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Effects of Radial Shockwave therapy in the treatment of chronic lateral elbow tendinopathy: a non-randomised controlled trial

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EFFECTS OF RADIAL SHOCKWAVE THERAPY IN THE TREATMENT OF CHRONIC LATERAL ELBOW TENDINOPATHY: A NON-RANDOMISED CONTROLLED TRIAL

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A dissertation submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfilment of the requirement for the degree of Master of Science in Physiotherapy

Johannesburg, 2017

DECLARATION

I, Sandra Crafford, declare that this research report is my original work, with exception of those works indicated in the reference citations and acknowledgements. It is being submitted in complete fulfilment of the requirements for the degree of Master of Science (Physiotherapy) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University

_____

Signature of Candidate

_____day of _____ 2017

DEDICATION

In fond memory of my beloved mother

Adelaide Steyn

1946-2011

ABSTRACT

Introduction: Lateral elbow tendinopathy (LET), more commonly known as tennis elbow, is the most common chronic musculoskeletal pain condition affecting the elbow. It affects from 1-3% of active working people. It is an overuse injury mostly affecting the extensor carpi radialis brevis tendon. There are many treatment approaches for this condition, including medical treatment (conservative treatment as well as surgery), physiotherapy, bracing, rest, or a 'wait and see' approach. No single intervention has been proven to be more efficient than another. Radial shockwave is a non-invasive modality, and may be an alternative treatment option. There is conflicting evidence regarding the effectiveness of radial shockwave treatment for lateral elbow tendinopathy. Although it has been reported to be effective in some trials, in others it was no more effective than the placebo. Good quality evidence of effective physiotherapy-based treatment (such as radial shockwave) for chronic lateral elbow tendinopathy is lacking.

The primary aim of this study was to determine the effects of radial shockwave therapy in the treatment of chronic lateral elbow tendinopathy. A non-randomised controlled trial was conducted for this purpose, consisting of an intervention and a control group, comparing radial shockwave treatment to placebo treatment. Patients were selected that had persistent (three months and longer) symptoms of chronic lateral elbow tendinopathy not responding to conservative treatment, and complying to the inclusion criteria.

Methods: Forty-one participants were included in the study; they were systematically assigned to either an intervention or control group. They received one treatment per week for three weeks of either radial shockwave or placebo treatment, as well as an eccentric exercise program.

Their pain levels, grip strength and upper limb function were assessed at baseline, one week and three months' post treatment. The data were collected and statistical analysis done using the Mann-Whitney U test as well as the Fisher Exact test.

Results: There was no statistical significance found for pain, grip strength and upper limb function in patients with chronic lateral elbow tendinopathy treated with radial shockwave therapy, compared to patients receiving placebo treatment.

Conclusion: The intervention group presented similarly to the control group. The null hypothesis was thus accepted in this study. There are notable limitations to this study such as the small sample size, as well as the many treatment variables (type of shockwave and application methods used), and protocols (dosage-intensity, specifications of apparatus, focal energy, treatment frequency, localisation methods and combination of therapies) available when using radial shockwave treatment. Therefore, further research is required with larger sample sizes and specific treatment parameters to find an effective treatment strategy for chronic lateral elbow tendinopathy.

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LIST OF ABBREVIATIONS

AAOS	- American Academy of Orthopaedic Surgeons
ABI	- Autologous Blood Injection
ADL	- Activities of Daily Living
BOTOX	- Botulin Toxin
DASH	- Disabilities of the Arm, Shoulder and Hand
ECRB	- Extensor Carpi Radialis Brevis
ECRL	- Extensor Carpi Radialis Longus
ECU	- Extensor Carpi Ulnarus
EDC	- Extensor Digitorum Communis
EFD	- Energy Flux Density
ESWT	- Extracorporeal Shockwave Therapy
G1	- Group One
G2	- Group Two
GTN	- Glycerol Trinitrate
LET	- Lateral Elbow Tendinopathy
LLLT	- Low Level Laser Therapy
MRI	- Magnetic Resonance Imaging
NSAIDS	- Non-Steroidal Anti-Inflammatory Drugs
McGill-T	- McGill Total
MPQ-SF	- McGill Pain Questionnaire - short form
PPI	- Present Pain Intensity
PRI	- Pain Rating Index
PRP	- Platelet-Rich Plasma
RCT	- Randomised Controlled Trials
RSW	- Radial Shockwave
SWT	- Shockwave Therapy
TENS	- Transcutaneous Electrical Stimulation
T-Vas	- Thomsen’s Vas
VAS	- Visual Analog Scale

CHAPTER ONE

1. BACKGROUND AND PURPOSE

1.1 INTRODUCTION

Tennis elbow or better known as lateral elbow tendinopathy (LET) by clinicians, is a musculoskeletal disorder presenting with pain and discomfort over the lateral part of the elbow, with the onset of the pain being gradual (Waseem et al., 2012). Other symptoms of lateral elbow tendinopathy include weakness of the forearm muscles, decreased grip strength, as well as dysfunction of the upper extremity. The most common functional limitation of patients with lateral elbow tendinopathy includes movements of the upper limb with elbow extension and forearm pronation, as well as handling of objects (Bisset and Vicenzino, 2015).

1.1.1 Tendinopathy

Previously, the term tendinitis was used to describe pain associated with tendon overuse. Research indicates tendons exposed to overuse demonstrate little or no inflammation, although the aetiology of tendinitis suggests an inflammatory process (Weinreb et al., 2014). Although there are no inflammatory cells present in the affected or surrounding area, it does not imply that inflammatory mediators is not a contributing factor to tendinopathies (Rees, Stride and Scott, 2006; Riley, 2008 and Kaux et al., 2011). The literature suggests that localised tendinopathies pertain more to degenerative than inflammatory processes (Dirks and Warden, 2011; Chan and Fu, 2012 and Weinreb et al., 2014). It is possible that degeneration and inflammation are not opposing each other, but work together in the pathogenesis of tendinopathy (Abate et al., 2009).

The degenerative process of tendinopathy is characterised by fibroblasts, vascular hyperplasia, and disorganised collagen in the tendon, as well as ineffective vascular supply to the affected area (Cook and Purdam 2009; Abate et al., 2009; Kaux et al., 2011; Weinreb et al., 2014). During injury or disease when circulation has been impaired in the damaged tissues new blood vessels (neovascularization) and nerves (neonerves) are formed. These neonerves may be a contributor, or even be responsible for the pain in chronic tendinopathy (Tol, Spiezia and Maffuli, 2012; Rees, Stride and Scott, 2013).

There may also be signs of neurogenic inflammation in tendinopathies. This further supports the possibility that tendinopathy could be related to the central nervous system which in turn could relate it to the chronic pain cycle (Alfredson and Cook, 2007). A lecture on sensory motor system studies presented by Vicenzino during an International Scientific Tendinopathy Symposium held in Vancouver (2012), strongly associates central nervous system involvement with lateral elbow tendinopathy (Scott et al., 2012).

1.1.2 **Lateral elbow tendinopathy**

Lateral elbow tendinopathy is usually caused by overuse of wrist and forearm movements such as wrist extension, pronation and supination. The same wrist movements involved when playing tennis can intensify symptoms, hence the term “tennis elbow" (Hall and Brody, 1999). Lateral elbow tendinopathy is prevalent in approximately 1-3 % of the general population (Kohia et al*.,* 2008; Bisset and Vicenzino, 2015). The characteristic patient with lateral elbow tendinopathy is aged between 45-54 (McMurtrie and Watts, 2012). Men and woman are equally affected, with the dominant arm being more symptomatic (Calfee et al., 2008). It is generally a work, or sport related disorder of the upper limb (Stasinopoulos and Johnson, 2005).

While often perceived as an irritating condition, lateral elbow tendinopathy can be quite painful and may limit patients with this condition to do their work or to participate sport and social activities. This condition is often diagnosed in tennis players (as high as 40% - 50%), with many of those affected (as much as 15%) being workers doing physically strenuous jobs (for example workers using hand-held tools such as painters and manual labourers), where patients are required to participate in activities involving overuse of the elbow, forearm and wrist (Baskurt, Ozcan and Algun*,* 2003).

Lateral elbow tendinopathy is usually caused by pathology of the extensor carpi radialis muscle (Janikowska and Chomiuk, 2013). Lateral elbow tendinopathy (Coombes, Bisset and Vicenzino*,* 2015; Matocha et al*.*, 2015) has also been referred to as radio humeral bursitis (Staples et al., 2008), lateral epicondylitis (Afsar et al., 2015) or lateral epicondylalgia (Luk, Tsang and Leung, 2014; Bisset and Vicenzino, 2015). The latest literature still refers to all these terms - lateral epicondylalgia, lateral epicondylitis, tennis elbow and lateral elbow tendinopathy. In this study the term lateral elbow tendinopathy will be used as it gives the best description of the painful area and pathology.

Lateral elbow tendinopathy affects the tendons of the extensor carpi radialis brevis (ECRB) muscles and extensor digitorum communis (EDC) muscles. The ECRB is most often the source of symptoms. The tendons become irritated and inflamed, causing swelling and pain in the early stages of the disorder (Kohia et al., 2008). Resistance applied to wrist extensor muscles during contraction elicits symptoms (Janikowska and Chomiuk, 2013). These movements could elicit pain (Bisset and Vicenzino, 2015)

1.1.2.1 **Pathology of Lateral elbow tendinopathy**

The understanding of lateral elbow tendinopathy pathology has not progressed very much since the groundbreaking work done by Kraushaar and Nirschl (1999). However, Coombes et al., (2009) presented an integrated model where tissue pathology interacts with the nervous system to cause widespread mechanical hyperalgesia and motor control deficits, similar to central sensitization in patients with chronic pain. This integrated model can assist clinicians to recognise and treat patients with lateral elbow tendinopathy more effectively through clinical reasoning, as the aforementioned patients may react differently to the usual clinical interventions and may need alternative treatment methods to address the dysfunctional central nervous system (Scott et al., 2012).

1.1.2.2 **Classification of Lateral elbow tendinopathy**

There are various classifications of tendinopathies (refer to section 2.2 of Terminology) such as the classification by Blazina et al., (1973). This classification differentiates four stages. However, Nirschl et al., (2003) suggested another classification system using staging systems by observing the histology of LET during surgery, as well as pain phase systems based on the patient's feedback of the intensity and duration of the pain (Nirschl and Ashman, 2003).

Chronic LET is characterised by persistent activity-related pain that is well localised. Most conservative treatments do not alleviate patient's symptoms (Fu et al., 2010). Their symptoms last longer than the normal healing period, as the healing responses were initiated, but failed healing of the collagenolytic injury occurred (Fu et al., 2010). A typical episode of lateral elbow tendinopathy lasts from six to 24 months (Staples et al., 2008).

A study conducted in Holland concluded that 10% of patients diagnosed with lateral elbow tendinopathy lost work productivity resulting from sick leave secondary to this pathology (Struijs et al*.,* 2004). There are significant economic implications, with up to 30% of those affected needing an average of approximately 12 weeks off work (Bisset et al*.,* 2003; Wilson and Best, 2005).

1.1.2.3 **Treatment of Lateral elbow tendinopathy**

Treatment strategies in the acute stage have been directed at relieving inflammation. Conservative options include relative rest, avoidance of painful activities, non-steroidal anti-inflammatory drugs (NSAIDS), bracing, as well as physiotherapy treatment (dry needling, laser, ultrasound and manipulation techniques, as well as an eccentric exercise programme), platelet-, autologous blood-, corticosteroid injections and shockwave therapy (Kohia et al., 2008; Ozturan et al., 2010). Corticosteroid infiltrations have been proven to be effective for immediate pain relief (Rees, Maffuli and Cook, 2009). Radial shockwave is a non-invasive modality that consists of single-pulsed acoustic waves. These waves transmit energy at the junction of two materials with different densities for example bone and tendon (Calfee et al*.,* 2008). Studies showed that shockwave initiates repair of the tissues by tissue regeneration, and facilitates tendon healing after trauma, as well as significantly improving blood supply to tissue (neovascularization) and reducing adhesion formation (Wang, 2003; Orhan et al., 2004). Shockwave could be a beneficial treatment to use in the remodeling phase of tendon healing. Shockwave has been promoted as being effective when used for non-unions and delayed healing bone fractures not requiring surgery, thus stimulating bone growth (Mittermayr et al., 2013). The known side-effects of shockwave are temporary reddening, transient pain, minor local swelling or petechial bleeding (Mittermayr et al., 2013).

Surgery is considered when these conservative measures fail to provide pain relief, and consists of open, percutaneous, or arthroscopic surgery where debridement of the pathological area is done (Ozturan et al*.,* 2010). Although there are many treatment approaches for this condition, no single intervention has been proven to be more efficient than another. In a large study published by Szabo et al., (2006) on a comparative series of surgical debridement techniques 5.8% of surgeries were classified as failures (Calfee et al., 2008), whereas a 3% failure was reported in a large study done on surgical results of tenolysis of pathological tendons in lateral elbow tendinopathy patients (Cusco et al., 2013).

Most of patients diagnosed with lateral elbow tendinopathy will have good outcomes with conservative treatment. LET is usually a self-limiting disorder from which 10% of patients will need surgical intervention, the other 90% may recover in a year (Sims et al., 2014).

1.1.3 **Radial shockwave treatment**

Radial shockwave has been studied as an alternative to surgery for managing lateral elbow tendinopathy (Sems, Dimeff and Ianotti, 2006). The evidence in the literature reporting on the effectiveness of radial shockwave for chronic lateral elbow tendinopathy is conflicting (Wang, 2012). There are several clinical trials evaluating the efficacy of shockwave treatment in patients with chronic lateral elbow tendinopathy with varying results. Several authors reported good or excellent outcomes in their studies (Pettrone and McCall, 2005; Radwan et al., 2007; Collins, Hildreth and Jafarnia, 2011). Pettrone and McCall (2005) found that patients who crossed over to shockwave treatment after unsuccessful placebo treatment had significantly better results at three months following active treatment. Their results concluded that with placebo treatment, the mean pain score had only improved slightly (with 8), whereas during the intervention, the mean pain score had improved more (with 42) at twelve weeks. Comparing the mean pain score during the intervention, the patients in the crossover group had significantly improved pain scores compared to the placebo treatment group ($p=0.339$ at baseline, $p=0.0027$ at week 1, and $p<0.0001$at three months).

It was found by Radwan et al., (2007) in their study that extracorporeal shockwave (ESWT) could be a potentially helpful additional treatment that could be an alternative to surgery. Their study compared the outcome of high-energy extracorporeal shockwave therapy in patients with chronic LET to debridement of the pathological tendon, and found comparable results of outcomes measures such as pain relief, improvement of grip strength and improvement of upper limb function. There was a lack of statistical significance in this study that was not attributed to a small sample size ($n=56$) or type - II errors. It was concluded that extracorporeal shockwave treatment is an alternative comparable treatment to that of surgery. In the final analysis of the study done by Collins, Hildreth and Jafarnia, (2011) it was concluded that a single dosage of high–energy shockwave performed with local anaesthetic was an effective treatment for lateral elbow tendinopathy ($p=0.018$). Contrary to the aforementioned, some authors could not find any clinically relevant efficacy for the use of shockwave therapy on lateral elbow tendinopathy when

compared to placebo (Chung and Wiley, 2005; Buchbinder, Green and Struijs, 2008*).* Staples et al., (2008) found that there was an overall improvement of pain and function even though no clinical meaningful differences were found between the extracorporeal shockwave and placebo groups. However, all of the outcome measures at the six week and six-month follow-up visits yielded insignificant results when comparing the intervention and placebo group.

Shockwave therapy studies have contradictory outcomes, due to the many variables used such as the patient selection techniques, the use of local anesthetic, the equipment used, and the different methods of outcome measurement (Wang, 2012). Local anesthesia may alter the effect of shockwave on the tissue, or simply prevent treating the most painful area due to the analgesic effect of the anesthesia (Pettrone and McCall, 2005).

1.1.4 **Conclusion**

Lateral elbow tendinopathy is a more complex condition than a simple soft-tissue injury of the extensor tendons (Alagesan, Saxena and Ramadass, 2012). An effective and consistent management strategy for lateral elbow tendinopathy remains challenging, and that could be a plausible reason why lateral elbow tendinopathy becomes a chronic condition. Both failed conservative and surgical management of chronic lateral elbow tendinopathy are motivation for further research. Radial shockwave therapy could be an alternative conservative treatment if proven effective.

1.2 **PROBLEM STATEMENT**

Lateral elbow tendinopathy is a painful musculoskeletal condition most frequently affecting the elbow, limiting participation in sport and work activities, with a tendency to become chronic. It affects between 1 - 3 % of active working people (Janikowska and Chomiuk, 2013).

There are many treatment methods for the management of lateral elbow tendinopathy ranging from physiotherapy, medical treatment such as NSAIDS, injection therapy and surgery. No single intervention has been proven to be effective to manage this condition, and subsequently the condition becomes chronic and limits the patient's activity at work, home and on the sports field.

Radial shockwave therapy could be an alternative management option for lateral elbow tendinopathy. Further proof is needed to substantiate the efficacy of radial

shockwave therapy for chronic lateral elbow tendinopathy (Radwan, Elshobi et al., 2007*).*

1.3 RESEARCH QUESTION

What are the effects of radial shockwave therapy in the treatment of chronic lateral elbow tendinopathy?

1.4 AIM AND OBJECTIVES OF THE STUDY

The aim of this study was to determine if radial shockwave therapy is an effective treatment for chronic lateral elbow tendinopathy.

The objectives of this study were:

- To determine the demographic profile of the study participants.
- To compare pain levels between the control and intervention group at baseline, one-week as well as three months' post treatment in patients with chronic lateral elbow tendinopathy.
- To compare grip strength between the control and intervention group at baseline, one-week as well as three months' post treatment in patients with chronic lateral elbow tendinopathy.
- To compare upper limb function between the control and intervention group at baseline, one-week, as well as three months' post treatment in patients with chronic LET.

1.5 SIGNIFICANCE OF THE STUDY

This study aimed to provide patients with chronic lateral elbow tendinopathy with an effective, non-invasive and cost-effective treatment option to improve their function during their daily activities, at work and playing sports. Radial shockwave is a noninvasive therapeutic modality that could be an effective treatment for patients with chronic LET, with minimal side-effects.

Radial shockwave therapy remains a controversial treatment option for tendinopathy. Further evidence is needed to justify the use of radial shockwave therapy for chronic lateral elbow tendinopathy.

1.6 RESEARCH HYPOTHESIS

H_1: There will be a significant improvement in upper limb function, grip strength and pain in patients with chronic lateral elbow tendinopathy treated with radial shockwave treatment, compared to patients receiving placebo treatment.

H_0: There will not be a significant improvement upper limb function, grip strength and pain in patients with chronic lateral elbow tendinopathy treated with radial shockwave treatment, compared to patients receiving placebo treatment.

CHAPTER TWO

2. LITERATURE REVIEW

2.1 INTRODUCTION

The literature relevant to this study will be discussed in this chapter. A comprehensive literature search was done between January 2012 and December 2016. The following search engines were used for the literature search: Pedro; PubMed; Ebscohost and Google Scholar. The keywords used for the literature search were: extracorporeal shockwave, shockwave, radial shockwave, chronic lateral elbow tendinopathy, tendinopathy, tendinitis and tennis elbow.

In 1873 F. Runge was the first person to describe **lateral elbow tendinopathy** as pain originating from the lateral epicondyle of the elbow. He called this "Schreibkrampf", interpreted as "writer's cramp" (Donaldson et al*.,* 2013). In 1883 H. Morris described lateral elbow tendinopathy using the words "rider's sprain" (Donaldson et al*.,* 2013). In 1883 the term "Tennis Elbow" was first mentioned by H. Major as he associated lateral elbow pain with lawn tennis players (Donaldson et al., 2013). Lateral elbow tendinopathy presents with localised pain and tenderness medial to the lateral epicondyle, the symptoms are aggravated by gripping of the hand, as well as resisted extension of the wrist, middle finger or both (Buchbinder, Green and Struijs, 2008; Janikowska and Chomiuk, 2013).



Figure 2.1: Tennis elbow (*Waseem et al., 2012*)

2.2 **TERMINOLOGY**

The term "**tendinitis**" has often been used to describe pain in the tendon (Brett, Andres and Murell, 2008; Rees, Stride and Scott, 2013). This term is similar to a dysfunction where a histopathological description of inflammation in the tendon is given, where inflammation is a response of the tendon to injury characterised by pain, swelling, redness and heat (Rees, Stride and Scott, 2013). "**Tendinosis**" has been used to give a histopathological description of the degeneration of the tendon, where degeneration is the gradual deterioration of the tendon with loss of function caused by injury, without correlation with clinical symptoms and without inflammatory signs. In the last few years this theory has gradually developed and the term "**tendinopathy**" has been suggested to clinically diagnose tendon pain (Dirks and Warden, 2011). Tendinopathy refers to the clinical presentation of activity-related pain, with a progressive loss of elasticity in the tendon, as well as impaired upper limb function. There could be edema, tenderness and crepitation's on palpation around the affected area (Kaux et al., 2011), as well as intratendinous imaging changes (Dirks and Warden, 2011).

There are various classifications of tendinopathy, such as the functional and clinical classification of tendinopathy suggested by Blazina et al., (1973):

Pain after sports activity.

- Pain at the beginning of sports activity that usually disappeared with warm up, and often reappeared with exhaustion.
- Pain during activity and at rest.
- Tendon rupture (Kaux et al., 2011).

Another classification of tendinopathy as proposed by Cook and Purdam, (2009) was:

- Reactive tendinopathy.
- Tendon disrepair.
- Degenerative tendinopathy.

Reactive tendinopathy is a reactive response that is a short-term adaptation to overload of the tendon, that thickens the tendon, reduces stress and increases stiffness in the tendon (Cook and Purdam 2009).

The following phases of pain were based on the observed histology during surgery for LET, from the patient's feedback, as well as the intensity of pain and the duration thereof (Nirschl and Ashman, 2003):

- Phase I: mild pain after exercise, lasting less than 24 hours.
- Phase II: pain after exercise, lasting more than 48 hours, settling with warm-up.
- Phase III: pain with exercise, does not change the activity.
- Phase IV: pain with exercise that changes the activity.
- Phase V: pain caused by strenuous daily living activities.
- Phase VI: intermittent pain at rest that does not interrupt sleep; pain caused by moderate daily living activities.
- Phase VII: constant pain at rest, and pain that interrupts sleep.

A chronological classification of tendinopathy is the following: it is classified as "acute"the first six weeks ; "sub-acute" from six to twelve weeks, and as "chronic" if symptoms persist for more than three months (Kaux et al., 2011).

2.3 ANATOMY OF THE ELBOW COMPLEX

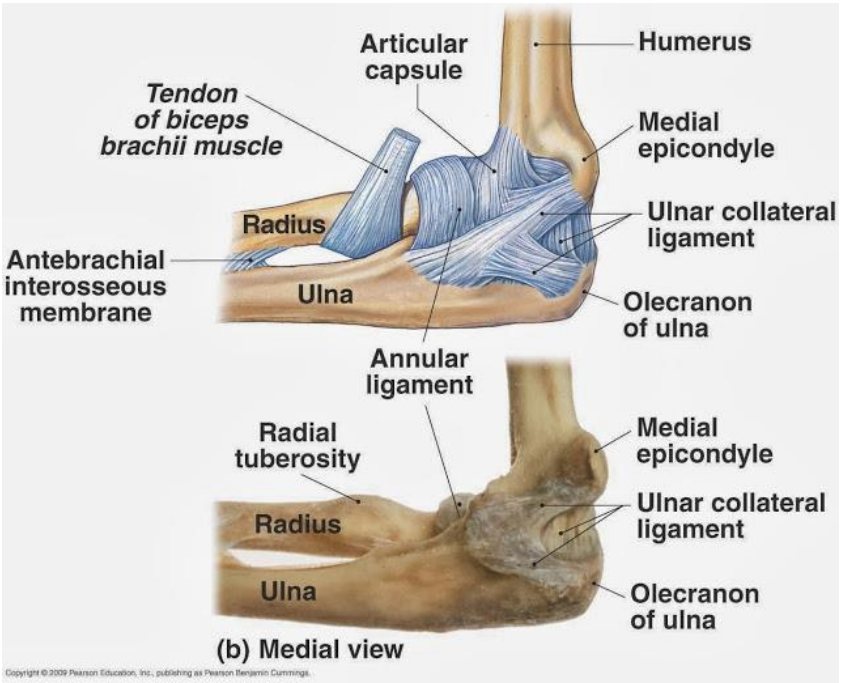


Figure 2.2: Anatomy of the Elbow (*Netter, 2011*)

The anatomical structures involved with lateral elbow tendinopathy are the common extensor origin. The ECRB muscle is mostly affected, with or without involvement of the EDC (De Smedt et al., 2007).

The elbow joint (Figure 2.2) consists of the bony anatomy and ligaments. The bony components are the distal humerus, proximal radius and ulna. The elbow joint comprises three joints, the proximal radioulnar joint, humeroulnar joint and humeroradial joint are the articulations that form the elbow complex (Hoogenboom, Voight and Prentice, 2014). The movements of the elbow are pronation, supination as well as flexion and extension. The radial collateral ligament originates from the lateral epicondyle and attaches to the annular ligament. The ulnar collateral ligament arises posterior to the radial collateral ligament and passes superficially to the annular ligament to attach to the bony tubercle of the ulna. The function of these ligaments is to stabilise the elbow. These ligaments are specialised thickenings of the joint capsule (Waseem et al., 2012).

The capsule is continuous among the three articulations and highly innervated, and plays an important role in joint support and proprioception (Hoogenboom, Voight and Prentice, 2014). The posterior part of the capsule is taut in flexion and becomes lax with extension and vice-versa (Waseem et al., 2012).

There are seven bursae surrounding the elbow. The radio humeral (sub extensor carpi radialis brevis) bursa is located deep to the common extensor tendon, below the brevis and superficial to the radio humeral joint capsule. This bursa has been identified and mentioned by several authors in the aetiology of lateral elbow tendinopathy. It was stated by McVay (1984) that radioulnar bursitis may occur from the irritation of repeated wrist extension with the forearm in pronation (Waseem et al., 2012).

The common extensor origin consists of the combined tendons of ECRB, EDC and, to a lesser extent, extensor carpi ulnaris (ECU) (Donaldson et al., 2013). The ECRB originates from the lateral inferior aspect of the lateral epicondyle and is covered by the ECRL and its fibres that are almost indistinguishable from those of the ECRL and EDC in most cases. The ECRB muscle also has additional attachment to the radial collateral ligament and the intermuscular septa between it and common extensor muscle. The ECRB tendon inserts to the dorsal surface of the base of the second metacarpal bone.

The extensor carpi radialis longus (ECRL) originates from the supracondylar ridge below the origin of the brachioradialis, the origin is between the brachialis medially and the ECRB inferolaterally. The ECRL crosses the elbow and carpal joint to insert

onto the dorsal base of the second metacarpal and is covered by the brachioradialis over most of the forearm.

The EDC originates from the anterior distal aspect of the lateral epicondyle and accounts for most of the contour of the extensor surface. Parts of the EDC are also attached to the septum and tendon from which the ECRB surfaces. The action of the ECRL is wrist extension, radial deviation, and possibly elbow flexion, whereas the main action of the ECRB is wrist extension with some assistance in radial deviation. (Waseem et al., 2012).

2.4 EPIDEMIOLOGY

2.4.1 Prevalence

Lateral elbow tendinopathy is prevalent in 1.3% of the general population globally (De Smedt et al*.,* 2007; Staples et al., 2008; Shiri and Viikari-Juntura, 2011). Prevalence varies between 0.3% and 13.5% in working populations globally, and is most commonly found in manually intensive occupations (Shiri and Viikari-Juntura, 2011).

There is an equal distribution between men and women, with the highest occurrence in those aged between 45-54 years (Longo et al., 2012; McMurtrie and Watts, 2012). Symptoms are more commonly seen in the dominant arm (Calfee et al., 2008; Longo et al., 2012). It seems to occur equally among blue-collar and white-collar workers, and amongst all socio-economic classes (Waseem et al., 2012).

2.4.2 Incidence

There is a reported incidence of lateral elbow tendinopathy of up to 4-7/1000 patients per year worldwide (Longo et al., 2012; McMurtrie and Watts, 2012). The incidence rate of medical consultations in medical practices in Europe has been estimated at 0.3 - 1.1% for lateral elbow tendinopathy per year per 100 patients (Shiri and Viikari-Juntura, 2011). The incidence rate in the working population is slightly higher than the general population at 2-4% for lateral elbow tendinopathy (McMurtrie and Watts, 2012; Longo et al., 2012). In a study that included 94 tennis players in five very active tennis clubs, Nirschl (2015) found that the incidence of lateral elbow tendinopathy was present in more than 50% of tennis players.

The natural progression of this condition seems to be positive, with spontaneous healing within one to two years in 80 to 90 per cent of patients (Waseem et al., 2012).

Lateral elbow tendinopathy is normally a self-limiting disorder, and lasts between six and 24 months (Chesterton, Mallen and Hay, 2011).

2.4.3 **Impact**

Lateral elbow tendinopathy has a substantial impact both on athletes and in the workplace (Longo et al., 2012). Lateral elbow tendinopathy causes functional disability due to productivity loss, and is costly due to high health-care use (Shiri and Viikari-Juntura, 2011). Even in the acute stage a substantial number of workers with lateral elbow tendinopathy reported a loss of productivity in their working environment. The average length of sick leave for workers with lateral elbow tendinopathy is close to two weeks (Shiri and Viikara-Juntura, 2011). Between 10–30% of patients with lateral elbow tendinopathy have an extended period of sick leave of as much as eleven to twelve weeks (Shiri and Viikara-Juntura 2011). In a study by Walker–Bone et al., (2012) it was stated that approximately 5% of workers diagnosed with lateral elbow tendinopathy consequently took sickness absence. The estimated time of work loss was 29 days in 12 months. According to Chesterton, Mallen and Hay, (2011) up to 30% of workers with LET report being absent from work because of lateral elbow tendinopathy. Lateral elbow tendinopathy can cause a change of a worker's occupation because of the physical strain of some types of occupations. Moreover, it may restrict leisure time activities such as certain sport and hobbies (Shiri and Viikari-Juntura, 2011).

2.5 **AETIOLOGY**

The aetiology of tendinopathy is currently still a challenge, and many probable causes have been suggested such as ischemic damage, matrix metalloproteinase imbalance, hypoxia, inflammatory mediators, oxidative stress, hyperthermia, fluoroquinolones, and impaired apoptosis (Sharma and Maffuli, 2006).

Lateral elbow tendinopathy is most probably caused by overuse of the ECRB muscle, alone or in combination with the EDC (De Smedt et al., 2007). The onset of symptoms is usually caused by an overuse of the upper extremity by using repetitive wrist extension in combination with alternating forearm pronation/supination movements. Another cause of LET could be a work history of repetitive manual tasks causing significant strain such as manual labour with heavy tools (Longo et al., 2012). Overuse is what initially causes this condition, which then causes micro tearing of tendon fibres. Thereafter there is a complex process taking place predominantly in the areas of poor blood supply such as tendons. Overload not only

affects the matrix components (collagen and proteoglycans), but also elicits an essential response in tenocytes that appears designed to adapt the matrix to the increased load. Matrix load is transmitted into the cell and alters protein and enzyme production. Tensile load itself can actually cause in situ cell nucleus deformation. Mechanical loading of human tendon fibroblasts increases production of both prostaglandin E2 and leukotriene B4, and these intermediaries can contribute to the tendon changes discovered in tendinopathy (Rees and Maffuli, 2009). Tendinopathy causes changes in that the tendon looks grey or yellow-brown and is friable (a solid substance that has a tendency to break into smaller pieces with friction), weak and flimsy or swollen (Nirschl and Ashman, 2003; Scott and Ashe, 2006). Calcification, or the accumulation of lipid cells sometimes replaces the degenerated and degraded type one collagen fibres (Abate et al., 2009). When collagen fibres begin to denature (destroy the characteristic properties), it causes a progressive focal area of intratendinous degeneration that could lead to partial tears and ruptures (Sharma and Maffulli, 2006; Kaux et al., 2011).

Peripheral local noxious stimulation makes peptidergic group IV fibres release peptides from their terminals. In view of the fact that these neuropeptides such as substance P and calcitonin gene-related peptide are in the tendon, there might still be inflammation in the tendon. The release of these peptides triggers various pathophysiological processes contributing to neurogenic inflammation (Alfredson and Cook, 2007).

There are many factors that needs to be taken into consideration in the aetiology of lateral elbow tendinopathy, such as internal or external factors. These factors work either in isolation or in combination with each other. When there are intrinsic risk factors involved such as malalignment and biomechanical factors, excessive loading may contribute to cause the tendinopathy (Sharma and Maffuli, 2006).

Tendinopathy can also be associated with medical conditions such as diabetes, obesity, hypertension, high cholesterol, and other metabolic factors. Metabolic disease such as atherosclerosis and impaired glucose metabolism have been identified as contributing factors in tendinopathy. In conditions such as diabetes and inflammatory disorders (rheumatoid arthritis), the peripheral nervous system has been identified as a common cause of failed healing of connective tissue and malfunction of homeostasis (Ackerman and Renstrom, 2012). Certain drugs such as treatment for high cholesterol with statins, and quinolone antibiotics should be avoided among active sports participants, as it has been associated with an

increased risk of tendinopathy (Ackerman and Renstrom, 2012). Low molecular weight heparin and immunosuppressive drugs such as cortisone (especially intratendinous) and cyclosporine may have harmful effects on tendon metabolism and repair, and should be used with caution as it could cause rupture of the tendon (Ackerman and Renstrom, 2012).

2.6 RISK FACTORS FOR LATERAL ELBOW TENDINOPATHY

2.6.1 General Risk Factors

Controversy exists in the literature regarding the risk factors contributing to lateral elbow tendinopathy. Mesenchymal syndrome has a genetic component that could cause abnormal collagen formation. Patients with this syndrome are likely to have more than one area of tendinopathy that may include, carpal tunnel syndrome, rotator cuff pathology, lateral elbow tendinopathy, trigger finger and De Quervan's disease. In other studies many of these tendinopathies such as rotator cuff pathology, De Quervan's disease and carpal tunnel syndrome have been associated with lateral elbow tendinopathy (Walker-Bone et al*.,* 2004*;* Abate et al., 2009; Titchener, Fakis et al. 2013). A large case-controlled study including 4 998 patients conducted by Titchener et al., (2012) used a database from the Health Improvement Network to quantify and assess the intrinsic and extrinsic risk factors for lateral elbow tendinopathy in the general population (United Kingdom). The study randomly selected patients out of a database of approximately 50 000 with a diagnosis of lateral elbow tendinopathy from 2 000, and the placebo's were individually matched to each patient by age, gender and general practice. Through multivariate analysis the following was found to be associated risk factors for lateral elbow tendinopathy: oral corticosteroid therapy (OR 1.68), rotator cuff pathology (OR 4.95), De Quervan's disease (OR 2.48), carpal tunnel syndrome (OR 1.50), and a history of previous smoking (OR 1.20). Rotator cuff pathology was very strongly associated with lateral elbow tendinopathy whereas diabetes, current tobacco use, alcohol intake, rheumatoid arthritis, trigger finger and obesity were not (Titchener et al., 2012). In a smaller cross-sectional study undertaken by Walker-Bone et al*.,* (2012) in Southampton (England), they collected data through a physical examination and screening a long questionnaire and confirmed that being overweight, smoking and having diabetes were not associated risk factors for lateral elbow tendinopathy.

2.6.2 **Occupational Risk Factors**

There are various contributing factors that can predispose patients to lateral elbow tendinopathy. Lateral elbow tendinopathy is strongly associated with work that requires as a combination of forceful and repetetive activities, as well as being exposed to these activities for a longer length of time (Shiri et al., 2006).

In a review by Van Rijn et al., (2009), they investigated the association between occupations, physical and psychosocial risk factors and the occurrence of lateral elbow tendinopathy. Physical risk factors (frequent handling of loads, forceful work and highly repetitive movements) were associated with the occurrence of lateral elbow tendinopathy. However, psychosocial risk factors (postural load, low social support and low job control) were also associated with lateral elbow tendinopathy.
In a cross-sectional study of 9 696 randomly selected adults conducted by Walker - Bone et al., (2012) it was found that lateral elbow tendinopathy was significantly associated with psychological distress, manual work [odds ratio (OR) 4.0,95%, CI 1.9,8.4], as well as being associated with reported bending/straightening the elbow for more than one hour per day (OR 2.5,95%, CI 1.2,5.5). Other exposures including keyboard use as well as working with arms above shoulder height and exposure to hand transmitted vibration, were not significantly associated with lateral elbow tendinopathy (Walker-Bone et al., 2012).

2.7 **DIAGNOSIS OF LATERAL ELBOW TENDINOPATHY**

Lateral elbow tendinopathy is diagnosed by the patients subjective history and physical examination done by the clinician (Shiri et al., 2011). The diagnosis for LET is confirmed if there is pain and tenderness on palpation of the common extensor tendon at the attachment of the the lateral epicondyle, resistance of wrist and/or middle finger extension elicits pain, as well as pain in gripping and pinching with the hand and fingers, and lifting or handling of objects (Longo et al., 2012). The specific test that confirms the diagnosis of LET includes the Tompson maneuver, in which pain is elicited by giving resistance to wrist extension with elbow extension and forearm pronation. Several other provocative tests could assist in the diagnosis of LET, including the Chair-, Cozen's-, Bowden's- and Mill's test. By putting the ECRB in either eccentric contraction or passive stretching these tests cause pain over the lateral epicondyle (Luk, Tsang and Leung, 2014). The elbow is painless during passive range of motion testing and whilst at rest (Waseem et al., 2012). If there is clinical uncertainty imaging may be helpful, but it is not usually needed to confirm the diagnosis. Although basic X-rays may show the bony alignment as well as

calcification of the tendons, ultrasonography and magnetic resonance imaging (MRI) are the more specialised imaging modalities, and will show an abnormal signal within the tendon origin (McMurtrie and Watts, 2012). On sonography of elbow tendinopathy, the tendon seems poorly defined. There is decreased echogenicity of the tendon, and thickening or thinning of the tendon is visible. On MRI of lateral elbow tendinopathy, there are areas of thickening, and high signal intensity of the tendon. Ultrasonography is more cost-effective; however, it is not as accurate as MRI. When diagnosing lateral elbow tendinopathy MRI is the most effective procedure, but also the most expensive (Shiri et al., 2011).

2.8 DIFFERENTIAL DIAGNOSIS OF LATERAL ELBOW TENDINOPATHY

During the examining of the patient with LET, the source of pain should be at the lateral epicondyle. If the painfull area is a wider generalised lateral elbow pain, the clinician should reconsider their diagnosis (McMurtrie and Watts, 2012). The differential diagnosis of lateral elbow tendinopathy includes posterior interosseous nerve entrapment syndrome, referred pain from the cervical spine or shoulder, osteoarthritis, osteochondral lesions of the radiocapitellar joint, varus or postero-lateral rotatory instability due to ligament laxity, a loose body or synovial plica (McMurtrie and Watts, 2012).

2.9 MANAGEMENT OF LATERAL ELBOW TENDINOPATHY

The available evidence for managing tendinopathies is limited. Although there are many treatment options available, very few randomised placebo-controlled trials have been done to guide medical practitioners in making an informed decision on the best evidence-based treatment options (Maffuli et al., 2010).

In a literature review undertaken by Ozturan et al., (2010) it was mentioned that treatment strategies in the acute stage have been directed at relieving inflammation. Conservative options include non-steroidal anti-inflammatory drugs, corticosteroid injections, rest, activity modification, bracing as well as physiotherapy treatment (dry needling, laser, ultrasound and manipulation techniques, as well as an eccentric exercise programme), autologous blood injections, platelet-rich plasma injections, and shockwave therapy. Surgery is considered when the conservative management does not provide pain relief, using either an open-, percutaneous-, or arthroscopic tenotomy.

In a clinical trial undertaken by Ozturan et al., (2010) that included 60 patients diagnosed with LET, they compared the short-, medium- and long-term effects of corticosteroid injections, autologous blood injection and extracorporeal shockwave using pain, grip strength and upper limb function as outcome measures. Their results concluded that treatment with corticosteroid injections provided symptomatic pain relief in the short term, but there was a high recurrence rate for LET. However, autologous blood injections and extracorporeal shockwave therapy yielded better long-term results. A limitation of this clinical trial is that there was no control group, as well as the small sample size.

2.9.1 **Medical Management**

The medical management of lateral elbow tendinopathy that will be discussed is the conservative options, injection therapy as well as surgery.

2.9.1.1 **Conservative management**

The conservative options that will be discussed are non-steroidal anti-inflammatory drugs, nitroglycerine and bracing.

2.9.1.1.1 Non-steroidal anti-inflammatory drugs

What may present as an “acute tendinopathy” clinically is in fact a failed healing process in chronic lateral elbow tendinopathy, where there are no signs of inflammation. The results for the efficacy of the many available pharmaceutical treatment options yielded controversial results when tested in randomised controlled trials (Maffuli et al., 2012). The literature known to us suggests that when there is no active inflammatory process present, there is no clinical reason to support the use of non-steroidal anti-inflammatory drugs for the treatment of chronic LET (Maffuli et al., 2010).

In a Cochrane collaboration review published by Pattanittum et al., (2013) 15 randomised or quasi-randomised controlled trials were reviewed involving 664 participants comparing topical NSAIDS or oral NSAIDS to placebo. The results were inconclusive and conclusions about the benefits or disadvantages of topical or oral NSAIDS when treating lateral elbow tendinopathy could not be made. Although data from five placebo controlled trials suggest that topical non-steroidal anti-inflammatory drugs may be beneficial for pain relief (lasting up to four weeks), non-normal distribution of data (indicating limited trials with risk of bias), and other methodological

issues (no blinding and concealed allocation, appropriateness of sequence generation used, management of incomplete outcome data) precluded firm conclusions. Evidence about the advantages of oral non-steroidal anti-inflammatory drugs have been inconclusive, however oral non-steroidal anti-inflammatory drugs may result in gastrointestinal side-effects in some patients. This is confirmed by a review done by Erickson and Hall, (2015) where there was a higher incidence of gastrointestinal related side-effects in patients with LET treated with oral NSAIDS.

2.9.1.1.2 Nitroglycerine

Topical nitroglycerine (glycerol trinitrate) or (GTN) is a treatment option that can be used by applying the GTN patch over the site of lateral elbow tendinopathy. GTN patches contain organic nitrate that produces nitric oxide, which stimulates tendon healing, probably by stimulating fibroblastic production of collagen (Valen and Foxworth, 2010).

There is some controversy in the literature about the efficacy of GTN. In a randomised, double-blinded, placebo-controlled trial conducted by Paoloni et al., (2003) consisting of 86 participants with LET, continuous topical GTN combined with exercise rehabilitation done daily, was effective in reducing pain levels with activity at two weeks, tenderness at six and twelve weeks, and there were asymptomatic patient outcomes at twenty-four weeks. In another study by the aforementioned authors three different doses of continuous topical GTN in combination with a daily stretching programme yielded a significant reduction in pain with elbow activity after treatment, but at eight weeks the outcome was insignificant (Paoloni et al., 2008).

In a comparative study including 58 patients done by McCallum, Paoloni and Murrell, (2011) it was found that while GTN appeared to offer short-term benefits (up to six months) in the treatment of lateral elbow tendinopathy, there was no significant clinical long-term benefits (at five years) when compared with patients that only received a standard tendon rehabilitation programme.

The standard tendon rehabilitation programme included the best practice management for lateral elbow tendinopathy at the time. The programme consisted of resting from pain provoking activities in the acute stage (especially repetitive wrist and forearm movements, as well as forceful

gripping), wearing a counter force brace until the completion of the first phase of the muscle-strengthening programme, regular stretching of the ECRB muscle, as well as a progressive muscle-strengthening programme whilst gradually increasing the resistance (Paoloni et al., 2003).

2.9.1.1.3 Bracing

The two braces used most often in the treatment of LET is the wrist extension brace and the proximal forearm strap (counter force brace). The wrist extension brace keeps the wrist in this position, and is considered to unload the extensor origin and relax the wrist extensors. One explanation as to how the counter force brace could be beneficial for LET is that it reduces the force exerted on the common extensor origin, being that its compressive force limits expansion and thereby the amount of force generated by the extensors. Another is that the brace serves as a secondary origin for the ECRB muscle, reducing the force generated proximally. Both these mechanisms could theoretically decrease the mechanical stress on the damaged tendons, promoting healing (Sims et al., 2014).

There is some controversy in the literature about the efficacy of bracing for lateral elbow tendinopathy. Work published by Struijs et al., (2004*)* reported short-term improvement in activities of daily living whilst wearing the brace, however bracing was found to be no more effective than placebo or physical therapy in the treatment of lateral elbow tendinopathy in the long-term (26 weeks). Similar findings were published by Bisset et al., (2003), where they stated that no firm conclusions on the efficacy of orthotics could be made. However, significant improvements were reported by Faes et al., (2006*)* using pain scores and grip strength, comparing a dynamic extensor brace to placebo after twelve weeks of use. The improvement continued at twenty-four weeks without further use of the brace beyond twelve weeks (Faes et al., 2006). While bracing may offer some symptomatic relief in the short-term, its long-term effects on symptoms and muscle strength for LET are not well documented, and long-term use of the brace could lead to weakening of the muscles if the they are not maintained with strengthening exercises.

2.9.1.2 **Injections**

Injection therapy can be used as an effective second-line therapy in patients that present with recalcitrant symptoms of lateral elbow tendinopathy, not responding to

conservative therapy, thus preventing surgery in a majority of patients who would previously have had no other option than surgery (Creaney et al., 2011).

2.9.1.2.1 Corticosteroid injections

Corticosteroid injections have been used for pain relief in LET. The point of maximal tenderness, usually over the origin of the ECRB, is injected with betamethasone, dexamethasone, and triamcinolone mixed with a local anesthetic such as bupivacaine or lidocaine (Sims et al., 2014). Corticosteroid injections have been used to give relief of the acute pain of lateral elbow tendinopathy, allowing patients to begin early rehabilitation.

Several clinical trials have compared the efficacy of steroid injections versus NSAIDS and placebo treatment. Although participants experienced a brief period of post-injection discomfort, the pain relief during early follow up (five days to six weeks) has been shown to be more significant in the steroid group when compared to the NSAIDS and placebo group ($p \leq 0.05$). In a study conducted by Rees, Maffuli and Cook, (2009) it was confirmed that corticosteroid injections have therapeutic value in the short term. However, at long term follow up (three to twelve months), the outcome of those who received steroid injections were the same or even worse than those of the other treatment groups who received NSAIDS or placebo (Calfee et al., 2008). Worse clinical outcomes were reported by Coombes et al., (2013) one-year post corticosteroid injection when compared to placebo injection, and higher recurrence rates of LET were demonstrated by Bisset et al., (2006) in the corticosteroid injection group. Corticosteroid injections can give pain relief in the acute stage but is not beneficial in the long term and can cause reoccurrence (Bisset et al., 2006).

2.9.1.2.2 Autologous blood injections

Autologous blood injections (ABI) are collected by withdrawing blood from the patient and reinjecting the untreated blood into the painful area (Sims et al., 2014). Autologous blood injections have also been used for the treatment of LET to provide humoral and cellular mediators, and to promote healing in areas where failed healing has taken place. Autologous blood injections promote the regeneration of collagen, as well as stimulating the production of new blood vessels that may lead to tendon healing (Kaux et al., 2011). It was found in a study undertaken by Creany et al., (2011) which consisted of a group of 150 patients that received either PRP (80 participants) or ABI (70

participants) injections, that both interventions significantly reduced the pain and improved upper limb function of the participants, using the patient - related tennis elbow evaluation questionnaire. The ABI group had a success rate of 72%.

Autologous blood injection could be beneficial because it is the simplest method of delivering blood derived growth factors containing the growth factors in platelets. However red and white blood cells are also injected which have no healing properties. Consequently, the results of ABI have been inconsistent (Dhillon et al., 2014).

2.9.1.2.3 Platelet-rich plasma injections

Platelet-rich plasma (PRP) contains a high concentration of various growth factors such as platelet-derived growth factor, endothelial-growth factor and transforming-growth factor beta. The platelets is collected by withdrawing the patients' blood and centrifuging it to isolate the platelets before re-injecting it into the painful area (Sims et al., 2014).

In a systematic review consisting of six studies that was done on the efficacy of PRP injections for chronic LET, it was concluded that there was evidence indicating that PRP injections was not an effective treatment for chronic LET (de Vos, Windt and Weir, 2014). However, in a double-blind, prospective, multicenter (12 centers) controlled trial conducted using two hundred and thirty patients with chronic LET treated over a period of five years, it was concluded the PRP treatment is a safe treatment option, and results in clinically meaningful improvements (in pain scores and elbow tenderness with a statistically significant success rate p=0.12) compared with a control group (Mishra, Skrepnik et al. 2013). In a randomised controlled trial conducted by Creaney et al., (2011) consisting of eighty patients that received platelet-rich plasma (PRP) it was found six months after the intervention that there was a success rate of 66% in the PRP group.

Platelet rich plasma appears to be the preferred choice of treatment when compared to ABI. Platelet rich plasma has minimal side-effects. It is easy to apply, is cost effective and it is possible to complete the procedure as a day care procedure (Dhillon et al., 2014).

2.9.1.2.4 Hyaluronic acid injections

Hyaluronic acid is an injection treatment that is quite often used in the treatment of osteoarthritis. It was found in certain randomised controlled trials that periarticular injections of sodium hyaluronate (a hyaluronic acid derivative) was more effective compared to placebo injections (in terms of pain relief) for lateral elbow tendinopathy patients (Coombes, Bisset and Vicenzino, 2010; Petrella et al., 2010).

It is possible that lateral elbow tendinopathy could have more joint pathology involvement than was previously thought. It could be that cartilage and the degenerative tendon have many similarities. Results of animal studies have shown that hyaluronic acid could improve tendon healing (Orchard and Kountouris, 2011). A randomised clinical trial conducted by Petrella et al., (2010) included 331 racquet sport athletes. The objective of this clinical trial was to determine if peri-articular hyaluronic acid injections was safe and effective treatment option for the treatment of chronic LET. Peri-articular hyaluronate acid injections for LET gave significantly better results compared to the placebo group, by improving pain at rest, and after maximal grip testing.

2.9.1.2.5 Prolotherapy

Prolotherapy is a regenerative injection treatment that has been used for pain relief in chronic lateral elbow tendinopathy. The tender tendon attachments are usually injected with a small amount of a sclerosing mixture such as sodium morrhuate (an extract of cod liver oil) and dextrose. It is rationalised that prolotherapy may strengthen and enlarge tendon insertions (Chesterton, Mallen and Hay, 2011). A pilot study conducted by Scarpone et al., *(*2008) concluded that prolotherapy was effective (significance of $p \leq 0.05$) in improving pain and grip strength when comparing the effectiveness of prolotherapy to placebo injection in the treatment of chronic LET. In another pilot study conducted by Rabago et al., (2013) they found significant improvements in the intervention group treated with prolotherapy, (with regards to the following outcomes: quality-of-life, pain and function measures, as well as grip strength) compared to the placebo group treated with a wait–and-see approach. Outcomes were compared at baseline, sixteen and thirty-two weeks. Although prolotherapy could be effective for patients with refractory LET, larger well designed randomised controlled trials need to be undertaken (Rabago et al., 2013).

2.9.1.2.6 Botulin toxin

Since the 1990s, botulin toxin, also known as 'BOTOX', has become well known to the public as an anti-wrinkle drug for cosmetic facial enhancement. In 1997, botulin toxin was also injected into the common wrist extensor tendon to treat lateral elbow tendinopathy. Botulin toxin reduces muscular activity depending on the dosage used. The muscle relaxation will last between 12 and 16 weeks. It has been suggested that botulin toxin reduces the tension on the tendons by causing incomplete paralysis of the wrist and/or finger extensors, and thereby reproducing the effects of surgical release of the tendon. Botulin toxin is also thought to have some analgesic effect (Smidt, Dingjan et al. 2011). Conflicting evidence regarding the effectiveness of Botulin toxin for lateral elbow tendinopathy was found in a systematic review conducted by Sims et al., (2014). Hayton et al., (2005) could not find any significant differences between the intervention and placebo group with regards to pain, grip strength or quality of life in their study. However, Wong et al., (2005) and Espandar et al., (2010) found significant differences in pain score but the grip strength score was insignificant. These injections may have adverse effects such as digit paresis and weakness of finger extension (Wong et al., 2005).

In summary, injection of PRP or hyaluronic acid would appear to be the most reasonable choices of injections considering the good results seen in randomised controlled trials according to Donaldson et al., (2013) and Luk, Tsang and Leung, (2014).

2.9.1.3 **Surgical management**

Estimates suggest that up to 5% of patients who do not respond to conservative physical interventions undergo surgery, with variable outcomes reported in the literature (Maffuli et al., 2010; Coombes, Bisset and Vicenzino, 2015). Surgical management of lateral elbow tendinopathy is recommended when functional disability and pain persist after six to twelve months of nonsurgical management (Calfee et al., 2008). Arthroscopic and percutaneous surgical approaches have also been described, (Erickson and Hall, 2015).

In a literature review summarising the evidence regarding treatment of common extensor tendinopathy done by Erickson and Hall, (2015) (consisting of 91 references)

the following was cited: the surgical technique, now commonly referred to as the ‘‘Nirschl procedure’’, involved an open excision of the diseased portion of the ECRB and subsequent repair of the ECRL and EDC as needed. Initial short-term results were reported as excellent in 75% of patients. Subsequent long-term follow-up (minimum ten years) reported by Dunn et al., (2008) demonstrated good to excellent results in 84% with an overall improvement rate of 97%. Coleman, (2010) reported 95% good to excellent results at a mean of nearly ten year follow - up using a modified open technique.

When using the arthroscopic approach, the lateral capsule and enfolded tissue is debrided, or the extensor tendon is debrided (Calfee et al*.,* 2008). It was reported by Baker, (2008) that there was 87% patient satisfaction after arthroscopic resection of pathologic tissue with a mean follow-up of 10 years. Cohen and Romeo, (2009) compared arthroscopic with open release at two year follow up, and concluded that there was no significant difference between the two techniques regarding outcomes. However, the arthroscopic group was able to return to work/sport sooner. In a case-controlled series published by Solheim, Hegna et al., (2013) 305 elbows were followed up for three to six years after either open or arthroscopic surgery for common extensor tendinopathy. They reported excellent outcomes with both surgeries, but a statistically significant difference in the disability of the arm, shoulder and hand (DASH) score improvements was found in the arthroscopic group. Furthermore, arthroscopic treatment has the advantage of evaluation for concomitant intra-articular pathology at time of surgery. Complications, including nerve injury, have also been reported by Carofino, Bishop et al., (2012) following surgery. A few years ago Koh et al., (2013) reported the use of a percutaneous device (Tenex Health, Lake Forrest, California) that allows for precise debridement of pathologic tendon tissue via a percutaneous approach under live sonographic guidance. In their initial trial of 20 patients, one-year follow-up showed significant improvement in visual analogue scale (VAS) and DASH scores with 95 % patient satisfaction.

Sonographic improvements in tendon thickness, reductions in tendon neovascularity, and improvement in tendon echotexture were also reported in 85 – 95% of patients by six months (Erickson and Hall, 2015). The surgical result for lateral elbow tendinopathy is generally encouraging as supported by the work done by Nirschl and Pettrone, (1979) on lateral elbow tendinopathy (Calfee et al., 2008).

2.9.2 **Physiotherapy Management**

2.9.2.1 **Treatment modalities**

Physiotherapy is commonly employed as a first-line treatment for lateral elbow tendinopathy (Erickson and Hall, 2015). There are different physiotherapy treatment modalities for lateral elbow tendinopathy such as: manual therapy (mobilisation with movement), Cyriax (deep transverse frictions combined with Mill's manipulation), stretching and strengthening exercises, electrotherapy (ultrasound, low-level laser therapy, and transcutaneous electrical nerve stimulation), taping and dry needling (Valen and Foxworth, 2010).

2.9.2.1.1 Manual therapy

Moderate evidence was found for the short-term effects of various manual therapy techniques on pain and grip strength, when used alone or in combination with graded exercise. Mulligan (mobilization with movement) techniques that can be used for elbow symptoms (pain and stiffness) is the radial head postero-anterior glide and the ulnar-humeral lateral glide. The patient does the pain-producing movement while the physiotherapist applies the abovementioned sustained mobilization techniques. These treatment techniques are effective when they provide significant immediate relief (e.g., 50% reduction in pain and improvement of pain free grip strength); (Coombes, Bisset and Vicenzino, 2015). If these techniques do not improve symptoms significantly during treatment, other treatment techniques or modalities should be considered using clinical reasoning.

2.9.2.1.2 Electrotherapy

Low level laser therapy (LLLT), also known as photobiomodulation has been shown to accelerate tissue healing, including an increase in collagen formation of the affected common extensor tendons (Roberts, Kruse and Stoll, 2013).

The efficacy of laser treatment for LET has been contested. In a systematic review with adequate design and treatment procedures conducted by Bjordal et al., (2008) including 13 RCT (randomised controlled trial) consisting of 730 participants, low level laser therapy (LLLT) with an irradiation of a 904nm wavelength applied to the common extensor tendon insertion at the elbow

could be a safe and effective alternative treatment option to corticosteroid injections and NSAIDS. Low level laser therapy also seems to be effective when used in conjunction with exercise and stretching programmes.

Ultrasound is a modality that is often used to treat lateral elbow tendinopathy patients, it is especially used in the acute phase, as it is readily available in most physiotherapy practices, and a safe treatment option (Luk, Tsang and Leung, 2014). Lundeberg et al*.,* (1988) reported that when comparing ultrasound to placebo, there was an improvement in pain of lateral elbow tendinopathy three months after the ultrasound treatment, but they could find no significant difference in global improvement. Another study compared ultrasound to acupuncture and found that both yielded improvements in all outcome measures, but there was no significant difference when comparing the treatment groups (Davidson, Vandervoort and Lessard, 2001). It is difficult to draw any firm conclusion on the efficacy of ultrasound for lateral elbow tendinopathy due to the shortage of high-quality randomised controlled trials (Luk, Tsang et al. 2014).

It has been recommended that transcutaneous electrical nerve stimulation (TENS) can provide safe and effective pain relief in a wide variety of musculoskeletal conditions, and can be applied by patients themselves at home. In a randomised controlled trial undertaken by Chesterton et al., (2013), which included 241 participants, it was concluded that TENS as an additional treatment option to primary care management of lateral elbow tendinopathy does not provide any other clinical benefits (Chesterton et al., 2013) .

2.9.2.1.3 Education

Patients with lateral elbow tendinopathy should be educated by reassuring them that in all probability, the condition will gradually improve over time with rest. Advice would be to avoid activities that exacerbate symptoms such as pain (for example not lifting objects with forearm pronation), to rest, and avoid loading of the upper limb. This advice is very important when rehabilitating lateral elbow tendinopathy. Ergonomic advice may focus on minimising use of the wrist in ulnar or radial deviation with work tasks, forceful exertion of the upper limb, as well as highly repetitive movements. Patients should also be encouraged to gradually introduce more strenuous tasks, and to lessen pain

provoking activities when recurrence of LET is experienced (Coombes, Bisset and Vicenzino, 2015).

2.9.2.1.4 Eccentric exercises

The understanding of eccentric exercise is founded on the musculotendinous units that structurally adapt to protect themselves from increased loading and thereby preventing injuries. The basic principles in the progression of eccentric strengthening programmes are to increase the length of tendon, as well as the load and speed exerted on the tendon. The length of the tendon is increased before movement by pre-stretching the tendon, hence there will be less strain on the tendon during movement. During progressive increased loading of the tendon, there should be an improvement in the inherent strength of the tendon. Greater force will be generated by increasing the contraction speed, (Maffuli et al., 2010).

Eccentric strengthening exercise has become the preferred choice of treatment for tendinopathies since Stanish et al., (1986) first reported its effectiveness whilst treating achilles tendinopathy. However, in a review conducted by Raman et al., (2012) it was concluded that patients with LET doing any type of exercise (isotonic, eccentric, concentric, isometric, or isokinetic strengthening exercises) can all have improvement in outcomes measures such as: pain, grip strength, and upper limb function with long term follow up. A review done on eccentric exercise for tendinopathies supported its use for LET. When combining eccentric exercise with passive physical therapy patients with chronic LET experienced less pain and disability, thus having improved upper limb function, as found in the reviewed study "Eccentric training for the treatment of tendinopathies," by Murtaugh and Ihm, (2013).

Cullinane et al., (2014) reviewing 12 studies, with ten being of medium or high quality, evaluated the effect of eccentric exercise on the treatment of LET. They established that adding eccentric exercise gives positive outcomes. Most of the studies in Cullinane's, (2014) review included eccentric exercise combined with other treatment modalities (i.e. ultrasound, stretching, iontophoresis). Based on the reviewed studies, patients that had eccentric exercise included in their treatment had better outcomes for pain scores and function. There was only one low quality study in the review by Cullinane et

al., (2014) comparing eccentric exercise with placebo, and there was no significant difference in their outcome after four weeks. Although evidence shows that eccentric exercise combined with other treatment modalities gives better outcomes, further studies are needed to determine if eccentric exercise when used in isolation can significantly improve outcomes (Erickson and Hall, 2015).

Valen and Foxworth, (2010) reviewed clinical trials and systematic reviews for evidence supporting the use of physical modalities, and other conservative treatments in selected upper extremity musculoskeletal conditions such as lateral elbow tendinopathy, and found that most trials had significant design flaws and that conclusive evidence in support of any particular intervention is lacking. It should also be noted that some studies have failed to show a significant difference between physical therapy and a 'wait–and-see' approach in the long-term, which most likely represents the natural history of disease (Erickson and Hall, 2015).

Although multiple options have been proposed for the treatment of lateral elbow tendinopathy, there is no agreement in the literature on when and which treatment modalities should be employed. There is strong evidence that combining an eccentric exercise programme with advice, as well as a passive physiotherapy modality such as mobilisation techniques, dry needling, myofascial release or shockwave therapy will have the best outcome for the patient with chronic lateral elbow tendinopathy (Bisset et al., 2006; Jones 2009; Bisset and Vicenzino, 2015). However, evidence-based treatment of lateral elbow tendinopathy should be implemented when choosing a treatment option (Erickson and Hall, 2015).

2.10 SHOCKWAVE THERAPY

2.10.1 Definition

Extracorporeal shockwave is a noninvasive procedure in which single pulsed acoustic, or sonic, waves are generated outside the body, and focused at a specific site within the body as a therapeutic modality (Ioppolo et al., 2014).

2.10.2 History

The influence of shock waves on biological (human) tissue was first documented on castaways who were exposed to water bomb explosions during World War II. They

suffered severe lung injuries, but showed no overt clinical signs of traumatic injury (Wang, 2003). Approximately 40 years later, in 1980, high energy focused extracorporeal shock waves were first introduced in Munich, Germany, to disintegrate urinary stones (i.e. lithotripsy) (Wang, 2003). Over the ensuing 15 years, more than two million patients with nephro-ureterolithiasis were successfully treated with shockwaves, with few treatment-related side effects (Mittermayr et al., 2012). Extracorporeal shockwave therapy began with an incidental observation of osteoblastic response pattern during animal studies in the mid–1980's that generated an interest in the application of extracorporeal shockwave to musculoskeletal disorders (Wang, 2012). At the beginning of the 1990's, the first reports on high-energy focused shock wave therapy for calcific tendinopathy of the shoulder was published (Mittermayr et al., 2012). In October 2000, the Food and Drug Administration approved extracorporeal shockwave (the Ossatron device) for chronic plantar fasciitis, and in 2003 for chronic lateral elbow tendinopathy. Further investigations and clinical trials using extracorporeal shockwave had shown clinical efficacy of therapeutic shock waves for a variety of orthopaedic pathologies including calcific tendonitis of the rotator cuff, lateral elbow tendinopathy, plantar fasciitis, achillodynia, and calcaneal spurs (Mittermayr et al., 2012). During the previous 10 to 15 years' (1997-2002) shockwave therapy had emerged as the leading choice in the treatment of many orthopaedic disorders (Wang, 2012).

2.10.3 **Background**

There is increased emphasis on finding alternative modalities to treat tendinopathies, such as extracorporeal shockwave therapy (Valen and Foxworth, 2010). Tendinopathy in the chronic stage is mainly a degenerative condition and inflammation plays a minor role. This has led to a shift from treatments that target inflammation towards treatment options that promote regeneration. One of these treatments is extracorporeal shockwave therapy, a physical therapy modality that uses pressure waves to treat tendinopathy (Van der Worp et al., 2013).

Other clinical applications of ESWT in the treatment of vascular skin lesions include chronic post-traumatic, venous and diabetic ulcers (Romeo, Lavanga and Sansone, 2013). Extracorporeal shockwave has been shown to be effective in the early stages of femoral head osteonecrosis by reducing the extension of the necrotic area, avoiding further bone collapse (Romeo, Lavanga and Sansone, 2013). Bone resorption is typical in periodontal inflammation. In vivo experience has demonstrated that shockwaves could enhance alveolar bone regeneration in infected

gingivalis tissue (Romeo, Lavanga and Sansone, 2013). Extracorporeal shockwave is also currently one of the newer alternative treatments for cardiac ischemia (Romeo, Lavanga and Sansone, 2013).

Radial shockwave has been studied as an alternative to surgery for managing lateral elbow tendinopathy for many years (Sems, Dimeff and Iannotti, 2006). Several studies investigated the effect of shockwave therapy in patients with lateral elbow tendinopathy with varying results. Several authors reported good or excellent outcomes in their studies (Wang and Chen, 2002; Pettrone and McCall, 2005; Radwan et al., 2007; Collins, Hildreth and Jafarnia, 2011), whereas others concluded no clinically relevant efficacy for the use of shockwave therapy on lateral elbow tendinopathy (Haake et al., 2002; Speed et al., 2002; Buchbinder et al., 2005; Staples et al., 2008).

The advantages of shock wave therapy are the non-invasiveness (avoidance of surgery), low associated complication rates (e.g. minimal petechial skin hemorrhage, minor local swelling and hematoma), and efficacy for indications refractory to other standards of practice (e.g. osseous non-union); flat learning curve; and cost-effectiveness (Mittermayr et al., 2013).

2.10.4 Types of Shockwave

There are various types of shockwave therapy: focused shockwave therapy, unfocused or radial shockwave therapy, as well as de-focused shock wave therapy.

Extracorporeal shockwave therapy originally used focused shockwaves (Van der Worp et al., 2011). Focused shockwave therapy is called focused because a pressure field is generated that converges in the adjustable focus at selected depth in body tissues where maximal pressure is reached, (Van der Worp et al., 2013). Focused shock waves are generated by electro-hydraulic, electromagnetic and piezoelectric devices. The acoustic energy is concentrated in a well-defined point of the target tissue, with varying focal volume, depth of penetration, level of Energy Flux Density (EFD) and total energy administered (Romeo, Lavanga and Sensone, 2013). The use of focused shock waves, especially when high energy levels are used, requires accurate identification of the area to be treated. This allows the most favourable therapeutic effect, and avoids damage to the surrounding tissue. For this purpose, radiographic or ultrasound guidance is necessary. In the treatment of easily

located soft tissue injuries, patient feedback is usually sufficient to localise the area (Romeo, Lavanga and Sensone, 2013).

Unfocused or radial shockwave is a form of extracorporeal shockwave. It refers to a diverging pressure field which has a more superficial effect on tissues than focused shockwaves which reach a maximal energy in the focus that is located deeper into the tissue (Van der Worp et al., 2013). Radial shockwave or pressure waves are produced by pneumatic generators, whose physical properties significantly differ from focused shock waves.

The linear pressure, low energy values, relatively low velocity of propagation and, above all, the short duration of the rise time, differentiate radial waves from focused shock waves. In radial shock wave generators, the compressed air strikes a bullet contained in a cylinder. At the top of this cylinder is the applicator, which is in contact with the skin during treatment. The energy produced by the pressure wave is highest at the skin surface, diverging and weakening as it penetrates deeper (Romeo, Lavanga and Sansone, 2013).

De-focused shock waves are generated by electromagnetic and electro-hydraulic devices that convert the acoustic wave into planar or into de-focused (soft-focused) waves, which retain the same physical characteristics, but deliver the energy to a larger surface area. The depth of penetration will obviously be lower and therefore, the therapeutic use is limited to superficial lesions like cutaneous ulcers (Romeo, Lavanga and Sensone, 2013).

2.10.5 Principle of Shockwave Generation

Shockwave could be described as a large-amplitude compression wave, that was produced by an explosion, or by the supersonic motion of a body in a medium. Clinically useful shockwave is effectively a controlled explosion, and when it enters the tissues, it will be reflected, refracted, transmitted and dissipated like any other energy form (Ogden et al., 2001). The energy content of the wave will vary and the propagation of the wave will vary with tissue type. Just like an ultrasound wave, the shock wave consists of a high-pressure phase followed by a low pressure (or relaxation) phase. When a shockwave reaches a 'boundary', some of the energy will be reflected and some transmitted (Watson, 2014).

A shock wave is defined as an acoustic wave, at the front of which pressure rises from the ambient value to its maximum within a few nanoseconds. Shockwaves are

characterised by high peak-pressure amplitudes (500 bar) with rise times of less than ten nanoseconds, a short lifecycle (<10 ms), and a frequency spectrum ranging from 16 Hz to 20 MHz, after reaching the positive peak the pressure rapidly drops to negative values within microseconds (Ioppolo et al., 2014).

Both the positive and the negative phase of a shockwave have an effect on interface between tissues with different density (acoustic impedance). During the positive phase shock waves with high pressure may hit an interface, leading to reflections, or they may pass and gradually become absorbed. The negative (tensile) phase of the shock wave causes cavitation at the tissue interfaces. During cavitation air bubbles are formed as a result of the negative pressure which implodes with high speed generating a second wave of shock waves or micro jets of fluid. This causes the direct (physical) and indirect (biological) effects of the shockwaves on the treating tissue (Ioppolo et al., 2014).

2.10.6 Techniques of Shockwave Generation

Shock waves are generated through four techniques, these are electromagnetic, electrohydraulic, piezoelectric or electro-pneumatic (Ioppolo et al., 2014).

The electromagnetic technique involves the electric current passing through a coil to produce a strong magnetic field, which induces a high current in the opposing membrane. This current accelerates the metal membrane away from the coil to the 100 000-fold of gravity, thus producing an acoustic impulse in surrounding water. The impulse is focused by an acoustic lens to direct the shock wave energy to the target tissue. The lens controls the focus size and amount of energy produced within the tissue (Ioppolo et al*.,* 2014).

The electrohydraulic technique represents the first generation of orthopedic shockwave machines. Electrohydraulic shock waves are high-energy acoustic waves generated by an underwater explosion with high-voltage electrode spark discharge, and the acoustic waves are then focused with an elliptical reflector and targeted at the diseased area to produce a therapeutic effect (Wang, 2012). The electrohydraulic technique incorporates an electrode submerged in a water-filled housing compartment comprised of an ellipsoid, and the patient interface. The electrohydraulic generator initiates the shock wave by an electrical spark produced between the tips of the electrode. Vaporization of the water molecules between the tips of the electrode produce an explosion thus creating a spherical shock wave. The

wave is then reflected from the inside wall of a metal ellipsoid to create a focal point of shock wave energy in the target tissue. The size and shape of the ellipsoid control the focal size and the amount of energy within the target (Ioppolo et al., 2014).

The piezoelectric technique involves a large number (usually > 1 000) of piezo crystals mounted in a sphere and receives a rapid electrical discharge that induces a pressure pulse in the surrounding water steepening to a shockwave. The arrangements of the crystals cause self-focusing of the waves towards the target centre, and lead to extremely precise high-energy within a defined focal volume (Wang, 2012).

The electro-pneumatic technique is generated through the acceleration of a projectile inside the hand piece of the treatment device and then transmitted radially from the tip of the applicator to the target zone. Radial shockwaves show a lower peak pressure and a considerably longer rise time than focused shockwaves; the focal point is not centered on the target zone as occurs in focused shock wave, but on the tip of the applicator (Ioppolo et al., 2014).

2.10.7 Parameters of Shockwave Therapy

The most important parameters of shockwave therapy for the treatment of musculoskeletal disorders include pressure distribution, energy flux density, total acoustic energy and frequency (Wang, 2012).

The energy flux density is the energy at the focal point of the shock wave per impulse, and is recorded as joules per area. The effective total energy of a treatment is defined by the number and energy flux density of the single impulses and by the geometrical measurement of the focal point. Focused shock waves have a high (>0.2 mj /mm) energy flux density. The energy flux density is one of the most important parameters of shock wave therapy in the treatment of musculoskeletal disorders (Ioppolo et al., 2014). The number of shocks, interval between shocks, number of treatments, and interval between treatments are additional parameters that can determine the therapeutic response (Ioppolo et al., 2014). The frequency of shock wave therapy which is measured in hertz, is the number of shockwaves delivered per second (Sems, Dimeff and Iannotti, 2008).

2.10.8 **Biological Effects of Shockwave**

The mechanism by which an acoustic signal is converted into a biological reaction was not fully understood. Potential mechanisms include initial neovascularization with ensuing durable and functional angiogenesis. Furthermore, recruitment of mesenchymal stem cells, stimulated cell proliferation and differentiation, and anti-inflammatory and antimicrobial effects as well as suppression of nociception are considered important factors of the biological responses to therapeutic shockwaves (Hayashi et al., 2012).

2.10.8.1 **Tissue regeneration**

Extracorporeal shockwave therapy induces tissue regeneration and facilitates tendon healing after trauma, as well as significantly increasing neovascularization and reduction of adhesion formation (Orhan et al., 2004).

Shockwave microscopically causes interstitial and extracellular biological responses and tissue regeneration (Notarnicola and Moretti, 2012). It is possible to hypothesise that mechanotransduction is the basis of the biological response to a shockwave impulse. Mechanotransduction is the mechanism by which reactive cells recognise and respond to mechanical stimulation, converting physical forces into biochemical signals. Mechanotransduction stimulate extracellular matrix binding proteins and the nucleus via the cytoskeleton resulting in response leading to tissue regeneration. Recent histologic, biochemical, and immunologic basic science studies have greatly advanced the understanding of how shockwaves affect tissue regeneration. These effects include enhanced neovascularity, accelerated growth factor release, selective neural inhibition, osteogenic stem cell recruitment, and inhibition of molecules that play a role in inflammation (Ioppolo et al., 2014).

2.10.8.2 **Release of growth factors**

A study by Notarnicola and Moretti, (2012) has demonstrated that shockwave treatment can increase the number of neovessels at the normal tendon-bone junction, through the release of growth factors and some other active substances. The first evidence that extracorporeal shock wave promoted tendinitis repair coincides with an increase in TGFb1 and IGF-I. These growth factors have been found to up-regulate extracellular matrix biosynthesis by tenocytes. It has been proposed that these increased mitogenic and anabolic responses of tendon tissue can be responsible for the clinical success of shockwave treatment in resolving

tendon pathologies. Tenocytes can respond to mechanical stimulation by increasing TGF-b1 gene expression. These findings seem to indicate that tendon tissue can convert shockwave stimulation into biochemical signals via release of growth factors (TGF-b1 and IGF-I) for tendonitis repair.

2.10.8.3 **Pain relief**

Healthy tendons are relatively avascular. Neovascularization and the accompanying neonerves have been hypothesized to be the source of pain in chronic tendinopathy (Tol, Spiezia and Maffuli, 2012). Shockwave increases neovascularization which stimulates the formation of neonerves which could explain the reason for the initial increase in pain with shockwave therapy. When the initial treatment pain subsides there is secondary analgesia.

Pain relief with extracorporeal shockwave might work by means of hyper stimulation analgesia; overstimulation of the treated area would lead to a decreased transmission of signals to the brainstem (Van der Worp et al., 2013).

2.10.8.4 **Destruction of calcifications**

It has been proposed that the therapeutic effect of shockwave on calcific tendinopathies is that increasing pressure within the therapeutic focus causes fragmentation and cavitation effects inside amorphic calcifications and leads to disorganization and disintegration of the deposit (Mouzopoulos et al., 2007).

2.10.8.5 **Bone remodelling**

The effect of shock waves on bony tissue is thought to occur primarily at the interface between cortical and cancellous bone. It is thought that acoustic streaming causes cavitation and increases cell permeability allowing increased vascularity and bony regeneration. More specifically, an increase in stromal cells seems to allow osteogenesis. Additionally, the increase in osteoprogenitor cells coupled with local increase in growth factor, neovascularization and protein synthesis suggests that shockwaves can improve the tissue environment for healing to occur (Thigpen, 2011). Animal experiments showed stimulated fracture healing, and histological investigations confirmed the influence of shockwaves on the activation of osteoblasts with associated increased bone density (Mittermayr et al., 2013).

2.10.8.6 **Lubricin production**

Lubricin is a lubricating glycoprotein that facilitates tendon gliding, and is upregulated by mechanical as well as biochemical stimuli. In a study conducted by Zhang et al*.,* (2011) extracorporeal shockwave was found to increase lubricin expression in both low-dose and high-dose. Lubricin expression generally increased with an increasing dose of extracorporeal shockwave.

Results showed that extracorporeal shockwave stimulated endogenous lubricin production in tendons and septa in the rat hind limb, reflected in the percentage of cells containing lubricin and the percentage of the extracellular matrix displaying the presence of the mucinous glycoprotein. Being a form of mechanical loading, extracorporeal shock wave stimulates the upregulation of lubricin, pointing to the fact that this form of physical stimulus induces excessive expression of lubricin in vivo (Zhang et al., 2011).

This result provides a basis for the hypothesis that increased lubricin deposits in tendons and septa following extracorporeal shock wave contribute to the beneficial effects of extracorporeal shockwave by facilitating movement macroscopically among gross structures, as well as microscopically among collagen fascicles. Increased lubricin expression may contribute to the beneficial effects of extracorporeal shockwave in providing pain and symptom relief in musculoskeletal disorders by decreasing erosive wear (Zhang et al*.,* 2011).

Experimental results show that extracorporeal shockwave significantly stimulated the ingrowth of neovascularization associated with increased expressions of angiogenic growth indicators in tendon, bone and tendon-bone interface. Neovascularization may play a role in the improvement of blood supply and healing of the tendon. There is a close relationship between the decrease in Substance-P release, with consecutive pain reduction when applying shockwave treatment to the tendon insertion where there is pathology (Notarnicola and Moretti, 2012).

2.10.9 **The use of Shockwave Therapy in Tendinopathy**

Extracorporeal shockwave treatment is generally used for soft tissue injuries such as the following tendinopathies: plantar fasciitis, lateral elbow, patellar and Achilles tendinopathy (Maffuli et al., 2010). Low-energy (radial) shockwave therapy stimulates soft tissue healing and inhibits pain receptors. The rationale for its clinical

use is stimulation of soft tissue healing and inhibition of pain receptors. It is widely used for soft tissue pathology. Effects after repetitive application were significantly greater than after single application. Low-energy shockwave therapy also enhances angiogenesis (Maffuli et al., 2010).

2.10.10 **Conclusion**

In 1929, Dr Kellog Speed (professor of orthopaedic surgery) came to the conclusion: ‘‘The aetiology of tennis elbow is various, its pathology is obscure and its cure is uncertain’’, and in many ways, this holds true today.

Advances have been made in our understanding of the histopathology of the condition, but it remains a challenge why these changes occur and why some cases become recalcitrant. Despite a multitude of treatment options, there remains lack of consensus regarding best practice (Erickson and Hall, 2015).

The most effective and consistent management strategy for chronic lateral elbow tendinopathy remains unknown. Both failed conservative and surgical management of chronic lateral elbow tendinopathy is motivation for further research. Radial shockwave therapy could be an alternative conservative treatment if proven effective. It is a safe procedure and there are not many known adverse side-effects of extracorporeal shockwave therapy (Mittermayr et al., 2013).

CHAPTER THREE

3. METHODOLOGY

3.1 STUDY DESIGN

A non-randomised, single-blinded, placebo controlled study.

3.2 POPULATION AND SAMPLING

The following section describes the source and selection of participants for this clinical trial.

3.2.1 Source of Participants

Patients with chronic lateral elbow tendinopathy from the Virgin Active gym in Krugersdorp, tennis clubs (Noordheuwel as well as Krugersdorp) and industry (Plascon) were invited to participate in this study. Patients were also referred from general practitioners, orthopaedic surgeons as well as other physiotherapists in the area.

3.2.2 Sample Selection

The calculation of the sample size (refer to appendix 9) was done with the power set at 90%, the standard deviation at 15, the effect to be detected at 15 and the alpha at 5%; n (per group) was calculated at 35 (Whitley and Ball 2002).

A sample of 41 patients with lateral elbow tendinopathy was recruited for the study. The study was conducted at the Noordheuwel medical centre (a private medical setting) where the shockwave machine was located. There were rooms for general practitioners, a physiotherapy practise, a pathology practise and an emergency procedure room in the centre. Systematic sampling was used to allocate patients to the intervention and control group, by including all participants in the study with lateral elbow tendinopathy that met the inclusion criteria. Recruited patients were systematically assigned to a radial shockwave treatment group (intervention), or a placebo treatment (control) group through a computer-generated list, created by a computer programmer. The researcher was blinded to the systematic sampling process.

3.3 INCLUSION CRITERIA

- Subjects over the age of 18, presenting with chronic lateral elbow tendinopathy for at least three months.
- Tenderness near the lateral epicondyle over the origin of the extensor carpi radialis brevis and extensor digitorum communis muscles.
- Pain with wrist extension against resistance.

- Functional impairment of the upper limb due to symptoms in the elbow.

3.4 EXCLUSION CRITERIA

- Patients with pacemakers.
- All other known causes of elbow pain such as: elbow arthritis, neurological pathology such as carpal- or cubital tunnel syndrome and radial nerve entrapment, previous elbow surgery, elbow fracture or dislocation.
- Cervical spondylosis.
- Severe systemic illness, rheumatologic disease, malignancies.
- Pregnancy.
- Previous shockwave treatment for their lateral elbow tendinopathy.
- Patients on anti-coagulation therapy.
- Patients currently using NSAIDS.

3.5 VARIABLES

3.5.1 Independent Variable

Radial shockwave treatment.

3.5.2 Dependant Variable

Pain, grip strength and upper limb function.

3.5.3 Extraneous Variable

Patients using NSAIDS or other treatment options, such as cortisone injections or platelet rich plasma injections prior to the clinical trial.

3.6 OUTCOME MEASURES

The demographic information including age, gender, smoking, involvement of the dominant or non-dominant arm, work that affects upper limb function, as well as sport that affects upper limb function was completed by the participants using the demographic data sheet (appendix 16).

The Visual-analog scale (VAS) (appendix 10) is a psychometric response scale that can be used in questionnaires. This measuring instrument can be used for the subjective measurement of pain. Pain assessed with the VAS scale is a unidimensional measure of pain intensity. Participants express their pain intensity by marking a position along a continuous line between two end-points on a 100 mm horizontal line. It usually takes less than one minute to complete the measurement. Scoring on the VAS is determined by measuring the distance (mm) with a ruler on the 100 mm line between the "no pain" and the patient's mark, providing a range of scores from 0 – 100mm. According to research the visual analogue scales metrical characteristics are superior to discrete scales, therefore a wider range of statistical methods can be applied to the measured parameters. The characteristic of the instrument is based on calculated intra-class correlation coefficients (ICC) of 0.97 for acute pain, and Cronbach's alpha varies depending on the studies from 0.79 to 0.91 (Janikowska and Chomiuk, 2013). The VAS scale was used in this study to assess pain before physical assessment and treatment with the Mc Gill Pain Questionnaire Short Form and during the Thomsen provocation test at baseline, as well as at one week and three month's follow up.

The Thomsen provocation test (appendix 10) was used when resistance was applied for wrist extension; the pain experienced during this test was rated using the VAS scale. This test was done with the patient's shoulder in 60 degrees' flexion; full elbow extension; forearm pronation and the wrist in 30 degrees' extension (through observation). The physiotherapist then applied pressure to the dorsum of the second and third metacarpal bones against extension and radial deviation to resist the extensor carpi radialis brevis, and longus muscles (Rompe et al., 2004).

The McGill Pain Questionnaire Short Form (MPQ-SF) (appendix 7) was used to evaluate subjective pain. The Pain Rating Index (PRI) contains 15 words, 11 sensory and four affective, one item tests Present Pain Intensity (PPI), and another item test pain with the visual analogue scale (VAS). Each word is rated on a four - point scale from 0 (none) to 3 (severe). Scores for the questionnaire ranged from 0 - 45 on the PRI, from 0 - 5 on the PPI totaling 50, and between 0 - 100 mm on the VAS scale. The MPQ-SF is a reliable (retest over three to seven days indicated that respondents chose the same words in the Pain Rating Index as well as the Present Pain Intensity) and a valid (the respondents' tendency to use all 20 subclasses of pain words was consistent when retested) instrument that is quick and easy to use (Burckhardt and Jones, 2003).

The Disabilities of the Arm, Shoulder and Hand (DASH) (appendix 4) Outcome Measure is a 30-item, self-report condition specific questionnaire. The questionnaire includes 21 physical function items, six symptom items, and three social/role function items. It also consists of two optional four-item modules, one is for the working population and the other is for athletes or performing artists. Each item of the DASH is scored on a five-point scale (1 - 5). Lower scores reflect less disability and higher scores reflect more disability. The DASH was developed to measure physical symptoms as well as physical function in patients with upper limb musculoskeletal dysfunctions, and was published in 1996.

This tool was designed by the Institute for Work & Health and the American Academy of Orthopaedic Surgeons (AAOS), and supported by the American Association for Hand Surgery, the American Orthopaedic Society for Sports Medicine, the American Shoulder and Elbow Surgeons, the Arthroscopy Association of North America, and the American Society of Plastic and Reconstructive Surgeons and the American Society for Surgery of the Hand, (Janikowska and Chomiuk, 2013). The DASH is a reliable, valid and responsive measuring tool and can be used for research and clinical purposes with a Cronbach's alpha of 0.96-0.97, (Finch et al., 2002). The DASH can be used for patients with one or more upper extremity musculoskeletal dysfunctions.

The Quick DASH is a shortened version of the DASH Outcome Measure. Instead of 30 items, the Quick DASH consists of 11 items. Scoring is divided into the two components: the disability/symptom section, consisting of 11 items; after scored 1 –5; and the optional high-performance sport/music or work modules with four items, scored 1 - 5. At least 10 of the 11 items must be completed to calculate the score. This tool was developed to measure disability; hence the scaling was ranked from 0 indicating lowest disability to 100 indicating highest disability. Both instruments (DASH and Quick DASH) are reliable, valid and responsive and can be used for research and clinical purposes. The tools are characterised by rating of intra - class correlation coefficient on 0.94 and Cronbach's alpha also on 0.94 (Janikowska and Chomiuk, 2013). The Quick DASH was used in this study, as it is shorter but also reliable (ICC (2.1) = 0.90 and valid Pearson r > 0.70) (Mintken, Glynn and Cleland, 2009; Beaton, Wright and Katz, 2005).

The most common functional limitation in LET is pain on gripping, and this can be measured as pain-free grip strength, which is a reliable and valid measure that is more sensitive to change than maximal grip strength where the patient is asked to

grip a dynamometer until the onset of pain. Three tests are done with one-minute between each, the mean is then calculated of the three measurements (Bisset and Vicenzino, 2015). For the purposes of this study three repetitions of pain-free grip strength were measured with the Jamar dynamometer, and using the mean of the three scores.

The Jamar dynamometer (appendix 12) is often used in studies as an objective measuring instrument to measure grip strength, the pressure being registered in kg/cm^2 (Staples et al., 2008; Rompe et al., 2004). It is calibrated before use, and is a valid and reliable measuring tool (Peters et al., 2011).

Measurements were taken at baseline, one-week and three months' post treatment, for the intervention and control groups. The differences in values at baseline and follow up were compared between the two groups. The data collected by these outcome measures were statistically analysed by the principal researcher, the second supervisor and a statistician to evaluate the outcome of the intervention.

3.7 PROCEDURES

3.7.1 Pilot Study

A pilot study with seven participants (four men and three women) was done before the clinical trial was undertaken. These patients all received radial shockwave therapy as per protocol to test procedures and methods before commencing the main study. The aim of the pilot study was thus to test the amount of time it took to complete the outcome measures, to test the operation of the shock wave machine, and the administration of shock wave treatment (intervention and placebo); and to train the research assistants regarding the aforementioned. The outcome of the pilot study was that the main study was feasible in terms of design and procedures. The pilot study confirmed that the main study could be carried out as planned.

3.7.2 Main Study

The main study consisted of 41 participants (21 men and 20 women), with a diagnosis of lateral elbow tendinopathy who all met the inclusion criteria. Treatment started within seven days of recruitment. The participants read the information document and signed the consent form (appendix 2). They completed the McGill pain Questionnaire including the VAS scale, and the quick-DASH questionnaire that assessed upper limb function.

The researcher completed the physical examination which included palpation of the elbow to localise the pain; the Thomsen provocation test rated with the VAS scale to assess pain intensity, and three measurements of maximal pain free grip-strength with the dynamometer, using the average of the three measurements as the final score.

The two physiotherapists (research assistants) carrying out the intervention and placebo treatment was briefed about the treatment protocol during the pilot phase. Information regarding the dosage, technique used as well as the specific eccentric exercise programme (see appendix 8), and placebo treatment was demonstrated and provided in hard copy to ensure standardization. The following was discussed with the research assistants and demonstrated: treatment of the placebo group included fitting a reflective cap on the shockwave applicator. The treatment area was localized by a clinical focusing method in which, through palpation, the shockwaves were administered to the most painful area with verbal feedback from the patient. The dosage of radial shockwave followed the protocol of the Klimatur shockwave therapy device. The setting on the machine was: epicondylitis humeri radialis (ECRL, ECRB and EDC). The dosage parameters were 2 000 shots, 45% pressure and a frequency of 8HZ (8 shots per second). The low energy RSW was done without local anaesthetic. The participants received three treatments in total; one treatment per week, for three consecutive weeks. The treatments consisted of radial shockwave or placebo treatment, as well as an eccentric exercise program (see appendix 8) that included stretching of the wrist extensors with a straight elbow, resisted eccentric wrist extension with a theraband, and resisted eccentric wrist pronation with a theraband. The research assistants advised the participants of both the groups to avoid pain provoking activities. Radial shockwave was the intervention tested in conjunction with eccentric exercises, as it is considered the best long-term solution for LET. Eccentric exercise was added to the radial shockwave treatment to find the best treatment option for LET, and to give participants some form of treatment if they received placebo treatment. All outcomes measures were retested one-week post treatment, as well as three month's post treatment. The researcher captured and analysed the data post-intervention.

3.8 DATA ANALYSIS

The outcomes measures used for data collection were: VAS - Thomsen, VAS – SF - MPQ, Quick-DASH and Jamar dynamometer.

The types of data collected from these outcomes measures were categorical with a nominal scale of measure (gender, arm dominance, smoking, effect of work and sport on upper limb function), and an ordinal scale of measure (McGill total values, Quick-DASH total, Q-DASH work, Q-DASH sport), and categorical with a ratio scale of measure (Thomson's VAS, McGill VAS and grip strength).

The statistical tests that were used for categorical data analysis was the Fisher Exact test (nominal scale) as well as the Mann Whitney U test (ordinal scale). The statistical test used for continuous data was the Mann Whitney U test.

This data was statistically tested and analysed by the researcher with assistance of the second supervisor and statistician, using the Statistica (Version 12) programme. The data was considered as significant if the p values were 0.05 or less. The data was tested for normal distribution. It was taken into consideration that the data was skew and unpaired.

Table 3.1: Data Analysis

Objective	Outcome Measure	Type of data	Statistical test
1.Demographic information	Age	Continuous data	Mann-Whitney U test
	Gender	Categorical data (nominal scale)	Fisher Exact p
	Arm dominance	Categorical data (nominal scale)	Fisher Exact p
	Smoking	Categorical data (nominal scale)	Fisher Exact p
	Effect of work and sport on upper limb function	Categorical data (nominal scale)	Fisher Exact p
2.To compare pain levels between the control and intervention group at baseline, one-week as well as three months' post treatment	Thomson's VAS	Categorical data (ratio scale)	Mann-Whitney U test
	McGill VAS	Categorical data (ratio scale)	Mann-Whitney U test
	McGill Total	Categorical data (ordinal scale)	Mann-Whitney U test
3.To compare grip-strength between the control and intervention group at baseline, one-week as well as three month's post treatment	Grip-strength kg/cm^2	Categorical data (ratio scale)	Mann-Whitney U test
4.To compare upper limb function between the control and intervention group at baseline, one-week as well as three month's post treatment	Q-DASH Total	Categorical data (ordinal scale)	Mann-Whitney U test
	Q-DASH Work	Categorical data (ordinal scale)	Mann-Whitney U test
	Q-DASH Sport	Categorical data (ordinal scale)	Mann-Whitney U test

3.9 ETHICS

Ethical clearance was procured from the Human Research Ethics Committee of the University of the Witwatersrand (appendix 5).

Permission was aquired from the owner/shareholder of Noordheuwel Medical Centre to conduct this research project on the premises (appendix 3).

All patients were treated in accordance with the Declaration of Helsinki (appendix13). The participants received an information form (appendix 1) explaining the procedure, benefits and risks of treatment, and signed a consent form (appendix 2).

The assessment forms were coded according to the computer generated list of numbers. The coded list of names was kept separately from the assessment forms.

Results of the study will be made available to the public through journal publication, and participants will have access to the results on request.

CHAPTER FOUR

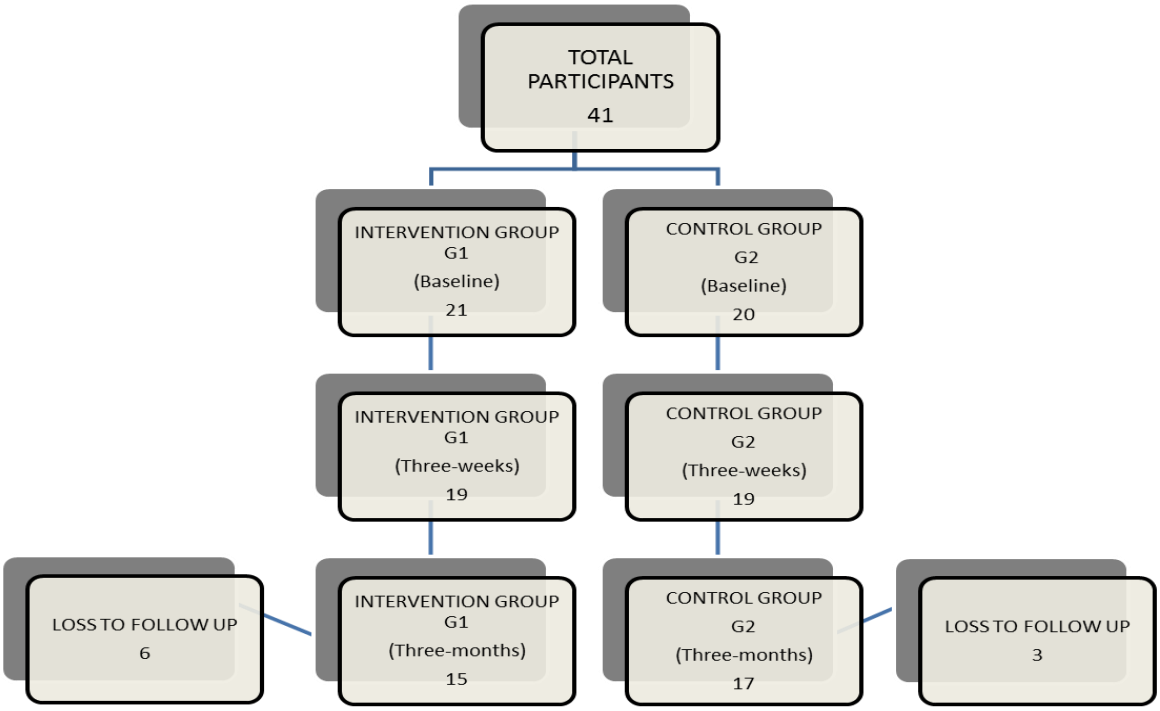
4. RESEARCH RESULTS

4.1 INTRODUCTION

This chapter presents the results as set out by the objectives of the study.

The intervention group is represented as G1, and the control group is represented as G2 for the purposes of this study.

Flow diagram 4.1: Participants



In the Q-DASH Questionnaire there was an optional module for sport and work which the participants completed if it was applicable to them, however the activities of daily living were a compulsory module, which explains the smaller response rate for the optional modules.

4.1.1 Demographic Information

4.1.1.1 Age

Table 4.1 presents the age distribution of the study participants.

Table 4.1: Age Demographics

Age			
	Intervention (n=21)	**Control** (n=20)	**p -value***
Percentile	**Median**		
25th	42.00	46.25	0.61
50th	46.00	49.00	
75th	54.00	60.25	

*p≤0.05 (Mann-Whitney U test)

Table 4.1 above shows that the groups were comparable by age.

4.1.1.2 **Gender, Arm dominance, Smoking distribution, Work and Sport characteristics**

Table 4.2 presents the gender, arm dominance, smoking distribution, work and sport characteristics of the study participants.

Table 4.2: Gender, Arm Dominance, Smoking Distribution, Work and Sport Characteristics

Group	**Frequency (%)**		**p-value***
Gender	**Male**	**Female**	0.22
Intervention (n=21)	13 (31.7%)	8 (19.5%)	
Control (n=20)	8 (19.5%)	12 (29.3%)	
Arm dominance	**Dominant arm**	**Non-Dominant arm**	1.00
Intervention (n=21)	14 (34.1%)	7 (17%)	
Control (n=20)	13 (31.71%)	7 (17.1%)	
Smoking	**Smoking**	**Non-Smoking**	0.66
Intervention (n=21)	2 (4.9%)	19 (46.3%)	
Control (n=20)	3 (7.3%)	17 (41.5%)	
	Work affects upper limb function	**Work does NOT affect upper limb function**	
Intervention (n=21)	14 (34.1%)	7 (17.1%)	**3.5**
Control (n=20)	10 (24.4%)	10 (24.4%)	
	Sport affects upper limb function	**Sport does NOT affect upper limb function**	
Intervention (n=21)	12 (29.3%)	9 (22.0%)	**1.00**
Control (n=20)	12 (29.3%)	8(19.5%)	

***p≤0.05 (Fisher exact p)**

Table 4.2 above reports on the demographic information of the participants. Participants also reported on the effect that sport and their occupation had on upper limb function.

In Table 4.2 above no statistical significance was found between the aforementioned groups, thus the type of work that the participants were doing did not affect their upper limb function in the presence of chronic lateral elbow tendinopathy. No statistical significance was found for the intervention and control group for the sport, thus upper limb function during sporting activities was not affected by LET.

4.1.2 **Pain Levels**

The first objective of the study was to compare pain levels of the intervention and control group at baseline, one week, as well as three months' post treatment in patients with chronic lateral elbow tendinopathy.

The pain outcomes used in this study were:

- The Thomsen VAS scale.
- The McGill Pain Questionnaire VAS scale.
- The McGill Questionnaire-total score (refer to section 3.6)

4.1.2.1 **Pain levels: Thomsen provocation test (VAS scale)**

Table 4.3 presents the pain levels of the study participants measured with the Thomsen provocation test (VAS scale).

Table 4.3 Pain Levels: Thomsen Provocation Test (VAS Scale)

Thomsen VAS Scale						
Percentile	**Median**					
	Baseline		**One week post treatment**		**Three months post treatment**	
	Intervention (n=21)	**Control** (n=20)	**Intervention** (n=19)	**Control** (n=19)	**Intervention** (n=15)	**Control** (n=17)
25th	3.00	2.5	1.00	2.00	0.00	0.00
50th	5.00	5.00	2.00	4.00	1.00	0.00
75th	7.00	6.5	4.00	5.00	2.00	2.00
p-value*	0.86		0.15		0.77	

*p≤0.05 (Mann-Whitney U test)

In Table 4.3 above no statistical difference was found between the intervention and control group using the Thomsen provocation test VAS scale.

4.1.2.2 **Pain levels: McGill Pain Questionnaire (VAS scale)**

Table 4.4 presents pain levels of the study participants measured with the McGill Pain Questionnaire (VAS scale).

Table 4.4: Pain Levels: McGill Pain Questionnaire (VAS Scale)

McGill VAS Scale						
Percentile	**Median**					
	Baseline		**One-week post treatment**		**Three months' post treatment**	
	Intervention (n=21)	**Control** (n=20)	**Intervention** (n=19)	**Control** (n=19)	**Intervention** (n=15)	**Control** (n=17)
25th	3.0	3.5	1.0	1.0	0.0	0.0
50th	4.0	5.0	2.0	2.0	1.0	1.0
75th	6.0	6.0	3.0	4.0	2.0	2.0
p-value*	0.38		0.18		0.53	

*p≤0.05 (Mann-Whitney U test)

In Table 4.4 above no statistical difference was found between the intervention and control group using the McGill Pain Questionnaire (VAS scale).

4.1.2.3 **Pain levels: McGill Pain questionnaire (total score)**

Table 4.5 presents the pain levels of the study participants, measured with the McGill Pain Questionnaire (total score).

Table 4.5: Pain Levels: McGill Pain Questionnaire (Total Score)

McGill Total Score						
Percentile	**Median**					
	Baseline		**One-week post treatment**		**Three months' post treatment**	
	Intervention (n=21)	**Control** (n=20)	**Intervention** (n=19)	**Control** (n=19)	**Intervention** (n=15)	**Control** (n=17)
25th	6.0	5.5	2.0	3.0	0.0	0.0
50th	12.0	9.0	4.0	9.0	1.0	2.0
75th	19.0	19.5	7.0	16.0	4.0	6.0

p-value*	0.83	0.12	0.94

*p≤0.05 (Mann-Whitney U test)

In Table 4.5 above no statistical difference was found between the intervention and control group using the McGill Pain Questionnaire (Total Score).

4.1.3 Grip Strength

The second objective of the study was to compare grip strength between the intervention and control group at baseline, one week, as well as three months' post treatment in patients with chronic lateral elbow tendinopathy.

Table 4.6 presents grip strength of the study participants measured with a dynamometer.

Table 4.6: Grip Strength Measured in Kg/cm^2

Grip Strength						
Percentile	**Median**					
	Baseline		**One-week post treatment**		**Three months' post-treatment**	
	Intervention (n=21)	**Control** (n=20)	**Intervention** (n=19)	**Control** (n=19)	**Intervention** (n=15)	**Control** (n=17)
25th	21.0	19.5	25.0	21.0	28.0	26.0
50th	31.0	24.0	45.0	26.0	47.0	32.0
75th	47.0	45.5	52.0	45.0	55.0	49.0
p-value*	0.466		0.57		0.33	

*p≤0.05 (Mann-Whitney U test)

In Table 4.6 above no statistical difference was found between the intervention and control group for grip strength.

4.1.4 Upper Limb Function

The third objective of the study was to compare upper limb function between the intervention and control group at baseline, one week, as well as three months' post treatment in patients with chronic LET.

The upper limb function outcome measures used in this study were:

- The Quick-DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire-activities of daily living module, (as referred to in section 3.6).

- The Quick-DASH questionnaire, work-module.
- The Quick-DASH questionnaire, sport-module.

4.1.4.1 The Quick-DASH Questionnaire (A.D.L) activities of daily living module

Table 4.7 presents upper limb function of the study participants measured with the Quick-DASH questionnaire.

Table 4.7: Upper Limb Function Measured with the Quick-DASH Questionnaire (A.D.L) Activities of Daily Living Module

Q-DASH Total						
Percentile	**Median**					
	Baseline		**One-week post treatment**		**Three months' post treatment**	
	Intervention (n=21)	**Control** (n=20)	**Intervention** (n=19)	**Control** (n=19)	**Intervention** (n=15)	**Control** (n=17)
25th	27.0	45.0	9.0	14.0	0.0	2.0
50th	39.0	52.5	16.0	34.0	5.0	16.0
75th	48.0	59.5	30.0	41.0	16.0	23.0
***p-value**	**0.02**		0.12		0.166	

*p≤0.05 (Mann-Whitney u test)

In Table 4.7 upper limb function scores at baseline had better values for the intervention group compared to the control group. However, there was no statistical difference found in the Q-DASH total between the intervention and control group at one week and three months' post treatment, thus the intervention did not affect upper limb function.

4.1.4.2 The Quick-DASH Questionnaire, work-module

Table 4.8 presents upper limb function of the study participants measured with the Quick-DASH questionnaire work-module.

Table 4.8: Upper Limb Function Measured with the Quick-DASH Questionnaire Work Module

Q-DASH Work Module						
Percentile	**Median**					
	Baseline		**One-week post treatment**		**Three months' post-treatment**	
	Intervention (n=20)	**Control** (n=19)	**Intervention** (n=19)	**Control** (n=19)	**Intervention** (n=15)	**Control** (n=17)
25th	22.0	25.0	0.00	0.00	0.0	0.0
50th	38.0	38.0	6.0	25.0	0.0	0.0
75th	53.0	56.0	31.0	44.0	25.0	25.0
***p-value**	0.77		0.70		1.00	

*p≤0.05 (Mann-Whitney U test)

In Table 4.8 above there was no statistical difference found between the intervention and control group for the Q-DASH work module.

4.1.4.3 The Quick-DASH Questionnaire, sport-module

Table 4.9 presents upper limb function measured with the Quick-DASH questionnaire sport- module for the study participants.

Table 4.9: Upper Limb Function Measured with the Q-DASH Questionnaire Sport-Module

Q-DASH Sport-Module						
Percentile	**Median**					
	Baseline		**One-week post treatment**		**Three months' post - treatment**	
	Intervention (n=12)	**Control** (n=12)	**Intervention** (n=10)	**Control** (n=10)	**Intervention** (n=10)	**Control** (n=12)
25th	25.0	37.5	0.0	0.00	0.0	0.0
50th	40.5	75.0	25.0	25.0	0.0	25.0
75th	84.5	75.0	38.0	38.0	25.0	28.0
***p-value**	0.48		0.91		0.08	

*p≤0.05 (Mann-Whitney U test)

In Table 4.9 above there was no statistical difference found for the intervention and control group for the Q-Dash sport-module, thus upper limb function during sporting activities was not affected by treatment of LET.

4.1.5 **Conclusion**

The intervention did not have any effect on the pain experienced by the participants; their grip strength nor their upper limb function due to the insignificant findings yielded from this study.

Albeit this overarching finding, there were some changes seen in pain levels experienced, grip strength and function in the intervention and control groups, post intervention.

CHAPTER FIVE

5. DISCUSSION

5.1 INTRODUCTION

The primary aim of this study was to determine the effects of radial shockwave therapy in the treatment of chronic lateral elbow tendinopathy. A non-randomised controlled trial was conducted for this purpose, consisting of an intervention and control group, comparing radial shockwave treatment to placebo treatment. This chapter serves to discuss the results of this study.

Lateral elbow tendinopathy is a chronic musculoskeletal condition causing significant pain, disability and loss of productivity in the work place (Janikowska and Chomiuk, 2013). This condition is easy to diagnose, but difficult to treat. There is no single intervention that has been proven to effectively manage this condition. This motivates further research with well-designed clinical trials. The research hypothesis of this clinical trial states that there will be a significant improvement in pain, grip strength and upper limb function in patients with chronic LET treated with radial shockwave treatment, compared to patients receiving placebo treatment and vice - versa for the null hypothesis. Chronic LET can be defined as lateral elbow tendinopathy persisting for three months and longer. In this study the period that participants had chronic LET ranged from three months to ten years.

5.2 DEMOGRAPHIC INFORMATION

5.2.1 Age

The age group presenting with chronic LET is middle aged individuals largely in their forties and fifties, with the highest occurrence of those aged between 45 -54 years. Studies conducted by Longo et al., (2012) as well as McMurtrie and Watts, (2012) showed the same findings regarding age distribution. In this clinical trial the age of the participants was within these parameters.

5.2.2 Gender

Gender does not play a role in the presence of chronic LET as there is an equal distribution between men and women. This was confirmed in studies by Longo et al., (2012) and McMurtrie and Watts, (2012). In this clinical trial there was an equal gender distribution between male and female participants.

5.2.3 **Arm Dominance**

Although there was no significance found when comparing the groups for arm dominance, there was a higher occurrence for dominant arm involvement in this study, confirming the literature findings that arm dominance does affect the presence of chronic LET, and is more commonly seen in the dominant arm (Calfee et al., 2008; Longo et al., 2012).

5.2.4 **Smoking**

There is some controversy in the literature concerning the effects of tobacco smoking on chronic LET. In a population study conducted by Shiri et al., *(*2006) consisting of 4 783 participants, an association was found between tobacco smoking and LET. Tichener et al., (2013) also found that tobacco smoking could be associated with LET. Smoking could hinder the circulation to tendons, which not only predisposes these at risk tissues to injury but also slows or prevents their healing during the recovery period. Ex-smokers are also at higher risk of LET suggesting that previous exposure to tobacco may have damaging effects on the vascular system (Shiri et al., 2006). Increased risk of LET among smokers may also be due to other lifestyle factors associated with smoking, such as an inactive lifestyle. However, according to Walker-Bone et al., (2012) tobacco smoking was not an associated risk factor for lateral elbow tendinopathy. Smoking was not an associated risk factor that could be considered to contribute to the presence of LET in this study, as the majority of participants were non-smokers.

To summarize the demographic information, chronic lateral elbow tendinopathy is common amongst middle-aged individuals, ages ranging between 45 - 54 with men and women being equally affected. The dominant arm is more commonly involved. A clear conclusion cannot be made on the effects of smoking on LET from this clinical trial.

5.3 **OUTCOMES MEASURES**

In some studies, radial shockwave treatment is no more effective than placebo in relieving pain, improving grip strength and upper limb function, such as a study conducted by Chung, Wiley et al., (2005) consisting of sixty participants. The results of their study did not support the efficacy of shockwave treatment combined with a stretching programme. A study that had a similar outcome was conducted by Melikyan et al., (2003), with the following outcomes measures: VAS, grip strength

and the DASH questionnaire, and the results of their study concluded that all patients improved significantly over time, regardless if they were in the shockwave or control group.

Similar results to the current study was obtained by Staples et al., (2008) where they conducted a double-blinded RCT on 68 patients to determine whether ultrasound - guided ESWT (in this study radial shockwave guided by clinical focusing was used), decreased pain and improved function in patients with LET. The outcomes measures used were the VAS- scale for pain, DASH-Questionnaire for upper limb function as well as maximal pain-free grip strength using a Jamar dynamometer which correlates to the outcomes measures used in this study. At baseline the treatment groups did not differ on demographic or clinical characteristics. Both groups showed an improvement in almost all the outcome measures, but there were no differences between the groups indicating that the benefit of ESWT is likely to be small. However clinically there was no significance, and it may require a very large sample to demonstrate an effect. The methodology, outcomes measures, results and recommendation of Staples et al., (2008) is similar to this clinical trial.

5.3.1 **Pain Levels**

Some of literature has shown that shockwave treatment is not more effective than placebo or other treatments for relieving pain in LET (Bisset and Vicenzino, 2015; Weber et al., 2015). The results of nine placebo-controlled trials (1006 participants), in a 2005 Cochrane review by Buchbinder et al., concluded that shockwave treatment is not effective in reducing pain levels in LET. Data from the Cochrane review as well as a study by Staples et al., (2008) found that compared with placebo, shockwave treatment induced no greater pain relief (MD - 8, 95% CI -17 to 3) at six weeks. Similarly, the mean difference for pain on resisted wrist extension (Thomsen provocation test) at four to six weeks' follow-up was not significantly different between shockwave treatment and placebo (MD - 15, 95% CI - 36 to 6). This finding is supported by results of this study: there was no statistical difference found when pain levels were compared using the Thomsens' provocation test, and the McGill pain Questionnaire - short form (MPQ - SF) (see page 60 results section). There are similar studies with positive pain outcomes when comparing shockwave treatment to placebo such as studies conducted by Rompe et al., (2004) as well Pettrone and McCall, (2005). Two other studies that also concluded that shockwave was an effective treatment to reduce pain in LET was a study by Radwan et al., (2008) where they compared a single high - energy ESWT treatment to percutaneous tenotomy, as

well as a study conducted by Collins, Hildreth and Jafarnia, (2011) where they compared a single high-energy shockwave treatment to placebo. These two studies both used high-energy shockwave that is a different type and dosage to radial shockwave which is low-energy shockwave. There are contradicting results in the literature for the efficacy of shockwave treatment for chronic LET, thus optimal treatment parameters have not been established for the symptomatic relief of pain.

No statistical change was observed in this study in pain outcomes with all measures used, whilst pain levels decreased in general when comparing one-week post treatment to three months' post - treatment for both of the aforementioned outcomes measures as seen from the medians (tables 4.5-4.7). The null hypothesis was retained as these results were statistically insignificant. The intervention failed to significantly improve pain levels for both outcomes measures when compared to the control group.

The most likely explanation of the improvements in both groups is the natural progression of the condition, whereby most patients with LET recover within one to two years irrespective of the treatment administered (De Smedt et al., 2007; Staples et al.,2008; Longo et al., 2012).

The improvement in pain levels of the intervention and control group could be due to the "Hawthorne effect" which is the tendency of persons (the study participants) who are singled out for special attention (the shockwave or placebo treatment) to perform better (have better outcomes), (Portney and Watkins, 2009).

The insignificant improvement in pain levels of the intervention group compared to the control group could be due to a sub-optimal dosage received by the intervention group because of the painful effect of the shockwave treatment on participants. The applicator of the radial shockwave had to be moved around the painful area as some of the participants could not tolerate the full dosage of treatment using the clinical focusing method. The control group could possibly have had a trigger point effect of the reflective-cap that was fitted to the applicator tip due to the pressure applied to the painful area by the research assistants.

The patient's pain relief could be due to a combination of the treatment (intervention) specific agents as well as non-treatment specific agents such as spontaneous remission, conditioning, motivation, expectancy and other psychosocial agents

(Weber et al., 2015). The therapeutic outcome of any medical treatment is influenced by the surrounding psychosocial context. When a sham treatment (the placebo) is given, the patient believes it is effective and expects a clinical improvement. The placebo effect, or response, is the outcome after the sham treatment. The placebo effect is a psychobiological phenomenon that can be due to different mechanisms, including pavlovian conditioning as well as the expectation of clinical improvement (Benedetti et al., 2005).

The placebo response or effect has often not been taken into consideration in basic research and particularly in clinical research (Enck, Benedetti and Schedlowski, 2008). Scientific evidence has demonstrated however, that the placebo effect originates from highly active processes in the brain that are mediated by psychological mechanisms such as expectation of clinical improvement, and pavlovian conditioning (Benedetti et al., 2005). When an interaction (e.g., positive verbal suggestion by the therapist) creates the possibility of a reward (the therapeutic benefit of radial shockwave) certain cortical neurons become active. These cells send direct excitatory glutamatergic inputs to dopaminergic cell bodies along with indirect inhibitory gamma amino butyric acid input. The combination of these signals arriving at the dopaminergic neurons via direct and indirect pathways contributes to the probability of tonic activation (Enck, Benedetti and Schedlowski, 2008). Furthermore, during the expectation of reward it has been reported that neurons in the prefrontal cortex, nucleus accumbens, and the caudate-putamen display tonic activation. This strongly suggests that placebo responsiveness depends on the functioning and efficiency of the reward system, and this could explain why some individuals respond to placebos whereas others do not. Those who have a more efficient dopaminergic reward system would also be good placebo responders.

The design of clinical trials in which treatment is tested against a placebo will be affected by the growing knowledge on the neurobiology of the placebo response. Researchers need to consider the significance of the placebo effect in clinical trials as it could have an effect on the significance of outcomes measures (Enck, Benedetti and Schedlowski, 2008).

5.3.2 **Grip Strength**

Both groups had an improvement in grip strength values and thus improvement in muscle strength from baseline to one week and three months' post treatment (table 4.6). Although the intervention group had greater improvement in grip strength than

the control group at one week and three months' follow up, grip strength for both groups did not yield a statistical significance indicating that the null-hypothesis was accepted.

Literature confirming the results of this study for grip strength using a dynamometer includes the study of Melikyan et al., (2003). Their conclusion was that all patients' grip strength improved over time, regardless of treatment. Chung et al., (2005) indicated in their study that the use of ESWT combined with a stretching programme was not effective for the improvement of grip strength in LET patients, and improvement in grip strength could occur over time. Staples et al., (2008) concluded that their study did not find enough proof to support the use of ESWT to improve grip strength in LET patients, but it was rather due to the self-limiting nature of the condition that grip strength improved over time. These results confirmed that shockwave therapy did not have a positive effect on grip strength. However, a study by Pettrone and McCall, (2005) yielded an improvement in grip strength. Their study concluded that low-dose shockwave therapy was effective for LET thus improving muscle strength. This study like the other study's also used a dynamometer to measure grip strength. The difference however was the positioning of the participant when the measurements were done. The current study included radial shockwave treatment as well as an eccentric exercise programme, whereas the other studies consisted of extracorporeal shockwave treatment only. The one study that included a stretching programme was the study undertaken by Chung et al., (2005). The majority of the aforementioned studies concluded that outcomes measures of LET such as grip strength improved over time irrespective of the treatment.

Both groups received an eccentric exercise programme including a stretch of the wrist extensors with a straight elbow, eccentric wrist extensor and pronation strengthening with a theraband (appendix 8) that could have contributed to the improvement in grip strength. In a review conducted by Raman et al., in (2012) their conclusion was that patients with LET who performed isotonic, eccentric, concentric, isometric, or isokinetic strengthening exercises could all have improvement in pain, grip strength, and disability over time. The pain free grip strength could thus also have improved due to the decline in pain levels of both the groups, the positive changes could have been brought about by the eccentric strengthening of the tendon; and improvement over time due to the natural progression of LET.

5.3.3 **Upper Limb Function**

Upper limb function was measured using the Quick-DASH questionnaire, the questionnaire comprises of three modules, the activities of daily living (A.D.L) module (compulsory module), work module (optional module), as well as the sport module (optional module).

5.3.3.1 **Activities of daily living module (Q - DASH)**

There was a statistical difference for the Q-DASH total at baseline with the intervention group being more functional than the control group. Although there was a significant statistical difference at baseline, the results were insignificant for the Q-DASH total after the intervention; both groups had an improvement in their daily function irrespective of the treatment they received.

These results correlated with studies done by Melikyan et al., (2003) and Staples et al., (2008) where they both concluded that ESWT was not effective in the treatment of LET (using the Q-DASH as outcome measure), however Collins, Hildreth and Jafarna, (2011) found that a single ESWT treatment was effective for chronic LET (using the SF-Health Survey Questionnaire to determine upper limb function). The improvement of upper limb function in the intervention and control group could be due to the same advice given to both groups by the treating physiotherapist, they were advised to modify their daily activities, to do less repetitive and loading activities, and to rest the affected upper limb. The natural healing process of LET could also have brought about change in the intervention and control group over time in terms of daily function.

5.3.3.2 **Work Characteristics**

Although the groups were evenly matched, the frequency where work affected upper limb function was slightly higher (58.8%) compared to frequency where work did not affect upper limb function (41.5%), but the difference was not significant (table 4.2).

The frequency of heavy duty work done by the participants in the intervention group was (24%) whereas the frequency of heavy duty work done by the control group was (5%). The frequency of light duty work done by the participants in the intervention group was (76%) whereas the frequency of light duty work done by the participants in the control group was (95%) as per appendix 14.

Shiri and Viikari-Juntura, (2011) stated that the prevalence for LET varies between 0.3% and 13.5% in working populations which is higher than the prevalence of 1.3%

in the general population. Chronic lateral elbow tendinopathy has a substantial impact in the workplace, (Longo et al., 2012), and is most common in manually intensive occupations such as butchers, meat cutters, construction workers and automobile assembly workers (Walker-Bone, 2012). Productivity loss has been reported by inflicted workers with the length of sick leave due to LET being nearly two weeks (Shiri and Viikari-Juntura, 2011). Absenteeism in the working population (aged 25 - 64) due to LET in the United Kingdom alone is estimated to cost £27 million per year using the 2012 global population statistics and median wage (Hopkins et al., 2016). Repeated medical visits are also costly as LET is recurrent (Hopkins et al., 2016). Chronic lateral elbow tendinopathy can cause job changing in manually strenuous jobs (Shiri and Viikari-Juntura, 2011).

Although the literature states that there is a significant relationship between physical work and LET (Walker-Bone et al*.,* 2012), in this study the participants' work did not have a statistically significant impact on LET which could possibly be due to the type of occupations of the participants', as well as the limited amount of study participants.

5.3.3.3 **Work-module (Q - DASH)**

At baseline and three months' post treatment both groups had the same scores for upper limb function. There was a more noticeable improvement in upper limb function in the intervention group compared to the control group one-week post treatment (table 4.8). However, no statistical significance was found indicating that the null - hypothesis was accepted.

The literature states that manually intensive occupations could have statistically significant impact on LET (Walker-Bone et al., 2012).

5.3.3.4 **Sport Characteristics**

There was no statistical significance found between the intervention group and control group for sport characteristics, the groups were evenly matched (table 4.2).

In this clinical trial 62% of participants in the intervention group participated in sport, whereas 50% of the participants in the control group participated in sport. Gym was the sport most of the participants participated in, with 15% of participants in the intervention group and 50% in the control group. However, there were less participants participating in golf, tennis, squash and table tennis, with 15% of

participants in the intervention group and 10% in the control group participating in these sports (appendix 15).

Literature however indicates that chronic lateral elbow tendinopathy has a substantial impact on athletes (Longo et al., 2012). In a review by Abrams, Renstrom and Safran, *(*2012) on the epidemiology of musculoskeletal injury in the tennis player it was found that lateral elbow tendinopathy is one of the most common overuse injuries in tennis, particularly in the recreational tennis player, they reported that the overall prevalence of lateral elbow tendinopathy was between 35%-51% which is much higher than the 1.3% found in the general population.

5.3.3.5 **Sport-Module (Q-DASH)**

The intervention group had better function at baseline and three month's post treatment. Both groups had improvement in upper limb function during sport activity when comparing baseline to three months' post treatment (table 4.9), however there was no statistical significant difference found between the intervention and control group. The sport - module of the Q-DASH had a lower response rate as it was an optional module, and many participants of this study did not complete this optional module (refer to appendix 15 where 18 of the 41 participants did not complete the module). This could possibly explain the aforementioned results.

5.4 **CONCLUSION**

This study was thus unable to prove the efficacy of radial shockwave treatment with regards to pain, grip strength and upper limb function. This finding is supported by numerous studies as outlined in the discussion.

CHAPTER SIX

6.1 CONCLUSION

The limitations of the study, implications for future research as well as the clinical implications will be discussed briefly in this conclusive chapter.

The intervention group presented similarly to the control group. The research hypothesis was thus rejected in this study stating that there will not be a significant improvement in upper limb function, grip strength and pain in patients with chronic lateral elbow tendinopathy treated with radial shockwave treatment, compared to patients receiving placebo treatment.

There is insufficient evidence regarding the long-term effects of radial shockwave treatment. Patient selection criteria (inclusion and exclusion criteria) have not been adequately defined. Optimal treatment parameters (type of shockwave, application methods used, dosage-intensity, specifications of apparatus, focal energy, treatment frequency, localisation methods and combination of therapies) have not been established either.

6.2 LIMITATIONS OF THE STUDY

There are notable limitations to this study such as the small sample size. Over a period of two years 41 participants with lateral elbow tendinopathy were recruited to participate in this clinical study. The calculated sample size for this study was 70 but due to the difficulty and slow recruitment numbers over two years it was decided to halt recruitment after two years of data collection. The small sample size could explain the lack of statistical significance.

The “long term” follow-up period after the radial shockwave treatment could possibly have been extended from three to twelve months to determine the long-term effect of the intervention on LET. This would thus make provision for the natural progression of the condition which could be more significant at twelve months, than at three months follow up.

Although this study was conducted based on the best practise guidelines found in the literature, optimal (patient-specific) treatment parameters were not established. The causes and duration of LET also need to be considered as it could determine the treatment dosage and outcomes.

6.3 IMPLICATIONS FOR FUTURE RESEARCH

A consistent effective radial shockwave treatment protocol for chronic LET with clearly defined variables needs to be researched. There are many variables affecting the protocol of shockwave treatment such as the type of intervention (type of shockwave and exact dosage), outcomes measures (validity and reliability), selection criteria for participants (inclusion and exclusion criteria), and the length of time for follow-up evaluation (long-term follow up could be extended to one year after the intervention). Larger, well designed RCT's need to be conducted in order to evaluate best treatment practises and protocols of radial shockwave treatment for patients with chronic lateral elbow tendinopathy.

6.4 CLINICAL IMPLICATIONS

Until clear treatment guidelines of radial shockwave therapy are established, the use of radial shockwave treatment in the management of LET is not recommended.

CHAPTER 7

7 **REFERENCES**

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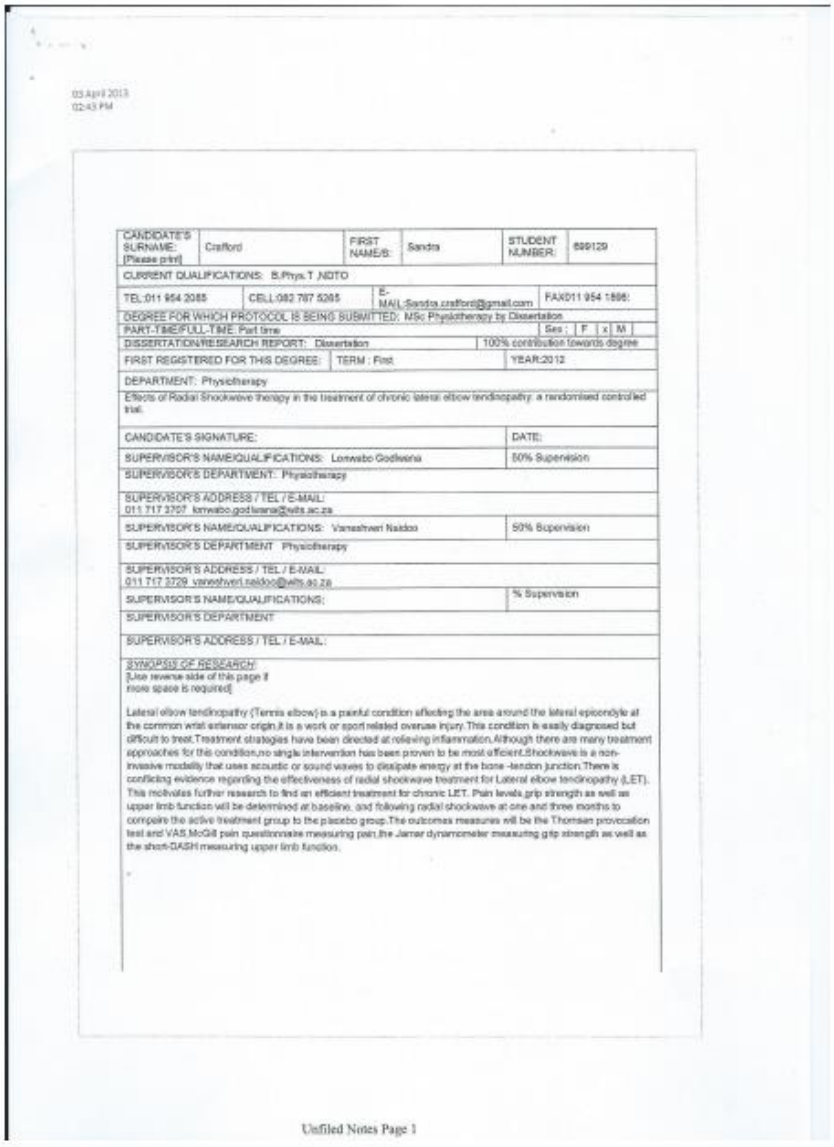
APPENDIX A

- **PROTOCOL COVER**



03 April 2013
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CANDIDATE'S SURNAME: [Please print]	Crafford	FIRST NAME/S:	Sandra	STUDENT NUMBER:	699129
CURRENT QUALIFICATIONS: B.Phys.T ,NDTO					
TEL:011 954 2085	CELL:082 787 5265	E-MAIL:Sandra.crafford@gmail.com		FAX011 954 1898:	
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: MSc Physiotherapy by Dissertation					
PART-TIME/FULL-TIME: Part time				Sex : F x M	
DISSERTATION/RESEARCH REPORT: Dissertation				100% contribution towards degree	
FIRST REGISTERED FOR THIS DEGREE:	TERM : First			YEAR:2012	
DEPARTMENT: Physiotherapy					
Effects of Radial Shockwave therapy in the treatment of chronic lateral elbow tendinopathy: a randomised controlled trial.					
CANDIDATE'S SIGNATURE:				DATE:	
SUPERVISOR'S NAME/QUALIFICATIONS: Lonwabo Godlwana				50% Supervision	
SUPERVISOR'S DEPARTMENT: Physiotherapy					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: 011 717 3707 lonwabo.godlwana@wits.ac.za					
SUPERVISOR'S NAME/QUALIFICATIONS: Vaneshveri Naidoo				50% Supervision	
SUPERVISOR'S DEPARTMENT Physiotherapy					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: 011 717 3728 vaneshveri.naidoo@wits.ac.za					
SUPERVISOR'S NAME/QUALIFICATIONS:				% Supervision	
SUPERVISOR'S DEPARTMENT:					
SUPERVISOR'S ADDRESS / TEL / E-MAIL:					

SYNOPSIS OF RESEARCH:
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Lateral elbow tendinopathy (Tennis elbow) is a painful condition affecting the area around the lateral epicondyle at the common wrist extensor origin.It is a work or sport related overuse injury.This condition is easily diagnosed but difficult to treat.Treatment strategies have been directed at relieving inflammation.Although there are many treatment approaches for this condition,no single intervention has been proven to be most efficient.Shockwave is a non-invasive modality that uses acoustic or sound waves to dissipate energy at the bone -tendon junction.There is conflicting evidence regarding the effectiveness of radial shockwave treatment for Lateral elbow tendinopathy (LET). This motivates further research to find an efficient treatment for chronic LET. Pain levels,grip strength as well as upper limb function will be determined at baseline, and following radial shockwave at one and three months to compare the active treatment group to the placebo group.The outcomes measures will be the Thomsen provocation test and VAS,McGill pain questionnaire measuring pain,the Jamar dynamometer measuring grip strength as well as the short-DASH measuring upper limb function.

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APPENDIX B

- **PLAGIARISM DECLARATION**

Postgraduate Office, Faculty of Health Sciences
Wits Medical School, 7 York Road, PARKTOWN, 2193, Johannesburg • Tel: (011) 717 2745 • Fax: (011) 717 2119 • e-mail: healthpg@health.wits.ac.za

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I SANDRA CRAFFORD (Student number: 699129) am a student registered for the degree of MSC PHYSIOTHERAPY in the academic year 2013.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this in not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: Crafford Date: 2013/04/03

APPENDIX 1

- **INFORMATION DOCUMENT**

Shockwave therapy in the treatment of chronic tennis elbow

Good day

We, Sandra Crafford and colleagues, are doing research on chronic tennis elbow. Research is just the process that we use to find the answer to a question. In this study we want to find out if shockwave therapy will be effective in treating chronic tennis elbow. It is an alternative treatment where the usual treatment (medication, physiotherapy and injections) has not been helpful, and to avoid surgery we offer this as an alternative conservative physiotherapy treatment.

In this study there are two groups, one group receiving shockwave treatment and the other group receiving sham treatment. Each patient will be evaluated by filling in questionnaires about the amount of pain when using the arm, and the functioning of the arm. By palpating, (feeling on the painful area), testing the grip strength with a measuring instrument and then to rate the pain on a scale of 1-10. Each patient will have three treatments once a week. An evaluation and treatment should take no longer than half an hour. After the three treatments the patients will be followed up at one week and three months after the last treatment. All patients will receive an exercise programme to do at home.

In this treatment shockwaves are passed through the skin to the affected area (elbow). The possible side - effects involved with this treatment could be local pain and discomfort, bruising and reddening of the skin as well as swelling of the treatment area; if any side - effects should occur they won't last long.

The benefits of participating in this study is that, it is an alternative treatment to the previous treatment received (physiotherapy, splints, medication including tablets and injections) which didn't relieve the symptoms, and the treatment is free of charge if you should decide to participate in this study.

You as the patient have already received abovementioned routine treatment and could wait and see if the symptoms improve or can consider surgery. If you decide to take part in this study, you will not lose any benefits or be penalised in any way. You may withdraw consent to this study at any time. Every effort will be made to keep personal information confidential,

absolute confidentiality cannot be guaranteed as, personal information may be disclosed if required by law.

The research ethics committee and the medicines control council may inspect or copy the research records for quality control. The results may be published and that may lead to individual or group identification.

Contact details of researcher: Sandra Crafford – 082 787 5265
For further information, or reporting of study - related adverse effects.
Contact details of REC administrator: Ms Anisa Keshav – (011) 717 1234
REC chairman: Professor P Cleaton-Jones – (011) 717 1234
for reporting of complaints or problems.

APPENDIX 2

- **CONSENT FORM**

I _____ hereby give written consent to participate in the study that Sandra Crafford is doing for her Master's degree in Physiotherapy.

I have read and understand the information document for the study of shockwave therapy in the treatment of chronic tennis elbow, and am aware of risks, benefits, alternative treatment and procedure of this study.

I understand that this study may be terminated by the investigator due to unforeseen circumstances.

I understand that it is within my rights to withdraw from this research, either verbally or in writing without any penalty or loss of benefits to which I am otherwise entitled.

I understand that there are no costs involved for the participants of this study.

_____

Signature

APPENDIX 3

- **PERMISSION FROM OWNER OF CLINIC**



JüRGENS & BOTHA INC.
ALGEMENE PRAKTISYNS/GENERAL PRACTITIONERS

Posbus 84
Paardekraal
1752

Tel: (011) 954-1021
Faks: (011) 954-1054

Written permission from Owner / Shareholder of Clinic

I hereby give permission that Sandra Crafford and Physiotherapists may conduct a research project at the Noordheuwel Medical Centre (70 Shannon Road, Noordheuwel, Krugersdorp).

I am fully informed about the research being done on the effects of Shockwave therapy in the treatment of chronic lateral epicondylitis, and I hereby give my consent that the research project may be done at the abovementioned medial centre.

The patients will be selected by diagnoses of lateral epicondylitis and referred for shockwave therapy.

Kind regards

Dr J. Jurgens

APPENDIX 4

- **QUICK-DASH QUESTIONNAIRE**

THE QuickDASH OUTCOME MEASURE

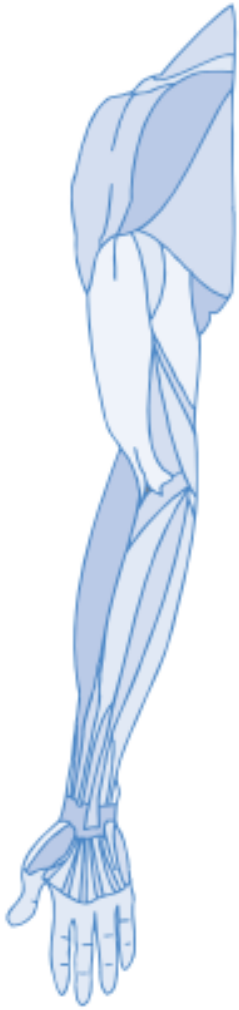
INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.



QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

QuickDASH DISABILITY/SYMPTOM SCORE = $\left(\left[\frac{\text{(sum of n responses)}}{n}\right] - 1\right) \times 25$, where n is equal to the number of completed responses.

A QuickDASH score may not be calculated if there is greater than 1 missing item.

QuickDASH

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

❒ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

❑ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may not be calculated if there are any missing items.

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APPENDIX 5

- **ETHICAL CLEARANCE**

M130517

R14/49 Mrs Sandra Crafford

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130517

NAME: (Principal Investigator)	Mrs Sandra Crafford
DEPARTMENT:	Department of Physiotherapy Medical School
PROJECT TITLE:	Effects of Radial Shockwave Therapy in the Treatment of Chronic Lateral Elbow Tendinopathy: A Randomised Controlled Trial
DATE CONSIDERED:	31/05/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Vaneshveri Naidoo
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 03/07/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate H
University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned res
and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, fro
research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to sub**
yearly progress report.

Principal Investigator Signature

Date 2013/07/20

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 6

- **PROFORMA INVOICES FOR PROJECTED BUDGET**

HITECH THERAPY
Rehabilitation, Exercise & Wellness Products

Unit 52, Northlands Deco Park, New Market Road, Northriding, 2064
P O Box 130299, Bryanston, 2074
sales@htherapy.co.za
www.htherapy.co.za
VAT No. 4060142249 Co. Reg No. 91/07769/23
Telephone +27 11 704 0002 Fax + 27 11 704 4999

PROFORMA INVOICE

CUSTOMER:	CRAFFORD & LANDMAN	**DATE:**	28 MARCH 2013
ADDRESS:	70 SHANNON RD		
ACCOUNT:	NOORDHEUWEL	**INVOICE NO.:**	AL13067
	KRUGERSDORP		
DELIVERY:	DRIVER TO DELIVER	**SALES CODE:**	9

PRODUCT CODE	QTY	DESCRIPTION	PRICE INC VAT	NETT PRICE
0037	1	DYNAMOMETER JAMAR [5030J1]	R4,265.00	R4,265.00
100040	1	DELIVERY FEE	R45.00	R45.00
		8-12 WEEK DELIVERY PERIOD		
		Please send proof to 0866 27 6618 or Alungile@htherapy.co.za		

PLEASE MAKE PAYMENT INTO OUR BANK ACCOUNT		
STANDARD BANK SANDTON BRANCH BRANCH CODE : 019205 ACCOUNT NO : 022688307 SWIFT NO : SBZAZAJJ	**TOTAL EX VAT** **14% VAT** **TOTAL INC VAT**	R 3,780.70 R 529.30 **R4,310.00**

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HITECH THERAPY



PHYSIO AND WELLNESS WAREHOUSE
123 Wekker Street
Moreleta Park, Pretoria
0181

Vat no:
4230258974

P.O Box 50588
Pretoria
0097
Tel: 012 751 8225
Fax: 086 7290423

Quotation

TO: Crafford & Landman FAX NO: 011 954 1898
ATTENTION:
Date: 03/05/2013 REF NO: SANDRA
Dear Thank you for your interest in our products. Herewith the quotation as requested:

Code	Description	Quantity	Unit	Unit Price	Disc%	Tax	Nett Price
MISC	REFILL KIT FOR TUR SHOCKWAVE	1.00	each	3 900.00		14.00%	3 900.00

Signed_____ Date_____

Sub Total		3 421.05
Discount @	0.00%	0.00
Amount Excl Tax		3 421.05
Tax		478.95
Total		3 900.00

Terms and Conditions:

1. Returns will ONLY be accepted within 7 days after delivery. All products must be returned unused and as they were received. Credits will not be passed on delivery fees.
2. All equipment will remain the property of Physio and Wellness Warehouse until it is paid up in full.
3. Consumable orders are to be paid in full within 30 days of delivery date.
4. Interest will be charged on overdue invoices at prime, compiled monthly.
5. No delivery fees will be charged for orders exceeding R1500.00.

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APPENDIX 7

- **MCGILL PAIN QUESTIONNAIRE (MPQ-SF)**

SHORT-FORM McGILL PAIN QUESTIONNAIRE

PATIENT'S NAME_____ DATE

Instructions: Since you have reported that one of your problems is **physical pain**, the purpose of this checklist is for you to give us an idea about what your **physical pain** feels like. Each of the words in the left column describes a quality or characteristic that pain can have. So, for each pain quality in the left column, check the number in that row that tells how much of that specific quality your pain has. Rate every pain quality.

PAIN QUALITY	NONE	MILD	MODERATE	SEVERE
1. Throbbing	(0)_____	(1)_____	(2)_____	(3)_____
2. Shooting	(0)_____	(1)_____	(2)_____	(3)_____
3. Stabbing	(0)_____	(1)_____	(2)_____	(3)_____
4. Sharp	(0)_____	(1)_____	(2)_____	(3)_____
5. Cramping	(0)_____	(1)_____	(2)_____	(3)_____
6. Gnawing	(0)_____	(1)_____	(2)_____	(3)_____
7. Hot-burning	(0)_____	(1)_____	(2)_____	(3)_____
8. Aching	(0)_____	(1)_____	(2)_____	(3)_____
9. Heavy	(0)_____	(1)_____	(2)_____	(3)_____
10. Tender	(0)_____	(1)_____	(2)_____	(3)_____
11. Splitting	(0)_____	(1)_____	(2)_____	(3)_____
12. Tiring-exhausting	(0)_____	(1)_____	(2)_____	(3)_____
13. Sickening	(0)_____	(1)_____	(2)_____	(3)_____
14. Fearful	(0)_____	(1)_____	(2)_____	(3)_____
15. Punishing-cruel	(0)_____	(1)_____	(2)_____	(3)_____

A. PLEASE MAKE AN "X" ON THE LINE BELOW TO SHOW HOW BAD YOUR PAIN IS RIGHT NOW.

NO PAIN |----------| WORST POSSIBLE PAIN

B. PLEASE CHECK THE ONE DESCRIPTOR BELOW THAT BEST DESCRIBES YOUR PRESENT PAIN.

0 NO PAIN _____
1 MILD _____
2 DISCOMFORTING _____
3 DISTRESSING _____
4 HORRIBLE _____
5 EXCRUCIATING _____

C. IS YOUR PAIN ?

(check one word)

_____ Brief
_____ Intermittent
_____ Continuous

Note: Adapted with permission from the "Short Form McGill Pain Questionnaire". Copyright 1987 Ronald Melzack.

S = ___/33 A/E = ___/12

APPENDIX 8

- **ECCENTRIC EXERCISE PROGRAM**

Exercise Program For: Date: 2013/03/31
Tennis Elbow exersices Page: 1



Resist wrist ext eccentrics w/elastic

- Place forearm on table, palm down.
- Attach elastic at floor.
- Grasp elastic in hand.
- Use other hand to raise wrist fully upward.
- Release wrist and slowly lower.
- Repeat.

Perform 3 sets of 15 Repetitions, once a day.

Use Elastic.
Rest 1 Minute between sets.
Perform 1 repetition every 5 Seconds.

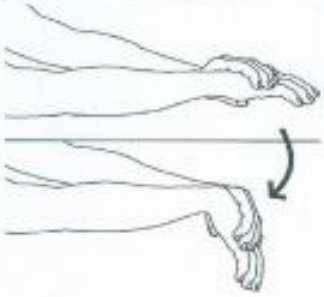
Resist wrist pron w/elastic protocol

- 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.

Perform 3 sets of 15 Repetitions, once a day.

Use green Elastic.
Rest 1 Minute between sets.
Perform 1 repetition every 5 Seconds.





Stretch wrist extensors straight arm protocol

- Begin with elbow straight.
- With other hand, grasp at thumb side of hand and bend wrist downward.
- To increase the stretch, bend wrist toward small finger.

Perform 1 set of 3 Repetitions, once a day.

Hold exercise for 20 Seconds.

Issued By: SANDRA CRAFFORD **Signature:** _____

These exercises are to be used only under the direction of a licensed, qualified professional.
Caution: User must wear suitable eye protection such as safety goggles during this exercise to protect against possibility of eye injury as a result of the band or tube snapping towards the face if grip is lost or if the band or tube breaks.

crafford e landman physiotherapists

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APPENDIX 9

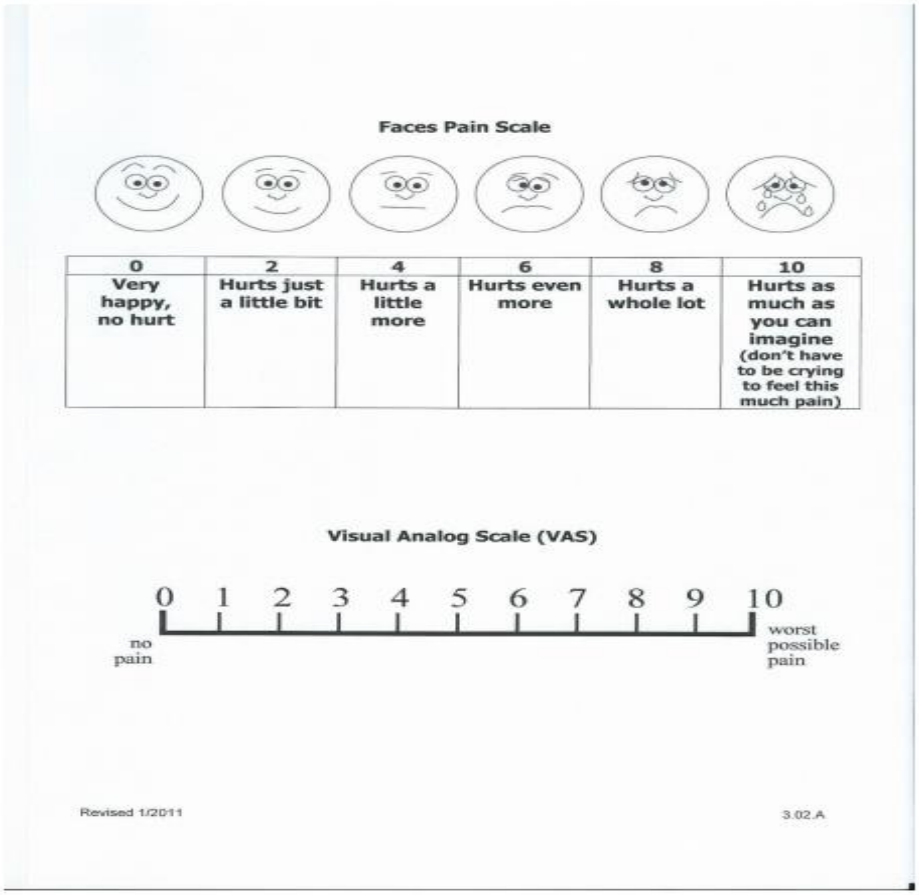
- **SAMPLE SIZE CALCULATION**

ENTER INPUTS HERE … (asterisked items are compulsory)	effect to be detected*:	15
	SD*:	15
	alpha (suggest 5%)*:	5
	power (suggest 80%)*:	90
	non-compliance (%):	15
	dropouts (%):	15
	intraclass correlation co-efficient	0
	mean cluster size	0
	correlation (r) with covariate:	0
ANSWER IS RETURNED HERE …	n (per group):	35
	width of confidence interval:	+/- 4.63

Whitley and Ball (2002)

APPENDIX10

- **THOMSEN VAS - SCALE**



Faces Pain Scale

0	2	4	6	8	10
Very happy, no hurt	Hurts just a little bit	Hurts a little more	Hurts even more	Hurts a whole lot	Hurts as much as you can imagine (don't have to be crying to feel this much pain)

Visual Analog Scale (VAS)

0 1 2 3 4 5 6 7 8 9 10

no pain — worst possible pain

Revised 1/2011 3.02.A

APPENDIX 11

- **TUR KLIMATUR SHOCKWAVE MACHINE AND APPLICATION**





APPENDIX 12

- **JAMAR DYNAMOMETER**



APPENDIX 13

- **DECLARATION OF HELSINKI**

652 Bulletin of the World Health Organization |August 2008, 86 (8)
Special theme – Ethics and public health

Declaration of Helsinki

Recommendations guiding doctors in clinical research
Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964

INTRODUCTION

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration" and the International Code of Medical Ethics declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world.

Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries. In the field of clinical research, a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. BASIC PRINCIPLES

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. CLINICAL RESEARCH COMBINED WITH PROFESSIONAL CARE

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. NON-THERAPEUTIC CLINICAL RESEARCH

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgement, it may, if continued, be harmful to the individual.

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APPENDIX 14

- **LIST OF OCCUPATIONS OF PARTICIPANTS**

1.	Farmer		22.	Admin work
2.	Piano teacher		23.	Computer work
3.	Editor		24.	Credit manager
4.	Machine setter		25.	Housewife
5.	Hairdresser		26.	Accountant
6.	Musician		27.	Sound Engineer
7.	Sales Lady		28.	Supervisor
8.	Table setter		29.	Cricket coach
9.	Office clerk		30.	Teacher
10.	Secretary		31.	Admin work
11.	Consultant		32.	Driver
12.	Housewife		33.	Graphic design
13.	Marketing-Admin		34.	Admin work
14.	IT-Specialist		35.	Electrician
15.	Farmer/Businessmen		36.	Nurse/Training
16.	CEO of company		37.	General manager
17.	Computer work/Admin		38.	Director of company
18.	Housewife		39.	Handy man
19.	Project manager		40.	Owner of company
20.	Customer relations/Admin		41.	Works manager
21.	Supervisor work and maintenance			

Table: Occupations of participants(frequencies)

Occupations of participants (Frequencies)			
Heavy duty		**Light duty**	
Intervention (n=21)	**Control** (n=20)	**Intervention** (n=21)	**Control** (n=20)
5 (24%)	1 (5%)	16 (76%)	19 (95%)

APPENDIX 15

- **LIST OF PARTICIPANTS SPORT**

1.	Enduro riding
2.	Musical instrument-Piano
3.	Gym/Guitar
4.	-
5.	-
6.	Guitar
7.	Bowls
8.	-
9.	Cycling/Swimming
10.	Cake decorating
11.	Cricket
12.	-
13.	Cycling
14.	Golf
15.	Cycling/Cross Fit
16.	Gym
17.	Musical instrument-Piano
18.	Gym
19.	Squash/Gym
20.	-
21.	-
22.	-
23.	-
24.	-
25.	-
26.	-
27.	-
28.	Golf
29.	Cricket
30.	-
31.	-
32.	Gym
33.	Musical instrument-drums
34.	Gym
35.	Swimming
36.	-
37.	Gym
38.	Golf/Tennis/Squash/Cycling
39.	-
40.	Squash/Tennis/Table tennis
41.	Cycling

Table: Participants sport (frequencies)

Participants sport (Frequencies)		
	Intervention (n=13) 65%	**Control** (n=10) 50%
Musical instruments	4 (31%)	1 (10%)
Gym	2 (15%)	5 (50%)
Golf	2 (15%)	1 (10%)
Tennis /Squash/Table tennis	2 (15%)	1 (10%)
Cycling	4 (31%)	1 (10%)
Enduro-riding	1 (8%)	0 (0%)
Bowls	0 (0%)	1 (10%)
Swimming	1 (8%)	1 (10%)
Cake decorating	0 (0%)	1 (10%)
Crossfit	1 (8%)	0 (0%)
Cricket	0 (0%)	1 (10%)

APPENDIX 16

- **DEMOGRAPHIC INFORMATION**

Age	
Gender	
Smoker	
Dominant arm involved	
Work affects upper limb function	
Sport affects upper limb function	

The participants filled in their age and answered yes or no to the other questions.

APPENDIX 17

- **TURN-IT-IN REPORT**

Turn-it-in Originality Report

- Processed on: 05-May-2017 9:11 PM SAST
- ID: 783460877
- Word Count: 20297
- Submitted: 9

Effects of radial shockwave therapy in the treatment of chronic lateral elbow tendinopathy: a non-randomised controlled trial by Sandra Crafford

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http://www.enimed.no/pdf/press/Rees_et_al_Am_J_Sports_Med_in_press_Management_of_tendinopathies.pdf
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Susan E. G. Sims, Katherine Miller, John C. Elfar, Warren C. Hammert. "Non-surgical treatment of lateral epicondylitis: a systematic review of randomized controlled trials", HAND, 2014
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Pattanittum, Porjai, Tari Turner, Sally Green, Rachelle Buchbinder, and Rachelle Buchbinder. "Non-steroidal anti-inflammatory drugs (NSAIDs) for treating lateral elbow pain in adults", Cochrane Database of Systematic Reviews Reviews, 2013.
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McMurtrie, A., and A.C. Watts. "(vi) Tennis elbow and Golfer's elbow", Orthopaedics and Trauma, 2012.
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Titchener, A. G., A. Fakis, A. A. Tambe, C. Smith, R. B. Hubbard, and D. I. Clark. "Risk factors in lateral epicondylitis (tennis elbow): a case-control study", Journal of Hand Surgery (European Volume), 2013.
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Coombes, Brooke K., Leanne Bisset, and Bill Vicenzino. "Management of Lateral Elbow Tendinopathy: One Size Does Not Fit All", Journal of Orthopaedic and Sports Physical Therapy, 2015.
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R. M. van Rijn. "Associations between work-related factors and specific disorders at the elbow: a systematic literature review", Rheumatology, 02/17/2009
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"Posters", Knee Surgery Sports Traumatology Arthroscopy, 2016.
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S. D. McCallum. "Five-year prospective comparison study of topical glyceryl trinitrate treatment of chronic lateral epicondylosis at the elbow", British Journal of Sports Medicine, 06/23/2009
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