronation or supination. Pain caused by a plica is found more distally over the lateral epicondyle, than the pain caused by L.E (Whaley and Baker, 2004).

- Intra-articular body following trauma:

Anteroposterior and lateral radiographs are important if there is any doubt as to the diagnosis of L.E, particularly following trauma. These radiographs can show loose bodies, calcific deposits and the integrity of the elbow joint itself (Field and Savoie, 1998). In up to 7% of routine radiographs performed on people with L.E calcification was identified in the region of the lateral epicondyle. This presence

of a loose body, however, does not alter the treatment of L.E (Whaley and Baker, 2004).

- Myofascial trigger points:

A myofascial trigger point is defined as a “hyperirritable (hypersensitive) spot in a taut band of skeletal muscle fibers” (Hong, 2006). An active myofascial trigger point is “a focus of hyperirritability in a muscle or its fascia that is symptomatic with respect to pain; it refers a pattern of pain at rest and/or on motion that is specific to the muscle.” Active trigger points in the ECRL and ECRB muscles refer pain over the lateral epicondyle and the dorsum of the forearm and the hand (Travell and Simons, 1999). It can be noted from these findings that myofascial trigger points can produce a pain similar to the pain found in L.E. Therefore, it is important to determine the presence of a trigger point through palpation of the muscle and identifying the characteristic pattern of referred pain that the specific muscle produces.

- Cervical dysfunction:

Cervical nerve root compression or cervical osteoarthritis, generally observed in C6-C7, can cause pain to be felt in the lateral elbow. It causes different symptoms to L.E as it causes decreased and painful motion of the neck, and not the point tenderness at the lateral elbow that is felt in L.E (Viola, 1998).

- Non union radial neck fracture:

Faber and Verhaar, (1995) reported on a case of persistent lateral elbow pain that did not respond to L.E treatment. They recommended that radiographs should be taken in the case of therapy-resistant epicondylitis, even if there was only minor trauma.

- Bicep brachii or tricep brachii tendon rupture:

Tendon ruptures around the elbow are not nearly as common as L.E, but they result in more significant disability and loss of function than L.E. The cause of biceps brachii and triceps brachii tendon rupture is generally due to forceful eccentric contraction of the biceps brachii or triceps brachii muscles (Rineer and Ruch, 2009), which is very different to the cause of L.E.

- Torn or strained lateral collateral ligament:

Injury to the lateral collateral ligament (LCL) complex will result in a painful or lax varus stress test, and the aetiology is also different to L.E as LCL injuries are generally caused by a traumatic stress or force to the medial side of the elbow. Lateral collateral ligament injury results in posterolateral instability and may be associated with the subsequent development of L.E (Mahmoud and Kotb, 2009).

2.3.6 Treatment of L.E

Lateral epicondylalgia is a chronic disorder that is difficult to successfully treat in primary care (Bisset *et al.*, 2005). Reports concerning the treatment of L.E date back to 1882, but despite this, there is currently still no consensus as to the most effective treatment regimen (Radpasand *et al.*, 2009). This is possibly due to the poor understanding of its pathogenesis and, therefore, of the best treatment strategy for the condition (Herd and Meserve, 2008).

There have been over 40 different treatment regimes used to treat L.E, with not one standing out as being largely superior to the rest (Labelle *et al.*, 1992; Erturk *et al.*, 1997; Struijs, 2001; Vicenzino *et al.*, 2007). Some of the more common treatment regimes include: stretching and strengthening, ergonomic counselling, education, manipulation, friction massage, steroid injection, orthotic braces and therapeutic ultrasound (Viola, 1998; Greenfield and Webster, 2002; Hong *et al.*, 2004; Peterson *et al.*, 2005; Struijs *et al.*, 2006; Johnson *et al.*, 2007). There are numerous articles on L.E, but the studies have a large diversity of methods and often result in

inconclusive findings. For this reason there is evidence that suggests the relative effectiveness of particular treatments, but the optimum treatment for L.E is still unknown (Radpasand *et al.*, 2009).

Some examples of the more commonly used and more recent treatment options will now be discussed.

2.3.6.1 Surgery

Candidates for surgery are those who have not responded to an organized rehabilitation programme within six to twelve months of injury (Field and Savoie, 1998). Whaley and Baker, (2004) state that operative treatment is rarely necessary and should only be performed after the failure of extensive conservative care or when the pain is extremely severe and prevents the sufferer from being able to perform their activities of daily living. There are many different types of procedures available in the surgical treatment of L.E, but using the open, arthroscopic and percutaneous techniques have reportedly produced the best results (Whaley and Baker, 2004).

There is a specific technique of surgery known as the Nirschl technique, which after being performed on over 1000 cases reportedly resulted in 85% of patients being fully recovered in terms of pain and strength, and being able to return to all their previous activities without experiencing any pain. In terms of pain and strength, 12% of the patients had marked recovery but occasionally suffered symptoms of L.E, especially during aggressive or rigorous activity (Budoff and Nirschl, 2001). There were 3% of patients who felt no relief after the surgery, and one patient who felt their symptoms deteriorated after surgery (Budoff and Nirschl, 2001).

2.3.6.2 Injections

2.3.6.2.1 Corticosteroid injections

Corticosteroid injections are commonly prescribed as a conservative treatment for L.E (Coombes *et al.*, 2009). Corticosteroids have been shown to reduce the formation of adhesions, connective tissue and granulation tissue (Speed, 2001). Thus, they are used to reduce inflammation which is contradictory as inflammation is not a key feature in most tendinopathies and because the inflammatory process is vital for the healing response.

It was found that combining steroid injection with physiotherapy provided no additional benefit to the injection alone. The injection alone relieved pain, allowed the patient to return to activity and was more time and cost efficient than physiotherapy. Steroid injections also reportedly have minor and few side effects. For these reasons steroid injections alone have been suggested as the first line of treatment for patients who want to return to their daily activities as quickly as possible (Tonks *et al.*, 2006).

Systematic reviews have supported the use of steroid injections, finding them to be effective in the short term; however, they found that steroid injections produce high recurrence rates and delayed long term recovery (Coombes *et al.*, 2009). The recurrence rate after corticosteroid injections is reportedly 72%, compared to physiotherapy at 8% and adopting a wait and see policy at 10% (Coombes *et al.*, 2009). Bisset *et al.*, (2006), recommended that patients and their doctors should consider the high recurrence rates, general delay in recovery and the overall poor performance of corticosteroid injections before choosing them as a treatment option for L.E.

2.3.6.2.2 Botulinum toxin injection

Injection with botulinum toxin into the ECRB muscle seems to be showing promising results as a treatment option for L.E (Oskarsson *et al.*, 2009). It is believed to increase the diminished intramuscular blood flow that is evident in the ECRB muscle in L.E, thus increasing the oxygen to the muscle, changing the muscle metabolism

from anaerobic to aerobic and reducing the lactate build up, therefore, reducing the symptom of pain in L.E (Oskarsson *et al.*, 2009). It is thought to produce its effects through temporarily paralysing the damaged common extensor origin, however, according to Johnson *et al.*, (2007) it cannot be recommended as an efficient treatment option for L.E until more trials have been performed.

2.3.6.2.3 Autologous blood injection

Autologous blood injections are thought to initiate healing through triggering an inflammatory response in the degenerated tissue (Johnson *et al.*, 2007). There are however an insufficient number of trials that include a placebo group, and until these have been performed the effectiveness of autologous blood injections will not be known and no recommendations for its use in L.E can be made (Johnson *et al.*, 2007). However, Rabago *et al.*, (2009), state that autologous whole blood and platelet rich plasma injection therapies show promise as therapy options for L.E.

2.3.6.3 Electrotherapies

2.3.6.3.1 Therapeutic ultrasound

Therapeutic ultrasound works on the premise of assisting in relieving the symptoms of L.E through thermal and non thermal effects (Baker *et al.*, 2001) as well as through mechanical effects resulting in an increase in: metabolism, the extensibility of tissues, the regeneration of tissue and in improving circulation (Johnson *et al.*, 2007). It is a controversial treatment option as it has been shown to be no more effective than placebo ultrasound (Haker and Lundeberg, 1991, Viola 1998, Lundeberg *et al.*, 1988, D'Vas *et al.*, 2006). Baker *et al.*, (2001) revealed that there was inadequate biophysical evidence to scientifically justify the clinical use of therapeutic ultrasound to relieve pain and soft tissue injury. Yet, Smidt *et al.*, (2003) stated weak evidence for the effectiveness of ultrasound in comparison to placebo and Trudel *et al.*, (2004), reviewed the literature and found there to be evidence that ultrasound had a positive effect on function and pain reduction in patients with L.E. The judgement shared by Bisset *et al.*, (2005) is that there is not enough evidence to either support or negate the use of ultrasound in the treatment of L.E.

2.3.6.3.2 Ionophoresis

Ionophoresis involves a transfer of ions across the skin using a direct current of low amperage (Tonks *et al.*, 2006). Often corticosteroids (such as dexamethasone) are used in ionophoresis as it is considered effective as well as safe (Tonks *et al.*, 2006). Patients find the ionophoresis of corticosteroids to be a lot less painful and invasive than the injection of corticosteroids, and therefore, this has made ionophoresis more agreeable to patients (Tonks *et al.*, 2006). However, Johnson *et al.*, (2007) found that evidence of the benefit of corticosteroid ionophoresis is poor, but that the ionophoresis of non-steroidal anti inflammatory drugs showed benefits after 2-4 weeks.

2.3.6.3.3 Laser therapy

The mechanism of action of low level laser therapy is not well known and the opinions surrounding it are controversial, but it is believed to have effects on the cellular function and behaviour (Basford *et al.*, 2000). After a review of the literature Trudel *et al.*, (2004), found laser therapy was ineffectual in the treatment of L.E. In a later review performed by Bisset *et al.*, (2005), it was determined that laser therapy showed no evidence in the short or long term of being more beneficial than a placebo intervention. These two reviews concluded that laser is not recommended in the treatment of L.E. These findings positively correspond with reviews by Smidt *et al.*, (2003) and Johnson *et al.*, (2007). However, Bjordal *et al.*, (2008) suggests that low level laser therapy is safe and effective and that it has biological mechanisms that help control tendon inflammation as well as tendon repair processes.

2.3.6.3.4 Extracorporeal shockwave therapy (ESWT)

ESWT involves sending vibrations of shock waves through tissues in order to activate the inflammatory cycle so that it can complete its course, resolve the symptoms and result in healing (Whaley and Baker, 2004). The literature shows contradictory results in terms of the effectiveness of low dose shockwave therapy: it has been recommended for the relief of pain in the short term treatment of L.E (Kohia *et al.*, 2008). This is contradictory to the conclusion drawn by Bisset *et al.*,

(2005), who stated that extracorporeal shockwave therapy produced no added benefit over placebo in the treatment of L.E. Similarly, Johnson *et al.*, (2007) found that the data available does not support the use of ESWT in the treatment of L.E.

2.3.6.4 Conservative treatment

Patients suffering from L.E are generally looking for a safe and non invasive treatment that will reduce the pain and allow them to return to their activities of daily living as soon as possible (Tonks *et al.*, 2006). The usual conservative treatment approach consists of relative rest, bracing, controlling the apparent inflammation, exercises, manipulation, electrical stimulation and phonophoresis (Kohia *et al.*, 2008). Physiotherapy generally involves a combination of conservative treatments which are discussed as follows:

2.3.6.4.1 Wait and see policy or watchful waiting

The natural history of L.E is to improve (without any treatment) within 12 months (Olaussen *et al.*, 2009). This is widely accepted and true for 70-80% of patients. In many countries this wait and see approach is recommended (Olaussen *et al.*, 2009). This does, however, mean that the patient is left in pain for up to 12 months which affects their daily life and often their economic productivity (Tonks *et al.*, 2006). It was concluded that with the correct information and ergonomic advice that most cases of L.E will improve in the long term (Bisset *et al.*, 2006).

2.3.6.4.2 Manipulative therapy

Manipulation has been a suggested treatment for lateral epicondylalgia since the 1920's (Herd and Meserve, 2008). The mechanical hypothesis of manual therapy is that it aims to reduce the soft tissue and mechanical dysfunctions that are linked to disorders of the neuromusculoskeletal system (Bergmann and Peterson, 2002). There is evidence that manipulating the elbow joint produces changes in the pain and motor systems, and results in a complex multi system physiological response (Vicenzino *et al.*, 2007). Although limited, there is literature that supports the use of manipulation in treating a tendinopathy, making it a recommended option for

appropriate patients (Pfefer *et al.*, 2009). The literature concerning and supporting the use of manual therapy in treating lateral epicondylalgia is growing (Nagrle *et al.*, 2009) and the body of literature concerning manipulation in the treatment of L.E involves a wide variety of techniques and comparison treatments thus making it difficult to create a systematic review (Herd and Meserve, 2008). Although there is evidence that elbow manipulation produces positive immediate effects, there is a need for further research in this field (Bisset *et al.*, 2005).

2.3.6.4.3 Acupuncture

Acupuncture has the effect of improving local blood flow and producing anti-inflammatory effects, with the traditional acupuncturist working with the body's vital energy that flows through meridians to restore its flow and bring about holistic healing (Zijlstra *et al.*, 2003). Trinh *et al.*, (2004) performed a systematic review evaluating the effectiveness of acupuncture, a form of treatment growing in acceptance for treating pain, as a treatment for lateral epicondyle pain. They concluded that there is strong evidence supporting the use of acupuncture in the short term relief of lateral epicondyle pain. Trudel *et al.*, (2004) reviewed the literature and found there to be evidence that acupuncture had a positive effect on increasing function and reducing pain in patients with L.E, whereas Johnson *et al.*, (2007), stated that contradicting evidence exists and therefore no conclusions can be drawn.

2.3.6.4.4 Deep transverse friction massage (also known as cross friction massage)

According to its function, cross friction massage aims to break up any scar tissue and adhesions, realign the collagen fibers to their usual structure and promote healing through hyperaemia. However, conclusions cannot be drawn as to the efficacy of deep transverse massage in the treatment of L.E due to insufficient evidence (Johnson *et al.*, 2007).

2.3.6.4.5 Topical Nitrates

It has been proposed that topical nitrates stimulate the synthesis of collagen, which would thus repair injured tendons (Johnson *et al.*, 2007). In a study by Oehley (2002), it was determined that flurbiprofen local action transcutaneous (TransAct®) patches were no more effective than the placebo patches in the treatment of L.E. A recent review by Johnson *et al.*, (2007) found one clinical trial that suggested that topical nitrate patches may be effective, but stated that further studies are necessary to confirm this finding.

2.3.6.4.6 Dry needling

There are many mechanisms by which dry needling produces its effects, such as mechanically disrupting abnormal contractile elements or nerve endings and causing a local release of intracellular potassium resulting in a depolarization block of nerve fibers (Travel *et al.*, 1999). Kalichman *et al.*, (2010) concluded that dry needling is a treatment being employed more recently by physicians and physical therapists in the treatment of L.E. They stated that dry needling is minimally invasive, cheap and carries a low risk. In terms of dry needling in the treatment of L.E, Haswell (2002) showed that it may be an effective method in treating L.E. And this effectiveness has been confirmed and its use has been recommended by Kalichman *et al.*, (2010).

2.3.6.4.7 Combination therapy

In a study by Shaik (2000), Mill's manipulation and cross friction were compared to cross friction alone and neither was found to be any more effective than the other. In a study by Marquis (2002), dry needling and cross friction combined were found to be more effective than cross friction massage on its own. Hughes (2010) found that combining elbow manipulation with dry needling and combining manipulation with cross friction massage both produced significant improvements ($p=0.05$) in all measurements. According to Kocher and Dogra, (2002) combining Mulligan's mobilisation with movement to ultrasound and progressive exercises brought about greater benefits than the ultrasound and progressive exercises alone. These few examples show that combining two treatment options may bring about increased

benefits, but that this is not always the case and is dependent on the synergistic combination of the treatment modalities.

From the above literature on treatment options for L.E, it is clear that there is much controversy surrounding its most effective treatment. So this research focuses on therapeutic exercises and orthotic bracing as treatment options for L.E. This will now be discussed.

2.3.6.5 Therapeutic exercises

According to Taylor *et al.*, (2007), therapeutic exercise is defined as “the prescription of a physical activity programme that involves the patient undertaking voluntary muscle contraction and / or body movement with the aim of relieving symptoms or improving function, or improving, retaining or slowing deterioration of health.”

A concentric muscle contraction is when the ends of a muscle move closer together, shortening a muscle, due to the movement of the bony skeleton. An eccentric muscle contraction is when the ends of a muscle move further away from each other due to lengthening of the muscle by an external force (Knuttgen *et al.*, 1987).

Two of the principle aims of rehabilitation are to reduce pain and restore a muscle to its optimum condition (Vicenzino, 2003). According to Vicenzino (2003), muscles are best rehabilitated through a progressive resistance exercise programme. Exercises that transmit a force to tendons, ligaments and bones will result in the maintenance and an increase in strength and functional capability of these structures which was found to be true in the case of chronic L.E (Pienimaki *et al.*, 1996).

Thus, Vicenzino (2003), states that the mainstay of treatment for L.E is therapeutic exercise that aims to reduce the primary physical impairment of the condition, which is the reduced grip strength that results from pain which in turn causes motor dysfunction. Bisset *et al.*, (2005), identified that most studies in their systematic review included exercise in combination with other modalities, thereby making it difficult to determine the effect that the exercise alone has had on the condition. Despite this, the therapeutic exercises, particularly eccentric exercises, are well

supported as being an effective treatment option for L.E (Pienimaki *et al.*, 1996; Pienimaki *et al.*, 1998; Svernlöv and Adolfsson, 2001; Stasinopoulos *et al.*, 2005; Martinez-Silvestrini *et al.*, 2005; Stasinopoulos and Stasinopoulos, 2006; Croisier *et al.*, 2007 and Oken *et al.*, 2008). Increasing the strength of the forearm muscles has been suggested to reduce the chance of chronicity and recurrence in L.E (Coombes *et al.*, 2009). Therapeutic exercise has also been shown to have long term beneficial effects in treating L.E, as the exercise has been shown to reduce pain, at rest and when in use, improve muscle performance and work functionality and reduce the number of sick days required by sufferers. Therapeutic exercise has also been found to prevent the injury from becoming chronic (Pienimaki *et al.*, 1998). Exercise is therefore recommended as a treatment option for L.E (Pienimaki *et al.*, 1998).

It has been suggested that the L.E tendinosis is due to repetitive external forces being placed on a tendon that exceed the mechanical strength of that tendon, thus resulting in microtrauma and degeneration. In the past it was termed an inflammatory condition and anti-inflammatory strategies had been applied in its treatment, which has now been deemed inappropriate. More recently, tendinosis has been termed a connective tissue disease that is due to collagen being produced that is not remodelled into the normal tendon (Croisier *et al.*, 2007).

Eccentric training of a tendon aims to increase the tendons tensile strength thereby making it less susceptible to damage from external forces placed on it (Croisier *et al.*, 2007). Eccentric training stimulates the tenocytes to produce collagen which helps repair the injured tendon; it helps the collagen to be laid out in a parallel fashion which contributes to its strength and reduces the abnormally high amounts of glycosaminoglycans found in injured tendons (Stasinopoulos *et al.*, 2005). Research indicates that strengthening may decrease neovascularisation which is a causative factor in painful tendinopathies (Alfredson *et al.*, 2003; and Ohberg and Alfredson, 2004).

Eccentric exercises have been shown to be superior to stretching (Svernlöv and Adolfsson, 2001), polarized polychromatic non-coherent light and cyriax physiotherapy (Stasinopoulos and Stasinopoulos, 2006) and therapeutic ultrasound (Pienimaki *et al.*, 1996), as well as being effective when combined with a specific

physiotherapy regime (Croisier *et al.*, 2007). Promising results have been demonstrated despite limited literature and differences in parameters between the various studies (Malliaras *et al.*, 2008). Subsequent to this, it has been found that combining progressive eccentric and concentric training is cheap, convenient and has produced positive long term pain relief. The eccentric exercise generates enough tension at the tendon to produce fibrous tissue that reduces the pain felt in L.E, and the concentric exercise decreases the tension which decreases the pain felt and any damage that may occur during the exercises (Finestone and Rabinovitch, 2008).

Bisset *et al.*, (2005) concluded after a meta analysis of studies on the treatment of L.E that there is little consensus on its treatment but that there is an indication for further research with long term follow up into exercise as a treatment option for L.E.

2.3.6.6 Orthotic braces

Orthoses are defined as: “orthopaedic appliances used to support, align, prevent or correct deformities of a body part or to improve function of movable parts of the body (Edelstein and Bruckner, 2002).

Orthotic braces are a common treatment option for L.E (Struijs *et al.*, 2001; Van De Streek *et al.*, 2004; Johnson *et al.*, 2007). As L.E has been known to resolve spontaneously within eight to twelve months (Oken *et al.*, 2008) orthotic braces are often bought by patients without advice or prescription from a health care provider in the hope that it will resolve without the need of further assistance (Hijmans *et al.*, 2004).

The most common type of brace is a band or strap that sits around the bellies of the wrist extensor muscles in the forearm (Struijs *et al.*, 2001). This type of bracing is referred to as counterforce bracing, which was a term coined by Nirschl and Pettrone in 1974. There are two main proposed mechanisms of action whereby the brace produces its effects:

- 1) By placing a strap around the extensor muscle bellies, the amount of expansion possible by the muscle is reduced. This results in less force being generated and transferred to the common extensor tendon which, therefore, decreases the pain felt by the patient during activity (Wuori *et al.*, 1998; Struijs *et al.*, 2001).
- 2) Counterforce bracing provides an artificial second muscle origin, which decreases the load placed on the muscular attachment by dispersing the pressure applied to it (Wuori *et al.*, 1998).

Orthotic braces have been shown to be equal to a physical treatment programme in reducing pain in L.E, and patients were happier using the orthotic brace than receiving the physiotherapy (Dwars *et al.*, 1990). Braces were also found to be as effective as corticosteroid injections (Erturk *et al.*, 1997; Jenson *et al.*, 2001). However, Jensen's (2001) article states that braces should rather be used than corticosteroid injections as they are simpler and have fewer side-effects. It is also proposed that using an orthotic brace may decrease the amount of sick leave taken by sufferers affected by L.E due to a reduction in pain during activities (Struijs *et al.*, 2001).

Wuori *et al.*, (1998) compared a L.E orthotic brace to a placebo and an elbow sleeve brace, and concluded that no significant differences in pain free grip strength and pain visual analogue scale were noted between either the L.E counterforce brace and the placebo or the elbow sleeve. In contrast, a study by Luginbuhl *et al.*, (2008), concluded that a forearm support band, a strengthening exercise programme, and a combination of these two treatments all resulted in equal improvement, and they deduced that improvement occurs with time regardless of the treatment used. Struijs *et al.*, (2004), also found that combining physical therapy with a brace was no more effective than physical therapy alone but they concluded that the combination therapy was better than brace-only treatment. Yet, they demonstrated that brace-only treatment showed great improvement in the outcome of "inconvenience during daily activities" (Struijs *et al.*, 2004). This finding by Struijs *et al.*, (2004) supports Svernlov and Adolfsson (2001), who found evidence of the advantage of combining the use of a brace with physical therapy.

No solid conclusions on the efficacy of orthotic bracing can be drawn from the current literature due to the majority of studies having a low methodological quality (Bisset *et al.*, 2005). In clinical practice, treatment usually consists of a combination of therapies (Pienimäki *et al.*, 1996) and further research into orthotic bracing used with multi-modal treatments is needed (Struijs *et al.*, 2004).

2.4 Conclusion

From this chapter it can be concluded that despite the prevalence of the condition, and the numerous studies on L.E, there is still no consensus as to the best treatment option. From this literature review, it is evident that therapeutic exercise and orthotic bracing are two of the most promising treatment options. Whether a combination of these two treatments is more beneficial than the therapeutic exercise alone has not yet been confirmed or denied. This research will aim to either confirm or deny these treatment options. The following chapter will discuss the methodology applied to carry out this research procedure.

Chapter Three: Methodology

3.1 Introduction

This chapter discusses the methodology applied to this research study. It details the design of the study, participant recruitment, inclusion and exclusion criteria, group allocation, ethical considerations, treatment interventions and outcome measures. This chapter also includes the method of data collection and analysis used in the study.

3.2 Study design

This was a stratified, quantitative, prospective clinical trial. It was stratified in terms of gender in order to remain consistent with previous studies on L.E performed at Durban University of Technology (DUT) and The University of Johannesburg (UJ) (du Coudray, 2006; Puchner, 2008; Hughes, 2010). This research was approved by the Durban University of Technology through its Faculty of Health Sciences Research and Ethics committee, declaring that this research complies with the Declaration of Helsinki and Nuremburg codes (Johnson, 2005) (Appendix 14).

3.3 The study sample

3.3.1 Participant recruitment

Participants were recruited via advertisements and flyers (Appendix 1) placed in the DUT Chiropractic Day Clinic, at local sports clubs: specifically tennis and squash clubs, as well as in gyms, at golf courses (Dutton, 2004) and other public areas including shopping centres. The advertisement stated that free treatment was available to those who qualified to take part in the research study. Advertising via word of mouth was also encouraged.

3.3.2 Sample size and participant requirements

A sample size of 30 participants, 15 in each group, was used. This amount is similar to the sample size of previous studies performed at both DUT and UJ on L.E. (Owen, 2003; du Coudray, 2006; Puchner, 2008; Hughes, 2010).

3.3.3 Inclusion criteria

For participants to be included in the study they had to have a diagnosis of L.E. based on the following:

- Participants had to be between the ages of 18 and 70 years, as the peak incidence of L.E. is between 45 and 54 years of age (Shiri *et al.*, 2006). The wide age range allowed for a variety of ages and causes of L.E. to be included in the study. Bishai and Palmer, (2006) described the average patient being 42 years old and the range being 30-50 years. Lateral epicondylalgia is seldom seen in patients below the age of 30 (Viola, 1998). Both males and females were included in this study.
- For a diagnosis of L.E in this research the following guideline criteria were used: pain around the lateral epicondyle that increased with palpation of the lateral humeral epicondyle (Shiri *et al.*, 2006), pain specifically localized to below the midpoint of the affected lateral epicondyle, pain that generally was felt 5-6mm anterior and distal to the lateral epicondyle (Hyde and Gengenbach, 2007), as well as a positive finding from at least two of the following tests:
 - 1) Cozen's test: this test is performed whilst the participant is seated with the elbow flexed at about 90°, the forearm is in pronation with the wrist extended and radially deviated against resistance. A positive test will provoke pain along the lateral epicondyle (Cook and Hegedus, 2008).

- 2) Lateral Epicondylitis test: this test is performed whilst the elbow is in full extension and the participant tries to extend their third digit against the examiner's resistance. A positive test will provoke pain along the lateral epicondyle (Cook and Hegedus, 2008).
- 3) Mill's test: this test is performed when the affected elbow is held in full extension, the forearm is pronated, the wrist flexed and held in ulnar deviation behind the participant's back. This position will stretch the injured tissue and provoke pain in the case of lateral epicondylalgia (Hyde and Gengenbach, 2007).
- 4) Grip strength test: Grip strength is tested on both the affected and non-affected elbow. When testing grip strength on the affected side, participants often complain of pain and weakness on gripping (Scher *et al.*, 2006).
- 5) Kaplan's sign or test: this test is performed whilst the participant is seated with their arm held straight out in front of them with their wrist held in slight dorsiflexion. The examiner then measures the participant's grip strength using a dynamometer. The examiner then places a strap fairly tightly around the participant's forearm, 2,5cm-5cm below the joint line of their elbow, and repeats their grip strength measurement using a dynamometer. Kaplan's sign or test is considered positive if the strap reduces pain at the elbow and if the grip strength increases when the strap is placed around the forearm (Evans, 2009).
- 6) Palpatory tenderness over the lateral epicondyle: On palpation, pain can be felt at the lateral humeral epicondyle and is referred along the dorsal aspect of the forearm and wrist extensors (Evans, 2009).

- 7) Resisted wrist extension: The examiner resists extension of the wrist by the participant. On resistance, pain is felt at the lateral epicondyle (Greenfield and Webster, 2002).

3.3.4 Exclusion criteria

Participants were not included in the study if they:

- Had an injection of corticosteroids administered for treating their L.E within the last six months (Bennell *et al.*, 2007; Park *et al.*, 2010).
- Had undergone previous surgery (Bennell *et al.*, 2007) to or dislocated their elbow joint (Park *et al.*, 2010).
- Had a history of a fracture to the radius, ulna or distal humerus in the last twelve months (Park *et al.*, 2010).
- Suffered tendon rupture at the elbow within the last twelve months (Park *et al.*, 2010).
- Had been receiving any form of treatment for their L.E. besides the treatment provided in this study (Manias and Stasinopoulos, 2006).
- Had any systemic musculoskeletal disorder or neurological (Wood *et al.*, 2006) or arthritic disorders (Bennell *et al.*, 2007).
- Had any contraindications to therapeutic exercise or stretching of the upper limb (as well as to the use of a Thera-band) which included, but were not limited to: joint hypermobility, malignancy, bone disease, unhealed fractures, weakened connective tissue due to medication, post operative disuse, systemic connective tissue disease or the presence of joint inflammation and effusion, trauma, infection, vascular compromise or vascular disorders, anti-coagulation therapy, severe diabetes mellitus, sensory deficit, acute

inflammation, acute thrombosis or embolism and any skin infection, abrasion or bruising that may have inhibited the use of a Thera-Band or be detrimental to the participant's health (Broome, 1999; <http://appliedexerciselab.tamu.edu>, 2010).

- Required radiographs to aid in the diagnosis of L.E or to exclude other conditions (Bennell *et al.*, 2007).
- Did not complete the informed consent procedure, or were unable to give consent or elected not to participate in the study.
- Did not return for their follow up treatments or evaluation. Any participants that were excluded were replaced to ensure 30 participants completed the study.

3.3.5 Group allocation

Once a diagnosis of L.E was made, thirty participants were assigned to two groups of 15 in each group, using stratified sampling based on gender. This was to ensure an equal representation of genders in each group in order to remain consistent with previous studies on L.E performed at the Durban University of Technology (Shaik, 2000; Roodt, 2001; Haswell, 2002; Marquis, 2002; du Coudray, 2006).

3.4 Procedure

Once the research procedure had been explained to the participants and they had an opportunity to ask any questions, they signed the letter of information and informed consent (Appendix 2). They then underwent a case history (Appendix 3), and a physical (Appendix 4) and an elbow regional examination (Appendix 5). Once all the inclusion and exclusion criteria were met, the participants were enrolled in the research and were strategically assigned to one of the two groups. The outcome measures were then performed to be used as the baseline measurements for each participant. They completed the Patient Rated Tennis Elbow Evaluation (PRTEE) (Appendix 8) and the Numerical Pain Rating Scale (NPRS) (Appendix 9), and then

performed the Pain Free Grip Strength (PFGS) test (Appendix 10) and the Pressure Pain Threshold (PPT) test (Appendix 10). Each participant was then supplied with the necessary equipment to perform the exercises, and were shown how to perform the strengthening and stretching programme. The participants in Group Two were shown how to wear the orthotic brace, that was sponsored by Ossur (Appendix 12), and given a hand out with this information (Appendix 11). All relevant information was then explained in detail to each participant, including how, when and how often to perform the exercises. The participants were then all shown how to complete the Exercise Diary (Appendix 7). The appointments that each participant was required to attend was explained. Each participant then performed the strengthening and stretching programme under the supervision of the researcher to ensure correct technique.

Group One performed a therapeutic strengthening and stretching programme over a six week treatment period. Group Two performed the therapeutic strengthening and stretching programme combined with the use of an Ossur Airform Tennis Elbow Brace over a six week period. The participants were required to attend appointments one, four and seven but had the option of attending one of either appointment two or three and one of either appointment five and six. This was to allow for any circumstances that prevented a participant from being excluded from the study if they could not make a appointment, but also meant that over the seven week period the researcher saw the participants five times each to ensure compliance and that the strengthening and stretching programme was being performed correctly.

As explained at the initial appointment the baseline measurements were taken. At appointment four these measurements, except the PRTEE, were taken again, and at appointment seven all the measurements were then taken for the last time. These measurements all comprised the data that was then analysed in this study.

Table 3.1: Summary week by week of procedures at each appointment

	Group One	Group Two
WEEK 1	<ul style="list-style-type: none">• Information & informed consent were obtained.• The case history, physical and elbow regional examinations were performed.• All participants received an exercise diary and a Thera-Band.• All participants were educated on how to perform the exercises.• The following measures were taken: pain free grip strength, pressure pain threshold, numeric pain rating scale, patient rated tennis elbow evaluation questionnaire.• Then appointment 1, consisting of a supervised strengthening and stretching programme, was performed.	<ul style="list-style-type: none">• Information & informed consent were obtained.• The case history, physical and elbow regional examinations were performed.• All participants received an exercise diary and a Thera-Band.• Participants in Group 2 received an elbow brace and were educated on when and how to wear the brace.• All participants were educated on how to perform the exercises.• The following measures were taken: pain free grip strength, pressure pain threshold, numeric pain rating scale, patient rated tennis elbow evaluation questionnaire.• Then appointment 1, consisting of a supervised strengthening and stretching programme, was performed
WEEK 2	<ul style="list-style-type: none">• Appointment 2, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.	<ul style="list-style-type: none">• Appointment 2, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.
WEEK 3	<ul style="list-style-type: none">• Appointment 3, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.	<ul style="list-style-type: none">• Appointment 3, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned
WEEK 4	<ul style="list-style-type: none">• The following outcome measures: pain free grip strength, pressure pain threshold and numeric pain rating scale were taken.• Appointment 4, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.	<ul style="list-style-type: none">• The following outcome measures: pain free grip strength, pressure pain threshold and numeric pain rating scale were taken.• Appointment 4, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.
WEEK 5	<ul style="list-style-type: none">• Appointment 5, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.	<ul style="list-style-type: none">• Appointment 5, consisting of a supervised strengthening and stretching programme, was performed.• The completed exercise diary from the previous week was returned.

	Group One	Group Two
WEEK 6	<ul style="list-style-type: none"> • Appointment 6, consisting of a supervised strengthening and stretching programme, was performed. • The completed exercise diary from the previous week was returned. • The participants were told that they were now to no longer perform the exercises as this was the beginning of their week of rest before the final appointment the following week. 	<ul style="list-style-type: none"> • Appointment 6, consisting of a supervised strengthening and stretching programme, was performed. • The completed exercise diary from the previous week was returned. • The participants were told that they were now to no longer perform the exercises as this was the beginning of their week of rest before the final appointment the following week
WEEK 7	<ul style="list-style-type: none"> • The following outcome measures: pain free grip strength, pressure pain threshold, numeric pain rating scale and the patient rated tennis elbow questionnaire were performed. 	<ul style="list-style-type: none"> • The following outcome measures: pain free grip strength, pressure pain threshold, numeric pain rating scale and the patient rated tennis elbow questionnaire were performed.

3.5 Treatment approach

The study was conducted over seven weeks and involved one treatment session a week for six weeks and a follow-up appointment one week after the sixth appointment where only outcome measures were taken.

During the one treatment session per week all the participants performed the stretching and strengthening programme under supervision to ensure the exercises were performed correctly. This was performed on the recommendation that patients who undergo clinic based, supervised exercise regimes are more compliant than those in unsupervised exercise programmes (Stasinopoulos and Stasinopoulos, 2006; Malliaras *et al.*, 2008). The strengthening programme consisted of performing wrist flexion and extension as well as forearm rotation (pronation and supination) exercises using a Thera-band to provide the resistance. The participants also performed finger extension exercises using an elastic band, and performed a hand gripping exercise using a stress ball. These exercises were performed in three sets of ten repetitions with a stretch of the forearm extensor muscles between each set. All participants were required to perform the stretching and strengthening programme on a daily basis and were required to complete an exercise diary to ensure participant compliance. The participants in Group Two had additional

treatment in the form of the Ossur Airform Tennis Elbow Brace which was worn throughout the day, except while sleeping. If the brace was uncomfortable it could be removed for up to an hour, but participants were encouraged to wear it as much as possible.

3.6 Data collection

3.6.1 Subjective measurements

At the beginning of the first and fourth appointments and at the follow up appointment the participants were required to complete the NPRS. The PRTEE questionnaire was filled out by each participant before the first appointment and at the follow up appointment.

a) Numerical Pain Rating Scale (NPRS):

The NPRS has been shown to be valid, reliable and appropriate for use in a clinical setting (Williamson and Hoggart, 2005). Pain rating using a NPRS was measured with whole numbers, between 0 and 10, with 0 being no pain at all and 10 being the most severe pain ever experienced. The participant rated the pain that they were currently feeling. The NPRS is easy for the participants to understand and was used to determine how the participants responded to the treatment in terms of how they perceived the pain they experienced.

b) Patient Rated Tennis Elbow Evaluation questionnaire (PRTEE):

The PRTEE has been shown to be a reliable, reproducible and sensitive assessment of L.E, and is recommended as a standard outcome measure for the condition (Newcomer *et al.*, 2005). It measures pain in the participants affected arm, and their functional disability that they experience during activities.

3.6.2 Objective measurements

At the beginning of the first and fourth appointments and at the follow up appointment the participants from Group One and Group Two underwent PFGS and PPT measurements.

a) Pain free grip strength (PFGS):

Pain free grip strength was measured using a hand held dynamometer. Grip strength has been shown to be a useful assessment in L.E, and has been recommended for use in both research and in the clinical setting (Smidt *et al.*, 2002), it has been demonstrated to be inexpensive, reliable and sensitive to change, and was found to be the most useful measurement tool of change over time for patients suffering from L.E. PFGS readings have been found to be closely comparable to readings of the patient's perception of their improvement, unlike those of maximum grip strength (Tonks *et al.*, 2006).

Two measurements were taken and recorded and the mean value determined. All the measurements were recorded in the objective data collection table (Appendix 10).

The grip strength was measured with the participant seated and their elbow flexed at ninety degrees as grip strength may be reduced when the elbow is fully extended in participants with L.E (Shyam Kumar *et al.*, 2008).

b) Pressure pain threshold:

Pressure pain threshold was measured using an algometer. Smidt *et al.*, (2002), stated that many authors have recommended the clinical use of pressure pain threshold readings when conducting research and when in clinical practice. However, Smidt *et al.*, (2002) concluded that the PPT readings showed unsatisfactory reliability. Despite this conclusion by Smidt *et al.*, (2002), pressure pain threshold was used in this research.

The pressure pain threshold was measured with the participant seated, their arm at 30 degrees and their elbow flexed at 90 degree's with their forearm held in neutral position and supported on their thigh. The researcher palpated for the most sensitive spot over the common extensor tendon origin and the algometer was placed over that point (Smidt *et al.*, 2002). Pressure was then slowly and consistently applied over this spot. The participant was required to say “now” as soon as they felt pain or discomfort due to the applied pressure. At this point the reading was taken and recorded, the dial was reset to zero and a second reading was then taken. The two measurements and the resultant mean value were all recorded in the objective data collection table.

Table 3.2: Summary of outcomes performed at appointments 1, 4 and 7

	Week 1	Week 4	Week 7
Group One	1) Pain free grip strength 2) Pressure pain threshold 3) Numerical pain rating scale 4) Patient rated tennis elbow evaluation	1) Pain free grip strength 2) Pressure pain threshold 3) Numerical pain rating scale	1) Pain free grip strength 2) Pressure pain threshold 3) Numerical pain rating scale 4) Patient rated tennis elbow evaluation
Group Two	1) Pain free grip strength 2) Pressure pain threshold 3) Numerical pain rating scale 4) Patient rated tennis elbow evaluation	1) Pain free grip strength 2) Pressure pain threshold 3) Numerical pain rating scale	1) Pain free grip strength 2) Pressure pain threshold 3) Numerical pain rating scale 4) Patient rated tennis elbow evaluation

3.7 Statistical analysis

Statistical data was obtained through the subjective and objective outcome measures taken over the seven appointments. SPSS version 18 was used to analyse the data. The significance value was set as the *p* value of <0.05 and this is representative of the level of significance of the results. Demographics were compared between treatment groups using Pearson's chi square tests and independent t-tests. Repeated measures ANOVA testing was used to compare the outcomes between the groups over the time points. A significant time*group interaction effect indicated a significant effect of the intervention. Profile plots were done to establish the direction and trend of the intervention. The statistical results

were only representative of a small sample of the population and therefore no assumptions can be made with respect to the population as a whole.

3.8 Conclusion

A sample size of 30 participants diagnosed with L.E was used in this study. They were divided into two equal groups of 15 participants based on gender and roughly on age. Group One consisted of a strengthening and stretching programme alone, and Group Two consisted of a combination of the same strengthening and stretching programme and an Ossur Airform Tennis Elbow Brace. The participants were expected to perform the stretching and strengthening programme daily at home, and under researcher supervision once a week for six weeks. The data was then statistically analysed using the SPSS package and is presented in the following chapter.

Chapter Four: Results

4.1 Introduction

This chapter presents the results obtained during this clinical trial. The sample group consisted of 30 participants, 15 in Group One, the therapeutic strengthening and stretching programme, and 15 in Group Two, the therapeutic strengthening and stretching programme combined with the use of an intervention, the Ossur Airform Tennis Elbow Brace.

The analyses included primary data from:

- 1) Demographic data which compared the gender, age, elbow affected and dominant arm of the participants in Group One and Group Two.
- 2) Objective measurements consisted of: pressure pain threshold (PPT) at the point of most tenderness in the region of the lateral epicondyle, using an algometer; and pain free grip strength (PFGS) of the affected arm, using a hand held dynamometer.
- 3) Subjective measurements consisted of a numerical pain rating scale (NPRS) to measure the participant's perceived pain, and the use of the patient rated tennis elbow evaluation (PRTEE) to assess the participant's functional capabilities and pain.

The secondary data was collected from a variety of different sources including journal articles and text books. The literature from these sources was screened and the data relevant to this study was selected and utilized in this research.

The abbreviations and key terms pertinent to this chapter are:

F	=	female
L	=	left
M	=	male
MCID	=	minimally clinically important difference
N	=	sample size
n	=	sample size per group
NPR	=	numerical pain rating
p	=	the value which deems if information is of statistical importance
R	=	right
Std.	=	standard

Notes:

- 1) X axis=
Time 1 – appointment one baseline reading;
Time 2- appointment four;
Time 3- appointment seven.
(With the exception of Figure 4.7 where 2 – visit seven).
- 2) Wilks lambda results are inversely proportional to the outcome (i.e. the lower the Wilks lambda scores the higher/greater improvement made in terms of readings).

Consort diagram:

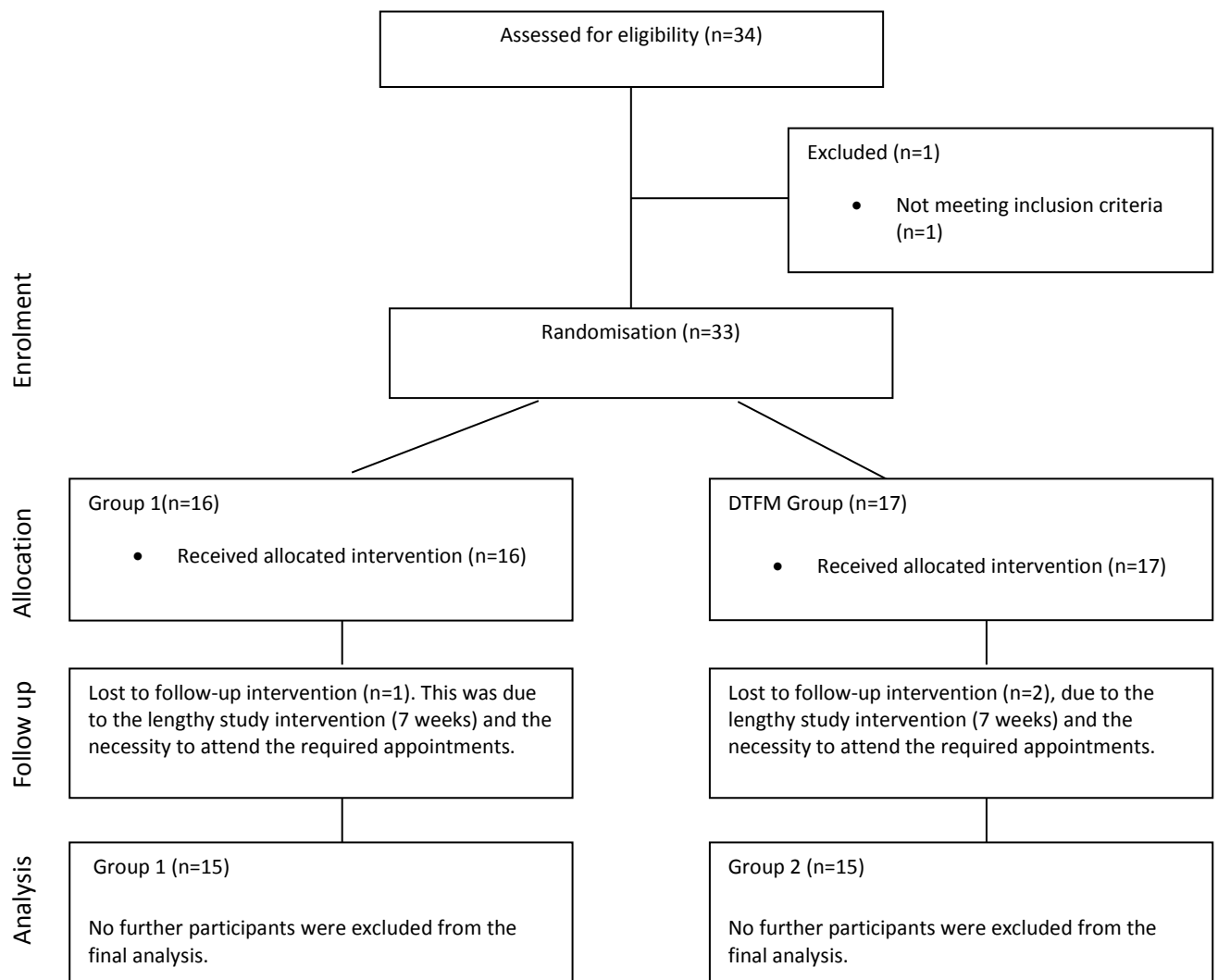


Figure 4.1: Consort diagram depicting the flow of the inclusion and exclusion of participants

Results :

4.2 Demographic data

Group One and Group Two both consisted of 15 participants; Group One had six females and nine males and Group Two had five females and ten males. The mean age of the females in Group One was 43.2 years where as the mean age of the females in Group Two was some years older at 51.6 years. The mean age of the males in Group One was 44.9 years where as the mean age of the males in Group Two was slightly younger at 42.9 years. Combined, the mean age of Group One was 44.2 years where as the mean age of Group Two was 45.8 years.

In Group One, 11 participant's right elbows and four participant's left elbows were affected, and in Group Two, 13 participant's right elbows were affected and two participant's left elbows.

There were no significant differences between Group One and Group Two in terms of age ($p=0.717$), gender ($p=0.705$) and elbow affected ($p=0.651$). There was however a statistically significant difference in dominant arm ($p=0.017$), with Group Two having no left handed participant's while 40% of Group One were left handed.

Table 4.1: Comparison of demographics between treatment groups

		Group				<i>p</i> value
		One		Two		
		Count	%	Count	%	
Age: mean (SD)		44.20	12.62	45.80	11.31	0.717
Female / Male	F	6	40.0%	5	33.3%	0.705
	M	9	60.0%	10	66.7%	
Dominant arm	L	6	40.0%	0	.0%	0.017
	R	9	60.0%	15	100.0%	
Elbow affected	L	4	26.7%	2	13.3%	0.651
	R	11	73.3%	13	86.7%	

Table 4.1 depicts that at the onset of the research, Group One and Group Two were comparable in mean age, gender and elbow affected as the p value was larger than 0.05 for both of them. Figures 4.2, 4.3 and 4.4 all depict the mean age, elbows affected and dominant arm according to group. The dominant arm however had a p value of 0.017 which is less than the 0.05 p value, and therefore is statistically significant. This will be further discussed in Chapter Five, Section 5.2.

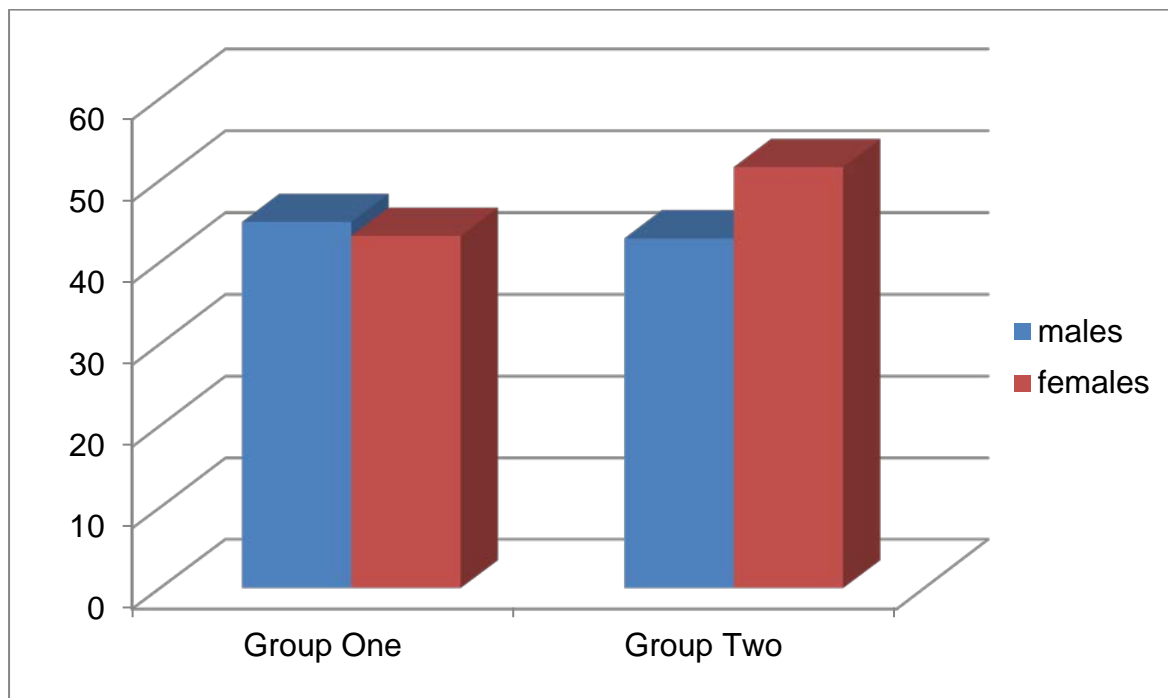


Figure 4.2: Mean age by group and gender

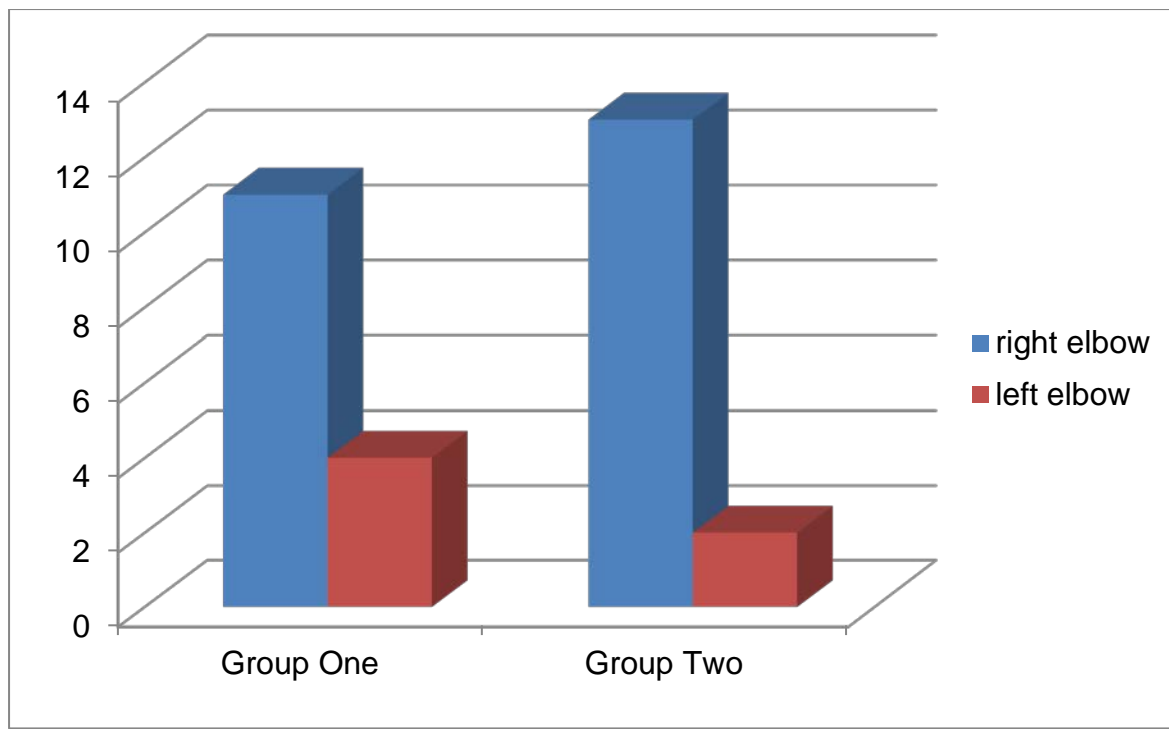


Figure 4.3: Elbows affected according to group

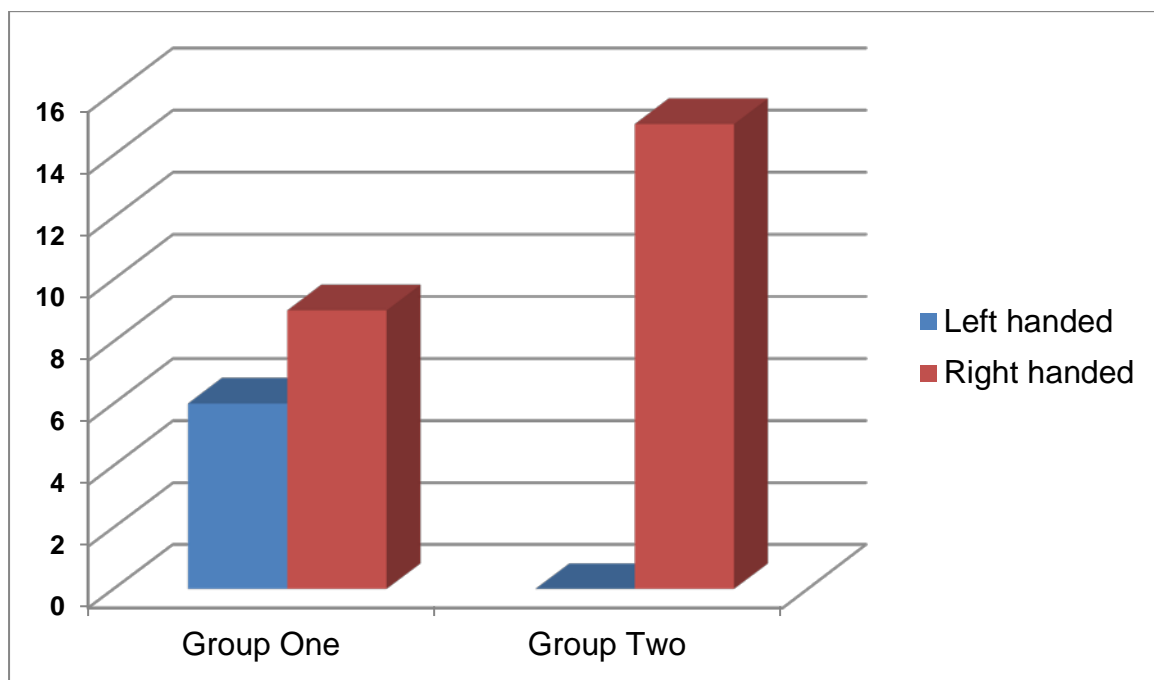


Figure 4.4: Dominant arm according to group

4.3 Objective data

4.3.1 Pressure pain threshold (PPT)

The PPT was measured using an algometer. PPT has been noted as a reliable measure, especially when taken by the same examiner (Nussbaum and Downes, 1998), which was the case in this study. Smidt *et al.*, (2002) recommended the clinical use of PPT readings when conducting research and when in clinical practice. Jones *et al.*, (2008), stated that the algometer is widely used, and therefore accepted in research literature and in the clinical environment, as a tool to measure an aspect of pain.

In this study, readings were taken with the participant seated, their arm at 30 degrees of flexion, the elbow flexed at 90 degrees and the forearm held in neutral position (viz. neither pronated nor supinated), such that their forearm was supported on their thigh. The researcher palpated for the most sensitive spot over the common extensor tendon origin, placed the algometer over that point (Smidt *et al.*, 2002) and then applied pressure until the participant felt discomfort. This was performed twice and the mean result was determined and used for statistical purposes.

There was a significant increase in PPT over time in both groups ($p < 0.001$), meaning that both Group One and Group Two showed improvement, but the increase over time was the same in both groups ($p = 0.110$) (Table 4.2), thus there was no statistical evidence of an intervention effect, meaning Group Two did not show evidence of a statistically significantly greater improvement than Group One.

However, Figure 4.5 shows that there was a trend towards the intervention group (Group Two) showing a faster rate of increase than the control group (Group One), Group Two improved by 0.58 kg/cm^2 from appointments 4-7, whereas Group One only improved by 0.13 kg/cm^2 . In addition, overall improvements, from appointments 1 to 7, were shown as :

- Group One improved by 0.97 kg/cm^2 and
- Group Two improved by 1.77 kg/cm^2 .

The above results indicate that, according to Chesterton *et al.*, (2007), Group Two exceeded the magnitude for measurement error and may, therefore, indicate true change. This implies that Group Two has reached the clinically significant level, which Group One did not. This is of importance in the clinical setting in that it suggests that the participants in Group Two were better able to deal with pressure induced tenderness after the application of the intervention (viz. the Ossur Airform Tennis Elbow Brace) in conjunction with the therapeutic exercise programme, as compared to their counterparts who only received the therapeutic exercise programme.

Table 4.2: Repeated measures ANOVA showing within and between subjects effects for PPT

Effect	Statistic	<i>p</i> value
Time	Wilk's lambda=0.362	<0.001
Group*time	Wilk's lambda=0.849	0.110
Group	F=1.044	0.316

Table 4.3: Table of mean changes in PPT over time by group

Group		Change in PPT from appointment 1 to 4	Change in PPT from appointment 4 to 7
Group One	Mean	0.4200	0.5467
	N	15	15
	Std. Deviation	0.75517	0.67598
Group Two	Mean	.5933	1.1733
	N	15	15
	Std. Deviation	1.09575	1.02363
Total	Mean	0.5067	0.8600
	N	30	30
	Std. Deviation	0.92882	0.90995

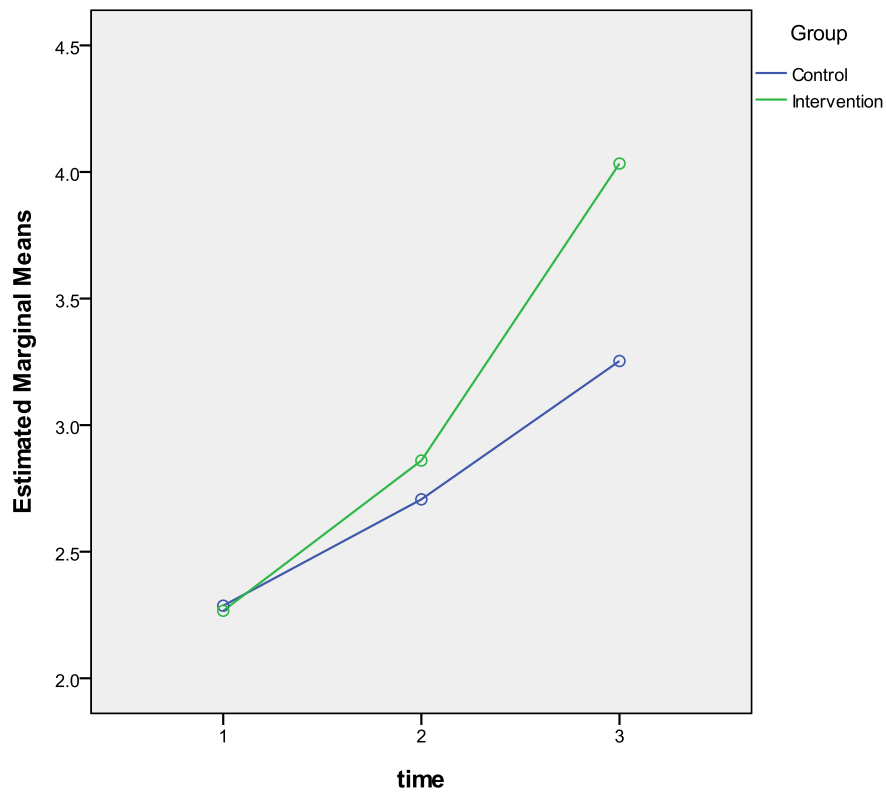


Figure 4.5: Profile plot of mean PPT over time by treatment group

Table 4.4: Table of mean changes in PPT between appointments by group

	Group One	Group Two
Appointment 1 average PPT	34,3	34
Appointment 4 average PPT	40,6	42,9
Difference from appointment 1-4	6,3	8,9
Average improvement per participant	0,42	0,59
Was the MCID met?	no	no
Appointment 4 average PPT	40,6	42,9
Appointment 7 average PPT	48,8	60,5
Difference from appointment 4-7	8,2	17,6
Average improvement per participant	0,55	1,2
Was the MCID met?	no	no
Appointment 1 average PPT	34,3	34
Appointment 7 average PPT	48,8	60,5
Difference from appointment 1-7	14,5	26,5
Average improvement per participant	0,97	1,8
Was the MCID met?	no	yes

4.3.2 Pain free grip strength (PFGS)

PFGS was measured using a hand held dynamometer. Grip strength has been shown to be a useful assessment in L.E, and has been recommended for use in both research and in the clinical setting (Smidt *et al.*, 2002; Blanchette *et al.*, 2011). Stratford and Levy, (1994) showed PFGS to be the preferred measure over maximal grip strength when assessing valid change over time in patients with L.E.

Prior to this research, the dynamometer was calibrated in order to ensure accurate readings were taken. Measurements were taken with the participant seated (their

hips and knees at 90 °) and their elbow flexed at 90°, with their shoulder adducted and in neutral and the forearm pronated with their wrist in neutral position (i.e. their forearm rested on their thigh). Studies have shown contradictory results as to which is the best position for the elbow to be in, but the reason behind the elbow being flexed is that grip strength may be reduced when the elbow is fully extended in participants with L.E (Shyam Kumar *et al.*, 2008). However, subsequent to the research being conducted, it was found that performing the grip strength with the elbow in extension is the preferred strength measurement for patients recovering from L.E (Blanchette *et al.*, 2011). Therefore it is suggested that future studies consider this more closely.

The participants performed the exercise twice and the mean result was determined and used for statistical purposes.

There was no statistical evidence of an intervention effect for PFGS, meaning Group Two did not show evidence of greater improvement than Group One. There was a general significant increase in PFGS over time in both groups ($p < 0.001$), but the increase over time did not differ between the groups ($p = 0.180$). Figure 4.5 shows almost parallel profiles of the two treatment groups. It is worth noting that Group Two increased in pain free grip strength by 6.87 kg in appointments 1-4 and Group One increased by 3.13 kg. In appointments 4-7 Group One increased by 5.47 kg and Group Two only increased by 2.47 kg. This shows that Group Two showed a much greater improvement in PFGS in the first three weeks of treatment; whereas Group One had a greater increase in PFGS in the last three weeks of treatment. In keeping with a study by Suputtitada *et al.*, (2004), the MCID, in terms of grip strength, for this research was set at 10% of the total range of the scale. The lowest reading of all the participants average PFGS was 3 kg and the highest reading of all the participants average PFGS was 63 kg. Therefore, the MCID was set at 10% of 60 which was 6.

As can be seen in Table 4.7, in terms of the clinical significance Group Two showed a clinically significant improvement in terms of PFGS from appointment 1-4 and Group One did not. Both Group One and Two did not show a clinically significant improvement from appointments 4-7. Both the groups did, however, show clinically significant improvements in PFGS when assessed from appointment 1 to

appointment 7. This indicates that the therapeutic exercise programme alone, as well as when combined with the Ossur Airform Tennis Elbow Brace, produces a clinically significant effect in PFGS. It is important to note that the Ossur Airform Tennis Elbow Brace had a clinically significant effect a lot sooner (from appointments 1-4) than the control group, (viz. the therapeutic exercise programme).

Table 4.5: Repeated measures ANOVA showing within and between subjects effects for PFGS

Effect	Statistic	<i>P value</i>
Time	Wilk's lambda=0.474	<0.001
Group*time	Wilk's lambda=0.881	0.180
Group	F=0.736	0.398

Table 4.6: Table of mean changes in PFGS over time by group

Group		Change in PFGS from appointment 1 to 4	Change in PFGS from appointment 4 to 7
Group One	Mean	3.1333	5.4667
	N	15	15
	Std. Deviation	7.18994	5.40987
Group Two	Mean	6.8667	2.4667
	N	15	15
	Std. Deviation	9.81884	4.62704
Total	Mean	5.0000	3.9667
	N	30	30
	Std. Deviation	8.66622	5.17609

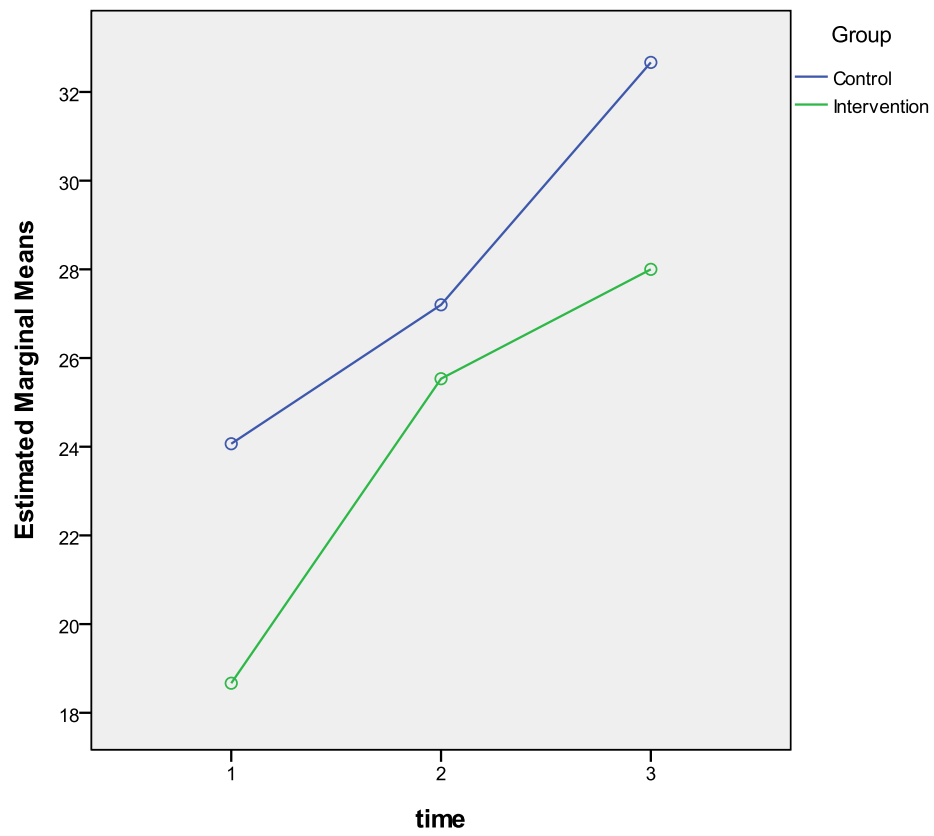


Figure 4.6: Profile plot of mean PFGS over time by treatment group

Table 4.7: Table of mean changes in PFGS between appointments by group

	Group One	Group Two
Appointment 1 average PFGS	361kg	280 kg
Appointment 4 average PFGS	408 kg	383 kg
Difference from appointment 1-4	47 kg	103 kg
Average improvement per participant	3.1 kg	6.9 kg
Was the MCID met?	no	yes
Appointment 4 average PFGS	408 kg	383 kg
Appointment 7 average PFGS	490 kg	420 kg
Difference from appointment 4-7	82 kg	37 kg
Average improvement per participant	5.5 kg	2.5 kg
Was the MCID met?	no	no
Appointment 1 average PFGS	361 kg	280 kg
Appointment 7 average PFGS	490 kg	420 kg
Difference from appointment 1-7	129 kg	140 kg
Average improvement per participant	8.6 kg	9.3 kg
Was the MCID met?	yes	yes

4.4 Subjective data

4.4.1 Numerical pain rating scale (NPRS)

The NPRS has been shown to be valid, reliable and appropriate for use in a clinical setting (Williamson and Hoggart, 2005) and has been shown to be more reliable than the visual analogue scale (Salaffi *et al.*, 2003). Pain rating using the NPRS was measured with whole numbers, between 0 and 10 (with 0 being no pain at all and 10 being the most severe pain that the participant had ever experienced). The participant rated their pain at the time accordingly.

It can be seen in Table 4.8, that there was a statistically significant improvement ($p < 0.001$) in time for both groups with regard to NPRS. But, there was no difference between the treatment groups in terms of NPRS response over time ($p=0.791$). Figure 4.6 shows parallel profiles of the two groups over time. Table 4.9 depicts that Group One had a fairly similar decrease in pain over appointments 1-4 (-2.33) and appointments 4-7 (-2.07). This, however, was different to Group Two who demonstrated a greater reduction of pain in appointments 1-4 (-2.80) than in appointments 4-7 (-1.6).

With regards to clinical significance, Salaffi *et al.*, (2003) chose to implement a 15% reduction in pain as the MCID for grip strength, this figure was chosen by them as it was supported by a number of other studies as well as in three emergency department settings (Jaeshcke *et al.*, 1989; Bird and Dickson, 2001; Gallagher *et al.*, 2001; Bijur *et al.*, 2003). The lowest pain rating reported by a participant was 0 and the highest was 9. This means that the MCID at 15% of 9 is 1.4, and this amount will be used in this study to determine whether the MCID was met or not. Both Group One and Two showed clinically significant improvements at appointments 1-4, appointments 4-7 and appointments 1-7. This means that both the therapeutic exercise programme alone, and in conjunction with the Ossur Airform Tennis Elbow Brace, brought about clinically significant reductions in pain.

Table 4.8: Repeated measures ANOVA showing within and between subjects effects for NPRS

Effect	Statistic	P value
Time	Wilk's lambda=0.137	<0.001
Group*time	Wilk's lambda=0.983	0.791
Group	F=0.053	0.820

Table 4.9: Table of mean changes in NPRS over time by group

Group		Change in NPRS from appointment 1 to 4	Change in NPRS from appointment 4 to 7
Group One	Mean	-2.3333	-2.0667
	N	15	15
	Std. Deviation	1.58865	1.27988
Group Two	Mean	-2.8000	-1.6000
	N	15	15
	Std. Deviation	2.85857	2.32379
Total	Mean	-2.5667	-1.8333
	N	30	30
	Std. Deviation	2.28463	1.85850

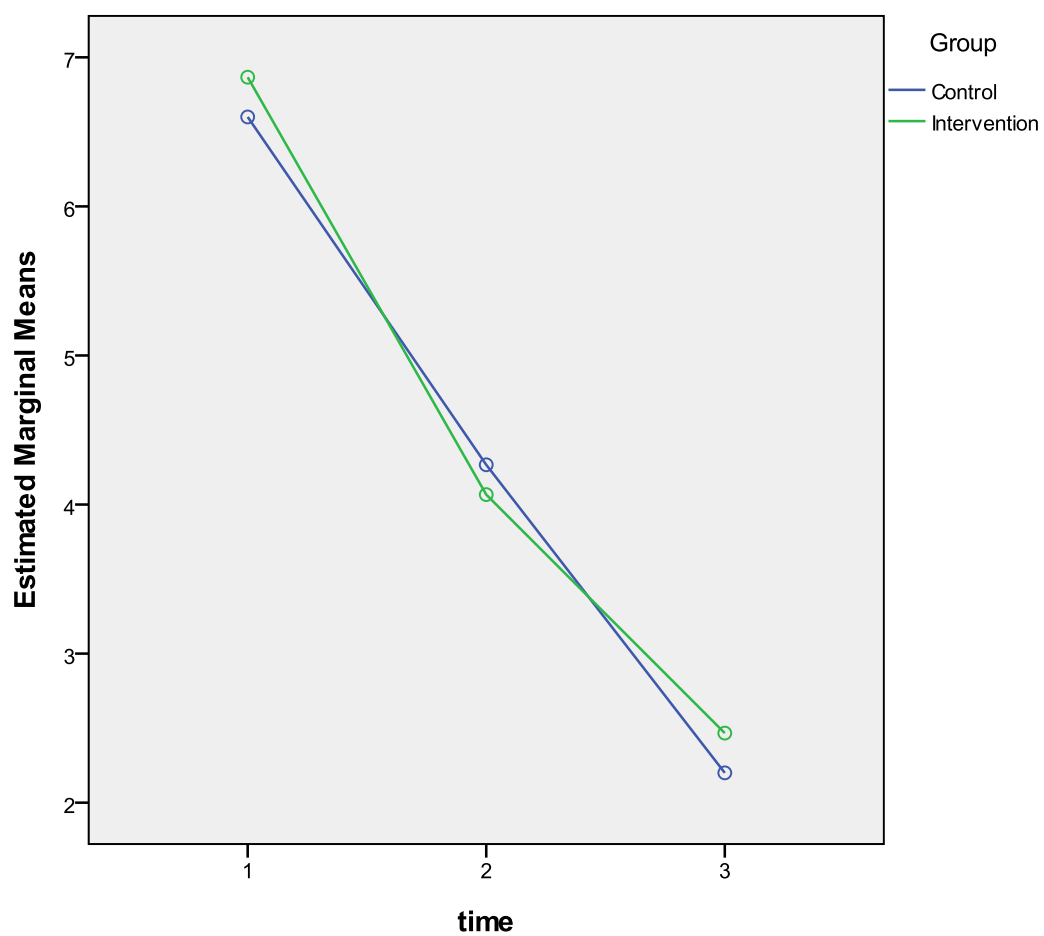


Figure 4.7: Profile plot of mean NPRS over time by treatment group

Table 4.10: Table of mean changes in NPRS between appointments by group

	Group One	Group Two
Appointment 1 NPR	99	103
Appointment 4 NPR	64	61
Difference from appointment 1-4	35	42
Average improvement per participant	2.3	2.8
Was the MCID met?	Yes	yes
Appointment 4 NPR	64	61
Appointment 7 NPR	32	37
Difference from appointment 4-7	32	24
Average improvement per participant	2.1	1.6
Was the MCID met?	Yes	yes
Appointment 1 NPR	99	103
Appointment 7 NPR	32	37
Difference from appointment 1-7	67	66
Average improvement per participant	4.5	4.4
Was the MCID met?	Yes	yes

4.4.2 Patient rated tennis elbow evaluation (PRTEE)

The PRTEE has been shown to be a reliable, reproducible and a sensitive assessment of L.E, and is recommended as a standard outcome measure for the condition (Newcomer *et al.*, 2005; Rompe *et al.*, 2007). Blanchette *et al.*, (2011) felt that the PRTEE demonstrated sufficient psychometric properties, in that it was valid, reliable and sensitive to change, but they felt further measures needed to be found in

order to objectively monitor patients suffering from L.E in conjunction with the PRTEE. Therefore, in this research the PRTEE was used in conjunction with other clinical measures such as the NPRS, PFGS and PPT.

Each participant completed the PRTEE questionnaire before beginning the trial and then at the final appointment of the trial, and the two scores were then compared to investigate if there was a statistically significant improvement ($p < 0.001$) in time for both groups with regard to PRTEE. However there was no difference between the treatment groups in terms of PRTEE response over time ($p=0.174$) (Table 4.11). Figure 4.7 shows parallel profiles of the two groups over time.

In terms of clinical significance a MCID value specifically for the PRTEE has either not been established or was not acquired by the researcher. However, the PRTEE is comparable to the DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire (Rompe *et al.*, 2007). A 10 point difference in mean DASH score can be considered a minimally important change (Gummeson *et al.*, 2003). Seeing as the PRTEE and the DASH questionnaires are comparable, an MCID of 10% was used in this research to determine the clinical significance of the results.

The mean difference in PRTEE was calculated from deducting the lowest PRTEE score, 1, from the highest PRTEE score, 80, which resulted in 79. 10% of 79 is 7,9 and was used as the MCID for PRTEE in this research. As can be seen in Table 4.12, both Group One and Group Two showed a clinically significant improvement in terms of pain and function disability as assessed by the PRTEE.

Table 4.11: Repeated measures ANOVA showing within and between subjects effects for PRTEE

Effect	Statistic	<i>P value</i>
Time	Wilk's lambda=0.228	<0.001
Group*time	Wilk's lambda=0.935	0.174
Group	F=0.029	0.886

Table 4.12: Table of mean changes in PRTEE over time by group

Group		Change in PRTEE from appointment 1 to 7
Group One	Mean	-33.3333
	N	15
	Std. Deviation	17.19081
Group Two	Mean	-42.6000
	N	15
	Std. Deviation	25.88105
Total	Mean	-37.9667
	N	30
	Std. Deviation	22.09616

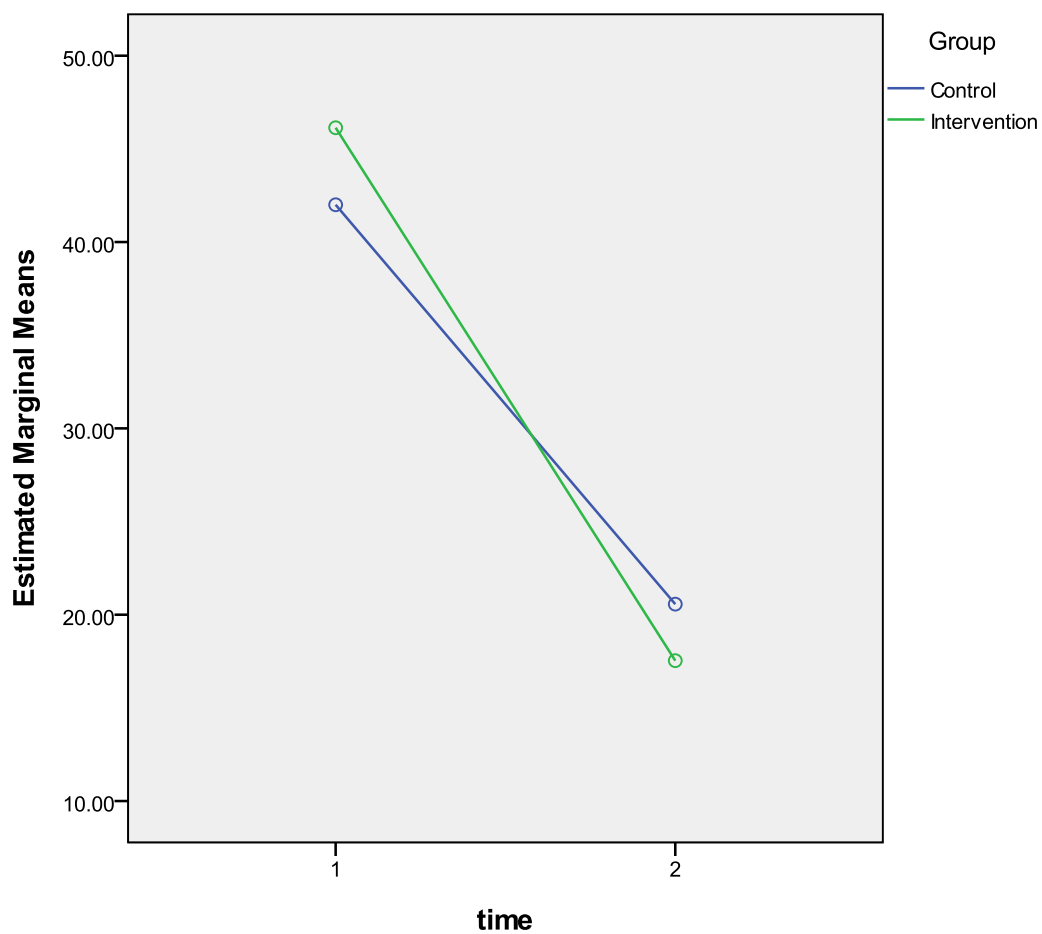


Figure 4.8: Profile plot of mean PRTEE over time by treatment group

Table 4.13: Table of mean changes in PRTEE between appointments by group

	Group One	Group Two
Appointment 1 PRTEE	630	692
Appointment 7 PRTEE	308.5	263
Difference from appointment 1-7	321.5	429
Average improvement per participant	21.4	28.6
Was the MCID met?	yes	yes

4.5 Conclusion

Both Group One and Group Two showed significant statistical improvement ($p<0.05$) in terms of all the outcome measures. But there was no statistical evidence in any of the subjective or objectives outcomes that the intervention, the Ossur Airform Tennis Elbow Brace, had any effect.

For the PPT there was a non significant trend showing the possibility that in the intervention group (Group Two), the rate of increase over time was faster than in the control group. However, this difference could have arisen by chance or may have been masked by the group sizes ($n=15$) or may have been accentuated if further follow up readings were taken. These are supported by the fact that there was a possibility that this study was underpowered to statistically detect what might have been an important difference between the groups at the $p<0.05$ level of significance.

In terms of clinical significance, however, Group Two showed a clinically significant effect in terms of PPT, whereas Group One did not. This indicates that the Ossur Airform Tennis Elbow Brace combined with the therapeutic exercise programme used in this research is more beneficial in terms of pain tolerance with pressure than just the therapeutic exercise programme alone.

The other outcomes, PFGS, NPRS and the PRTEE, showed clinically significant improvement in both the groups, indicating that the intervention, the Ossur Airform Tennis Elbow Brace, demonstrated to be no more beneficial than the therapeutic exercise programme alone.

The following chapter, Chapter Five, will discuss these results in the context of the literature.

Chapter Five: Discussion

5.1 Introduction

This chapter discusses the results of the clinical trial that was presented in Chapter Four of this research. It states possible explanations for the results obtained by referring to the literature and previous studies discussed in Chapter Two.

5.2 Demographic data

The two groups were comparable in terms of age according to the p value in Table 4.1 ($p=0.717$). The average age of the participants in Group One was 44.2 and in Group Two was 45.8 years old, which is in keeping with the literature that states that the average age of the typical L.E patient is 42 years old (Bishai and Palmer, 2006). The highest prevalence of L.E is more often found in people between the ages of 45 and 64 years old, with L.E occurring more commonly between the ages of 45 and 54 years (Shiri *et al.*, 2006).

The gender ratio's in each group was controlled using stratified sampling based on gender; as there is still controversy as to whether there is an association between genders and L.E (Shiri *et al.*, 2006). Some literature states equal prevalence in males and females (Alton and Kanat, 2008) but it has reportedly been of a greater severity and longer duration in females (Stasinopoulos *et al.*, 2005). Therefore, it was important to keep the genders as similar in each group as possible in order to remain consistent with previous studies on L.E performed at the Durban University of Technology (Shaik, 2000; Roodt, 2001; Haswell, 2002; Marquis, 2002; du Coudray, 2006). It was also important to keep the gender ratios as similar as possible to ensure that the results are not biased by:

- The duration of L.E generally being longer in females than in males (Stasinopoulos *et al.*, 2005).

- The differences in physical strength according to gender. In an article by Massey-Westropp *et al.*, (2011), it was said that an analysis of hand grip strength by gender showed grip strength to be higher in males than females at all ages.
- Pain perception discrepancies due to different gender ratios. Wiesenfeld-Hallin, (2005), stated that there have been many studies that have shown noxious stimuli to be perceived as more painful by healthy women than by healthy men. It has also been determined in a study of noxious thermal stimuli that women showed a lower mean pain threshold, lower pain tolerance and greater unpleasantness with pain (Wise *et al.*, 2002).

Group One consisted of nine males and six females whereas Group Two consisted of ten males and five females. Although the ratios were not equal in each group the difference was small enough so as not to generate a statistically significant difference / effect on the results.

Similarly, the “elbow affected” in Group One reflected: 11 participant’s right elbows and four participant’s left elbows were affected, and in Group Two, 13 participant’s right elbows were affected and two participant’s left elbows. Although there is a difference between the two groups, it is not a statistically significant difference, and therefore it has had a limited effect on the results.

There was, however, a significant difference in dominant arm ($p=0.017$), with Group Two having no left handed participant’s while 40% of the participants in Group One were left handed. It is unknown whether this would have affected the results.

Table 5.1: The correlation between dominant arm and elbow affected

Data	Group One	Group Two	Total number of participants	Percentage of total participants
Right handed patients With their right side symptomatic	8	13	21	70%
Right handed patients with their left side symptomatic	1	2	3	10%
Left handed patients With their left side symptomatic	3	0	3	10%
Left handed patients with their right side symptomatic	3	0	3	10%

There are many differences in opinion as to whether L.E is more common in the dominant arm. This research indicated that 24 of the 30 participants (80%), suffered with L.E in their dominant arm, suggesting that L.E is more common in the dominant arm. This supports the findings of Jobe *et al.*, (1994); Erturk *et al.*, (1997); Stasinopoulos *et al.*, (2005); Manias and Stasinopoulos, (2006); Radpasand *et al.*, (2009) and Scher *et al.*, (2009).

Manual work and playing racquet sports are all considered factors that significantly affect the prognosis of patients with L.E (Croisier *et al.*, 2007). This was evident as a flaw in the sampling of this study as although the groups were sampled according to age and gender, they were not sampled according to occupational or recreational activities. A number of participants who played tennis, squash or badminton may have re-injured themselves during the study and it so happened that majority of the participants who engaged in these activities were in Group Two, the intervention group. This, therefore, may have had a significant effect on the results and has been added as a recommendation in Chapter Six.

5.3 Objective data

Table 5.2: Showing the overall statistical and clinical significance of the outcome measures between the groups

	Group One	Group Two
PPT		
Statistical significance	YES	YES
Clinical significance	NO	YES
PFGS		
Statistical significance	YES	YES
Clinical significance	YES	YES
NPRS		
Statistical significance	YES	YES
Clinical significance	YES	YES
PRTEE		
Statistical significance	YES	YES
Clinical significance	YES	YES

5.3.1 Pressure Pain Threshold (PPT)

According to the PPT readings taken in this study there was a significant improvement in PPT over time in both groups. Group Two, however, did show a faster rate of improvement than Group One. Group Two improved by 0.59 from appointments 1 to 4 and improved by a further 0.58 from appointments 4 to 7. Whereas Group One improved by 0.42 from appointments 1 to 4 and only improved by a further 0.13 from appointments 4 to 7.

One of the mechanisms of action of counterforce bracing is to provide an artificial second muscle origin, which decreases the load placed on the muscular attachment by dispersing the pressure applied to it (Wuori *et al.*, 1998). This may be the reason for the faster rate of improvement in Group Two, as with less pressure applied

directly onto the injured part of the common extensor tendon it may have healed faster, thus allowing the participants in Group Two to withstand more pain induced by pressure. Physiologically both groups would have been expected to improve as eccentric training has been shown to stimulate the tenocytes to produce collagen which helps repair the injured tendon; helping the collagen to be laid out in a parallel fashion which contributes to its strength and reduces the abnormally high amounts of glycosaminoglycans found in injured tendons (Stasinopoulos *et al.*, 2005). This process aids in healing the tendon and would therefore help the participants withstand more pressure applied to the tendon before it is painful, resulting in an increased PPT reading.

The PPT was measured using an algometer and performed over the most tender part of the common extensor tendon origin, with pressure being applied until the participant perceived the sensation of pain. This means that different areas of the common extensor tendon would have been tested each time the participants' readings were taken as no indication of where the algometer had previously been placed was made. This may have led to the data obtained not being consistent and comparable which would have affected the results.

Group Two showed a similar increase in PPT from appointment 4 to appointment 7 as from appointment 1 to 4. This indicates that it is important to perform the stretching and strengthening programme over the six week period. Group One also continued to improve in terms of PPT from appointment 4 to 7. This suggests that it may be beneficial in a future study to continue the therapeutic exercise programme for longer than six weeks, perhaps over eight to 12 weeks; to investigate whether there would be continued improvement after six weeks of treatment in the respective groups.

The participants did complete an exercise diary, but this diary was not analysed and used in conjunction with the outcome measures to ascertain whether any non-compliance to the therapeutic exercise programme may have affected the outcomes and results. This analysis would be recommended for any future studies. In the same light any non-compliance to the wearing of the Ossur Airform Tennis Elbow Brace was not recorded and, therefore, it is not known if non-compliance may have

affected the outcome measures and the results. Both these factors should be considered in future research.

5.3.2 Pain free grip strength (PFGS)

PFGS is reportedly the most sensitive measurement of the physical damage caused by L.E (Vicenzino, 2003). Burton (1985) demonstrated an immediate increase in PFGS with the use of forearm bracing. This result is contradictory to Forbes and Hopper, (1990) in which it was determined that symptomatic and non-symptomatic participants showed no immediate significant change in grip strength when wearing or not wearing the brace. As a result, this study recorded the effect of the brace on PFGS after three and six weeks, and not immediately.

From this study it was determined that there was a general significant increase in PFGS over time in both groups ($p < 0.001$), but the increase over time did not differ considerably between the groups ($p = 0.180$). Therefore, both Group One and Group Two improved in terms of PFGS. It is interesting to note that Group Two improved in terms of PFGS more between appointments 1 and 4 at 6.87 compared to Group One at 3.13, whereas Group One improved more between appointments 4 and 7 at 5.47 compared to Group Two at 2.47.

The initial improvement of Group Two may be attributed to the effect of the orthotic brace but this would contradict the study performed by Wuori *et al.*, (1998), where the pain free grip strength was calculated under four different conditions: testing two elbow braces, a placebo brace and a no-brace situation. Wuori *et al.*, (1998) concluded that no immediate advantage of elbow bracing was detected. In contrast to the findings by Burton (1985); Wuori *et al.*, (1998) and Forbes and Hopper, (1990), the participants in this study had been wearing the counterforce bracing for three weeks before the second readings were taken. This meant the bracing had been in effect for three weeks, and would lead one to believe that over time the continued decreased load off the injured tendon allowed healing to occur and, therefore, allowed for an increase in PFGS.

There does not seem to be a clear improvement due to stretching and strengthening exercises on grip strength in terms of the literature (Johnson *et al.*, 2007) which is supported by Bisset *et al.*, (2005), who stated that exercise may decrease pain but has no positive effect on maximum grip strength. Physiologically, one could assume that strengthening exercises would increase the grip strength, especially because the exercise programme was fairly comprehensive, and worked the forearm muscles as well as muscles within the hand which are mostly responsible for grip strength (Flatt, 2000).

5.4 Subjective data

5.4.1 Numerical pain rating scale (NPRS)

There was no difference between the treatment groups in terms of NPRS response over time ($p=0.791$). This showed that according to the groups' reactions, the perception of pain both the treatment protocols provided similar pain relief. Group One had a fairly similar decrease in pain over appointments 1-4 (-2.33) and appointments 4-7 (-2.07). This, however, was different to Group Two who had a greater reduction of pain in appointments 1-4 (-2.80) than in appointments 4-7 (-1.6). This measurement is subjective and, therefore, is the perception of each participant which in itself allows for large variance and inaccuracies.

A study performed by Oken *et al.*, (2008), demonstrated that bracing only has an effect when worn, meaning that pain decreases when wearing a brace, and returns as soon as the brace is taken off. This study did not perform a long term follow up or test whether the reduction in pain continued after not wearing the brace. Therefore it is recommended that future studies address whether discontinuing wearing the Ossur Airform Tennis Elbow Brace would cause a relapse or deterioration of symptoms.

Alton and Kanat, (2008) found that braces helped reduce resting pain and they suggested that braces may be used as a strategy to wait out the natural course of the condition, which according to Olausson *et al.*, (2009), is 12 months.

A study by Manias and Stasinopoulos, (2006) concluded that an exercise programme and static stretching reduced pain in patients with L.E, which was supported by Bisset *et al.*, (2005) and Johnson *et al.*, (2007) who both stated that evidence exists that stretching and strengthening programmes reduce pain. Pienemaki *et al.*, (2006) found exercise therapy to be beneficial, more so than ultrasound treatment, in reducing pain. This beneficial effect of exercise therapy is in keeping with the results of this study.

Physiologically, by dispersing the load placed on the attachment of the injured tendon through the use of the forearm brace, one would expect the pain felt to be decreased, which is what Group Two demonstrated. Similarly, one would expect that the production of new collagen, laid down in a parallel fashion in the injured tendon, would increase the tensile strength in the tendon (Stasinopoulos *et al.*, 2005) resulting in a decrease in pain.

Additionally, Pienemaki *et al.*, (1998) found that not only was pain reduced, but that exercise may reduce the chronicity of L.E. However, chronicity was not noted in this study and it is recommended that a future study address this.

5.4.2 Patient Rated Tennis Elbow Evaluation (PRTEE)

There was no significant difference between the treatment groups in terms of PRTEE response over time ($p=0.330$). The overall improvement of Group One was 33.33 according to the mean value, and the overall improvement of Group Two was 42.60 according to the mean value. This showed that the participants all perceived a reduction of pain felt during their functional and usual activities.

Alton and Kanat, (2008) concluded that an epicondylar bandage is superior to the use of a wrist splint as it made hand activities a lot easier and more comfortable to perform. This is supported by the conclusion that brace-only treatment, using a forearm strap, showed great improvement in the outcome of “inconvenience during daily activities” (Struijs *et al.*, 2004).

As discussed earlier under NPRS, physiologically by dispersing the load placed on the attachment of the injured tendon through the use of the forearm brace one would expect the pain felt to decrease and, therefore, for functionality to increase, as demonstrated by Group Two. Similarly, one would expect that the production of new collagen, laid down in a parallel fashion in the injured tendon, would increase the tensile strength in the tendon resulting in a decrease in pain and an increase in functionality shown by both groups.

5.5 Review of hypotheses

The hypothesis was that the strengthening and stretching programme of the forearm extensor muscles would be as effective in reducing pain and disability, in patients with L.E, as the strengthening and stretching programme combined with the orthotic brace. This was supported in the case of this study.

Therefore, the null hypothesis stated that the strengthening and stretching programme of the forearm extensor muscles combined with the orthotic brace would not be more effective than strengthening and stretching programme alone in terms of objective and subjective findings, in patients with L.E. This hypothesis was accepted.

However in terms of the specific outcome measures, the null hypothesis is differentiated as follows for the statistical analysis:

- Accepted for grip strength.
- Accepted for pain (NPRS).
- Accepted for tenderness (algometer).
- Accepted for functionality (PRTEE).

The only clinically significant difference between the groups was that of the tenderness measures (algometer), therefore it needs to be considered that the use of a brace may only be effective in reducing perceived tenderness (PPT).

5.6 Conclusion

To conclude, this study produced a similar result as the study by Luginbuhl *et al.*, (2008), who determined that a forearm support band, a strengthening exercise programme, and a combination of these two treatments all resulted in equal improvement. It also supports Struijs *et al.*, (2001) and Struijs *et al.*, (2004) who found that there was no added benefit when an orthotic brace was used as a supplement treatment to physical therapy, ultrasonography or corticosteroid injection.

The following chapter, Chapter Six, states the conclusion of the research and will discuss any recommendations for further research.

Chapter Six: Conclusions and Recommendations

6.1 Introduction

This chapter states the conclusion of this research and discusses the recommendations for further research in this topic.

6.2 Conclusions

The aim of this study was to investigate the relative clinical effectiveness of therapeutic exercises alone and in combination with orthotic bracing, in terms of subjective and objective clinical findings, in the treatment of L.E.

The subjective measures taken were the numerical pain rating scale and the patient rated tennis elbow evaluation. The objective measures taken were the pressure pain threshold, using an algometer, and the pain free grip strength, using a hand held dynamometer.

The inter-group examination of the results indicated that both Group One and Group Two improved for all the outcomes, showing that there was no statistical evidence in any of the subjective or objectives outcomes that the intervention, the Ossur Airform Tennis Elbow Brace, had any added beneficial effect. This was true for the clinical significance too excepting that Group Two showed a clinically significant rate of improvement over time in terms of pressure pain threshold.

Therefore, the aim of this study was achieved as the results show that there was a minimally significant clinical effectiveness when combining an orthotic brace with therapeutic exercises as opposed to performing the therapeutic exercises alone.

6.3 Recommendations

1. A larger number of participants could have ensured a more reliable result. Hong *et al.*, (2004) stated that although there have been many studies published on L.E, many of them are flawed as they have small patient populations which results in an underpowered study, rendering the results invalid. This was not addressed in this study due to feasibility issues of conducting a large scale study.
2. Participants should be strategically sampled (e.g. stratified sampling) according to ethnicity, occupation and recreational activities, as well as age and gender (the latter which was considered for this study). This is due to these groupings having a potential effect on the treatment and the outcomes as was noted in similar studies (Stasinopoulos *et al.*, 2005; Wiesenfeld-Hallin 2005; Shiri *et al.*, 2006; Croisier *et al.*, 2007; Massey-Westropp *et al.*, 2011).
3. The arm dominance, in association with the presentation, cause and duration of L.E (Hong *et al.*, 2004), may also have an effect on the outcomes of this study and it may be worth considering these criteria in terms of future sampling.
4. The amount and type of activity that each participant is engaging in whilst involved in the study should also be monitored as this is can play a huge part in the outcome of the study and can sway the results. An analogy could be drawn between this and the use of a headache diary in headache based studies (Yeomans, 2000).
5. In terms of the recorded outcomes, the inclusion of a one month, a six month and / or a 12 month follow up after the treatment period is completed would allow the determination in terms of the long term effects of the treatment.
6. Structuring future studies as either a single or double blinded study would eliminate any researcher and / or measurer bias (Viera *et al.*, 2007) and may also assist in removing the Hawthorne / placebo effect (Babbie *et al.*, 2001).

7. Future studies should consider the necessity of participant appointments. If the intention of the appointments is to ensure that the participants are performing the exercises correctly, this could be achieved in the first appointment and one follow up appointment. This would improve compliance with attendance at the clinic. This could be supported by telephone calls to the participants as a reminder and to improve compliance.
8. The use of an electronic / digital dynamometer for the pain free grip strength readings taken may have been more accurate than an analogue variety.
9. The use of an electronic / digital algometer for the pressure pain threshold readings taken may have been more accurate than an analogue variety.
10. When providing the participants with an orthotic brace, two braces should be given to them for practical purposes (viz. washing and cleaning of the orthotic brace over the time of the study).
11. Many of the participants are likely to re-injure themselves after returning to activities once they experience a reduction in symptoms. This negatively impacted on the results, therefore, it is recommended to advise participants to avoid any aggravating factors during the treatment period of the study. A record of any such incidents should be kept and controlled for statistical purposes.
12. Participants could also be sampled according to the area of the tendon affected, (i.e. the tenoperiosteal junction, musculotendinous junction or within the tendon itself). The area of the tendon affected could have an effect on the outcome of the treatment.

References for Chapters:

Alfredson, H. 2003. Chronic midportion achilles tendonopathy: an update on research and treatment. *Clinical Sports Medicine*, 22: 727-741.

Alton, L. and Kanat, E. 2008. Conservative treatment of lateral epicondylitis: comparison of two different orthotic devices. *Clinical Rheumatology*, 27: 1015-1019.

Babbie, E., Mouton, J., Payze, C., Vorster, J., Boshoff, N. and Prozesky, H. 2001. The practice of social research. Oxford: Oxford University Press.

Baker, K., Robertson, V. and Duck, F. 2001. A review of therapeutic ultrasound: biophysical effects. *Physical therapy*, 81(7): 1351-1358.

Basford, J., Sheffield, C. and Cieslak, K. 2000. Laser therapy: a randomised controlled trial of the effects of low intensity Nd:YAG laser radiation on lateral epicondylitis. *Archives of Physical and Medical Rehabilitation*, (81): 1504-1510.

Bennell, K., Hunt, M., Wrigley, T., Hunter, D. and Hinman, R. 2007. The effects of hip muscle strengthening on knee load, pain, and function in people with knee osteoarthritis: a protocol for a randomised, single-blind controlled trial. *Biomed Central Musculoskeletal Disorders*, 8(121).

Bergmann, T. and Peterson, D. 2002. *Chiropractic Technique: principles and procedures*. Mosby: Philadelphia.

Bijur, P., Latimer, C. and Gallagher, J. 2003. Validation of a verbally administered numerical rating scale of acute pain for use in the emergency department. *Academic Emergency Medicine*, 10(4): 390-392.

Bird, S. and Dickson, E. 2001. Clinically significant changes in pain along the visual analog scale. *Annals of Emergency Medicine*, 38(6): 639-643.

Bishai, S. and Plancher, K. 2006. The basic science of lateral epicondylitis: update for the future. *Techniques in Orthopaedics*, 21(4): 250-255.

Bisset, L., Paungmali, A., Vicenzino, B. and Beller, E. 2005. A systematic review and meta-analysis of clinical trials on physical interventions for lateral epicondylalgia. *British Journal of Sports Medicine*, 39:411-422.

Bjordal, J., Lopes-Martin, R., Joensen, J., Couppe, C., Ljunggren, A., Stergioulas, A. and Johnson, M. 2008. A systematic review with procedural assessments and meta-analysis of Low-Level Laser therapy in lateral elbow tendinopathy (tennis elbow). *Biomed Central Musculoskeletal Disorders*, 9: 75.

Blanchette, M. and Normand, M. 2011. Impairment assessment of lateral epicondylitis through electromyography and dynamometry. *Journal of the Canadian Chiropractic Association*, 55(2): 96-106.

Brabston, E., Genuario, J., and Bell, J. 2009. Anatomy and Physical Examination of the elbow. *Operative Techniques in Orthopaedics*, 19: 190-198.

Broome, R. (ed.) 1999. *Chiropractic peripheral joint technique*. Oxford: Butterworth-Heinemann.

Budoff, J. and Nirschl, R. 2001. Resection and repair of lateral tennis elbow. *Operative Techniques in Sports Medicine*, 19(4): 211-216.

Burton, A. 1985. A comparative trial of forearm strap and topical anti-inflammatory as adjuncts to manipulative therapy in tennis elbow. *British Journal of Sports Medicine*, 19(1): 37-38.

Chan, H. and Gabriel, Y. 2003. Effect of counterforce forearm bracing on wrist extensor muscles performance. *American Journal of physical and medical rehabilitation*, 82(4): 290-295.

Chesterton, L., Sim, J., Wright, C. and Foster, N. 2007. Interrater reliability of algometry in measuring pressure pain thresholds in healthy humans, using multiple raters. *Clinical Journal of Pain*, 23(9): 760-766.

Cook, C. and Hegedus, E. 2008. *Orthopedic physical examination tests: an evidence-based approach*. New Jersey. U.S.A. Prentice Hall Health.

Coombes, B., Bisset, L., Connelly, L., Brooks, P. and Vicenzino, B. 2009. Optimising corticosteroid injection for lateral epicondylalgia with the addition of physiotherapy: A protocol for a randomised control trial with placebo comparison. *Biomed Central Musculoskeletal Disorders*, 10(76).

Croisier, J., Foidart-Dessalle, M., Tinant, F., Crielaard, J. and Forthomme, B. 2007. An isokinetic eccentric programme for the management of chronic lateral epicondylar tendinopathy. *British Journal of Sports Medicine*, 41; 269-275.

Du., X. and Zhao, L. 2009. Anatomic and clinical study of a neurovascular cause of lateral epicondylitis. *Journal of Musculoskeletal Research*, 12(1): 11-19.

du Coudray, N. 2006. An investigation into the role of muscle imbalances within the wrist flexor and extensor muscle groups as an associated factor in the presentation of lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. Durban Institute of Technology. South Africa.

Dutton, M. 2004. *Orthopaedic examination, evaluation and intervention*. New York: McGraw-Hill Publishers.

D'Vas, A., Ostor, A., Speed, C., Jenner, J., Bradely, M., Prevost, A., Hazleman, B. 2006. Pulsed low-intensity ultrasound therapy for chronic lateral epicondylitis: a randomized controlled trial. *Rheumatology (Oxford)*, 45(5): 566-570.

Dwars, B., de Feiter, P., Patka, P. and Haarman, H. 1990. Functional treatment of tennis elbow. A comparative study between an elbow support and physical therapy. *Sports, Medicine and Health*, 237-241.

Edelstein, J. and Bruckner, J. 2002. Orthotics: a comprehensive clinical approach. Thorofare: Slack Incorporated.

Erturk, H., Celiker, R., Sivri, A., Cetin, A. and Cindas, A. 1997. The efficacy of different treatment regimes that are commonly used in the treatment of tennis elbow. *Journal of Rheumatology, Medicine and Rehabilitation*, 8(4): 298-301.

Evans, R. 2009. *Illustrated Orthopaedic Physical Assessment*. 3rd edition. Missouri: Mosby.

Faber, F. and Verhaar, J. 1995. Nonunion of radial neck fracture. *Acta Orthopaedica Scandinavica*, 66(2): 176.

Field, L. and Savoie, F. 1998. Common elbow injuries in sport. *Sports Medicine*, 26(3): 193-205.

Finestone, H. and Rabinovitch, D. 2008. Tennis elbow no more. Practical eccentric and concentric exercises to heal the pain. *Canadian Family Physician*, 54: 1115-1116.

Flatt, A. 2000. Grasp. *Baylor University Medical Center Proceedings*, 13(4): 343-348.

Forbes, A. and Hopper, D. 1990. The effect of counterforce bracing on grip strength in tennis players with painful elbows. *Australian Physiotherapy*, 36(4): 259-264.

Gallagher, J., Liebman, M. and Bijur, P. 2001. Prospective validation of clinically important changes in pain severity measured on a visual analog scale. *Annals of Emergency Medicine*, 38(6): 633-638.

Greenfield, C. and Webster, V. 2002. Chronic Lateral Epicondylitis: Survey of current practice in outpatient departments in Scotland. *Physiotherapy*, 88(10): 578-594.

Gummesson, C., Atroshi, I. and Ekdahl, C. 2003. The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: longitudinal construct validity and measuring self-rated health change after surgery. *Biomed Central Musculoskeletal Disorders*, 4(11): 11.

Haahr, J. and Andersen, J. 2003. Physical and psychosocial risk factors for lateral epicondylitis: a population based case-referent study. *Occupational and Environmental Medicine*, 60: 322-329.

Haker, E., Lundeberg, T. 1991. Pulsed ultrasound treatment in lateral epicondylalgia. *Scandinavian Journal Rehabilitative Medicine*, 23:115-118.

Haswell, G. 2002. The efficacy of dry needling in patients suffering from lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. Durban Institute of Technology. South Africa.

Herd, C. and Meserve, B. 2008. A systematic review of the effectiveness of manipulative therapy in treating lateral epicondylalgia. *The Journal of Manual and Manipulative Therapy*, 16(4): 225-237.

Hijmans, J., Postema, K. and Geertzen, J. 2004. Elbow orthoses: a review of literature. *Prosthetics and Orthotics international*, 28: 263-272.

Hinton, P. 2001. *Statistics Explained. A Guide for Social Science Students*. Routledge: Great Britain.

Hong, Q., Durand, M. and Loisel, P. 2004. Treatment of lateral epicondylitis: where is the evidence? *Joint Bone Spine*, 71(5): 369-373.

Hong, C. 2006. Treatment of myofascial pain syndrome. *Current pain and Headache Reports*, 10: 345-349.

<http://appliedexerciselab.tamu.edu>. 2010. Accessed 03 August 2010.

Hughes, N. 2010. The Effects of elbow manipulation combined with dry needling compared to manipulation combined with cross friction in the treatment of lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. The University of Johannesburg. South Africa.

Hyde, T. and Gengenbach, M.S. (ed.) 2007. *Conservative management of sports injuries*. 2nd ed. Boston: Jones and Bartlett Publishers.

Jaeschke, R., Singer, J. and Guyatt, G. 1989. Measurement of health status. *Controlled Clinical Trials*, 10: 407-415.

Jensen, B., Bliddal, H. and Danneskiold-Samsoe, B. 2001. Comparison of two different treatments of lateral humeral epicondylitis -"tennis elbow". A randomized controlled study. *Ugeskr Laeger*, 163:1427-1431.

Jobe, F., and Ciccotti, M. 1994. Lateral and medial epicondylitis of the elbow. *Journal of the American Academy of Orthopaedic Surgeons*, 2: 1-8.

Johnson, C. 2005. On the subject of human subjects. *Journal of Manipulative and Physiological Therapeutics*, 28: 79-80.

Johnson, G., Cadwallader, K., Scheffel, S. and Epperly, T. 2007. Treatment of lateral epicondylitis. *American Family Physician*, 76: 843-48, 849-50, 853.

Jones, D., Kilgour, R. and Comtois, A. 2008. Test-Retest Reliability of Pressure Pain Threshold Measurements of the Upper Limb and Torso in Young Healthy Women. *The Journal of Pain*, 8(8): 650-656.

Kalichman, L. and Vulfsons, S. 2010. Dry Needling in the Management of Musculoskeletal Pain. *The Journal of the American Board of Family Medicine*, 23: 640-646.

Knuttgen, H. and Kraemer, W. 1987. Terminology and measurement in exercise performance. *Journal of Applied Sport Science Research*, 1(1): 1-10.

Kocher, M. and Dogra, A. 2002. Effectiveness of a specific physiotherapy regimen on patients with tennis elbow. *Physiotherapy*, 88(6): 333-341.

Kohia, M., Brackley, J., Byrd, K., Jennings, A., Murray, W. and Wilfong, E. 2008. Effectiveness of Physical therapy treatments on lateral epicondylitis. *Journal of Sport Rehabilitation*, 17: 119-136.

Kraushaar, B., Nirschl, R. 1999. Tendinosis of the elbow (tennis elbow): clinical features and findings of histological, immunohistochemical, and electron microscopy studies. *Journal of Bone and Joint Surgery*, 81(2): 259-278.

Labelle, H., Guibert, R., Joncas, J., Newman, N., Fallaha, M. and Rivard, C. 1992. Lack of scientific evidence for the treatment of lateral epicondylitis of the elbow: an attempted meta-analysis. *Journal of Bone and Joint Surgery*, 74: 646-651.

Luginbuhl, R., Brunner, F. and Schneeberger, A. 2008. No effect of forearm band and extensor strengthening exercises for the treatment of tennis elbow: a prospective randomised study. *La Chirurgia degli Organi di Movimento*, 91: 35-40.

Lundeberg, T., Abrahamsson, P., Haker, E. 1988. A comparative study of continuous ultrasound, placebo ultrasound and rest in epicondylalgia. *Scandinavian Journal of Rehabilitative Medicine*, 20(3): 99-101.

Mahmoud, M. and Kotb, H. 2009. Injury of collateral ligaments of the elbow: MRI findings. *Research Journal of Medicine and Medical Sciences*, 4(2): 257-262.

Malliaras, P., Maffuli, N. and Garau, G. 2008. Eccentric training programmes in the management of lateral elbow tendinopathy. *Disability and Rehabilitation*, 30 (20-22): 1590-1596.

Manias, P. and Stasinopoulos, D. 2006. A controlled clinical pilot trial to study the effectiveness of ice as a supplement to the exercise programme for the management of lateral elbow tendinopathy. *British Journal of Sports Medicine*, 40: 81-85.

Marquis, J. 2002. The relative effectiveness of dry needling the extensor muscles of the forearm as an adjunct to cross friction massage in the treatment of lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. Durban Institute of Technology. South Africa.

Martinez-Silvestrini, J., Newcomer, K., Gay, R., Schaefer, M., Kortebein, P. and Arendt, K. 2005. Chronic lateral epicondylitis: comparative effectiveness of a home exercise program including stretching alone versus stretching supplemented with eccentric or concentric strengthening. *Journal of Hand Therapy*, 18: 411-420.

Massey-Westropp, N., Gill, T., Taylor, A., Bohannon, R. and Hill, C. 2011. Hand grip strength: age and gender stratified normative data in a population based study. *Biomed Central Research Notes*, 4: 127.

Mazurek, M. and Shin, A. 2001. Upper extremity peripheral nerve anatomy. *Clinical Orthopaedics and Related Research*, 383: 7-20.

Moore, K. and Dalley, A. 2006. Clinically Orientated Anatomy. 5th edition. Baltimore: Lippincott Williams and Wilkins.

Nagrle, A., Herd, C., Ganvir, S. and Ramteke, G. 2009. Cyriax Physiotherapy versus phonophoresis with supervised exercise in subjects with lateral epicondylalgia: a randomized clinical trial. *The Journal of Manual and Manipulative Therapy*, 17(3): 171-178.

Newcomer, K., Martinez-Silvestrini, J., Schaefer, M., Gay, R. and Arendt, K. 2005. Sensitivity of the patient-rated forearm evaluation questionnaire in lateral epicondylitis. *Journal of Hand Therapy*, 18: 400-404.

Nirschl, R. 1974. The etiology and treatment of tennis elbow. *Journal of Sports Medicine*, 2: 308-328.

Nirschl, R. and Pettrone, F. 1979. Tennis elbow: the surgical treatment of lateral epicondylitis. *Journal of Bone and Joint Surgery*, 61(6): 832-839.

www.nismat.org accessed 8 September 2010.

Nussbaum, E. and Downes, L. 1998. Reliability of clinical pressure-pain algometric measurements obtained on consecutive days. *Physical Therapy*, 78(2): 160-169.

Oehley, D. 2002. The efficacy of a local action transcutaneous flurbiprofen patch, in the treatment of lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. Durban Institute of Technology. South Africa.

Ohberg, L., Alfredson, H. 2004. Effects on neovascularisation behind the good results with eccentric training in chronic midporiton achilles tendinosis? *Knee Surgery, Sports Traumatology, Arthroscopy*, 12: 465-470.

Oken, O., Kahraman, Y., Canpolat, S., Yorgancioglu, Z. and Oken, OF. 2008. The short term efficacy of laser, brace and ultrasound treatment in lateral epicondylitis: a prospective, randomized, controlled trial. *Journal of Hand Therapy*, 21(1): 63-68.

Olaussen, M., Holmedal, O., Lindbaek, M. and Brage, S. 2009. Physiotherapy alone or in combination with corticosteroid injection foe acute lateral epicondylitis in general practice: A protocol for a randomised, placebo-controlled study. *Biomed Central Musculoskeletal Disorders*, 10: 152.

Oskarsson, E., Piehl Aulin., K., Gustafsson, B. and Pettersson, K. 2009. Improved intramuscular blood flow and normalized metabolism in lateral epicondylitis after botulinum toxin treatment. *Scandinavian Journal of Medicine and Science in Sports*, 19: 323-328.

www.ottowagolf.com Accessed 2 August 2010.

Owen, D. 2003. The effectiveness of chiropractic treatment in the conservative management of lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. Technikon Witswatersrand. South Africa.

Park, J., Park, H., Choi, J., Moon, E., Kim, B., Kim, W. and O, K. 2010. Prospective evaluation of the effectiveness of a home-based program of isometric strengthening exercises: 12-month follow-up. *Clinics in Orthopaedic Surgery*, 2: 173-178.

Peterson, M., Elmfeldt, D. and Svardsudd, K. 2005. Treatment practice in chronic epicondylitis: a survey among general practitioners and physiotherapists in Uppsala County, Sweden. *Scandinavian Journal of Primary Health Care*, 23: 239-241.

Pfefer, M., Cooper, M. and Uhl, N. 2009. Chiropractic management of tendinopathy: a literature synthesis. *Journal of Manipulative and Physiological Therapeutics*, 32: 41-52.

Pienimäki, T., Tarvainen, T., Siira, P. and Vanharanta, H. 1996. Progressive strengthening and stretching exercises and ultrasound for chronic lateral epicondylitis. *Physiotherapy*, 82: 522-530.

Pienimäki, T., Karinen, P., Kemila, T., Koivukangas, P. and Vanharanta, H. 1998. Long-term follow-up of conservatively treated chronic tennis elbow patients. A prospective and retrospective analysis. *Scandinavian Journal of Rehabilitative Medicine*, 30: 159-166.

Puchner, N. 2008. The effectiveness of manipulation of the wrist in the management of lateral epicondylitis. Master's Degree in Technology: Chiropractic Dissertation. The University of Johannesburg. South Africa.

Rabago, D., Best, T., Zgierski, E., Ryan, M. and Crane, D. 2009. Asystematic review of four injection therapies for lateral epicondylitis: prolotherapy, polidocanol, whole blood and platelet rich plasma. *British Journal of Sports Medicine*, 43: 471-481.

Radpasand, M. and Owens, E. 2009. Combined multimodal therapies for chronic tennis elbow: pilot study to test protocols for a randomized clinical trial. *Journal of Manipulative and Physiological Therapeutics*, 32 (7): 571-585.

Rineer, C. and Ruch, D. 2009. Elbow tendinopathy and tendon ruptures: epicondylitis, biceps and triceps ruptures. *Journal of Hand Surgery*, 34A: 566-576.

Rompe, J., Overend, T. and MacDermid, J. 2007. Validation of the Patient-rated tennis elbow evaluation questionnaire. *Journal of Hand Therapy*, 20(1): 3-11.

Roodt, B. 2001. *The efficacy of manipulation of the elbow joint in patients suffering from lateral epicondylitis*. Masters Degree in Technology: Chiropractic Dissertation. Durban University of Technology, Durban.

Salaffi, F., Stancati, A., Silvestri, C., Ciapetti, A. and Grassi, W. 2003. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *European Journal of Pain*, 8: 283-291.

Scher, D., Moriatis Wolf, J. and Owens, B. 2009. Lateral Epicondylitis. *Orthopaedics*, 32(4): 276-282.

www.scribd.com Accessed 5 August 2010.

Shaik, J. 2000. The Relative effectiveness of cross friction and Mill's manipulation as compared to cross friction alone in the treatment of lateral epicondylitis ("tennis elbow"). Master's Degree in Technology: Chiropractic Dissertation. Durban Institute of Technology. South Africa.

Shiri, R., Viikari-Juntura, E., Varonen, H. and Heliovaara, M. 2006. Prevalence and determinants of lateral and medial epicondylitis: A population study. *American Journal of Epidemiology*, 164: 1065-1074.

Shyam Kumar, A., Parmar, V., Ahmed, S., Kar, S. and Harper, W. 2008. A study of grip endurance and strength in different elbow positions. *Journal of Orthopaedic Traumatology*, 9: 209-211.

Sinnatamby, C. 2006. *Lasts Anatomy: Regional and Applied*. 11th ed. China: Churchill Livingstone Elsevier.

Smidt, N., van der Windt, D., Assendelft, W., Mourits, A., Deville, W., Winter, A. and Bouter, L. 2002. Inter-observer reproducibility of the assessment of severity of complaints, grip strength, and pressure pain threshold in patients with lateral epicondylitis. *Archives of Physical Medicine and Rehabilitation*, 83: 1145-1150.

Smidt, N., Assendelft, W., Arola, H., Malmivaara, A., Green, S., Buchbinder, R., van der Windt, D. and Bouter, L. 2003. Effectiveness of physiotherapy for lateral epicondylitis: a systematic review. *Annals of Medicine*, 35: 51-62.

Speed, C. 2001. Corticosteroid injections in tendon lesions. *British Medical Journal*, 323: 382-386.

Stasinopoulos, D., Stasinopoulos, K. and Johnson, M. 2005. An exercise programme for the management of lateral elbow tendinopathy. *British Journal of Sports Medicine*, 39: 944-947.

Stasinopoulos, D. and Stasinopoulos, I. 2006. Comparison of effects of Cyriax physiotherapy, a supervised exercise program and polarized polychromatic non-coherent light (Biopton light) for the treatment of lateral epicondylitis. *Clinical Rehabilitation*, 20: 12-23.

Stratford, P. and Levy, D. 1994. Assessing valid change over time in patients with lateral epicondylitis at the elbow. *Clinical Journal of Sport Medicine*, 4: 88-91.

Struijs, P., Smidt, N., Arola, H., van Dijk, C., Buchbinder, B. and Assendelft, W. 2001. Orthotic devices for the treatment of tennis elbow: a systematic review. *British Journal of General Practice*, 51: 924-929.

Struijs, P., Kerkhoffs, G., Assendelft, W. and van Dijk, C. 2004. Conservative treatment of lateral epicondylitis: brace versus physical therapy or a combination of both- a randomized clinical trial. *The American Journal of Sports Medicine*, 32: 462-469.

Struijs, P., Korthals-de Bos, I., van Tulder, M., van Dijk, C., Bouter, L. and Assendelf, W. 2006. Cost effectiveness of brace, physiotherapy or both for the treatment of tennis elbow. *British Journal of Sports Medicine*, 40(7):637-643.

www.supurdue.com. Accessed 8 September 2010.

Suputtitada, A., Suwanwela, N. and Tumvitee, S. 2004. Effectiveness of constraint-induced movement therapy in chronic stroke patients. *Journal of the Medical Association of Thailand*, 87(12): 1482-1490.

Svernlov, B. and Adolfsson, L. 2001. Non-operative treatment regime including eccentric training for lateral humeral epicondylalgia. *Scandinavian Journal of Medicine and Science in Sports*, 11(6): 328-334.

Taylor, N., Dodd, K., and Bruder, A. 2007. Therapeutic exercise in physiotherapy practice is beneficial: a summary of systematic reviews 2002-2005. *Australian Journal of Physiotherapy*, 53: 7-16.

www.Thera-band.com accessed 8 September 2010.

Thomson, A., Skinner, A., Piercy, J. 1991. Tidy's Physiotherapy. 12th edition. Oxford. England. Butterworth-Heinemann.

Tonks, J., Pai, S. and Murali, S. 2006. Steroid injection therapy is the best conservative treatment for lateral epicondylitis: a prospective randomised controlled trial. *International Journal of Clinical Practice*, 61(2): 240-246.

Travell, J., and Simons, D. 1999. *Myofascial pain and dysfunction: The trigger point manual, the upper extremities*. Williams and Wilkins: Baltimore.

Trinh, K., Phillips, S., Ho, E. and Damsma, K. 2004. Acupuncture for the alleviation of lateral epicondyle pain: a systematic review. *Rheumatology*, 43: 1085-1090.

- Trudel, D., Duley, J., Zastrow, I., Kerr, E., Davidson, R. and Macdermid, J. 2004. Rehabilitation for patients with lateral epicondylitis: a systematic review. *Journal of Hand Therapy*, 17: 243-266.
- Van De Streek, M., Van de Schans, C., De Greef, M. and Postema, K. 2004. The effect of a forearm/hand splint compared with an elbow band as a treatment for lateral epicondylitis. *Prosthetics and Orthotics International*, 28 183-189.
- Viera, A. and Bangdiwala, S. 2007. Eliminating bias in randomized controlled trials: importance of allocation concealment and masking. *Family Medicine*, 39(2): 132-137.
- Vicenzino, B. 2003. Lateral epicondylalgia: a musculoskeletal physiotherapy perspective. *Manual Therapy*, 8(2): 66-79.
- Vicenzino, B., Cleland, J. and Bisset, L. 2007. Joint manipulation in the management of lateral epicondylalgia: a clinical commentary. *The Journal of Manual and Manipulative Therapy*, 15(1): 50-56.
- Viola, L. 1998. A critical review of the current conservative therapies for tennis elbow (lateral epicondylitis). *Australasian Chiropractic & Osteopathy*, 7(2): 53-67.
- Whaley, A. and Baker, C. 2004. Lateral epicondylitis. *Clinics in Sports Medicine*, 23: 677- 691.
- Wiesenfeld-Hallin, Z. 2005. Sex differences in pain perception. *Gender Medicine*, 2(3): 137-145.
- Williamson, A., Hoggart, B. 2005. Pain: a review of three commonly used pain rating scales. *Journal of Clinical Nursing*, 14: 798-804.
- Wise, E., Price, D., Myers, C., Heft, M. and Robinson, M. 2002. Gender role expectations of pain: relationship to experimental pain perception. *Pain*, 96(3): 335-342.

Wolf, J., Mountcastle, S., Burks, R., Sturdivant, R. And Owens, B. 2010. Epidemiology of lateral and medial epicondylitis in a military population. *Military Medicine*, 175(5): 336-339.

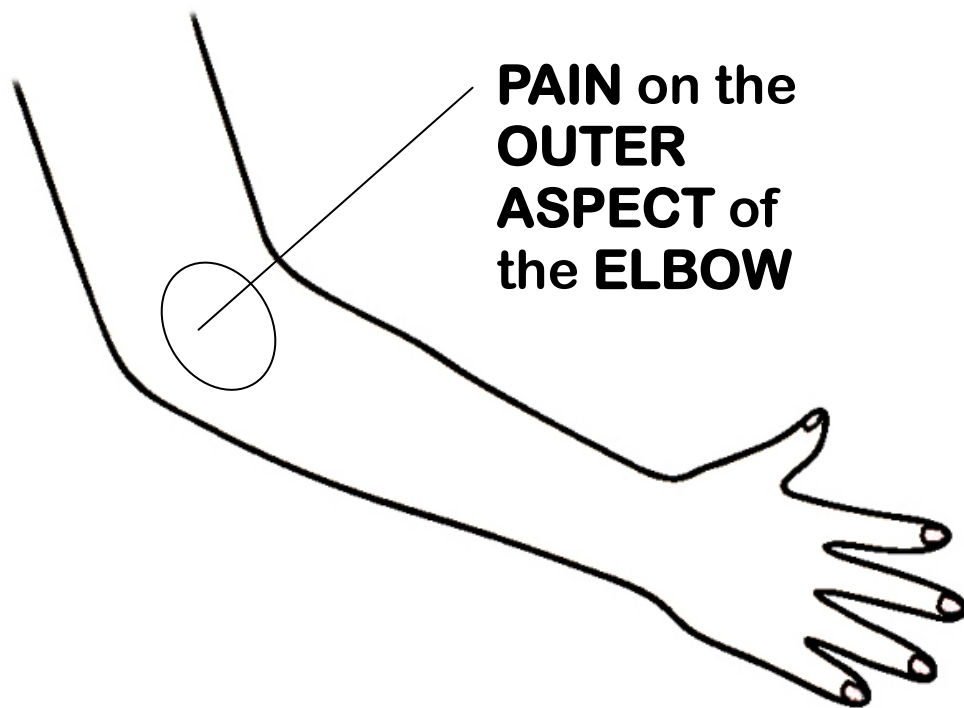
Wood, W., Stewart, A. and Bell-Jenje, T. 2006. Lateral epicondylalgia: an overview. *Physical Therapy Review*, 11: 155-160.

Wuori, J., Overend, T., Kramer, J. and MacDermid, J. 1998. Strength and pain measures associated with lateral epicondylitis bracing. *Archives of Physical Medicine and Rehabilitation*, 79: 832-837.

Yeomans, S. 2000. The clinical application of outcome assessment. Appleton & Lange: Connecticut.

Zijlstra, F., van den Berg-de Lange, I., Huygen., F. and Klein, J. 2003. Anti-inflammatory actions of acupuncture. *Mediators of Inflammation*, 12(2): 59-69.

FREE TREATMENT FOR TENNIS ELBOW



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

If you are between the ages of 18 – 70 and suffer from
Tennis Elbow, **FREE TREATMENT**
is available to those who qualify to take part in this study.
For more information call:

Megan 031-3732205 or 0823365639

Appendix 2: Letter of Information and Informed Consent:

Dear Patient,

Title of research project:

The clinical effectiveness of therapeutic exercises alone and in combination with orthotic bracing in the treatment of lateral epicondylalgia.

Principal Investigator:

Megan Flanders (Research student)
Tel: 031-3732205

Co-Investigator:

Dr. Charmaine Korporaal (M.Tech: Chiropractic, CCFC, CCSP, ICCSD) – Research Supervisor. Tel: 031-3732611

Dr. Praveena Maharaj (M.Tech: Chiropractic) – Research Co-Supervisor.
Tel: 031-2627490

Brief Introduction and Purpose of the study:

Thank you for your interest in participating in this research on the treatment of Lateral Epicondylalgia (Tennis Elbow). Tennis elbow refers to the condition in which pain occurs on the outer side, lateral side, of the elbow due to an irritation of the tendon of the forearm muscles. This injury most commonly occurs in racquet sports, but is also common in golf, repetitive activities as well as just generally in middle age. This letter serves to inform of you what the research procedure involves.

The purpose of this study is to determine if a specific exercise program is helpful in the treatment of tennis elbow, and whether wearing a tennis elbow brace as well as performing the exercise program is more beneficial than the exercise program alone.

Outline of the Procedure:

At your first visit, a history of your problem will be taken. You will be given a basic physical examination, as well as an examination of your elbow. From the results of these examinations, it will be decided whether or not you qualify as a candidate for the research.

If you do meet the requirements for the research you will be required to attend 6 treatments once a week for 6 weeks, as well as a “follow-up” visit 1 week after your last treatment. All consultations will take place at the DUT Chiropractic Clinic. All the consultations will involve performing a set of strengthening exercises and stretches specifically for your tennis elbow under my supervision. The exercises will be done using a Thera-band, a stress ball and an elastic band, all of which you will be given and shown exactly how to use in order to do the exercises correctly. You will be required to do the exercises and stretches at home on a daily basis. A pamphlet containing the exercises and stretches will be given to you, as well as an exercise diary to keep you on track. You will be shown how to fill these in.

If you fall into the group who has to use a tennis elbow brace, you will be given a brace and educated on when and how to wear the brace. If you are not in the group

that uses the tennis elbow brace, you will be given a brace at the end of the research process that you may use if you so wish.

You will be required to hand in your week's exercise diary at each follow-up visit, for data collection.

Risks/Discomforts:

This treatment may cause mild "tightness" and mild transient soreness of the common extensor tendon.

Benefits:

This treatment may help to reduce the symptoms of Lateral Epicondylalgia (Tennis Elbow). It will also help further the knowledge as to the best treatment option for tennis elbow.

Reason why you may be withdrawn from the study without your consent:

You may be excluded from the study for the following reasons:

- Failure to follow the instructions given to you by the researcher.
- Failure to perform the home exercises as outlined by the researcher.
- Failure to complete the "Daily Exercise Diary" as outlined by the researcher.
- Receiving any other form of treatment (including medication), during your participation in the study.
- Failure to attend your scheduled appointments, specifically appointments one, four and seven.
- If you suffer any adverse effects due to the treatment.

In the event that you are excluded from the study there will be no repercussions or negative consequences incurred by you.

Remuneration:

Participants will not receive any payment for their participation in this study, which is entirely voluntary. All treatment in this research is free. Patients will all receive a free Thera-band, stress ball and elastic bands to perform the exercises with, as well as a free orthotic brace.

Costs of the Study:

The participants will not be required to incur any costs in order to be involved in this study, however any transport arrangements are the sole responsibility of the participant.

Confidentiality:

All participant information will be kept strictly confidential, and will be used solely for the purpose of this research study.

Research-related injury:

If the participants adhere to the program and comply with the research and what is expected of them they are expected to have improved signs and symptoms. This is a result of the hypothesis of the research. However if a participant feels that they are

getting worse or have injured themselves they must report this to the researcher in order to be re-assessed and re-evaluated.

Persons to contact for Questions or Problems:

Please feel free to direct any questions or queries that you may have to either myself, Megan Flanders or Dr. Korporaal or Dr. Maharaj at the telephone numbers provided at the beginning of this letter.

Statement of Agreement to Participate in the Research Study:

I, _____ (subjects full name), _____ (ID number), have read this document in its entirety and understand its contents. Where I have had any questions or queries, these have been explained to me by _____ to my satisfaction. Furthermore, I fully understand that I may withdraw from this study at any stage without any adverse consequences and my future health care will not be compromised. I, therefore, voluntarily agree to participate in this study.

Subjects name (print): _____

Subjects signature: _____

Date: _____

Researchers name (print): _____

Researchers signature: _____

Date: _____

Witness name (print): _____

Witness signature: _____

Date: _____

Appendix 3: Case History:



DURBAN UNIVERSITY OF TECHNOLOGY

CHIROPRACTIC DAY CLINIC

CASE HISTORY



Patient: _____ Date: _____
 File # _____ Age: _____
 Sex : _____ Occupation: _____
 Intern : _____ Signature _____

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: _____ Signature : _____

Case History:

Case History:	
----------------------	--

Examination:

Previous:
Current:

X-Ray Studies:

Previous:
Current:

Clinical Path. lab:

Previous:
Current:

CASE STATUS:

PTT:	Signature:	Date:
------	------------	-------

CONDITIONAL:

Reason for Conditional:

CONDITIONAL: Reason for Conditional:	
Signature:	Date:

Conditions met in Visit No:	Signed into PTT:	Date:
-----------------------------	------------------	-------

Case Summary signed off: _____ Date: _____

Intern's Case History:

1. Source of History:

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

3. Present Illness:

	Complaint 1	Complaint 2
< Location		
< Onset : Initial:		
Recent:		
Cause:		
< Duration		
< Frequency		
< Pain (Character)		
< Progression		
< Aggravating Factors		
< Relieving Factors		
< Associated S & S		
< Previous Occurrences		
< Past Treatment		
1) Outcome:		

4. Other Complaints:

5. Past Medical History:

< General Health Status

< Childhood Illnesses

< Adult Illnesses

< Psychiatric Illnesses

< Accidents/Injuries

< Surgery

< Hospitalizations

6. Current health status and life-style:

- < Allergies
- < Immunizations
- < Screening Tests incl. x-rays
- < Environmental Hazards (Home, School, Work)
- < Exercise and Leisure
- < Sleep Patterns
- < Diet
- < Current Medication
- < Analgesics/week:
- < Tobacco
- < Alcohol
- < Social Drugs

7. Immediate Family Medical History:

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



8. Psychosocial history:

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

9. Review of Systems:

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

Appendix 4: Physical Examination:

 D U R B A N UNIVERSITY of TECHNOLOGY		Durban University of Technology PHYSICAL EXAMINATION: SENIOR		 D U R B A N UNIVERSITY of TECHNOLOGY	
Patient Name : _____			File no : _____		Date : _____
Student : _____			Signature : _____		
VITALS:					
Pulse rate:			Respiratory rate:		
Blood pressure:	R	L	Medication if hypertensive:		
Temperature:			Height:		
Weight:	Any recent change? Y / N		If Yes: How much gain/loss	Over what period	
GENERAL EXAMINATION:					
General Impression					
Skin					
Jaundice					
Pallor					
Clubbing					
Cyanosis (Central/Peripheral)					
Oedema					
Lymph nodes	Head and neck				
	Axillary				
	Epitrochlear				
	Inguinal				
Pulses					
Urinalysis					
SYSTEM SPECIFIC EXAMINATION:					
CARDIOVASCULAR EXAMINATION					
RESPIRATORY EXAMINATION					
ABDOMINAL EXAMINATION					
NEUROLOGICAL EXAMINATION					
COMMENTS					
Clinician: _____			Signature : _____		

ELBOW REGIONAL EXAMINATION

Patient: _____ File no: _____ Date: _____
 Intern / Resident: _____ Sign: _____
 Clinician: _____ Sign: _____

OBSERVATION

Posture and willingness to move _____
 Carrying angle (anatomical position) _____
 Swelling _____
 Bony and soft tissue contours _____
 Position of function (triangle sign) _____
 Colour and texture of skin _____

PALPATION

Anterior aspect

Cubital fossa		Medial epicondyle	
Biceps tendon		Medial collateral ligament	
Bicep & brachialis muscle		Ulnar nerve	
Coronoid process & radial head			
Brachial artery			

Medial aspect

Lateral aspect

Lateral epicondyle		Olecranon process and olecranon bursa	
Lateral collateral ligament		Triceps muscle	
Radial head & Annular ligament			
Supracondylar ridge (ECRL)			

Posterior aspect

ACTIVE MOVEMENTS

Flexion (140-150°)		Flexion (tissue approximation)	
Extension (0-10°)		Extension (bone to bone)	
Supination (90°)		Supination (tissue stretch)	
Pronation (80-90°)		Pronation (tissue stretch)	

PASSIVE MOVEMENTS

RESISTED ISOMETRIC MOVEMENTS (elbow at 90° flexion and supinated) **R**

L

Flexion		
Extension		
Supination		
Pronation		
Wrist flexion		
Wrist extension		
Upward glide of radial head on ulna		
Downward glide of radial head on ulna		
Rotation of radial head		
Medial to lateral side tilt		
Lateral to medial side tilt		
Distraction of olecranon process on the humerus (90° flexion)		

JOINT PLAY MOVEMENT

	R	L
Upward glide (I-S) of radial head of ulna		
Downward glide (S-I) of radial head of ulna		
Rotation of radial head of ulna		
Medial to lateral side tilt		
Lateral to medial side tilt		
Distraction of olecranon process on the humeral head (90°)		

FUNCTIONAL ASSESSMENT**SPECIAL TESTS**

	R	L
Ligamentous instability test (valgus/varus)		
Cozen's test		
Mill's test		
Lateral epicondyle test		
Medial epicondyle test		
Tinel's sign		
Wartenberg's sign		
Elbow flexion test		
Pronator teres syndrome		
Pinch grip test		

NEUROLOGICAL**Reflexes and cutaneous distribution**

		R	L
1. Reflexes	a. Biceps = C5-6		
	b. Triceps = C7-8		
	c. Brachioradialis = C5-6		
		R	L
2. Dermatomes	C4		C5
	C6		C7
	C8		
	T1		T2

MYOFASCIAL DYSFUNCTION SYNDROMES

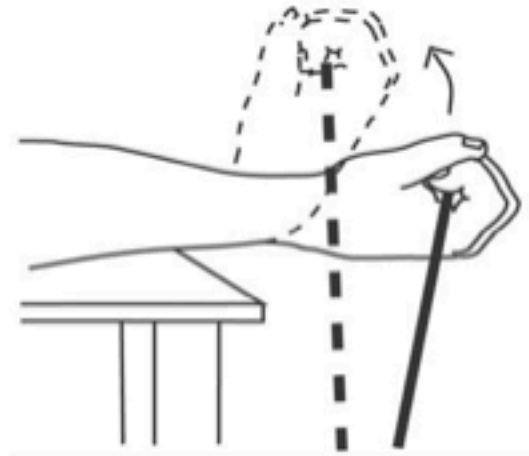
	Active	Latent	Not Present
Brachialis			
Brachioradialis			
Ext. Carpi rad. Brev.			
Ext. Carpi rad. Long.			
Supinator			
Ext. Carpi ulnaris			
Flex. Carpi rad.			
Flex Carpi ulnaris			
Flex Digit. Super			
Flex Digit. profund			
Coracobrachialis			
Biceps			
Triceps			

Appendix 6: Exercise Programme:

Exercise Program for Lateral Epicondylalgia:

Wrist Flexion

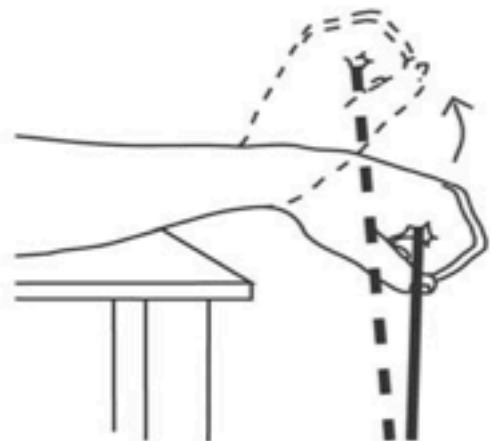
- Secure elastic under foot.
- Grasp elastic in hand.
- Place forearm on table with hand off edge of table, palm up, as shown.
- Move wrist upward.
- Slowly return to starting position.



Thera-band.com

Wrist Extension

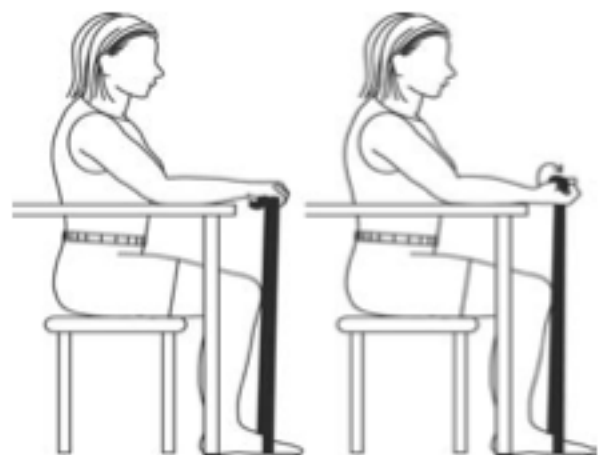
- Secure elastic under foot.
- Grasp elastic with hand.
- Place forearm on table with hand off edge of table, palm down as shown.
- Move wrist upward.
- Slowly return to starting position.



Thera-band.com

Supination

- Secure elastic near floor.
- Support forearm on table or armchair.
- Position hand palm down with elastic crossing over thumb as shown.
- Rotate hand to palm up, elastic should resist this movement.
- Slowly return to start position.



Thera-band.com

Pronation

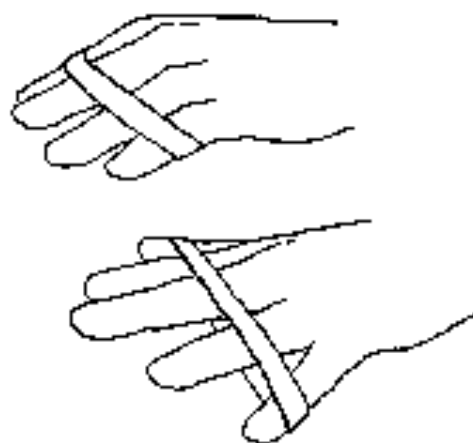
- Secure elastic near floor.
- Support forearm on table or armchair.
- Position hand palm up with elastic crossing under thumb as shown.
- Rotate hand to palm down, elastic should resist this movement.
- Slowly return to start position.



Thera-band.com

Finger extension

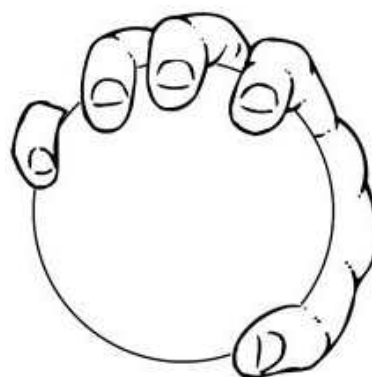
- Place the elastic band around all your fingers, at the base of your fingers.
- Straighten your fingers and hold for 2 seconds
- Slowly return to start position.
- Repeat 10 times and do 3 sets.
- After this becomes easy move the elastic band towards your fingertips to make the exercise more difficult



nismat.org

Ball squeeze

- Hold the ball in the palm of your hand
- squeeze the ball tightly and hold for 2 seconds
- Slowly return to start position.
- Repeat 10 times and do 3 sets.



supurdue.com

(Both the elastic band and ball squeeze exercises can be done repeatedly throughout the day.)

|Stretching the forearm:

- Stand with your arm out straight, palm facing downward and your shoulder lifted slightly
- Pull your wrist down so that your palm moves towards the palm side of your forearm
- Hold the stretch for 30 seconds and repeat twice.
- Note the stretch should not cause any pain, stop the stretch immediately if it does, then repeat it without placing as much force on the hand.



ottawagolf.com

Summary of exercise program:

Exercise:	How many to do:
Stretch	Twice before starting the exercise program. Before starting a new exercise. Twice before finishing the exercise program. Hold each stretch for 30 seconds.
Wrist flexion	10 repetitions in one set. Do 3 sets.
Wrist extension	10 repetitions in one set. Do 3 sets.
Radial deviation	10 repetitions in one set. Do 3 sets.
Ulnar deviation	10 repetitions in one set. Do 3 sets.
Finger extensions	10 repetitions in one set. Do 3 sets. Hold for 3 seconds.
Ball squeeze	10 repetitions in one set. Do 3 sets. Hold for 3 seconds.

Each exercise should take approximately 6 seconds to perform, 2 seconds to lift and 4 seconds to return to the starting position. This is to prevent re- injuring the tendon.

Each exercise should be performed 10 times, this makes up one set.

There must be a rest period of at least 1 minute between sets.

Each set of exercises should be performed 3 times.

(10 repetitions of the exercise (1 set), rest for at least 1 minute and repeat this 3 times.)

Appendix 7: Exercise Diary:

Daily exercise diary:

Name: _____

Group: _____

Please make a note of the day of your treatment and begin your exercise diary the day after that treatment and until the day before your next treatment.

	Note day of treatment	All sets of exercises performed	All stretches performed	Any comments (Note any pain, how you felt during the exercises etc.)
Monday (Wk1)		Y / N	Y / N	
Tuesday		Y / N	Y / N	
Wednesday		Y / N	Y / N	
Thursday		Y / N	Y / N	
Friday		Y / N	Y / N	
Saturday		Y / N	Y / N	
Sunday		Y / N	Y / N	
Monday (Wk2)		Y / N	Y / N	
Tuesday		Y / N	Y / N	
Wednesday		Y / N	Y / N	
Thursday		Y / N	Y / N	
Friday		Y / N	Y / N	
Saturday		Y / N	Y / N	
Sunday		Y / N	Y / N	

Appendix 8: Patient Rated Tennis Elbow Evaluation:

Name _____ Date _____

The questions below will help us understand the amount of difficulty you have had with your arm in the past week. You will be describing your **average** arm symptoms **over the past week** on a scale 0-10. Please provide an answer for all questions. If you did not perform an activity because of pain or because you were unable, then you should circle a "10". If you are unsure please estimate to the best of your ability. Only leave items blank if you never perform that activity. Please indicate this by drawing a line completely through the question.

1. PAIN in your affected arm											
Rate the average amount of pain in your arm over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means that you did not have any pain and a ten (10) means that you had the worst pain imaginable .											
	No Pain						Worst Imaginable				
When your are at rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with repeated arm movement	0	1	2	3	4	5	6	7	8	9	10
When carrying a plastic bag of groceries	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its least	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its worst	0	1	2	3	4	5	6	7	8	9	10
2. FUNCTIONAL DISABILITY											
A. SPECIFIC ACTIVITIES											
Rate the amount of difficulty you experienced performing each of the tasks listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do it at all .											
	No Difficulty						Unable To Do				
Turn a doorknob or key	0	1	2	3	4	5	6	7	8	9	10
Carry a grocery bag or briefcase by the handle	0	1	2	3	4	5	6	7	8	9	10
Lift a full coffee cup or glass of milk to your mouth	0	1	2	3	4	5	6	7	8	9	10
Open a jar	0	1	2	3	4	5	6	7	8	9	10
Pull up pants	0	1	2	3	4	5	6	7	8	9	10
Wring out a washcloth or wet towel	0	1	2	3	4	5	6	7	8	9	10
B. USUAL ACTIVITIES											
Rate the amount of difficulty you experienced performing your usual activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed before you started having a problem with your arm. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do any of your usual activities.											
	No Difficulty						Unable To Do				
1. Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
2. Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
3. Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10
4. Recreational or sporting activities	0	1	2	3	4	5	6	7	8	9	10

Comments:

Appendix 9: Numeric Pain Rating Scale

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

No pain

Worst pain
imaginable

Please rate the pain you are currently feeling by placing a cross over the relevant number.

Appendix 10: Table for Pressure Pain Threshold and Pain Free Grip Strength Readings

Name: _____ Group: _____		Pressure Pain Threshold			Pain Free Grip Strength		
Readings...	Date	Reading 1	Reading 2	Average Reading	Reading 1	Reading 2	Average Reading
Before consultation 1:							
Before consultation 4:							
Follow-up consultation:							

Appendix 11: Information on the orthotic braces and instructions on how to wear the brace:

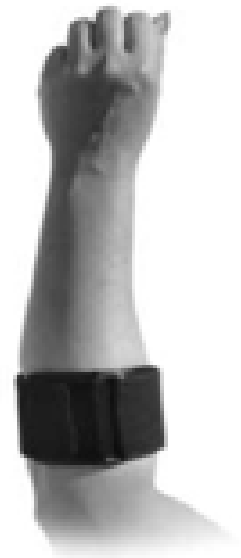
The Ossur Airform Tennis Elbow Support

(<http://www.scribd.com/doc/27016391/Airform-Tennis-Elbow-IFU> , :

Instructions for use:

(modified from the insert in the box the brace comes in)

- 2) Wrap the armband brace around the forearm arm with the logo facing outwards. Loosely secure the strap.
- 3) Adjust the armband so that the Pre-inflated Air Bladder is centered below the lateral epicondyle of the elbow (bump on the elbow on the same side as the thumb).
- 4) Readjust the strap so that the brace fits snugly around the forearm.



Washing instructions:

- 1) This product can be cleaned using a mild detergent and cold water.
- 2) Do not use bleach or strong detergent.
- 3) Do not wash in a washing machine.
- 4) Lay brace out on a towel and air dry.
- 5) Do not squeeze or wring out the brace.
- 6) Do not place in dryer or near a heater.

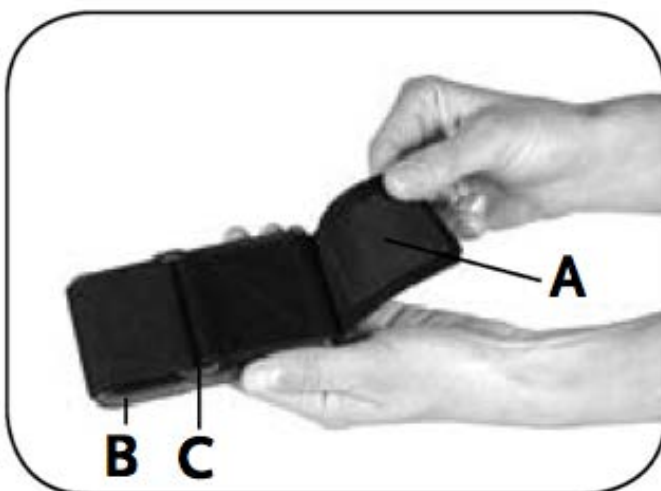


When to wear the brace:

The brace is to be worn throughout the day except at night. It must be worn whilst performing all activities.

If the brace is uncomfortable you may take it off for no more than an hour before putting it back on. The brace must be taken off when going to sleep, and put back on first thing in the morning.

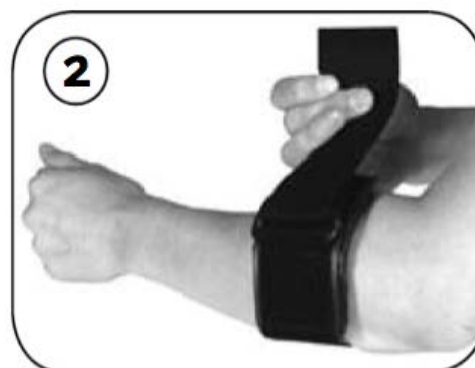
Please inspect your skin daily before putting the brace on, and when taking it off. Look for any signs of irritation, infection, bruising or anything other sign that may indicate a reaction to the brace.



A - Contact closure strap

B – D-ring

C – Compression pad / air bladder



modified from: <http://www.scribd.com/doc/27016391/Airform-Tennis-Elbow-IFU>, 2010



modified from: <http://www.scribd.com/doc/27016391/Airform-Tennis-Elbow-IFU>, 2010

Fitting instructions:	
1) Loosen the contact closure strap, but do not completely remove the strap from the D-ring.	3) Locate a spot about 5 cm below the lateral epicondylar of the elbow that is tender and is where you have been shown to place the air pad.
2) Place your arm inside the Tennis Elbow brace.	4) Tighten the strap until it fits snugly. Secure the contact closure to a comfortable fit.

modified from: <http://www.scribd.com/doc/27016391/Airform-Tennis-Elbow-IFU>, 2010

Appendix 12: Letter of sponsorship of tennis elbow braces:

From: Le Roux Viljoen [mailto:leroux@opafrika.co.za]
Sent: 12 July 2010 11:08 AM
To: 'Darryl Grobbelaar'; jackie@opafrika.co.za; meganflanders@gmail.co.za
Subject: RE: Quote on purchasing 30 tennis elbow braces

Dear Megan,

On behalf of Össur we would like to donate the 30 units, should you be interested.

Sincerely

Le Roux

Le Roux Viljoen
Orthopaedic Partner Africa (Pty) Ltd

Mobile +27 (0)82 786 2509
Phone +27 (0)21 905 0404
Fax +27 (0)21 905 0411
Address Unit 1, Cathkin Park, Cnr Zinfandel & Port Rds,
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Appendix 13: Letter of Consultation with the Statistician:

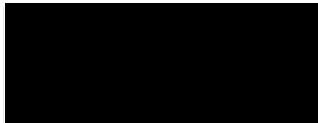
The Research Committee
DUT
23 September 2010

Re: Chiropractic Research: Megan Flanders

I have consulted with the above-mentioned student regarding her study design and methodology and I have proposed the following method of data analysis:

SPSS version 15.0 will be used to analyse the data. A p value of <0.05 will be considered as statistically significant. Repeated measures ANOVA testing will be used to compare the outcomes between the groups over the time points. A significant time*group interaction effect will signify a significant effect of the intervention. Profile plots will be done to establish the direction and trend of the intervention.

Yours sincerely



TM Esterhuizen (Mrs)
Biostatistician

EDITORIAL

ON THE SUBJECT OF HUMAN SUBJECTS

Claire Johnson, DC, MEd

Editor

What do Belmont, Helsinki, and Nuremburg have in common? If you answered the ethical treatment of human subjects in research, you are correct. These represent a few of the guidelines contributing to the foundation of the ethical handling of human research subjects. Web sites that contain excerpts of these original documents are found in Appendix A. Although committees that protect human subjects may be named differently depending upon region, such as Ethics Review Board, Human Research Ethics Committee, Research Ethics Board, Human Subjects Review Board, or Institutional Review Board (IRB), their purpose is essentially the same. The mission of an IRB/Ethics Review Board is to protect research subjects by maximizing possible benefits and minimizing possible harm during participation in research.

Whether it is a multicenter clinical trial or research conducted in a private clinic, a research proposal should be reviewed by an IRB/Ethics Review Board before initiation.^{1,2} The committee is typically made up of a diverse group of volunteers ranging from scientists and clinicians to laypersons, who are qualified and willing to review the contents of the research proposals.³ The scientific quality of the research protocols should receive substantive review before presentation for review to an IRB/Ethics Review Board because an IRB should only review research proposals that are scientifically meritorious, well designed, within ethical guidelines, relevant, and demonstrate public responsibility. Although each IRB/Ethics Review Board has its own set of forms, requirements, and protocols,⁴ the principles are essentially the same. In 2000, Emanuel et al² summarized 7 general requirements for ethical human subject research based upon major sources published on this topic. These same 7 principles are included in the National Institutes of Health clinical research training program.⁵ The National Institutes of Health provides an online course in clinical research training and upon completion participants receive a certificate of training (www.nihtraining.com/crtpub_508/). The following is a brief summary of these 7 requirements. It is suggested that all should be satisfied adequately before a research study involving human subjects receives final approval:

1. Social value. The findings of the proposed research should lead to improvements in health or provide advancement in generalizable knowledge. The results should be able to be implemented in a practical fashion.
2. Scientific validity. It is expected that the project will be conducted in a methodologically sound manner, have a clear scientific objective, and be designed using accepted principles, methods, and reliable practices. Review board members will look for unbiased instruments, potential conclusions, and statistical tests.
3. Fair subject selection. The inclusion criteria for participant should focus on the study objectives, not the vulnerability or convenient accessibility of the participant.
4. Favorable risk-benefit ratio. The risks to each subject should be minimized and the potential benefits must be equal to, or outweigh, the risks.
5. Independent review. Independent review helps to minimize the influence of potential conflicts of interest of the investigators and helps to assure that the study will not benefit from abuse of the participants. The IRB/Ethics Review Board determines if a research project is exempt from ethics review, not the investigator because of potential bias and other factors. One resource to assist authors with identifying exemption is found at the US Office for Human Research Protections. Their web site provides algorithms to help US IRBs and researchers determine if a project is considered research and if it is exempt from ethics review: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm. b The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Q is another of many resources that provides a list that helps define what projects should be reviewed (http://www.ncehr-cnerh.org/english/code_2/apdx01.html). Independent review from various groups, such as IRB/Ethics Review Boards, granting, and safety monitoring agencies, helps assure that the participants will be treated in an ethical manner and that the trial is designed appropriately.
6. Informed consent. Informed consent to the participants should include all of the following in the study design: the selected subjects are competent to make informed decisions; there is disclosure of relevant information; the information will be provided in a way that the subjects will understand; subjects will freely volunteer and are not coerced in any way (threats, excessive monetary reward, etc). The research proposal should demonstrate that subjects will be informed of the purpose, methods, risks, benefits, and alternatives to the research. Typically, consent is expected to be delivered in person and recorded appropriately.
7. Respect for human subjects. The design of the research project should accommodate the following: protection of subjects' confidentiality, permit subjects to withdraw from the study without penalty, monitor subjects' welfare and provide appropriate treatment of adverse events, and inform subjects of what was learned from the completed research.

When reading an article, I ask that you take note when a study has been approved through an IRB/Ethics Review Board and consider the above categories. Although the approval statement in an article is usually concluded in one sentence, the issues of quality assurance, time, and effort to assure ethical handling of human subjects are extensive and should be duly appreciated. Various constituents (eg, patients, policy makers, clinicians, scientists, educators, various health professions) are demanding high-quality research from both the basic science and clinical aspects of spinal manipulation and different aspects of chiropractic practice. One of many factors that determine the quality of clinical research is that if human subjects were involved, were they handled appropriately. Regardless, if scientific investigation is being done on mainstream treatment methods, complimentary or alternative medicine, chiropractic, bone setting, medicine, physical therapy methods, or whatever other category one can think of, clearly ethical standards should apply. No one is exempt. Although a demand for higher ethical standards requires the use of additional resources, it also promises to produce more meaningful results. IRB/Ethics Review Boards have many demands and

are currently facing potential requirements for both improvement, standardization of guidelines, and registration.⁶ How these groups will balance limited resources to ever-increasing demands remains to be seen. Fortification through the knowledge of the upcoming regulations may only improve those institutions that are dedicated to publishing meaningful research results. It is important that we support the protection of those who are willing to volunteer as subjects and only publish articles that have demonstrated their protection of research subjects by maximizing possible benefits and minimizing possible harm during participation in research. For, without people who are willing to participate in research, what research would be available to help us ultimately improve health care?

REFERENCES

1. Miller FG, Emanuel EJ, Rosenstein DL, Straus SE. Ethical issues concerning research in complementary and alternative medicine. *JAMA* 2004;291(Feb 4):599- 604.
2. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA* 2000;283:2701-11.
3. Code of Federal Regulations. Title 21 food and drugs, part 56 institutional review boards [documents on the Internet]. Washington (DC)7 National Archives and Records Administration; 2004 Jul 12. Available from: http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr56_04.html [cited 2005 Jan 4].
4. Goodyear-Smith F, Lobb B, Davies G, Nachson I, Seelau SM. International variation in ethics committee requirements: Comparisons across five Westernized nations. *BMC Med Ethics* 2002;3:E2.
5. d'Vinci Interactive. Protecting human research subjects [monograph on the Internet]. Bethesda (MD)7 National Institutes of Health Office of Human Subjects Research; 2003. Available from: <http://www.nihtraining.com> [cited 2005 Jan 4].
6. Code of Federal Regulations. Title 45 public welfare, part 46 protection of human subjects [documents on the Internet]. Washington (DC)7 National Archives and Records Administration; 2004 Jul 12. Available from: http://www.access.gpo.gov/nara/cfr/waisidx_03/45cfr46_03.html [cited 2005 Jan 4]