Cyriax physiotherapy, a supervised exercise programme and Bioptron light for the treatment of lateral epicondylitis

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A thesis submitted in partial fulfilment of the requirements of Leeds Metropolitan University for the degree of Doctor of Philosophy (PhD)

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Abstract

Lateral epicondylitis (LE) is one of the most common lesions of the arm. Physiotherapy is a conservative treatment that is usually recommended for LE patients and a wide array of physiotherapy treatments is used. Two of the most common physiotherapy treatments for LE are Cyriax physiotherapy and supervised exercise programmes. More recently physiotherapists are able to use a new modality called polarised polychromatic non-coherent light (Bioptron light) for the management of LE. The clinical value of these treatments for LE is not known. The aim of this project was to investigate the clinical use and clinical effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the treatment of LE. Systematic review (Chapter 2) found that there was strong evidence for the short-term effectiveness of acupuncture for LE. It also found that there was strong evidence that four physiotherapy modalities, low power laser light, ultrasound, extracorporeal shock wave therapy, and pulsed electromagnetic field therapy were not effective treatments for the management of LE. There was insufficient evidence available for other treatments used for LE, such as iontophoresis and home exercise programmes, to judge their effectiveness. Chapter 2 recommended that more evidence is needed for Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light). It is necessary to establish optimal protocols for these treatments before a suitable clinical trial can be designed. A critical literature review (Chapter 3) found that treatment protocols for Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) were mainly derived from the views of advocates of these treatments, based on their personal experience. Two preliminary clinical studies were conducted to pilot the use of treatment protocols derived from the critical review in Chapter 3 on overuses injuries that were similar to LE and were regularly presented to the clinic (Chapter 4). In the first study (section 4.3) Cyriax physiotherapy did not reduce the pain in patellar tendinopathy, while the supervised exercise programme did. In the second study (section 4.4) polarised polychromatic non-coherent light (Bioptron light) reduced nocturnal pain and paraesthesia in carpal tunnel syndrome (CTS). The findings of these two pilot studies should be interpreted cautiously because the number of patients

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included in the patellar tendinopathy was small and in the CTS study it was not possible to attribute changes to the light per se because the study lacked a control group. Before the effectiveness of these protocols could be tested, a questionnaire survey was conducted to establish the current clinical practices of these physiotherapy treatments for LE. This survey was based on the self-reporting of chartered physiotherapists in Athens using these treatments in their clinical practice (Chapter 5). It may be confidently assumed that the results of the questionnaire present a representative view of current clinical practice of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on LE at least as these treatments are applied in Athens. How much this reflects usage in the rest of the Greece, Europe, or even the world, is yet to be seen by extending the research. When the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for LE was compared, the three treatments reduced pain and improved function at the end of the treatment and at any of the follow-up time points (Chapter 6). Whether this is due to placebo effects is not known. The supervised exercise programme produced the largest effect in the short, intermediate and long term (Chapter 6). This finding suggests that, of the three treatments, the supervised exercise programme should be used as a first treatment option when physiotherapists manage LE patients (Chapter 6; Chapter 7). If this is not possible, Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) may be suitable (Chapter 6; Chapter 7). Although the three treatments are promising interventions for the management of patients with LE, further research is warranted to investigate and confirm the effectiveness of Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) in the treatment of impairment and disability resulting from LE.

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Abbreviations

LE	Lateral epicondylitis
TE	Tennis elbow
ECRB	Extensor carpi radialis brevis
NSAIDs	Non steroid anti-inflammatory drugs
RCTs	Randomised controlled trials
NRCTS	Non-randomised controlled trials
VAS	Visual analogue scale
ESWT	Extracorporeal shock wave therapy
LPLL	Low power laser light
TENS	Transcutaneous electrical nerve stimulation
DTF	Deep transverse friction
CTS	Carpal tunnel syndrome
PFGS	Pain free grip strength
1-way ANOVA	One –way analysis of variance

Declaration

Chapter 1: Introduction

1.1 Introduction

Lateral epicondylitis (LE) is one of the most common lesions of the arm and results in considerable morbidity and financial cost (patients lose many days of their work and spend a lot of money for the management of LE) because LE is a condition that is difficult to treat and is prone to recurrent boots (Labelle et al., 1992; Notteboom et al., 1994; Vicenzino and Wright, 1996; Vicenzino, 2003; Korthals-de Bos et al., 2004; Hong et al., 2004). LE without the appropriate treatment may last for several weeks or months, with the average duration of a typical episode reported to be between 6 months and 2 years (Murtagh, 1988; Hudac et al., 1996). In some cases, the condition may last for 48 months or more (Murtagh, 1988). It remains unknown whether spontaneous recovery of LE occurs or patients learn to live with the symptoms of LE after that period. If spontaneous recovery occurs in some patients, these patients will not stop to be symptomatic because the degenerative changes can cause dysfunction. LE is usually defined as a syndrome of pain in the area of lateral epicondyle (Haker, 1993; Vicenzino and Wright, 1996; Assendelft et al., 2003; Trudel et al., 2004; Hong et al., 2004). The pain can be reproduced by a therapist in three ways including: (i) digital palpation on the facet of the lateral epicondyle, (ii) resisted wrist extension and/or resisted middle-finger extension with the elbow in extension, and (iii) gripping (Haker, 1993; Noteboom et al., 1994; Plancher et al., 1996; Vicenzino and Wright 1996; Peters and Baker, 2001; Assendelft et al., 2003). Apart from pain, patients have decreased function (Vicenzino and Wright, 1996; Trudel et al., 2004; Hong et al., 2004). Both the previously reported complaints, pain and decreased function, may affect activities of daily living such as shaking hands, grasping, lifting, knitting, handwriting, driving a car and using a screwdriver. Over 40 different methods for treating LE have been reported in the literature (Kamien, 1990; Goguin and Rush, 2003; Hong et al., 2004). These include nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, many physiotherapy treatments, cast immobilasation, braces, a plethora of surgical operations and nutritional supplements (Labelle et al., 1992; Wright and Vicenzino, 1997; Sevier and Wilson, 1999; Sevier and Wilson, 2000). These treatments have different theoretical mechanisms of action, but all have the same aim: to reduce pain and improve function (Sevier and Wilson, 1999; Sevier and Wilson, 2000; Nirschl and Ashman, 2003).

However, such a variety of treatment options suggests that the optimal treatment strategy is not known, and more research is needed to establish the most effective treatment in patients with LE.

Conservative treatment is advocated as the primary choice of treatment for LE (Nirschl, 1992; Noteboom et al., 1994; Wright and Vicenzino, 1997; Pienimaki, 2000; Gorguin and Rush, 2003; Nirschl and Ashman, 2003; Trudel et al., 2004). It is believed that such treatment consisting of one or more components can give good clinical results in the majority of LE patients, since only 5%-10% of patients with LE require surgery (Nirschl, 1992; Noteboom et al., 1994; Gorguin and Rush; Nirschl and Ashman, 2003). But the effectiveness of available conservative medicinal treatments — NSAIDs and corticosteroid injections — for LE is controversial (Assendelft et al., 1996; Smidt et al., 2002a; Green et al., 2002a). Due to this, other conservative treatments such as physiotherapy are recommended and used (Stasinopoulos and Johnson, 2004a). Physiotherapy is a conservative treatment that is usually recommended for LE patients (Sevier and Wilson, 1999; Sevier and Wilson, 2000; Baskurt et al., 2003; Trudel et al., 2004) and a wide array of physiotherapy treatments are used: electrotherapeutic modalities, exercise programmes, soft tissue and manual techniques (Sevier and Wilson, 1999; Gorguin and Rush, 2003). However, the sheer variety of physiotherapy treatments with such different theoretical mechanisms of action suggests that the optimal physiotherapy treatment strategy is not known and more research to establish the most effective physiotherapy treatment in LE patients is needed.

Indeed, a cursory search of the literature revealed a systematic review published in 1992 that concluded that there was a lack of scientific evidence supporting physiotherapy treatments for LE (Labelle et al., 1992). Three recently published systematic reviews by Smidt et al (2003), Trudel et al (2004) and Bisset et al (2005) confirm these early findings and demonstrate the importance of improving the current physiotherapy management of LE.

Two of the most common physiotherapy treatments for LE are Cyriax physiotherapy and exercise programmes (Wright and Vicenzino, 1997; Sevier and Wilson, 1999; Pienimaki, 2000; Sevier and Wilson, 2000; Gorguin and Rush, 2003). In general, there are two types of exercise programmes for the management of common musculoskeletal

conditions: home exercise programmes and exercise programmes carried out in a clinical setting. This division of exercise programmes was first presented on tendinopathies such as LE (Stasinopoulos and Johnson, 2004b). A home exercise programme is commonly advocated for LE patients because it can be performed any time during the day without requiring the supervision from a physiotherapist. However, the difficulty with home exercise programmes is how patients comply with the regimen (Stasinopoulos and Johnson, 2004b) because patients may carry out the home exercise programmes incorrectly not only in the technique but also in the frequency of session, sets and repetitions. This difficulty can be managed by the exercise programmes performed in a clinical setting under the supervision of a physiotherapist. For the purposes of this report, "supervised exercise programme" will refer to such programmes. More recently physiotherapists are able to use a new modality called polarised polychromatic non-coherent light (Bioptron light) for the management of LE (Stasinopoulos and Johnson, 2004c). Although the clinical value of these treatments for LE is not known, these treatments are recommended for the management of LE.

Cyriax physiotherapy is a manual therapy, customized for each patient on the basis of the patient's verbal description of the pain experienced during the procedure. Cyriax physiotherapy is administered in a clinical setting by experienced physiotherapists in the technique (Chapter 3) with treatment consisting of three sessions per week for four weeks (Cyriax, 1982; Verhaar et al., 1996; Kesson and Atkins, 1998). A session consists of 10 minutes of deep transverse friction (DTF) and one instance of Mill's manipulation, which is performed immediately after the DTF (Cyriax, 1982). DTF is a specific type of connective tissue massage applied precisely to the soft-tissue structures such as tendons (Cyriax, 1982; Chamberlain, 1982; de Bruijn, 1984; Noteboom et al., 1994; Selvier and Wilson, 1999; Selvier and Wilson, 2000). Mill's manipulation is a passive movement performed at the end of the elbow-extension range, i.e. it consists of a minimal amplitude high-velocity extension thrust at the elbow once the full range of elbow extension has been taken up (Cyriax, 1982; Kushner and Reid, 1986; Kesson and Atkins, 1998). It is postulated that Cyriax physiotherapy can result in both symptomatic pain relief and tissue healing (Chapter 3). Research is needed to translate the physiological effects of Cyriax physiotherapy into clinically meaningful results and vice versa.

Exercise programmes are commonly used treatments that demand the active participation of the patient. Such programmes are individualised on the basis of the patient's report of pain experienced during the procedure. Exercise programmes are administered in clinical settings and/or homes. The treatment regimen of home exercise programmes is usually daily, once or twice, for at least three months based on patellar and Achilles tendinopathy studies (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silbernagel et al., 2001; Ohberg et al., 2004; Purdam et al., 2004; Roos et al., 2004). The treatment regimen of supervised exercise programmes is at least three times per week for four weeks based on one patellar tendinopathy study (Stasinopoulos and Stasinopoulos, 2004). The main explanations for this difference in the treatment regimen of exercise programmes may be the compliance of patients and/or the clinical route/routine. Exercise programmes for tendinopathies such as LE usually consist of slow, progressive eccentric exercises and static stretching exercises of the injured tendon (Stanish et al., 1986; Fyfe and Stanish, 1992; Stanish et al., 2000; Khan et al., 2002). Three sets of eccentric exercises with at least ten repetitions in each set are usually recommended (Stanish et al., 1986; Fyfe and Stanish, 1992; Noteboom et al., 1994; Hawary et al., 1997; Selvier and Wilson, 1999; Stanish et al., 2000; Selvier and Wilson, 2000). Six repetitions of static stretching exercises of the "injured" tendon are usually performed, three before and three after the eccentric exercises, with each stretching lasting 30-45 seconds (Stanish et al., 1986; Fyfe and Stanish, 1992; Stanish et al., 2000). It is reported that exercise programmes are used to promote tissue healing (Chapter 3). Research to translate the physiological effects of exercise programmes into clinically meaningful results and vice versa is needed.

Manufacturers of polarised polychromatic non-coherent light (Bioptron light) claim that the waves of this light move in parallel planes (polarization), cover a wide range of wavelengths (480nm-3400nm) including visible light and part of the infrared range (polychromy), and are not synchronized (incoherency). The polarised polychromatic non-coherent light (Bioptron light) treatment course is standardized. Polarised polychromatic non-coherent light (Bioptron light) should be administered at least three times per week for four weeks in a clinical setting, six minutes each time and that it does not require specific operating skills (Monstrey et al., 2002a; Monstrey et al., 2002a; Iordanou et al., 2002; Medenica and Lens, 2004; Stasinopoulos et al., 2005). The probe emitting polarised polychromatic non-coherent light (Bioptron light) should be

held at a 90º angle (perpedicular) 5-10 cm above the clean bare skin of the "injured" site in order to achieve the best therapeutic effect (Monstrey et al., 2002a; Monstrey et al., 2002a; Iordanou et al., 2002; Medenica and Lens, 2004; Stasinopoulos et al., 2005). It is claimed that polarised polychromatic non-coherent light (Bioptron light) has biostimulative effects assisting tissue healing at the cellular level (Chapter 3). Research is needed to determine whether claims about physiological effects of polarised polychromatic non-coherent light (Bioptron light) translate into clinically meaningful results and vice versa.

The aim of this project was to investigate the clinical use and clinical effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the treatment of LE.

The objectives of the project were to:

1. Establish the clinical effectiveness of treatments available to physiotherapists to manage pain and functional impairment associated with LE by conducting a systematic review of published clinical trials in order to find which of the available physiotherapy treatments has evidence supporting claims of effectiveness (Chapter 2).

2. Establish treatment protocols for Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the management of pain and functional impairment on LE. These protocols would be based on:

- information provided in clinical trials included in chapter 2
- the claims of manufacturers and anecdotal reports from therapists, gathered in the course of a critical review of the literature (Chapter 3).

3. Pilot the use of treatment protocols of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light), as derived from the critical review in chapter 3 on overuse injuries similar to LE that are regularly presenting to the clinic (Chapter 4).

4. Conduct a questionnaire-based survey to establish the current clinical practices for Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) in the treatment of LE, based on the self-reporting of chartered physiotherapists in Athens who are using these treatments in their clinical practices (Chapter 5).

5. Determine the clinical effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on LE by conducting a controlled clinical trial (Chapter 6).

6. Make recommendations for the use of these treatments in clinical practice (Chapter 7).

However, before conducting a systematic review of published clinical trials to establish the clinical effectiveness of treatments available to physiotherapists for the management of pain and functional impairment associated with LE, it is important to understand why it has proved difficult for previous workers to establish effective treatments for LE.

1.2 The difficulty of establishing effective treatments for LE

1.2.1 Difficulties with nomenclature

A cursory search through existing literature reveals a plethora of terms that have been used to describe LE (Vicenzino and Wright, 1996; Vicenzino, 2003; Nirschl and Ashman, 2003; Gorguin and Rush, 2003; Hong et al., 2004). These include (i) tennis elbow (TE), (ii) extensor tendonitis, (iii) extensor tendinosis, (iv) extensor tendinopathy and (v) lateral epicondylalgia. However, it was the description of hypothetical condition by Morris of "lawn tennis arm" in 1882 (Gellman, 1992; Haker, 1993) that instigated the use of the term LE in medicine.

The term "lateral epicondylitis" (LE) refers to the site of injury and the pathology of this condition (Gellman, 1992; Sevier and Wilson, 1999). The term "tennis elbow" (TE) refers to the cause of this condition, the motions entailed in the game of tennis (Plancher et al., 1996; Peters and Baker, 2001). The term "extensor tendonitis" refers to the pathology of the afflicted wrist extensor tendons (Gorguin and Rush, 2003). The term "extensor tendinosis" refers to the pathology of the afflicted wrist extensor tendons based on histopathological studies (Almekinders and Temple, 1998; Maffulli et al., 1998; Khan et al., 1999). The term "extensor tendinopathy" refers to the painful overuse of wrist extensor tendons without implying pathology (Almekinders and Temple, 1998; Maffulli et al., 1998; Khan et al., 1999; Cook et al., 2000; Khan et al., 2000a; Khan et al., 2000b; Khan et al., 2002). Finally, the term "lateral epicondylalgia" refers to the symptoms of this condition without implying pathology (Vicenzino and Wright, 1996;

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Wright and Vicenzino, 1997; Vicenzino, 2003; Silcock and Rivett, 2004; Waugh, 2005).

This variety of terms suggests that there is disagreement by workers in this field as to which is the most suitable. Physicians commonly use the terms LE and TE for clinical diagnosis and patients consequently know the condition by one of these two terms. LE is actually an inappropriate term to describe this condition because the primary pathology of LE is degenerative rather than inflammatory (section 1.2.2). In addition, the site of LE pathology is not over the lateral epicondyle, but just below of it, on the facet of lateral epicondyle. The term TE on the other hand is misleading since it implies that the condition is caused by only one activity, playing tennis. In fact, the term TE is now used to describe pain and functional impairment in the area of the elbow that has a wide variety of causes including occupational activities such as hammering, gardening and secretarial work (Kivi, 1982; Noteboom et al., 1994; Olliviere and Nirschl, 1996; Plancher et al., 1996; Almekinders and Temple, 1998; Haahr and Andersen, 2003a; Baskurt et al., 2003; Haahr and Andersen, 2003b; Paoloni and Murrell, 2004; Waugh et al., 2004). However, while making the recommendation that some future researcher should review the terminology to resolve the problem of inconsistency, this report will employ the term LE because this is the most common used term to describe this condition in medicinal literature (Smidt et al., 2003; Trudel et al., 2004).

1.2.2 Difficulties with pathophysiology

Considerable confusion concerning the actual location of LE has existed since the introduction of the term about a century and a half ago. The exact location of the pathophysiological changes was unknown for decades, since many structures around the elbow— the tendons of the wrist extensor muscles and possibly the anconeous muscle, the bursae, the radial collateral and annual ligament, the radiohumeral synovial fringe, the radiohumeral joint, the radial head and radial nerve — have been described in the pathogenesis of LE based on theoretical hypotheses and mechanisms through clinical examination and diagnosis (Cyriax, 1936; Coonrad and Hooper, 1973; Noteboom et al., 1994; Vicenzino and Wright, 1996; Peters and Baker, 2001). This problem seems now to have been resolved, because the structure most commonly reported as being responsible for LE is the origin of the extensor carpi radialis brevis (ECRB) tendon on the basis of surgical findings (Nirschl and Petrone, 1979; Lee, 1986; Nirschl, 1992;

Regan et al., 1992; Verhaar et al., 1993; Jobe and Ciccoti, 1994; Potter et al., 1995; Kraushaar and Nirschl, 1999; Nirschl and Ashman, 2003).

There was also some debate as to the pathogenesis of LE. At first LE was classified as an inflammatory process and physicians attributed the pain of LE to inflammation (Kraushaar and Nirschl, 1999; Sevier and Wilson, 2000). However, great progress has been made in this area, especially in the last two decades, and it has been found that the LE condition is a degenerative process that occurs when the ECRB has failed to heal properly after an injury or after repetitive microtrauma resulting from overuse (Nirschl, 1989; Doran et al., 1990; Regan et al., 1992; Leadbetter, 1992; Nirschl, 1992; Verhaar et al., 1993; Chard et al., 1994; Potter et al., 1995; Teitz et al., 1997; Kraushaar and Nirschl, 1999; Nirschl and Ashman, 2003). This finding was confirmed by histopathological investigations of biopsied materials. These investigations (Nirschl and Pettrone, 1979; Nirschl, 1992; Regan et al., 1992; Leadbetter, 1992; Verhaar et al., 1993; Potter et al., 1995; Teitz et al., 1997; Järvinen et al., 1997; Kraushaar and Nirschl, 1999; Alfredson et al., 2000) have resulted in a host of new findings:

- The tendon is dull, gray and friable.
- The total amount of collagen is decreased, since breakdown exceeds repair.
- The amounts of proteoglycans and glycosaminoglycans are increased, possibly in response to increased compressive forces associated with the repetitive motion.
- The ratio of Type III to Type I collagen is abnormally high.
- The normal parallel bundled fiber structure is disturbed; the continuity of the collagen is lost with disorganized fiber structure and evidence of both collagen repair and collagen degeneration.
- Microtears, mucoid and hyaline degeneration, calcification and collagen fiber separations are seen. Many of the collagen fibers are thin, fragile, and separated from each other.
- The number of fibroblast cells is increased; the tenocytes look different, with a more blast-like morphology (the cells look thicker, less linear). These differences show that the cells are actively trying to repair the tissue.
- The vascularity is increased, evidence of an immature repair process.
- Inflammatory cells are usually not seen in the tendon.

- Electronic microscopic observations have shown alterations in the size and shape of mitochondria in the nuclei of the tenocytes.

Based on these findings, physicians have begun to develop new or alternative theories about the source of pain associated with LE. Physicians believe that the pain of LE probably comes partly from the physical injury itself (separation of collagen fibers and mechanical disruption of tissue) and partly from irritating non-inflammatory biochemical substances that are produced as part of the injury process (Khan et al., 1999; Khan et al., 2000b). The biochemical substances probably irritate the pain receptors in the tendon and surrounding area (Khan et al., 1999; Khan et al., 2000b). The mechanism of pain associated with LE is yet to be confirmed by researchers and is beyond the scope of the present project.

Future research, although beyond the scope of this project, may also determine whether knowledge of the pathophysiology of LE may be translated to clinical effectiveness and vice versa.

1.2.3 Difficulties with etiology

It is commonly accepted that LE is the effect of overuse, over-stress or over-exertion of the extensor tendons of the wrist, especially ECRB, by quick, continuously monotonous, repetitive and/or strenuous activities of the wrist (Kivi, 1982; Kamien, 1990; Noteboom et al., 1994; Olliviere and Nirschl, 1996; Pienimaki et al., 1996; Plancher et al., 1996; Vicenzino and Wright, 1996; Almekinders and Temple, 1998; Haahr and Andersen, 2003a; Haahr and Andersen, 2003b; Paoloni and Murrell, 2004; Waugh et al., 2004).

If this were the only cause of LE, it would beg the question: why do researchers not face this cause and establish an effective treatment for LE? The answer is simple: the etiology of LE remains relatively unknown and unexplored because LE is a multifactorial condition in nature and, although the overuse of the wrist is the main cause, it is not the only one. Other factors that play a significant role in the etiology of LE can be age, sex, poor vascular supply of ECRB, anatomical variation such as differences in alignment and range of motion, decreased flexibility and cervical spine dysfunction.

Even though some studies showed that LE occurs most commonly in those between 30 and 60 years of age (Nirschl and Pettrone, 1979; Kivi, 1982; Hamilton, 1986; Kitai et al., 1986; Kannus et al., 1989; Verhaar, 1994; Vicenzino and Wright, 1996) and occurs with equal frequency in both sexes but is more severe in women (Allander, 1974; Kivi, 1982; Hamilton, 1986; Vicenzino and Wright, 1996; Waugh et al., 2004), no studies were found to show a relation between LE and poor vascular supply of ECRB, anatomical variation, or decreased flexibility (Almekinders and Temple, 1998). It has been purported that cervical spine dysfunction may contribute to the etiology of LE (Lee, 1986; Vicenzino et al., 1996; Cleland et al., 2004) but cervical spine dysfunction and LE are two different conditions while the symptoms of cervical spine dysfunction may mimic LE pain (section 1.2.5)

Overall, a determination of the causes of LE requires further research since, if clinicians were to understand the etiology of LE, firstly an effective treatment for LE might be more easily established and secondly LE might be more easily prevented. Such research is beyond the scope of this project.

1.2.4 Difficulties with epidemiology

The epidemiology of LE is the aspect of this condition that has been investigated in most detail, and it is clear that LE is a common clinical problem. It is generally accepted that the occurrence of LE is expressed as either an incidence or a prevalence rate (Vicenzino and Wright, 1996). The incidence rate of LE (the rate at which new cases appear over a year) is approximately 4-7 per 1000 patients per year in general practice (Kivi, 1982; Hamilton, 1986; Verhaar, 1994). The annual prevalence (the number of existing cases at a given time) of this condition is 1-3% in the general population (Allander, 1974; Kivi, 1982; Verhaar, 1994). Tennis players have been reported to account for 5-8% of all LE patients, and between 40-50% of all tennis players will be afflicted with this condition at some time during their career (Nirschl, 1986; Noteboom et al., 1994; Overend et al., 1999).

Factors such as age, gender, stress loads on the elbow and the interaction between these factors have been postulated to influence the incidence and prevalence rates of LE. Although LE occurs at all ages, the peak prevalence of LE is between 30 and 60 years (Nirschl and Pettrone, 1979; Kivi, 1982; Hamilton, 1986; Kitai et al., 1986; Kannus et

al., 1989; Verhaar, 1994; Vicenzino and Wright, 1996) because these are the most productive (creative) ages. The proportion of those afflicted by LE is not influenced by the sex of the patient, but the disorder appears to be of longer duration and severity in females (Allander, 1974; Kivi, 1982; Hamilton, 1986; Vicenzino and Wright, 1996; Waugh et al., 2004) because females are weaker than males in physical characteristics such as strength. Finally, LE is almost invariably experienced in the dominant arm (Nirschl and Pettrone, 1979; Kivi, 1982; Hamilton, 1986; Vicenzino and Wright, 1996) because this is the arm that is mainly used and is under stress in every day activities.

If research in this area is to help clinicians establish an effective treatment for LE, it must be sustained and in depth. Future surveys of the occurrence rates of LE should carefully attend to methodological issues such as differences in sampled populations, the classification of included and excluded cases, and the validation of such cases by trained health care personnel. Such research is beyond the scope of this project.

1.2.5 Difficulties with diagnosis

Although the diagnosis of LE is simple with the clinical picture fairly uniform, many conditions mimic LE pain, and thus the physicians can be easily misdiagnosed as LE, which complicates the prospect of optimal treatment for LE. These conditions include osteochondritis dissecans, cubital osteoarthritis, radial-tunnel syndrome, rheumatoid arthritis, severe cervical spondylosis or cervical radicular syndrome, painful shoulder or rotator cuff tendinopathy and increased neural tension (Nirschl, 1992; Gellman, 1992; Haker, 1993; Noteboom et al., 1994; Plancher et al., 1996; Vicenzino and Wright, 1996; Peters and Baker, 2001; Goguin and Rush, 2003; Nirscl and Ashman, 2003). However, an experienced clinician with LE patients can easily distinguish the pain of LE from the pain of other conditions that mimic LE pain.

A cursory survey of the existing literature reveals a plethora of diagnostic tests that have been used to diagnose LE (Halle et al., 1986; Gellman, 1992; Nirschl, 1992; Haker, 1993; Noteboom et al., 1994; Plancher et al., 1996; Kraushaar and Nirschl, 1999; Peters and Baker, 2001; Goguin and Rush, 2003; Nirscl and Ashman, 2003). These include (i) palpation on the facet of lateral epicondyle, where the ECRB tendon originates (Figures 1.1 and 1.2), (ii) the Tomsen test (Figure 1.3), (iii) resisted middle finger extension (Figure 1.4), (iv) the Mill's test (Figure 1.5), (v) the handgrip dynamometer test (Figure

1.6), (vi) resistance supination with the elbow in flexion and in extension (Figure 1.7), (vii) the chair test (Figure 1.8), and (viii) the coffee-cup test (Figure 1.9).

Although any therapist conducting one or more of these tests can reproduce the pain of LE, such a plethora of diagnostic tests suggests that the most variable and valid test for LE is not known. However, clinicians do not use all these tests to diagnose LE. They would normally palpitate the facet of the lateral epicondyle and one or two of the tests listed above, with tests (ii) to (v) being the most commonly used (Gellman, 1992; Haker, 1993; Noteboom et al., 1994; Plancher et al., 1996; Peters and Baker, 2001; Goguin and Rush, 2003). For this reason, to identify LE patients, similar diagnostic tests were used in our controlled clinical trial described in chapter 6. Future research might investigate these various and possibly inconsistent diagnostic tests, since different approaches to diagnosis of LE may lead to different choices of treatment for LE.

In the vast majority of LE patients the diagnosis is based on history and physical examination. Radiological investigation such as magnetic resonance imaging (MRI) or ultrasound examinations can add information in diagnosis, for example if the ECRB is the only affected structure or other structures such as supinator or extensor digitorum communis are also involved. Although such as investigation can help clinicians to modify their treatment in order to obtain the best therapeutic effects, it is not routinely obtained.

1.2.6 Difficulty with conservative treatments
Clinicians regarded LE as an inflammatory condition and recommended management with anti-inflammatory treatments such as NSAIDs and corticosteroid injections. However, it is now known that the LE condition is not an inflammatory process but a degenerative one (section 1.2.2) and clinicians must ask themselves how efficacious treatments using these medicinal conservative approaches actually can be.

Systematic reviews of the literature failed to turn up evidence not convincingly supporting the long-term effectiveness of injections (Assendelft et al., 1996; Smidt et al., 2002a). Definite conclusions cannot be drawn due to the lack of high quality studies. A recently systematic review found some support for the use of NSAIDs to relieve LE

pain at least in the short term; however, there was, insufficient evidence either to recommend or to discourage the use of NSAIDs (Green et al., 2002a).

Some narrative reviews report cases, although they do not provide details of the nature of the cases, in which NSAIDs and corticosteroid injections provide short-term but rapid symptom relief (Almekinders and Temple, 1998; Cook et al., 2000; Assendelft et al., 2003; Mellor 2003) It is believed that NSAIDs and corticosteroid injections are effective treatments in patients with a short duration (less than six weeks) of LE (Hay et al., 1999; Smidt et al., 2002b). Clinicians should accept that, at least until data appear demonstrating otherwise, that these two kinds of treatments do not provide significant long-term benefit in tendinopathy such as LE (Astrom and Westlin, 1992; Almekinders and Temple, 1998; Hay et al., 1999; Cook et al., 2000; Smidt et al., 2002). Given the known deleterious effect of corticosteroid injections into tendon and their inhibition of collagen repair when administered in the area of tendons, this treatment has lost favor (Unverferth and Olix, 1973; Price at el., 1991; Nirschl, 1992; Kraushaar and Nirschl, 1999; Khan et al., 1999; Khan et al., 2000a). Moreover, the use of NSAIDs can cause gastrointestinal problems that impede the healing process (Khan et al., 1999; Khan et al., 2000a; Riley et al., 2001; Khan et al., 2002). Therefore, the clinical use and effectiveness of these two treatments for LE are controversial. There remains a need for more effective, yet conservative and less hazardous, treatments.

Physiotherapy is a conservative treatment that is commonly used to manage patients with LE (Sevier and Wilson, 1999; Sevier and Wilson, 2000; Baskurt et al., 2003; Trudel et al., 2004). Physiotherapy treatments whose only role is to reduce inflammation may not prove helpful to treat patients with LE. Physiotherapy treatments that reverse the pathophysiology of LE may be effective for the management of this condition.

1.3 Summary

Though LE is a common clinical condition and physiotherapy a common form of treatment, there appears to be a lack of evidence for the effectiveness of physiotherapy interventions. This may be due to the difficulty of establishing nomenclature,

pathophysiology, etiology, epidemiology, diagnosis and conservative treatment of the condition.

It is important to systematically review existing clinical trial evidence to establish the clinical effectiveness of treatments available to physiotherapists to manage the pain and functional impairment associated with LE. This information will provide future treatment strategies for LE in the present project.

Figure 1.1

ECRB origin
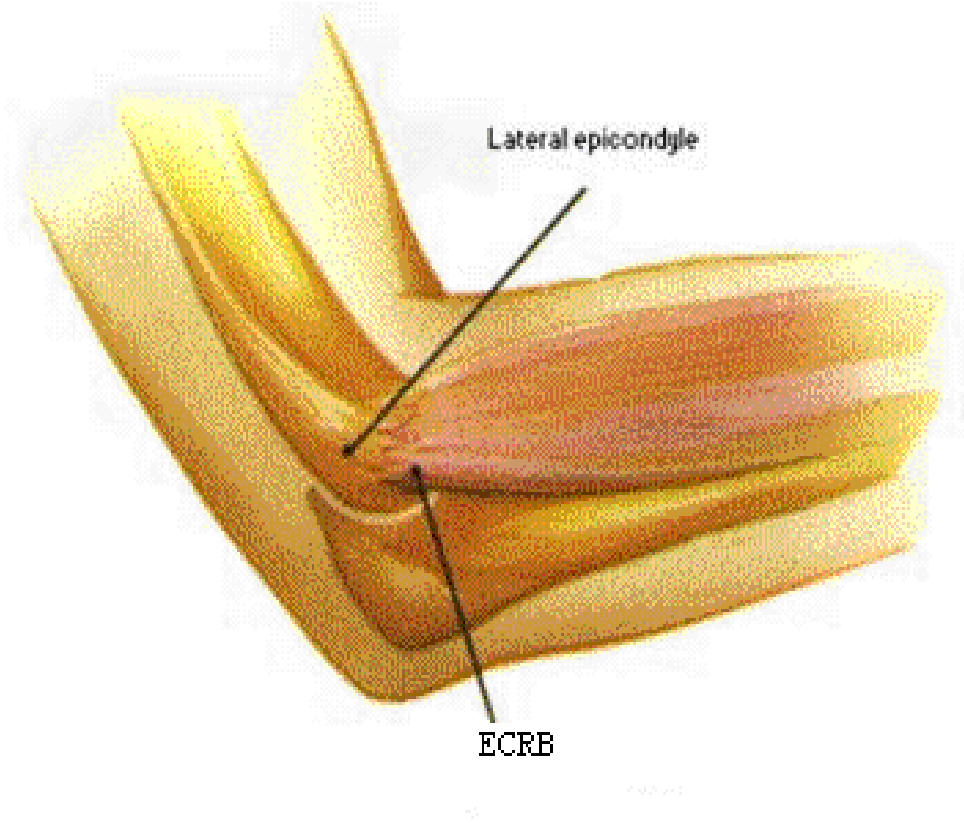
Adapted from Nirschl (1992)

Figure 1.2

Pain with palpation on the facet of lateral epicondyle (ECRB tendon origin)

Adapted from URL www.sportsinjuryclinic.net

Figure 1.3

Tomsen test

Pain with resisted wrist extension, with the elbow in full extension, forearm pronated and the wrist extended about 30°, giving the resistance at the heads of the second and third metacarpal bones
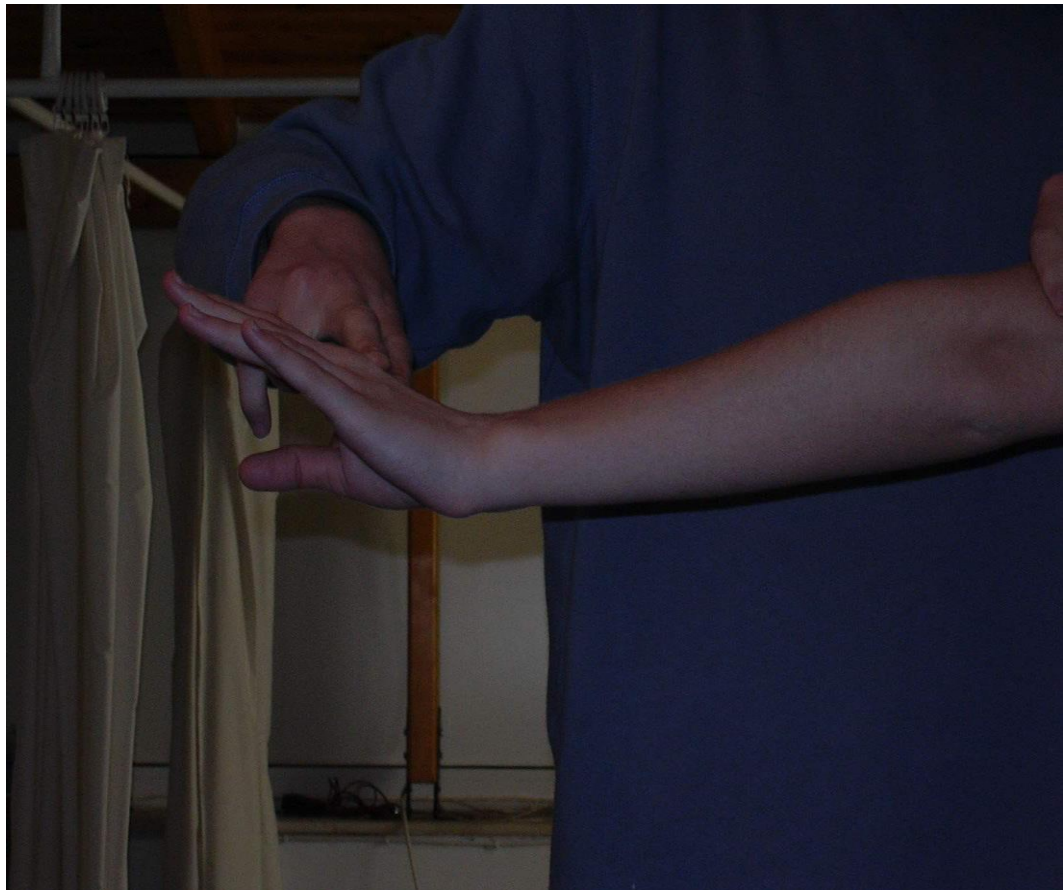
Figure 1.4

Pain with resisted middle finger extension
Pain with resisted middle finger extension with the elbow in extension, forearm
pronated and the wrist in neutral position

Figure 1.5

Mill's test

Pain with full passive flexion of the wrist with the elbow in extended position and the forearm pronated

__Figure 1.6__

Handgrip dynamometer test
Pain and decrease in grip strength when the patient is asked to squeeze the hand
dynamometer
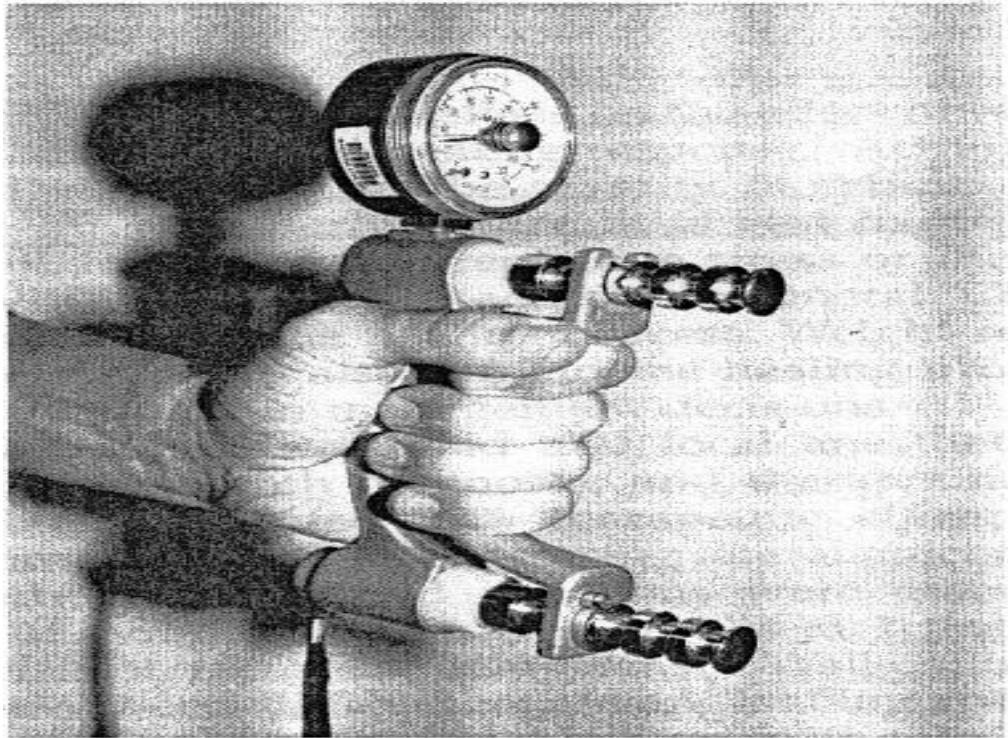
Adapted from Peters and Baker (2001)

Figure 1.7

Pain with resistance supination
Pain with resistance supination and the elbow in flexion (A) should be less than the pain with resistance supination and the elbow in extension (B). If the pain is equally severe with the elbow flexed and extended, then operative intervention is more likely to be needed

(A)

(B)
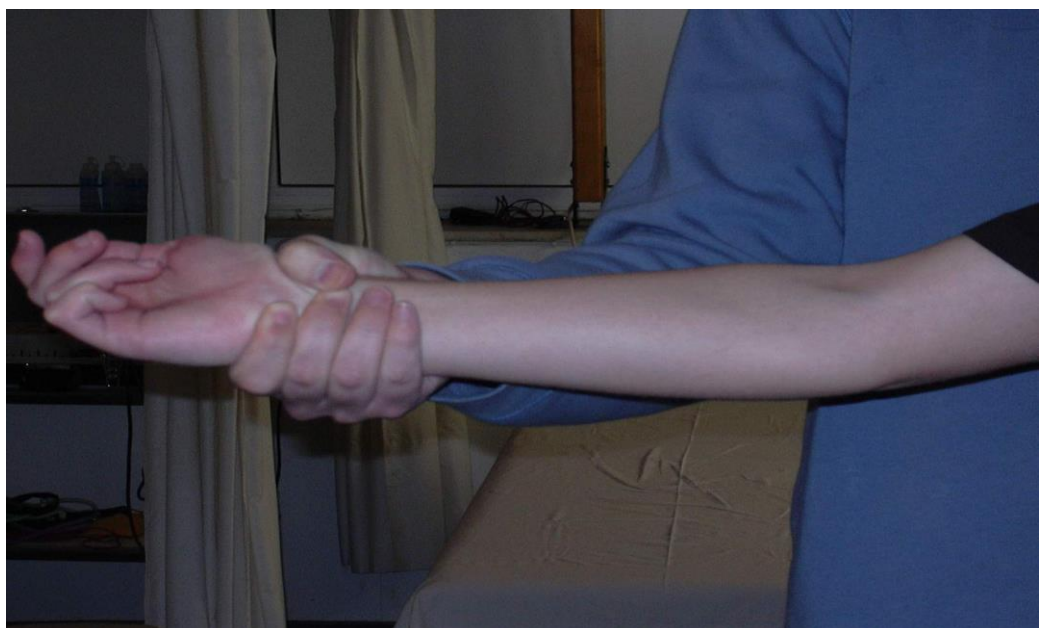
Figure 1.8

Chair test
Pain when the patient is asked to lift a chair with the shoulder adducted, elbow extended
and forearm pronated
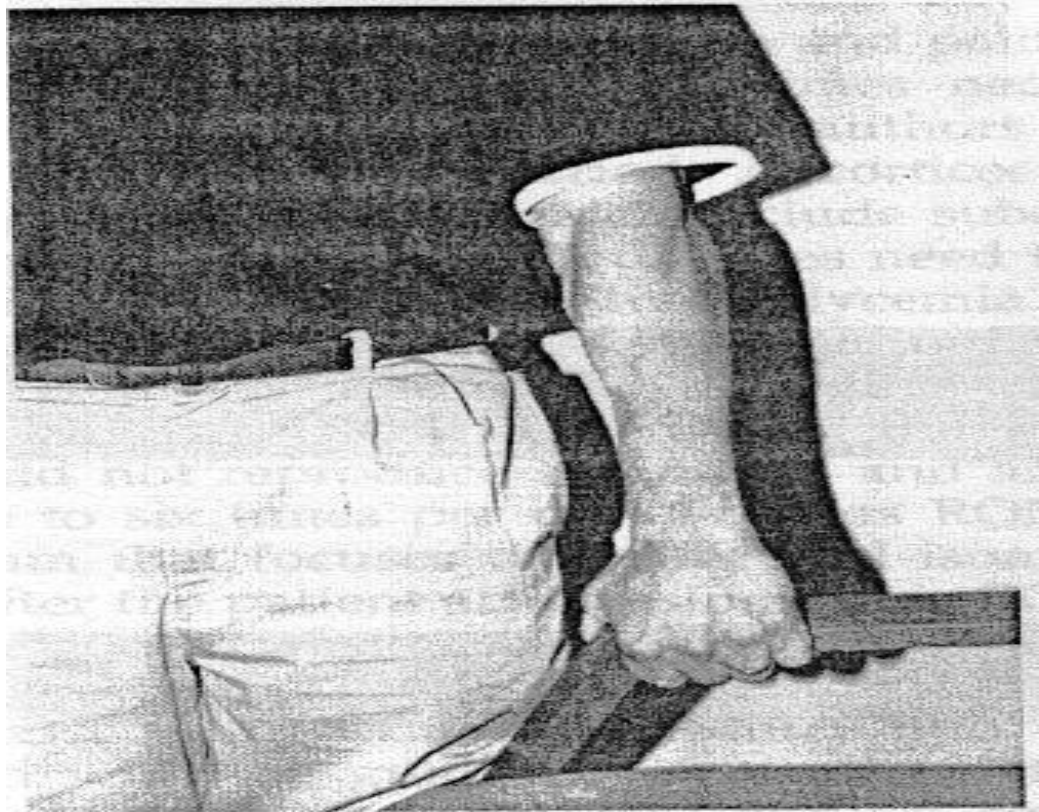
Adapted from Peters and Baker (2001)

Figure 1.9

Coffee cup test
Pain when the patient is asked to grasp or pinch with the wrist in extension

Chapter 2: A systematic review to establish the effectiveness of physiotherapy for lateral epicondylitis

2.1 Introduction

LE is a widespread condition that causes pain and reduced function in affected patients (Chapter 1). Although therapists can easily make a diagnosis of LE using common tests that reproduce the symptoms, the "ideal" treatment for LE remains unknown (Chapter 1). This may be due to the difficulty of establishing nomenclature, pathophysiology, etiology, epidemiology, diagnosis and conservative treatment of LE (Chapter 1). Physiotherapy including electrotherapeutic and non-electrotherapeutic interventions is the most commonly used non-operative treatment for LE (Sevier and Wilson, 1999; Sevier and Wilson, 2000; Baskurt et al., 2003; Trudel et al., 2004; Hong et al., 2004); pain relief and restoration of function are its primary objectives (Gorguin and Rush, 2003; Trudel et al., 2004). However, the optimal physiotherapy treatment strategy remains unknown and more research is required to establish the most effective physiotherapy treatment.

The need for more research on the efficacy of available physiotherapy treatments for this condition was supported by an earlier systematic review (Labelle et al., 1992). Labelle et al (1992) evaluated the clinical effectiveness of treatment methods used not only by physiotherapists but by physicians in general, for the treatment of patients with LE. Eighteen randomised controlled trials (RCTs) conducted prior to 1990 were included in the Labelle et al (1992) review. Physiotherapy had been used in seven of these eighteen RCTs. Because of the poor methodology of some of the studies reviewed, the authors concluded that there was not enough scientific evidence to favor any particular type of treatment for LE. They called for RCTs with proper methodological design to demonstrate the efficacy of different treatments utilized for LE. Other systematic reviews have attempted to determine the clinical effectiveness of physiotherapy treatments alone such as extracorporeal shock-wave therapy (Buchbinder et al., 2002) and acupuncture (Green et al., 2002b). However, conclusions could not be drawn from these reviews due to the low number of studies included.

Thus, to date Labelle et al (1992) remains the only published systematic review that examines the clinical effectiveness of physiotherapy in the management of LE. Several new RCTs have been published since, however, and an updated systematic review is required to evaluate the clinical effectiveness of available physiotherapy treatments.

The term "clinical effectiveness" requires attention. It may be defined as the provision of high quality treatments or services in a way that allows the recipient(s) to achieve the maximum health gain (Chartered society of Physiotherapy, 2002). Clinical effectiveness is evaluated through RCTs, which provide the best evidence for the effectiveness of a treatment (McNeely et al., 2003). Therefore in order to review the effectiveness of physiotherapy treatments it was necessary to conduct a systematic review of RCTs.

A narrative review was not conducted because, rather than address a particular issue in depth, narrative reviews deal with a broad range of issues related to a given topic (Mulrow, 1987). Narrative reviews are appropriate for describing the history or development of a problem and its management, but the connection between clinical recommendations and evidence in narrative reviews is often tenuous, incomplete, or — worse still — based on a biased citation of studies (Cook et al., 1997). The aim of systematic reviews, on the other hand, is to answer specific, often narrow, clinical questions in depth, and therefore to increase our precision in estimating treatment effects and risks (Mulrow, 1994). Systematic reviews address sharply defined clinical questions and may constitute a more reliable means of integrating existing information and providing clinicians with data for making rational decisions and providing optimal health care (Mulrow, 1994; Mulrow et al., 1997; Cook et al., 1997). Although demanding and time consuming, they constitute a more efficient scientific technique, one that tends to minimize error and bias (Cook et al., 1997; Egger and Smith, 1997).

2.2 Aim

The aim of this systematic review was to establish the clinical effectiveness of treatments available to physiotherapists for the management of the pain and functional impairment associated with LE. This would also enable me to identify which physiotherapy treatments lack evidence to determine their effectiveness.

2.3 Methods

2.3.1 Search strategy

Computerized searches using Medline (from 1966 to October 2002), Embase (from 1988 to October 2002), Cinahl (from 1982 to October 2002), Index to Chiropractic literature (from 1992 to October 2002), Chirolars (from 1994 to October 2002) and SportDiscus (from 1990 to October 2002) were performed. Only English language publications were retrieved. The search terms used individually or in various combinations were: "tennis elbow", "lateral epicondylitis", "lateral epicondylalgia", "extensor tendinopathy". "extensor tendonitis", "extensor tendinosis", "rehabilitation", "treatment", "management", "physiotherapy, "randomised control trials". Additional reports were also sought from the reference sections of papers retrieved, by contacting experts in the field, and from the Cochrane Collaboration clinical trial register (last search: October 2002). Unpublished reports and abstracts were not included in the review.

2.3.2 Selection of studies

To be included in the present review, a study had to fulfill the following conditions: it had to be a randomised control trial (RCT), with or without follow-up, that included subjects aged 18 years old and above who were treated for LE. For the purposes of this review, LE was defined as a syndrome of pain in the area of the lateral epicondyle. It had to be stated that the pain could be reproduced by a therapist in three ways including (i) digital palpation on the facet of the lateral epicondyle, (ii) resisted wrist extension and resisted middle finger extension with the elbow in extension, and (iii) gripping (Haker, 1993; Noteboom et al., 1994; Plancher et al., 1996; Vicenzino and Wright, 1996; Peters and Baker, 2001). The treatment had to be any type of physiotherapy and evaluated against at least one of the following: (i) placebo; (ii) no treatment; (iii) another treatment, either conservative (physical therapy intervention or medicinal) or operative. RCTs in which the physiotherapy was given as part of the treatment, that is, in combination with non-steroid anti-inflammatory drugs (NSAIDs) and/or ultrasound and/or exercise programmes and/or bracing, or RCTs in which physiotherapy was given in combination with physical therapy treatments such as ultrasound, exercise programmes and light therapy, were excluded since it would be impossible to know how the physiotherapy component contributed to the results. However, the effectiveness

of these management strategies has not been assessed previously in the literature. This review sought data for one of the following two primary outcome measures: pain (scales, tests or description words) and function (scales, tests or description words).

The titles and abstracts of all studies were assessed according to the above eligibility criteria. If it was absolutely clear from information provided in the title and/or abstract that the study was not relevant, it was excluded. If this was unclear from the available abstract and/or the title, the full text article was retrieved. This review was not blind as to the studies' authors, places of publication or results. Claims that there are differences between judgements of trial outcome between blinded and unblinded reviews have not been supported by experimental evidence which has shown little consistency in direction or magnitude of bias (Berlin, 1997; Moher et al., 1998). The content of all full text articles were assessed according to the selection criteria.

2.3.3 Methodological Quality

The Chalmers' scale was used to score methodological quality in line with the previous published systematic review by Labelle et al (1992). Chalmers' scale was validated and tested for reliability by Berard et al (2000). The version used in the present study consists of two evaluation forms, with 29 individually scored items, allowing for a maximum score of 100. The first form consists of 15 scored items and assesses the study's design by giving particular importance to the blinding of the study in respect to patients and physicians, and to the presence and method of randomisation of the patients and, where applicable, of the physicians (Table 2.1). The second form consists of 14 scored items and evaluates the quality of the data analysis, the statistical analysis and the presentation of results (Table 2.2).

2.3.4 Data abstraction and Analysis

The data extracted consisted of demographic data including characteristics of participants (e.g., age, gender, previous treatments, duration of disorder and etc), outcomes (type of outcome measure and instrument), interventions (type, dose or intensity, frequency, and duration) and raw data for all outcomes.

It was not possible to perform a meta-analysis because the data were statistically and clinically too heterogeneous. I therefore chose to vote count trial outcome as positive or

negative. The votes were summarized using a rating system for levels of evidence. The findings were organized and placed within themes that reflected the objectives of the review. The rating system consisted of four levels of scientific evidence that have been used previously in systematic reviews of back pain (Linton and Van Tulder, 2001) and that are based on the quality and the outcome of the studies:

- **Level A—Strong evidence**: consistent findings from multiple RCTs.
- **Level B--Moderate evidence**: one RCT or consistent findings from multiple non-randomised controlled trials (NRCTs).
- **Level C—Limited evidence**: only one NRCT
- **Level D—No evidence**: no RCTs or NRCTs

As NRCTs were not included in this review, level C became irrelevant and therefore only three levels remained: strong, moderate and no evidence.

2.4 Results

2.4.1 Trial flow

Examination of the titles and abstracts of "hits" identified 48 studies that could meet the potential inclusion criteria. Of these studies, 21 failed to meet all inclusion criteria when the full text was considered (Table 2.3), leaving 27 eligible RCTs to be included in the review (Table 2.4). Most investigation into LE concentrated on the effectiveness of light therapy that employed low-power laser light (LPLL) (9 studies), of ultrasound (5 studies), of acupuncture (5 studies) and of extracorporeal shock wave therapy (ESWT) (4 studies). A few studies had investigated the effectiveness of other physiotherapy treatments such as pulsed electromagnetic field therapy (2 studies), iontophoresis (1 study), Cyriax physiotherapy (1 study) and home exercise programme (1 study). The home-exercise programme study qualified as an ultrasound study because it compared the effectiveness of home exercise programmes to that of ultrasound. Taking all these together, 28 qualifying studies were identified.

2.4.2 Description of included studies

The characteristics of included studies are presented in Table 2.4. Randomisation procedures were stringently performed and well reported in all studies. Eleven studies had adequate blinded-outcome assessors (Deveraux et al., 1985; Chard and Hazleman,

1988; Molsberger and Hille, 1994; Pienimaki et al., 1996; Rompe et al., 1996; Speed et al., 2002; Haake et al., 2002a; Crowther et al., 2002; Runeson and Haker, 2002; Fink et al., 2002; Tsui and Leung, 2002). One study gave adequate details in respect to blinding of patients (Haake et al., 2002a). Four studies had adequately blinded the therapist(s) (Basford et al., 2000; Haake et al., 2002a; Fink et al., 2002; Runeson and Haker, 2002). All studies reported the dropping-out of patients when such was the case, but not the reasons for these drop-outs. Side effects were also reported in all studies where they occurred. Only three studies (Molsberger and Hille, 1994; Basford et al., 2000; Haake et al., 2002a) stated the power calculations for the sample size.

2.4.3 Methodological quality rating of studies

Table 2.4, in the column "quality score", shows the evaluation for the 27 included clinical trials. The table expresses the results as percentages of the maximum possible score and allows for items that were not applicable to every study and which were therefore excluded from the calculations. If the score of the study is below 40% (0-39), the design of the study is of low quality; if the score of the study is 40–69%, the design of the study is satisfactory; if the score of the study is 70% and over the design of the study is of high quality.

The average scores for the 27 trials were 50.6%, with a minimum of 15% for the weakest study design (Brattberg, 1983), and a maximum of 75% for the strongest design (Haake et al., 2002a). The majority of studies had a satisfactory quality design, and two studies exceeding 70% (Haake et al., 2002a; Fink et al., 2002). Studies were classified into groups according to the LE treatment studied.

2.4.3.1 Light therapy

Nine studies evaluated the effectiveness of light therapy using LPLL for the treatment of LE. In all these studies, pain and function were measured using a variety of outcome measures. Eight out of nine studies compared the effects of LPLL with placebo LPLL (Lundeberg et al., 1987; Haker and Lundeberg, 1990b; Haker and Lundeberg, 1991b; Haker and Lundeberg, 1991c; Vasseljen et al., 1992; Krasheninnikoff et al., 1994; Papadopoulos et al., 1996; Basford et al., 2000). In all these studies, the probe of placebo LPLL irradiated the same points with the probe of LPLL, but it was inactive, so that no light was emitted. Details of the LPLL application are presented in Table 2.4.

Six out of these eight studies found that LPLL was no more effective for the management of LE than placebo LPLL, as assessed by any of the outcome measures (Lundeberg et al., 1987; Haker and Lundeberg, 1990b; Haker and Lundeberg, 1991b; Krasheninnikoff et al., 1994; Papadopoulos et al., 1996; Basford et al., 2000). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these six studies. One of these six studies was a low-quality study (33%) (Lundeberg et al., 1987). The others were studies of satisfactory quality, with the scores ranging from 41% to 64%.

On the other hand, the findings of two studies suggested that LPLL is significantly better than placebo LPLL in short term, and that it reduces pain and improves the function of LE patients (Haker and Lundeberg, 1991c; Vasseljen et al., 1992). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these two studies. Both studies were satisfactory-quality studies with quality scores of 50% (Haker and Lundeberg, 1991c) and 58% (Vasseljen et al., 1992), respectively.

Finally, one study in which LPLL was compared with a combination of physical therapy treatments (ultrasound and deep transverse friction) found that LPLL was an ineffective treatment in patients with LE (Vasseljen et al., 1992). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of this study. Vasseljen et al (1992) study was a satisfactory quality study with quality score 61%.
A total of seven studies provide strong evidence (Level A) that LPLL is an ineffective treatment for LE patients in either the short or long term (Table 2.5).

On the other hand, no studies were found to investigate the effectiveness of other forms of light therapy such as those employing polarised, polychromatic non-coherent light (Bioptron light) for the treatment of LE and the effectiveness of this modality must be classified as Level D (Table 2.5).

2.4.3.2 Ultrasound

Five studies assessed the effectiveness of ultrasound on LE. Pain and function were measured in all these studies using a variety of outcome measures. Three out of five studies compared ultrasound with placebo ultrasound (Binder et al., 1985; Lundeberg et al., 1988; Haker and Lundeberg, 1991a). In all these studies placebo ultrasound and

ultrasound were applied in the same manner; however, during the application of placebo ultrasound, the machine was turned off. Details of the application of ultrasound are presented in Table 2.4.

Just one of these three studies found that ultrasound could decrease the pain and improve the functional status of LE patients (Binder et al., 1985). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these three studies. The study that showed positive effects of ultrasound was a low-quality study with a quality score of just 36% (Binder et al., 1985), while the other two studies were satisfactory-quality studies with quality scores of 46% (Lundeberg et al., 1988) and 54% (Haker and Lundeberg, 1991a), respectively.

One study comparing ultrasound therapy with the epicondylitis clasp found no significant difference in the results of the two treatments (Holdworth and Anderson, 1993). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of this study. This study was of satisfactory quality, with a quality score 42%.

One study compared ultrasound with a home exercise programme (Pienimaki et al., 1996). The home exercise programme consisting of slow progressive strengthening (isometric and isotonic contractions) and static stretching exercises, was demonstrated to be a more effective treatment for LE than was ultrasound. Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of this study. The Pienimaki et al (1996) study was of satisfactory quality, with a quality score 68%.

Overall, there is strong evidence (Level A) that ultrasound is an ineffective treatment in LE patients (Table 2.5), since a total of four studies showed that ultrasound resulted in no improvement for patients.

2.4.3.3 Acupuncture

Five studies evaluated the effectiveness of acupuncture for the treatment of LE. Pain and function were the outcome measures in all studies, which used a variety of outcome measures. The exception was one study, which only measured pain (Molsberger and

Hille, 1994). Details of the application of acupuncture in all studies are presented in Table 2.4.

Two out of these five studies compared acupuncture with placebo (Molsberger and Hille, 1994) and sham acupuncture (Fink et al., 2002), respectively. In the Molsberger and Hille study (1994) using the placebo acupuncture, a pencil-like probe was used to stimulate a point 1.5 cm lateral to T3 (mock acupuncture) for five minutes, 1 treatment in total. In the Fink et al. study (2002), six needles were used for sham acupuncture. The needles were inserted in the same way as in acupuncture, but investigators used puncture sites that were at least five cm from the classical acupuncture points and their interconnecting meridians but were also clear of painful pressure points (Ah-Shi or trigger points).

These two studies found that, for any outcome measures, acupuncture was a more short-term effective treatment for the management of LE than placebo and sham acupuncture respectively. Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these two studies. The design of one of these two studies was satisfactory, with a quality score of 41% (Molsberger and Hille, 1994) and the other study was of high quality, with a score of 73% (Fink et al., 2002).

Two other studies compared two different types of acupuncture. One study (Haker and Lundeberg, 1990a) compared deep acupuncture with superficial acupuncture and the other (Tsui and Leung, 2002) compared electro-acupuncture with manual acupuncture. These studies found that, for the management of LE, deep acupuncture and electro-acupuncture respectively were more short-term effective treatments than superficial and manual acupuncture for any outcome measures. Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these two studies. Both studies had a design of satisfactory quality, with quality score s of 43% (Haker and Lundeberg, 1990b) and 46% (Tsui and Leung, 2003), respectively.

A final study compared acupuncture with corticosteroid injection (Brattberg, 1983). Brattberg (1983) reported that, for the management of LE, acupuncture was a more effective treatment than steroid injection for any outcome measures. Based on the

reported findings, the reviewer agrees with the conclusion reached by the authors of this study. However, Brattberg (1983) was a low-quality study, with a score of 15%.

Thus, strong evidence (Level A) supports the acupuncture as a short-term effective treatment for LE patients (Table 2.5). A total of five studies showed positive results.

2.4.3.4 ESWT

Four studies assessed the effectiveness of extracorporeal shock-wave therapy (ESWT) for the treatment of LE. Pain and function were the outcomes measured in two studies (Rompe et al., 1996; Haake et al., 2002a), while only pain was measured in the other two studies (Speed et al., 2002; Crowther et al., 2002). Details of the application of ESWT in all studies are presented in Table 2.4.

Three out of the four studies compared ESWT with sham ESWT (Rompe et al., 1996; Speed et al., 2002; Haake et al., 2002a). Within each study, the ESWT and the sham ESWT were applied in the same way. In the Rompe et al (1996) study, sham ESWT was given as 10 impulses of 0.08 mJ/mm^2; in the Haake et al (2002a) study, polyethylene foil was filled with air and fixed with ultrasound gel to the front of the coupling cushion, thus totally reflecting the shock waves; in the Speed et al (2002) study, the sham ESWT was given as 0.04 mJ/mm^2.

Two of these three studies found that, for any outcome measure, ESWT was a no more effective treatment for the management of LE than sham ESWT (Speed et al., 2002; Haake et al., 2002a). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these two studies. One study was of satisfactory quality, with a score of 53% (Speed et al., 2002) and the other study was of high quality, with a quality score of 75% (Haake et al., 2002a).

On the other hand, a single study reported that ESWT could reduce the pain and improve the functional status of LE patients (Rompe et al., 1996). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of this study, which was of satisfactory quality, with a score of 55%.

Finally, a study compared the effectiveness of ESWT with steroid injection for the treatment of LE. This study found that the injection resulted in a greater reduction in pain than the ESWT (Crowther et al., 2002). Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of this study. This was a satisfactory-quality study, with a quality score of 55%.

Overall, there is strong evidence (Level A) that ESWT is an ineffective treatment for patients with LE (Table 2.5), since a total of three studies supported this finding.

2.4.3.5 Pulsed electromagnetic field therapy

Two studies assessed the effectiveness of pulsed electromagnetic field therapy in the treatment of LE by measuring pain and function using a variety of outcome measures. In both studies, pulsed electromagnetic field therapy was compared with placebo dummy coils (Deveraux et al., 1985; Chard and Hazleman, 1988). Details of the application of pulsed electromagnetic field therapy are presented in Table 2.4. The results of both studies indicated that, for the treatment of LE, pulsed electromagnetic field therapy was not significantly better than placebo dummy coils for any outcome measure. Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of these two studies, which were of satisfactory quality, with scores of 65% (Deveraux et al., 1985) and 43% (Chard and Hazleman, 1988) respectively. Therefore there is strong evidence (Level A) that pulsed electromagnetic field therapy is an ineffective treatment for LE (Table 2.5).

2.4.3.6 Iontophoresis

One study evaluated the effectiveness of iontophoresis for the treatment of LE by comparing iontophoresis with placebo iontophoresis (Runeson and Haker, 2002). Iontophoresis and placebo iontophoresis were applied in the same way, but in placebo iontophoresis, the patient was administered saline instead of daxamethasone sodium phospate. Details of the application of iontophoresis are presented in Table 2.4. The results of the Runeson and Haker (2002) study showed that iontophoresis could not reduce the pain and improve the functional status of LE patients better than placebo iontophoresis. Based on the reported findings, the reviewer agrees with the conclusion reached by the authors of this study. This was a satisfactory study, with a quality score

of 55%. Therefore, there is moderate evidence (Level B) that iontophoresis is an ineffective treatment for patients with LE (Table 2.5).

2.4.3.7 Cyriax physiotherapy

One study assessed the effectiveness of Cyriax physiotherapy for the treatment of LE (Verhaar et al., 1996). In the Verhaar et al (1996) study, Cyriax physiotherapy was compared with corticosteroid injection. In the short-term follow-up (six weeks after the end of treatment), corticosteroid injection had significantly greater reduction in pain and in the improvement of function than Cyriax physiotherapy. The authors of the study concluded that there was no significant difference between the treatments in long-term follow up (1 year after the end of treatment) but did not report whether the treatments were effective or ineffective and the reviewer was unable to make a further determination. This was a satisfactory-quality study (Verhaar et al., 1996) with a quality score of 44%. However, due to lack of sufficient information of the included study (Verhaar et al., 1996), it was concluded that no evidence (Level D) exists for the effectiveness of Cyriax physiotherapy in the treatment of LE (Table 2.5).

2.4.3.8 Exercise programmes

One study compared a home exercise programme with ultrasound (Pienimaki et al., 1996). This study has been previously reported herein (section ultrasound, 2.4.3.2). There is moderate evidence (Level B) that the home exercise programme can be an effective treatment in patients who suffer from LE (Table 2.5).

No studies that investigated the effectiveness of a supervised exercise programme were found. Therefore, there is no evidence (Level D) for the effectiveness of this treatment on LE (Table 2.5).

2.5 Discussion

A wide array of physiotherapy treatments has been recommended for the management of LE. The present review found strong evidence for the short-term effectiveness of acupuncture for LE. It also found that there was strong evidence that four physiotherapy interventions, LPLL, ultrasound, ESWT and pulsed electromagnetic field therapy, were not effective treatments for LE. There was not sufficient evidence to judge the

effectiveness of other treatments such as iontophoresis and home exercise programmes. Finally, there was no evidence available for the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light). It appeared most appropriate then to investigate the clinical use and effectiveness of Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light).

The systematic review conducted by Labelle et al (1992) could not determine the effectiveness of physiotherapy for LE due to small number of available studies (i.e. 7). Three recently published systematic reviews by Smidt et al (2003), Trudel et al (2004) and Bisset et al (2005) included a larger numbers of studies (i.e. 23, 31 and 28, respectively) but they concluded that there was insufficient evidence to support the effectiveness of physiotherapy treatments for LE. Reading the systematic review by Bisset et al (2005) carefully and in depth, they drew the same conclusions with the present systematic review about the effectiveness of physical therapy interventions for the management of LE. However, Bisset et al (2005) did not report evidence for the effectiveness of polarised polychromatic non-coherent light (Bioptron light). This lack of evidence probably occurred because Bisset et al (2005) did not experiment on this form of light therapy. The results obtained by Smidt et al (2003) and Trudel et al (2004) contrast with the results of the present review and the systematic review by Bisset et al (2005). This may be attributed to the different methods of data analysis employed by the reviews. In the present systematic review, a vote counting procedure was used and the results were summarized using a rating system for levels of evidence; Smidt et al (2003) performed a meta-analysis. Trudel et al (2004) also used a vote-counting procedure to summarize the results obtained by using a rating system for levels of evidence. However, the rating system for levels of evidence in the Trudel review was fundamentally different from the rating system for levels of evidence used in the present systematic review. Trudel et al (2004) used the Sackett's level of evidence, while in the present study the Linton and Van Tulder (2001) level of evidence was used. On the other hand, Bisset et al (2005) also performed a meta-analysis, using studies with at least 40% quality in a modified Pedro scale.

The most important aspect of a systematic review may be the authors' quality assessment of the included studies. If the raw material is flawed then the conclusions of

systematic review cannot be trusted (Egger et al., 2001). Traditionally, one of the corner stones of systematic reviews has been to base conclusions on the outcome of trials with the best-rated methodology (Bjordal, 2003). The choice of a quality scale may also dramatically affect the final results and conclusions of systematic reviews (Juni et al., 1999; Herbert et al., 2001) Though a number of scales have been developed, many have not been fully validated (Moher et al., 1999) and many include items that may not be related to the internal validity of a trial (Moher et al., 1995; Juni et al., 2001). In the present review, the Chalmers' scale was used to assess the quality of the included trials. The Chalmers' scale has been validated and tested for reliability by Berard et al (2000).

Overall, the studies covered in this review rated well on Chalmers' scale of quality. However, methodological shortcomings such as lack of (i) adequate allocation concealment; (ii) blinding of participants, assessors and therapists; (iii) standardised outcome measures; (iv) power analysis; (v) recruitment strategies; (vi) long term follow-up; (vii) reasons for drop-outs; and (viii) clear descriptions of interventions, were present. Many of the studies failed to provide adequate allocation concealment and some failed to blind the participants, assessors administering the interventions, or the assessors measuring outcomes. There is empirical evidence that inadequate methods of allocation concealment produce more generous estimates of the effects of treatments (Schulz et al., 1995; Moher et al., 1998). This potentially skews the findings of a systematic qualitative review in favour of the treatment under consideration (Schultz et al., 1995; Altman and Schultz, 2001). Other meta-analyses have found that lack of blinding can significantly bias treatment results (Gam et al., 1993). Although some interventions such as exercise programmes and Cyriax physiotherapy may be difficult to blind due to the manner of their application, it should be possible for trials to be blind with respect to the assessors. In addition, a number of trials were labelled "double blind", but they failed to provide any details of the blinding status of groups involved in the trials. The failure to use standardised outcome measures was another area of deficit. Too many different outcome measures, with their differences in validity, reliability and responsiveness, complicate the comparison of the effects of treatments and the interpretation of effectiveness. The lack of power analysis becomes an important issue in studies that fail to report any difference between interventions. There is a risk of the type II error (Wright and Vicenzino, 1997), i.e. it becomes difficult to determine whether the results are due to the fact that no treatment effect exists or to the fact that

the study lacked sufficient statistical power to detect any small but clinically important therapeutic effect (Stratford et al., 1993). Recruitment strategies were also often not described, making it difficult to generalise the results. Many of these studies failed to provide adequate long-term follow-up. Although patients may be mainly interested in a fast recovery, if a treatment's initial advantage is sustained in long-term follow-up, this will provide definite evidence for its effectiveness. Failure to give reasons for subject drop-outs was another shortcoming of the studies. The outcome of a study can be much influenced by the large numbers of dropouts. This is even more problematic if the drop-out is selective (Koes, 2004). It is possible, however, to deal with selective follow-up in the analysis phase of a study. Additional analysis using a 'worst case analysis' could be carried out (Koes, 2004). Finally, a study's lack of discussion of clinical and practical issues relating to the interventions themselves, including clear descriptions of the techniques, dosage, and progression as well as training or experience requirements, makes it difficult to replicate study interventions. Future research is recommended to resolve these issues.

LPLL has during the last fifteen or twenty years attracted much interest as it is applied to common musculoskeletal conditions such as LE (Wright and Vicenzino, 1997). Helium-neon (HeNe) and gallium arsenide (GaAs) are the two most common types of LPLL (Prentice, 1999). LPLL application is ideally done with light contact to the affected site and/or to the acupuncture points and should be perpendicular to the target (Prentice, 1999). LPLL is primarily used in practice to relieve pain and stimulate tissue healing at the cellular level (Baxter et al., 1991; Simunovic et al., 1998; Sevier and Wilson, 2000; Pienimaki, 2000). However, in the literature there is no agreement on the optimal treatment for pain relief with regard to the intensity, frequency, wavelength and the peak pulse (Sevier and Wilson, 2000). The present review and the review by Bisset et al (2005) revealed strong evidence (Level A) that LPLL is an ineffective treatment for LE. This is in accordance with the systematic review by Gam (1993), which concluded that LPLL has no effect on pain in musculoskeletal syndromes, and with the RCT by Mulcahy (1995), which concluded that LPLL acts primarily as a placebo. Contradicting these findings, one meta-analysis found that the effectiveness of LPLL treatment in treating tendinopathy was dependant on a range of application parameters such as dose 0.1-3 J/cm^2, power density 5-21 mW/cm^2 and frequency 3-5 times per week (Bjordal et al., 2001). In the present review and others (Gam et al., 1993; Smidt et al., 2003; Trudel

et al., 2004; Bisset et al., 2005), it has been difficult to test for dose response due to poor reporting of parameters and a dearth of clinical studies comparing the effectiveness of different physical-therapy-treatment parameters. However, LPLL cannot be ruled out as a subject of research; its dose-response modality and its optimal-treatment dosage for the management of LE and other musculoskeletal conditions may not as yet have been determined.

Polarised, polychromatic, non-coherent light (Bioptron light) has recently appeared on the market for the treatment of a wide range of medical conditions including LE. Details of the rationale behind the use of polarised, polychromatic non-coherent light (Bioptron light) are presented in chapter 3 (section 3.6). This review found no evidence (Level D) to support the effectiveness of polarised, polychromatic non-coherent light (Bioptron light) in patients with LE. The extent of clinical use of polarised polychromatic non-coherent light (Bioptron light) is not known although novel modalities like it are attractive to practitioners working in rehabilitation settings. Therefore, further research to investigate the effectiveness of this modality is required.

Ultrasound is a commonly used modality among physical therapists for the management of soft tissue injuries such as LE (Naslund, 2001). For LE, this modality can be applied continuously or pulsed over the origin of the common extensor tendon (Sevier and Wilson, 2000). Pulsed ultrasound at low intensities (mean 0.5 W/ cm^2) is commonly referred to in practice for soft tissue repair, because it has been found to have beneficial effects on collagen synthesis (Dyson and Suckling, 1978; Khan et al., 2000a). Ultrasound is primarily used for analgesia assisting tissue healing with the pulsed more than continuous ultrasound (Halle et al., 1986; Stratford et al., 1989; Kochar and Dogra, 2002). However, there is no agreement in the literature on the optimal treatment dosage of this modality for pain relief (Klaiman et al., 1998). This review and the systematic review by Bisset et al (2005) found strong evidence (Level A) that ultrasound is an ineffective modality as a sole treatment for patients with LE. Six reviews, four narrative and two systematic, accord with this finding, reporting that ultrasound is not an effective treatment approach for pain treatment (Falconer et al., 1990; Reitman and Esses, 1995; Balint and Szebenyi, 1997; Fedorczyk, 1997; Van der Heijden et al., 1997; Van der Windt et al., 1999). However, further research into the use of this modality cannot be ruled out: it is a dose-response modality and its optimal-treatment dosage for the

management of LE and other musculoskeletal conditions may not as yet have been determined.

The use of acupuncture is constantly growing in the Western world, but it has long been used with good results in China (Naslund, 2001). Acupuncture is recommended for a plethora of medical conditions (Wright and Vicenzino, 1997). One of these conditions is LE (Wright and Vicenzino, 1997; Sevier and Wilson, 2000). In acupuncture, needles are usually used. They are placed at acupuncture points dictated by traditional Chinese medicine (Sevier and Wilson, 2000). TENS and LPLL can also be used for acupuncture but no so common as needles. Acupuncture is mainly used for symptomatic pain relief (Pienimaki, 2000; Fink et al., 2002; Trinh et al., 2004). The improvement of function is related to the short-term analgesia and not to the promotion of tissue healing. However, the optimal acupuncture treatment to obtain pain alleviation is still unknown (Trinh et al., 2004). The findings of the present review and the systematic review by Bisset et al (2005) provide strong evidence (Level A) for the short-term effectiveness of acupuncture for LE patients. A recently published systematic review accords with this, reporting strong evidence to support the use of acupuncture on LE, especially in short-term (Trinh et al., 2004). However, further research is required to determine which acupuncture type is the most effective, in which dosage, and if this treatment can produce long-term effects.

ESWT is a relatively new treatment for the management of common tendon problems such as LE (Haake et al., 2002b). ESWT consists of single pressure pulses of microsecond duration that can be focused on a site of tissue damage, i.e. the origin of the common extensor tendon for LE (Speed et al., 2002). In practice, ESWT is mainly used for symptomatic pain relief (Krischek et al., 1999; Maier et al., 2001; Wang and Chen, 2002; Melegati et al., 2004). However, the optimal treatment protocol to achieve pain reduction remains uncertain (Rompe et al., 2004; Chung and Wiley, 2004)). This review and the review by Bisset et al (2005) found strong evidence (Level A) that ESWT is an ineffective treatment for the management of LE. A recently published systematic review revealed conflicting findings about the effectiveness of ESWT in the management of LE (Stasinopoulos and Johnson, 2005). In addition, two recently published RCTs found that the ESWT is not beneficial in the treatment of LE (Melikyan et al., 2003; Chung and Wiley, 2004). On the other hand, positive effects of ESWT on

LE were found by two recently published RCTs (Rompe et al., 2004; Pettrone and Leftan, 2005) and by a recently published systematic review in German language (Rompe et al., 2005). Specifically, Rompe et al (2004) found the ESWT an effective treatment in tennis players who suffered from LE. Based on the results of the previously reported studies there is chaos about the effectiveness of ESWT and definite conclusions cannot be drawn. Research on ESWT must be continued in order to determine the optimal treatment dosage of ESWT for the management of LE and which population of LE patients ESWT can treat effectively.

Pulsed electromagnetic field therapy is an accessory electrotherapeutic modality for the management of a variety of medicinal conditions (Pienimaki, 2000). This kind of therapy had good results in the treatment of ununited fractures (Bassett et al., 1982) and rotator cuff tendinopathy (Binder et al., 1984). Pulsed electromagnetic field therapy is recommended for tendon disorders such as LE to promote tissue healing and reduce pain by inference (Deveraux et al., 1985). The findings of the present review and of the systematic review by Bisset et al (2005) indicated strong evidence (Level A) that pulsed electromagnetic field therapy is an ineffective intervention for the management of LE. There is no objective evidence that clearly supports the therapeutic value of this modality for many of the conditions for which this is recommended such as LE. However, research with this treatment must be continued until it is possible to draw definite conclusions about its effectiveness on LE.

Iontophoresis is another "recommended" physiotherapy modality for the management of LE (Sevier and Wilson, 2000; Pienimaki, 2000). It is claimed that iontophoresis works by transmitting medication into the underlying tissues using a very low electrical current (Demirtas and Oner, 1998; Sevier and Wilson, 2000; Runeson and Haker, 2002; Baskurt et al., 2003). It can be used as an alternative to injections without the traumatic effects of injections, with no pain for the patient and no risk of infection (Wright and Vicenzino, 1997; Demirtas and Oner, 1998; Sevier and Wilson, 2000; Baskurt et al., 2003). Iontophoresis is recommended for symptomatic pain relief (Sevier and Wilson, 2000; Baskurt et al., 2003). However, the optimal protocol to obtain the pain relief remains unknown (Sevier and Wilson, 2000). The present review and the review by Bisset et al (2005) revealed moderate evidence (Level B) that iontophoresis offers no benefit in patients with LE. This finding is supported by a recently published and well-

designed RCT about iontophoresis for LE (Nirschl et al., 2003). However, more research is required to determine if there is evidence for iontophoresis' effectiveness for LE in appropriate dosage, although there is the claim that it should only be considered as part of the overall management of the patient as with all pharmacological agents (Demirtas and Oner, 1998).

Cyriax physiotherapy, consisting of deep transverse friction and Mill's manipulation, is currently used extensively for the management of LE (Stasinopoulos and Johnson, 2004d). Details of the rationale behind Cyriax physiotherapy are presented in chapter 3 (section 3.4). The present review found one study to show at least moderate evidence of the effectiveness of Cyriax physiotherapy for LE. However, the present review reports no evidence (Level D) for the effectiveness of Cyriax physiotherapy for LE, because the results of the Cyriax physiotherapy study (Verhaar et al., 1996) were not presented well and leave the reader with several questions. Further research is required if scientific evidence for the effectiveness of Cyriax physiotherapy for LE is to be determined.

Exercise programmes are a common physiotherapy treatment for LE patients (Sevier and Wilson, 1999; Sevier and Wilson, 2000; Pienimaki, 2000). The rationale behind exercise programmes is presented in chapter 3 (section 3.5). The goal of exercise programmes is to return the patient to full function with no pain (Sevier and Wilson, 1999; Sevier and Wilson, 2000). This review found moderate evidence (Level B) for the effectiveness of home exercise programmes for LE. The present review found no evidence (Level D) to support the effectiveness of supervised exercise programmes for LE. It might be argued that exercise programmes are only for home use. Home exercise programmes have been used in some previously published clinical trials as the sole treatment approach or as a part of a treatment programme (Pienimaki et al., 1996; Drechsler et al., 1997; Svelnlov and Adolfsson, 2001; Kochar and Dogra, 2002; Smidt et al., 2002b; Struijs et al., 2003; Struijs et al., 2004). The major advantage of home exercise programme is that patients carry them out independently, saving time for both patient and therapist (Stasinopoulos and Johnson, 2004b). However, it is difficult to monitor patient compliance in home exercise programmes. Patients need a physiotherapist to monitor the administration and progress of the programme and exercise programmes are consequently better performed in clinical settings under the

supervision of physiotherapists (Stasinopoulos and Johnson, 2004b). Further research is required to investigate the effectiveness of supervised exercise programmes on LE.

Due to the nature of this review (a PhD dissertation), the focus was on studies written in the English language. For the same reason, the researcher personally determined the selection criteria of included studies. Although the quality of the majority of included studies was found satisfactory on Chalmers' scale, they had some shortcomings such as insufficient blinding in respect to patients and therapists and a lack of power-statistical analysis. Chalmers' scale was validated and tested for reliability by Berard et al (2000) but one wonders whether Chalmers' system for rating methodological quality can adequately assess the true methodological quality of physiotherapy trials. Two possible explanations will be presented below to answer this issue.

One explanation is that some of these criteria (such as blinding in respect to therapists and patients) seem to be irrelevant and unrealistic for physiotherapy trials. Failure to meet these criteria does not affect the methodological quality in physiotherapy studies. Another explanation is that the Chalmers' scale does not fully express the true methodological quality of physiotherapy trials. It would therefore be useful to compare the results derived from using Chalmers' scale with those obtained by using other scales such as those of Pedro or Jadad (Smidt et al., 2003). In respect of the included studies, a correlation between the scores achieved by these scales would be significant.

In addition, the rating system for levels of evidence of the present review does not specify the kind of studies required, whether of high or low quality, to achieve a rating as "strong evidence". It might be wrongly assumed that a rating system for levels of evidence does not require a rating of methodological quality. In fact, if strong evidence is found for the effectiveness of a treatment, we must know what kind of studies, whether they were of high or low quality, this finding was based on. If these studies were of low quality, the effectiveness of this treatment would be controversial and more research with well-designed studies would be required. On the other hand, if the finding was based on high-quality studies, this treatment could be recommend as an "ideal" treatment for the investigated condition. In short, a methodological-quality rating is required in any rating system that assesses levels of evidence. This issue could be avoided if the results of the present review had been compared with other rating systems

that measure levels of evidence, systems such as the one developed by Van Tulder et al (1997), which requires high-quality studies to achieve strong evidence for the effectiveness of a treatment. Such a comparison would allow us to determine whether any correlation existed between the two compared level-of-evidence rating systems as applied to the effectiveness of the treatments included in the present study. However, a recently published meta-analysis and systematic review (Bisset et al., 2005) confirmed the conclusions of the present review and therefore the findings of the present review are valid and can be trusted.

2.6 Conclusion

This review showed that there was strong evidence for the short-term effectiveness of acupuncture for LE. It also found that there was strong evidence that four physiotherapy modalities, LPLL, ultrasound, ESWT and pulsed electromagnetic field therapy were not effective treatments on LE. Other treatments used for LE such as iontophoresis and home exercise programmes had insufficient evidence available to judge the results of their effectiveness. However, all the previously reported physiotherapy treatments for LE cannot be refuted or recommended as ideal treatment for LE, because the optimal treatment protocols are unknown. Additional well-designed RCTs are needed to provide definite conclusions for the effectiveness of these LE-treatment modalities. Finally, this review found no evidence for the effectiveness of Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) for LE. This is rather strange because Cyriax physiotherapy and a supervised exercise programme appear to be used extensively by physiotherapists for treating LE. In addition, polarised polychromatic non-coherent light (Bioptron light) is a new modality, which is gaining popularity for treating LE. Therefore, it is important to investigate the clinical use and effectiveness of Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) as treatments for LE.

Table 2.1

**Evaluation form A adapted from Chalmers et al. (1981) showing the 15 items
scored to evaluate the study design of a clinical trial**

Items	Possible points
Description of selection of subject was adequate	0-3
Description of patients screened was provided	0-3
Inclusion criteria for study included	0-2
Exclusion criteria for study included	0-2
Withdrawals and reason for withdrawal were described	0-3
Therapeutic regimen definition	0-3
Control appearance	0-2
Randomisation was blinded	0-10
Patients were blinded to treatment group	0-8
Investigators were blinded to treatment group	0-8
Power calculations (sample size requirements)	0-4
Adequacy of randomisation was evaluated	0-4
Adequacy of blinding was evaluated	0-3
Compliance with treatment has assessed	0-3
Measure of outcome of active therapy was made	0-2
	Total possible score 60

0-2: 0= no information available; 1=some information available; 2= all information available

0-3: 0= no information available; 1.5=some information available; 3= all information available

0-4: 0= no information available; 2=some information available; 4= all information available

0-8: 0= no information available; 4=some information available; 8= all information available

0-10: 0= no information available; 5=some information available; 10= all information available

Table 2.2

**Evaluation form B adapted from Chalmers et al. (1981) showing the 14 items
scored to evaluate the data analysis of a clinical trial.**

Items	Possible points
Dates of study description	0-2
Results of randomisation	0-2
Post type 2 estimate	0-3
Confidence limits	0-3
Time series analysis	0-2
Timing of evens	0-4
Correlation	0-2
Statistical analysis	0-4
P value	0-2
Withdrawals	0-4
Handling withdrawals	0-4
Side effects	0-2
Retrospective evaluation	0-3
Presentation of results	0-3
	Total possible score 40

0-2: 0= no information available; 1=some information available; 2= all information
    available

0-3: 0= no information available; 1.5=some information available; 3= all information
    available

0-4: 0= no information available; 2=some information available; 4= all information
    available

Table 2.3

Studies excluded from review with reasons

<u>**No randomisation performed**</u>

Abbott J, Patla C, Jensen R. (2001). The initials effects of an elbow mobilization with movement technique on grip strength in subjects with lateral epicondylalgia. *Manual Therapy*, 6 163-169.

Halle J, Franklin R, Karalfa B. (1986). Comparison of four treatment approaches for lateral epicondylitis of the elbow. *Journal of Orthopaedic and Sports Physical Therapy*, 8 62-69.

Johannsen F, Gam A, Hauschild B, Mathiesen B, Jensen L. (1993). Rebox: an adjunct in physical medicine? *Archives of Physical Medicine and Rehabilitation*, 74 438–440.

Krischek O, Hopf C, Nafe B, Rompe J. (1999). Shock-wave therapy for tennis and golfer's elbow-1 year follow up. *Archives of Orthopaedic and Trauma Surgery*, 119 62-66.

Maier M, Steinborn M, Schmitz C, Stabler A, Kohler S, Veihelmann Am Pfahler M, Refior H. (2001). Extracorporeal shock wave therapy for chronic lateral epicondylitis-prediction of outcome by imaging. *Archives of Orthopaedic and Trauma Surgery*, 121 379-384.

Simunovic Z, Trobonjaca T, Trobonjaca Z. (1998). Treatment of medial and lateral epicondylitis-tennis and golfer's elbow-with low lever laser therapy: A multicenter double blind, placebo controlled clinical study on 324 patients. *Journal of Clinical Laser Medicine and Surgery*, 16 145-151.

Solverborn A. (1997). Radial epicondylalgia (tennis elbow): treatment with stretching and forearm band. A prospective study with long term follow up including range of

Table 2.3 (continued)

motion measurements. *Scandinavian Journal of Medicine and Science in Sports*, 7 229-237.

Stratford P, Levy D, Gauldie S, Miseferi D, Levy K. (1989). The evaluation of phonophoresis and friction massage as treatments for extensor carpi radialis tendinitis: a randomized controlled trial. *Physiotherapy Canada*, 41 93-99.

Laboratory studies

Vicenzino B, Collins D, Wright A. (1996). The initials effects of a cervical spine manipulative physiotherapy treatment on the pain and dysfunction of lateral epicondylalgia. *Pain*, 68 69-74.

Vicenzino B, Paungmali A, Buratowski S, Wright A. (2001). Specific manipulative therapy treatment for chronic lateral epicondylalgia produces unique characteristic hypoalgesia. *Manual Therapy*, 6 205-212.

Wang C, Chen H. (2002). Shock wave therapy for patients with lateral epicondylitis of the elbow: A one to two year follow up. *American Journal of Sports Medicine*, 30 422-425.

Combination of treatments

Burton AK. (1988). A comparative trial of forearm strap and topical anti-inflammatory as adjuncts to manipulative therapy in tennis elbow. *Manual Medicine*, 3 141–143.

Demirtas N, Oner C. (1998). The treatment of lateral epicondylitis by iontophoresis of sodium salicylate and sodium diclofenac. *Clinical Rehabilitation*, 12 23-29.

Table 2.3 (continued)

Drechsler W, Knarr J, Mackler L. (1997). A comparison of two treatment regimens for lateral epicondylitis: a randomised trial of clinical interventions. *Journal of Sport Rehabiliation*, 6 226-234.

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

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

Rompe J, Riedel C, Betz U, fink C. (2001). Chronic lateral epicondylitis of the elbow (tennis elbow)-prospective comparison of low energy wave therapy with low energy shock wave therapy plus manual therapy of the cervical spine. *Archives of Physical Medicine and Rehabilitation*, 82 578-582.

Smidt N, Windt D, Assendelft W, Deville W, Bos I, Bouter L. (2002b). Corticosteroids injections, physiotherapy, or a wait and see policy for lateral epicondylitis: a randomised controlled trial. *Lancet*, 359 657-662.

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

General soft tissue injury (not exclusively LE)

Klaiman M, Shraded J, Danoff J, Hicks J, Pesce W, Ferland J. (1998). Phonophoresis versus ultrasound in the treatment of common musculoskeletal conditions. *Medicine and Science in Sports and Exercise*, 30 1349-1355.

Table 2.3 (continued)

Vecchini L, Grossi E. (1984). Ionization with diclofenac sodium in rheumatic disorders: a double-blind placebo-controlled trial. *Journal of International Medical Research*, 12 346–350.

Characteristics of included studies

Study	Patients No. of subjects (n) Sex M/F Age (ys) Duration of symptoms	Interventions Type (n) Time Frequency	Outcomes measures when administered	Author(s) conclusion	Reviewer conclusion	Quality score (%)
Lundeberg et al. (1987)	n=57 31M 26F 25-62 ys Symptoms at least three months	Ga-As pulse wave laser (19) Vs He-Ne continuous laser (19) Vs placebo laser (19). Laser was applied at surface of skin for 60sec in each acupuncture point which were Li 10,11,12 SJ 5,10, SI 4,8, H3,4, P3. No reported dose 2 treatments per week, 10 treatments totally over 5-6 weeks	Pain VAS Lifting test Grip strength Measurements taken at baseline, end of treatment and three months after the end of treatment	Laser was no significant better than placebo at the end of treatment and at follow ups	Laser not effective	33
Haker & Lundeberg (1990)	n=49 28M 21F 24-70 ys Symptoms for at least one month	Ga-As laser (23) Vs placebo laser (26). Laser was	Lifting test Grip strength Subjective reports of improvement.	No statistical significant differences between the	Laser not effective	50

		applied in L1,10,11,12,Lu5, SJ5 points for 30 in each point with wand held 1mm from skin and dose 0.36 J/point. 2-3 times per week, 10 treatment totally	Measurements taken at baseline, end of treatment three months and twelve months after the end of treatment.	groups at the end or at the follow-ups		
Haker & Lundeberg (1991b)	n=58 43M 15F 33-65 ys Symptoms for at least one month	Ga-As, He-Ne laser (29) Vs placebo laser (29). Probe was used to radiate the area over LE for eight minutes. Then pen laser was applied to acupuncture points LI11,12 for two minutes per point. 3 times per week, 10 treatments in all	Pain with diagnostic tests Grip strength Lifting test Subjective assessment Measurements taken at baseline, end of treatment, 1, 3 and 12 months after the end of treatment.	No significant difference between laser and placebo laser at the end of treatment or at follow-ups.	Laser not effective	50
Haker & Lundeberg (1991c)	n=49 31 M 18F 22-66ys Symptoms for at least one month	Ga-As laser (25) Vs placebo laser (24). Laser was applied to one point at anterior aspect of LE and five points around this site at 1.5-2	Pain with diagnostic tests Lifting test Grip strength Patient assessment Measurements taken at baseline, end of treatment, 3 months and 12 months after	Laser better than placebo at the end of treatment and at 3-month follow up.	Laser effective at the end of treatment and at 3-month follow up.	50

		cm. Each point was treated for 30 sec with laser held 1mm from skin and dose 0.36 J/point. 2-3 treatments per week, 10 treatments totally	the end of treatment			
Vasseljen et al. (1992)	n=30 15M 15 F 25-63 ys. Symptoms duration for at least one month	Infrared laser (15) vs placebo laser (15). Laser was applied 10 minutes in the painful site with $3.5 J/cm^2$, three times per week, 8 treatments totally.	Pain on VAS Lifting test Grip strength Goniometric measurements of wrist flexion Patient assessment. Measurements taken at baseline, end of treatment and at four weeks after the end of treatment	Laser better than placebo laser, but as sole treatment its effectiveness is controversial	Laser effective	58
Vasseljen (1992)	n=30 13M 17F 25-70 ys Symptoms for at least one month	Ga-As laser (15) Vs traditional physiotherapy (ultrasound and deep transverse friction) (15). Laser was applied 10 minutes in the painful site with dose $3.5 J/cm^2$, three times per week, 8 treatments	Pain on VAS Lifting test Grip strength Goniometric measurements of wrist flexion Patient assessment. Measurements taken at baseline, end of treatment and at four weeks after the end of treatment	Traditional physiotherapy better than laser	Traditional physiotherapy better than laser	61

		totally. Ultrasound 1Mhz 1.5 W/cm^2 pulsed, stationary head for seven minutes and deep transverse friction at the origin of ECRB as advocated by Cyriax for ten minutes. All treatments were given three times per week, 8 treatments in all.				
Krasheninnikoff et al. (1994)	n=36 19F 17M 37-64 ys Symptoms at least four weeks	Ga-Al-As laser (18) Vs placebo laser (18). Laser was applied to tender points on lateral epicondyle and in forearm extensors for 120 seconds (3.6 J/point). Two times per week, 8 treatments totally	Pain on VAS and four point verbal scale pain score Grip strength Tender points on LE and in forearm extensors Measurements taken at baseline, end of treatment, 10 weeks after the last treatment	No statistical significant difference between laser and placebo laser	Laser not effective	41
Papadopoulos et al. (1996)	n=29 10 M 19F mean age 45.3 ys. Symptoms for at	Ga-Al-As laser (14) Vs placebo laser (15).	Pain VAS Function with Marcy wedge	No statistical significant differences	Laser not effective	48

	least one month, with mean 25 weeks	Laser was applied to the most tender spot for 60 seconds. Three times per week for two weeks	Measurements taken at baseline and end of treatment.	between laser and placebo laser		
Basford et al (2000)	n= 47 28F 19M Mean age 45ys Symptoms for at least one month	Laser (23) Vs placebo laser (24). Laser was applied 60 seconds at seven sites along forearm (three sites immediately above, at and below LE, at distal wrist extensors, volar wrist, two sites on medical epicondyle with 12.24 J/point Three times per week for four weeks.	VAS pain Grip strength Pinch strength Tenderness on palpation Measurements taken at baseline, 6th treatment, end of treatment and one month after the end of treatment	No statistical significant differences between the groups at the end of treatment or at follow-up	Laser not effective	64
Binder et al. (1985)	n=76 28M; 48 F Age 29-65 ys Symptom duration at least one month	Ultrasound (38) Vs placebo ultrasound (38). Pulsed ultrasound 1:4; 1.0 Mhz; 1-2W/cm^2 5-10 min on the	Pain VAS Lifting test Grip strength Measurements taken at baseline, every two weeks until the end of treatment, 1 month and one year after the	Ultrasound better than placebo	Ultrasound effective	36

55

		affected area 12 treatments (2-3 times per week) for 4-6 weeks	end of treatment			
Lundeberg et al. (1988)	n=99 53M 46F age 21-68 ys Symptom duration at least one month	Ultrasound (33) Vs placebo ultrasound (33) Vs rest (33). Ultrasound continuous 1Mhz 1W/cm^2 10 minutes on the affected area 10 treatments 2 per week for 4-6 weeks	Pain VAS Pain with diagnostic tests Lifting test Grip strength Patient satisfaction Measurements taken at baseline, 1 month, three months and 12 months after the end of treatment	No significant difference between ultrasound and placebo. Significant difference between ultrasound and rest	Ultrasound= placebo Ultrasound better than rest	46
Haker and Lundeberg (1991a)	n=43 23M 20F age 34-67.2 ys Symptoms for at least one month	Ultrasound (21) Vs placebo ultrasound (22). Pulsed ultrasound 1 Mhz, 1:4; 1 W/cm^2, 2-3 times weekly at the tender site, 10 treatments in all. Each treatment 10 minutes	Pain with diagnostic tests Lifting test Grip strength Global improvement Measurements taken at baseline, end of treatment, 3 and 12 months after the end of treatment	No statistical significant differences between the groups.	Ultrasound not effective	54
Holdworth & Anderson (1993)	n=36 16M 20F age 21-66 For at least one month	Phonophoresis Vs epicondylitis clasp. Continuous ultrasound 3 Mhz, 1.5 W/cm^2	Pain VAS Lifting test Patient assessment Measurements taken at baseline, end of treatment, 1, 3 and 6	No difference between the treatments at the end of treatment and at the follow-	Ultrasound not effective	42

		3 times per week, 12 treatments in all. Epicondylitis clasp for one month	months after the end of treatment	ups.		
Pienimaki et al. (1996)	n=39 14M 25F 33-53 ys Symptom duration at least three months	Home exercise programme (20) Vs ultrasound (19) Home exercise group: progressive slow repetitive wrist and forearm stretching muscle conditioning, occupational exercises 10 reps for 2-3 sets for each exercise 4-6 times per day for 6-8 weeks Ultrasound group: pulsed ultrasound 1:5 1Mhz 0.3-0.7 W/cm^2 10-15 minutes on the affected site 2-3 times per week for 6-8 weeks	Pain and function assessment using VAS and questionnaire Isokinetic testing of wrist Grip strength Measurements taken before and after the treatment	Exercise programme more effective that ultrasound	Exercise programme more effective that ultrasound	68
Brattberg (1983)	n=60 40M 20F Age 30-60ys	Steroid injection (26) Vs	Pain using a six point scale from worse to	Acupuncture was better than	Acupuncture effective	15

57

	Persistent LE	acupuncture (34). Acupuncture was applied to L5 LI 10,11,12 TI1 points with needles for 15 minutes. 2 treatments per week for four weeks. No details of injections	no pain Measures were taken 1,3,6,12 months after the end of treatment	injection at the end of treatment and at any follow-up point		
Haker & Lundeberg (1990b)	n=80 50M 30F 25-70 ys Symptom duration at least one month	Deep acupuncture (44) Vs superficial acupuncture (36). Deep acupuncture: Needles inserted corresponding to traditional Chinese acupuncture (LI10, LI11, LI12, Lu5, SJ5), inserted to depth of 1.25–2.5 cm; all rotated to illicit The Chi every five min during 20 min Superficial acupuncture:	Pain with diagnostic tests Grip strength Lifting test Global measure of improvement Measurements taken at baseline, end of treatment, 3 months and 12 months after the end of treatment	After 10 treatments smaller number in traditional group suffered pain than in superficial group. No significant difference in any follow up point.	Deep acupuncture effective in short-term	43

		Needles inserted superficially at same points as deep acupuncture treatment group; 20 min; The Chi not obtained 2-3 times per week 10 treatments at all				
Molsberger & Hille (1994)	n=48 Symptom duration at least two months	Acupuncture Vs placebo Acupuncture. Acupuncture group: Needle on fibulatibial joint of homolateral leg, inserted 2 cm; needle manipulated until felling of dull pressure and warmth; 5 min Placebo group: Pencil-like probe stimulated a point 1.5 cm lateral to T3 (mock acupuncture); five min 1 treatment	Pain point scales were measured before, after and 12 hours after the end of treatment	Acupuncture better than placebo	Acupuncture effective	41

Fink et al. (2002)	n=45 Symptom duration at least 3 months	Acupuncture (23) Vs sham acupuncture (22) Acupuncture: six needles in Ash point, LI10, LI11, Lu5, LI4, SJ5; twisting needles until a De Qi sensation was induced; 25 min Sham acupuncture: six needles: Puncture sites five cm away from the classic points and their interconnecting meridians and also clear of painful pressure points(Ah-Shi or trigger points), 25 min 2 times per week for 2 weeks	Grip strength Pain VAS at rest, motion and resisted movement with a six point verbal rating scale (0-6) Functional impairment was measured with the Dash questionnaire Measurements taken at baseline, 2 weeks and 2 months after the end of treatment	Acupuncture better than sham	Acupuncture effective	73
Tsui & Leung (2003)	n=20 Chronic LE	Manual acupuncture (10) Vs electro-acupuncture (10). The acupuncture	Pain VAS Grip strength Measurements taken at baseline and end of treatment	Electro acupuncture is superior to manual acupuncture in treating LE	Electro acupuncture is more effective than manual acupuncture	46

		points GB34 and ST38 were used in both groups. In the manual acupuncture group the needle was retained for 20 minutes after the Deqi sensation obtained. In the electro-acupuncture group electrical stimulation with 4 pulses/second frequency was applied and treatment lasted for 20 minutes. 6 treatments in 2 weeks		patients		
Rompe et al. (1996)	n=100 42M 58F 26-61 ys Symptoms for more than 12 months	ESWT (50) Vs sham ESWT (50). ESWT: 1000 impulses of 0.08mJ/mm^2. Sham ESWT: 10 impulses of 0.08 mJ/mm^2. ESWT and sham ESWT were administered at	Pain VAS Pain with diagnostic tests Grip strength Global improvement Measurements taken at the end of treatment and at 3, 6 and 24 weeks after the end of treatment	ESWT more effective than ESWT placebo at the end of treatment and at follow-ups ups	ESWT better than placebo ESWT	55

		the anterior aspect of the lateral epicondyle and at three points around this site at a radius of 1.5 to 2 cm at a frequency of 3Hz at intervals of one week. 20-30 minutes each session				
Haake et al. (2002)	n=271 128M 143F Mean age 46.9+-8.5 and 46.3+-9.6 chronic LE	ESWT (134) Vs sham ESWT (137). ESWT was applied three times in three weeks with 2000 pulses and a energy flux density to be 0.07-0.09mJ/mm^2. Sham ESWT was given in the same regimen, but a polyethylene foil filled with air and fixed with ultrasound gel in front of the	Pain VAS Pain with diagnostic tests Grip strength Roles and Maudsley Score Measurements taken at the end of treatment, six weeks and 12 weeks after the end of treatment	No significant difference between ESWT and placebo therapy at the end of treatment and at follow-ups.	ESWT not effective	75

		coupling cushion totally reflected the shock waves.				
Speed et al. (2002)	n=75 33 M 42F 26-70 ys Symptoms for at least 3 months	ESWT (40) versus sham ESWT (35). ESWT was applied using 1500 pulses at $0.18mj/mm^2$. Sham ESWT was applied using 0.04 mj/mm^2. 20-30 minutes each session. Three times in a month.	Pain VAS Measurements taken at baseline and one month after the end of treatment	No significant difference between the two groups.	ESWT not effective	53
Crowther et al. (2002)	n=73 38M 35F 27-69ys Symptoms for at least 4 months	ESWT (48) Vs corticosteroid injection (25) Injection in the origin of ECRB using 20 mg of triamcinolone made up to 1.5ml with 1% lignocaine using an aseptic technique. ESWT in the origin of ECRB 2000waves maximum $0.1MJ/mm^2$ three times at weekly	Pain VAS Measurements taken at baseline, six weeks and three months after the end of treatment	Injection was more effective treatment than ESWT at the end of treatments and at follow-ups	ESWT less effective than corticosteroid injection	56

		intervals				
Deveraux et al. (1985)	n=30 17M 13F Treatment group 43.7+-2 and in placebo group 43.9 +-2.5 Symptom duration at least three months	Pulsed electromagnetic field therapy regime (15) Vs placebo dummy coils (15) 8 hours per day 1-2 sessions per day for eight weeks	Pain induced by lifting Incremental lifting test Pain with wrist dorsiflexion Effect on work Pain on routine daily tasks Tenderness over lateral epicondyle Grip strength Thermal gradient Measurements taken at baseline and every two weeks during the treatment period	No significant differences between the groups	Pulsed electromagnetic field therapy not effective	65
Chard & Hazleman (1988)	n=55 22M 23F 22-68ys Symptom duration at least three months	Pulsed electromagnetic field therapy regimen (23) Vs placebo dummy coils (22) 8 hours per day for six weeks	Pain VAS Grip strength Patient assessment Measurements taken at baseline and at the end of treatment	No significant differences between the groups	Pulsed electromagnetic field therapy not effective	43
Runeson & Haker (2002)	n=64 41M 23F age 22-64ys Pain at least for one month	Iontophoresis (33) Vs placebo iontophoresis (31). Iontophresis was applied with the IOMED device using 0.4% daxamethasone	Pain with diagnostic tests Grip strength Measurements taken at baseline, end of treatment, 3 months and six months after the end of treatment	No statistical significant difference between iontophoresis and placebo iontophoresis at the end of treatment and	Iontophoresis not effective	55

		sodium phospate. The placebo group received saline. Current was 4mA. This was given four times for 2 weeks, 10 minutes each time			at the follow-ups.		
Verhaar et al. (1996)	n=106 59M 47 Mean age 43ys Symptoms duration no specified	Corticosteroid injections Vs Cyriax physiotherapy Injection group: one injection and patients were then seen two and four weeks after the start of treatment and a second or third injection was given. Cyriax physiotherapy was given (deep transverse friction and Mill's manipulation) for four weeks 12 treatments, totally	Severity of pain Occurrence of pain Subjective loss of grip strength Grip strength Pain with diagnostic tests Result rating Patient satisfaction level Resumption of labor Measurements taken at baseline, 6 weeks and 52 weeks after the end of treatment	Corticosteroid injection better than Cyriax at 6-week assessment no significant differences in one year follow-up	Corticosteroid injection better than Cyriax at six weeks. No difference between the two treatments at long term follow up. Maybe both not effective. This is not specified	44

Abbreviations next page

M=male; F=female; VAS=visual analogue scale; n=number of patients; DASH=disabilities of the arm, shoulder, and hand; yr=years; reps=repetitions; ESWT=extracorporeal shock-wave therapy; He=Helium; Ne=Neon; Ga=Gallium; As=Arsenide; Al=Aluminium; W=watts; cm=centimeters; mm=millimeters; J=joule; min=minutes; LE= lateral epicondylitis; ECRB=Extensor carpi radialis brevis; Mhz= megahertz; Vs=versus

Table 2.5

Evidence of effectiveness for physiotherapy treatments for the treatment of LE

Treatment	Evidence	Effective	Ineffective
LLPL	Level A		++
Polarised polychromatic non-coherent light (Bioptron light)	Level D	??	??
Ultrasound	Level A		++
Acupuncture	Level A	++	
ESWT	Level A		++
Pulsed electromagnetic field therapy	Level A		++
Iontophoresis	Level B		??
Cyriax physiotherapy	Level D	??	??
Home exercise programme	Level B	??	
Supervised exercise programme	Level D	??	??

++ = Strong evidence, but further well-designed studies are needed in order to draw definite conclusions for recommendations. Acupuncture is a short-term effective treatment.

?? = More research

Chapter 3: A critical review of the literature to establish treatment protocols based on the claims of manufacturers and anecdotal reports from therapists for Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the management of the pain and functional impairment of lateral epicondylitis

3.1 Introduction

The systematic review conducted in the previous chapter found strong evidence for the short-term effectiveness of acupuncture for LE. It also found strong evidence that four modalities, LPLL, ultrasound, ESWT, and pulsed electromagnetic field therapy were not effective physiotherapy treatments for the management of LE. There was insufficient evidence to determine the effectiveness of other treatments (e.g. iontophoresis and home exercise programmes). The systematic review also revealed the possibility that treatments may have been incorrectly administered, since optimal treatment protocols are unknown and that this may have been accounted for the lack of effects in these RCTs. Chapter 2 recommended that more evidence is needed for Cyriax physiotherapy, supervised exercise programmes, and polarised polychromatic non-coherent light (Bioptron light). However, it is necessary to establish optimal protocols for them before a suitable clinical trial can be designed. Chapter 2 provided information only for the treatment protocol of Cyriax physiotherapy on LE, because this physiotherapy treatment was used in one RCT (Verhaar et al., 1996).

3.2 Aim

This chapter discusses a critical review of literature in an attempt to establish treatment protocols for Cyriax physiotherapy, supervised exercise programmes, and polarised polychromatic non-coherent light (Bioptron light), for the management of pain and functional impairment associated with LE.

3.3 Methods

An electronic search for clinical studies was carried out in six databases: Medline (from 1966 to December 2002), Embase (from 1988 to December 2002), Cinahl (from 1982 to December 2002), Index to Chiropractic literature (from 1992 to December 2002) SportDiscus (from 1990 to December 2002) and Chirolars (from 1994 to December 2002). A search took a very broad approach in order to capture all published material from any source including any clinical study, review, and letters to editors of journals. The following key words were used individually or in various combinations: "tennis elbow", "lateral epicondylitis", "lateral epicondylalgia", "extensor tendinopathy", "extensor tendonitis", "extensor tendinosis", "rehabilitation", "treatment", "management", "protocol", "optimal protocol", "Cyriax physiotherapy", "exercise programme", "exercise therapy", "polarized light", "polarized light therapy", "Bioptron light", "claims", "experts' claims", "manufacturers' claims" and "clinicians' claims".

Only English language publications were considered. Other references were attempted to identify from existing reviews, books and other papers cited in the publications searched. Additional reports were sought from the reference sections of papers that were retrieved, from contacting experts in the field, from the Cochrane Collaboration clinical trial register (last search December 2002) and from internet sites such as www.bioptron.com. Unpublished reports and abstracts were included in the review.

Treatment protocols would be developed using the following criteria:
(i) Methodological quality of the clinical study. Studies that report a treatment protocol that is effective will be given credence.
(ii) Clinical observations will be given greater credence over theoretical papers.
(iii) Credibility of particular commentators, authors and experts.

3.4 Cyriax physiotherapy

A review of the literature revealed that Cyriax physiotherapy for treating LE consists of DTF and Mill's manipulation (Cyriax, 1982; Kesson and Atkins, 1998). Mill's manipulation is performed immediately after the DTF (Cyriax, 1982). No literature was found to contradict this Cyriaxs' approach (Stasinopoulos and Johnson, 2004d). DTF and Mill's manipulation have been administered separately for LE in previously

published studies (Burton, 1988; Stratford et al., 1989; Dwars et al., 1990; Vasseljen, 1992; Drechsler et al., 1997; Smidt et al., 2002b; Struijs et al., 2003; Struijs et al., 2004). In all these studies, Cyriax physiotherapy was not administered but components of Cyriax physiotherapy were administered as advocated by Cyriax (1982). Cyriax (1982) claimed that, if clinicians intended to use Cyriax physiotherapy in treating patients with LE, it could only be considered Cyriax physiotherapy in treating patients with LE if the two therapy components were used together in the order mentioned, rather than separately or in another order. Cyriax physiotherapy consists of DTF only in the rest tendinopathies (Cyriax, 1982). The reasons why Cyriax physiotherapy is applied in a different way between LE and rest tendinopathies will be discussed in chapter 7. Both components of Cyriax physiotherapy are based on the clinician's experience and the patient's verbal feedback; for this reason, these two components cannot be given in a standardized way. Cyriax physiotherapy treatment is individualised on the basis of the patient's description of pain experienced during the procedure. If the patient reports too much pain the therapist reduces the intensity of DTF/Mill's manipulation. Cyriax (1982) and Kesson and Atkins (1998) stated that Cyriax physiotherapy was administered to patients three times per week for four weeks (a month).

3.4.1 DTF

DTF is a specific type of connective tissue massage applied precisely to the soft-tissue structures such as tendons, in the case of LE to the ECRB tendon (Cyriax, 1982; Chamberlain, 1982; de Bruijn, 1984; Noteboom et al., 1994; Selvier and Wilson, 1999; Selvier and Wilson, 2000; Wright and Sluka, 2001). Although some practitioners using this technique maintain that the word "friction" is technically incorrect and would be better replaced by the word "massage" (Kesson and Atkins, 1998; Sevier and Wilson, 1999), this project uses "friction" because this is the term advocated by Cyriax. DTF was developed in an empirical way by Cyriax and is currently used extensively in rehabilitation practice (Noteboom et al., 1994; Selvier and Wilson, 1999; Selvier and Wilson, 2000) because it is believed that the application way of DTF can really help in the management of collagen tissue (section 3.4.4). However, the experience of Cyriax is an unreliable tool to determine the effectiveness of DTF (Ernst, 1995) and therefore more research in the form of well-designed clinical trials is needed to determine its effectiveness.

DTF advocates claim that DTF should be administered only at the exact site of the lesion, with the depth of the DTF that is tolerable to the patient; relief cannot otherwise be expected (Cyriax, 1982; Chamberlain, 1982; de Bruijn, 1984; Kesson and Atkins, 1998). However, to find the exact site of lesion, the correct clinical diagnosis, the anatomical knowledge and palpation skills of the physical therapist must be considerable (Cyriax, 1982; Kesson and Atkins, 1998). In addition, the depth of DTF to reach and benefit the target issue is dependent upon the irritability of the lesion and the verbal feedback from the patient (Cyriax, 1982; Chamberlain, 1982; Kesson and Atkins, 1998; Selvier and Wilson, 1999; Selvier and Wilson, 2000).

Advocates claim that DTF should be administered transversely across the longitudinal orientation of the fibre of the specific structure involved. It is claimed that this kind of DTF application assist tissue healing (section 3.4.4). This is unlike superficial massage, which is given in a longitudinal direction, parallel to the vessels. Superficial massage is said to enhance circulation and the return of fluids (Cyriax, 1982; Kesson and Atkins, 1998). It is also claimed that the therapist's fingers and patient's skin should move as a single unit when DTF is performed; otherwise subcutaneous fascia could lead to blister formation or subcutaneous bruising due to friction (Chamberlain, 1982). The most efficient way to achieve the movement of the therapist's fingers and patient's skin as a single unit during the DTF application is to apply the DTF in two directions. Pressure is first directed down onto the structure and maintained whilst the transverse sweep is applied (Kesson and Atkins, 1998).

It is generally recommended that DTF be applied for 10 minutes every other day or at a minimum interval of 48 hours, preparing the tendon for Mill's manipulation (Cyriax, 1982; Chamberlain, 1982; Kesson and Atkins, 1998; Selvier and Wilson, 1999; Selvier and Wilson, 2000). Only empirical evidence does support the above suggested times. However, increasing the time of DTF application clinicians claim that this method places a considerable strain on the hands of the treating clinician, who find it exhausting (Stratford et al., 1989; Vasseljen, 1992; Noteboom et al., 1994; Selvier and Wilson, 1999; Selvier and Wilson, 2000; Wright and Sluka, 2001). The considerable strain on the hands of the treating clinician may result in the loose and no correct application of the technique or increase the possibility of injury. In addition, in the application of DTF daily the lesion would be tender from the previous day's encounter to tolerate adequate

treatment. Over the years, the technique has unfortunately developed a reputation for being very painful for the patient (Ingham, 1981; Woodman and Pare, 1982; de Bruijn, 1984). However, pain during DTF application is usually the result of a wrong indication, a wrong technique, an unaccustomed amount of pressure, or a combination of the above three and usually results from the administration of DTF by a physiotherapist inexperienced with this technique (Cyriax, 1982; Chamberlain, 1982; Kesson and Atkins, 1998). It is claimed that if DTF is administered by a physiotherapist experienced with this technique, one who has a certification or diploma in orthopaedic medicine based on Cyriax principles, DTF will not be at all a painful experience for the patient (Cyriax, 1982; Chamberlain, 1982; Kesson and Atkins, 1998).

Absolute contraindications to DTF are few. DTF should never be applied to active infections, bursitis and disorders of nerve structures, ossification and calcification of the soft tissues, and active rheumatoid arthritis. Care must be taken if there is fragile skin or if the patient is currently undergoing anticoagulant therapy (Cyriax, 1982; Chamberlain, 1982; de Bruijn, 1984; Galloway et al., 1992; Kesson and Atkins, 1998). These contraindications are overcome if (i) clinicians diagnose the condition correctly (bursitis, active rheumatoid arthritis, disorders of nerve structures and anticoagulant therapy); (ii) a plain X-ray of the affected structure has been taken (in the suspicion of ossification and calcification of the soft tissues) and (iii) clinicians check the skin for infections.

3.4.1.1 Recommendations for the application of DTF for the treatment of LE

It is claimed that, for the treatment of LE, DTF should be applied as in the following manner (Cyriax, 1982; Kesson and Atkins, 1998). The patient should be positioned comfortably on a bed with the elbow on a pillow fully supinated and in ninety degrees of flexion. The therapist should stand at the side of the affected elbow to locate the inferior-lateral aspect of the lateral epicondyle to identify the area of tenderness. The therapist applies DTF with the side of the thumb tip, applying pressure using the thumb in a posterior direction to the origin of ECRB tendon. The therapist maintains this pressure whilst imparting DTF and holding the other side of the patient's elbow to establish counter-pressure (Figure 3.1). The DTF is administered for ten minutes to prepare the tendon for the Mill's manipulation.

3.4.2 Mill's manipulation

Mill's manipulation is defined as a passive movement performed at end of the elbow-extension range, i.e. it is a minimal amplitude high-velocity extension thrust at the elbow once the full range of elbow extension has been taken up (Cyriax, 1982; Kushner and Reid, 1986; Kesson and Atkins, 1998; Selvier and Wilson, 1999; Selvier and Wilson, 2000). Cyriax (1982) claims that Mill's manipulation should be performed immediately after the DTF, otherwise the effectiveness of Mill's manipulation could be reduced. Several authors stated that Mill's manipulation was the most common manipulative technique among physical therapists (Kushner and Reid, 1986; Selvier and Wilson, 1999; Selvier and Wilson, 2000) because Mill's manipulation was the only known manipulative technique for the management of musculoskeletal injuries in the extremities. Although mobilization with movement developed by Mulligan is a new manipulative technique for the management of extremities' injuries, Mill's manipulation remains one of the most common manipulative techniques for musculoskeletal disorders.

It is claimed that Mill's manipulation is conducted once only at each treatment session since it is not a comfortable procedure for the patient (Cyriax, 1982; Kushner and Reid, 1986; Kesson and Atkins, 1998). In addition, Cyriax claims that Mill's manipulation should be performed when the patient has a full range of passive elbow extension (Cyriax, 1982). If the patient has limitations of passive elbow extension, the manipulative thrust is said to affect the elbow joint rather than the ECRB tendon, possibly causing a traumatic arthritis (Cyriax, 1982; Kesson and Atkins, 1998). Moreover, traumatic arthritis is also said to be a risk if Mill's manipulation is performed poorly by physical therapists who fail to maintain full wrist flexion during the application of Mill's manipulation. In that case the thrust is said to be absorbed mainly by the elbow joint. Finally, it is claimed that during the application of Mill's manipulation, the patient must avoid leaning away, either forwards or sideways from therapist, because this will reduce the tension on the ECRB tendon (Cyriax, 1982; Kushner and Reid, 1986; Kesson and Atkins, 1998).

3.4.2.1 Recommendations for the application of Mill's manipulation for the treatment of LE

Cyriax (1982) recommended that Mill's manipulation for LE is administered as follows. The patient should be positioned on a chair with a backrest. The clinician stands behind the patient and supports the patient's arm under the crook of the elbow with the shoulder joint abducted to ninety degrees and medially rotated. The forearm will automatically fall into pronation. The clinician places the thumb of his or her other hand in the web space between the patient's thumb and index finger and fully flexes the patient's wrist and pronates the forearm. The clinician moves the hand supporting the crook of the elbow onto the posterior surface of the elbow joint and, whilst maintaining full wrist flexion and pronation, fully extends the patient's elbow, then applies a minimal amplitude high-velocity thrust by simultaneously side-lexing the clinicians own body away from his or her arms and pushing smartly downwards with the hand over the patient's elbow (Figure 3.2).

3.4.3 Recommendations for the application of Cyriax physiotherapy for the treatment of LE

Cyriax physiotherapy for LE should consist of 10 minutes of DTF followed immediately by one instance of Mill's manipulation (Figure 3.3). Cyriax physiotherapy should be administered in a clinical setting by a physiotherapist experienced in providing this treatment and having a certificate or diploma in orthopaedic medicine based on Cyriax principles. DTF and Mill's manipulation should be delivered as described in sections 3.4.1.1 and 3.4.2.1, three times per week for four weeks. Cyriax physiotherapy treatment is individualised by the patient's description of the pain experienced during the procedure. In the only previously published RCT of Cyriax physiotherapy, the therapy was administered in a manner identical to Cyriaxs' views (Verhaar et al., 1996).

3.4.4 How Cyriax physiotherapy works

It has been postulated that Cyriax physiotherapy can be used for both symptomatic relief of pain and promotion of tissue healing. Although the exact mode of action of Cyriax physiotherapy to achieve the previously reported goals is not known, some theoretical explanations have been put forward in respect to DTF mainly.

3.4.4.1 Pain relief

A number of hypotheses have been proposed to explain the pain relief that is said to follow the application of DTF as part of Cyriax physiotherapy.

Pain relief during and after DTF application may be due to modulation of the nociceptive impulses at the level of the spinal cord: the ''gate control theory ''. Pressure stimulates low-threshold mechanoreceptors in the skin that reduces the excitability of the nociceptor terminals on the central nervous system by presynaptic inhibition, effectively "closing the gate" on the pain (Goats, 1994; Gregory et al., 2003). The greater the mechanoreceptor stimulation, the greater the level of pain suppression (Bowsher, 1988; Wells, 1988). Quite simply, rubbing a painful spot reduces pain, enabling the application of DTF to be graded in depth, specific to individual lesions, and thus to produce its beneficial effects (Kesson and Atkison, 1998).

According to Cyriax (1982) the application of DTF can produce vasodilatation and increase blood flow to the affected area (hyperemia). It may be hypothesised that hyperemia appears to diminish pain by firstly facilitating the removal of chemical irritants such as Lewis' P substance, probably due to release of histamine (Chamberlain, 1982) and secondly through diffuse noxious inhibitory controls (de Bruijn, 1984; Melzack and Walls, 1988), a descending pain suppression mechanism that releases endogenous opiates (Chamberlain, 1982; Walker, 1984; Galloway et al., 1992; Goats, 1994). The latter are inhibitory neurotransmitters that diminish the intensity of the pain transmitted to higher centers (Goats, 1994).

3.4.4.2 Tissue healing

It is now generally recognised that internal and external mechanical stress applied to the repair tissue is the main stimulus for remodeling immature and weak scar tissue with fibres oriented in all directions and through several planes into linearly rearranged bundles of connective tissue (Hardy, 1989). Therefore, during the healing period, the affected structures should be kept mobile by using them normally. However, because of pain, the tissues cannot be moved to their full extent. This problem can be solved by the application of DTF. DTF imposes rhythmical stress transversely to the remodeling collagenous structures of the connective tissue and thus reorients the collagen in a longitudinal fashion with the result of enhancing tensile strength (Chamberlain, 1982;

de Bruijn, 1984; Galloway et al., 1992). Tensile strength is the maximum stress or load sustained by a material (Kesson and Atkins, 1998). Tensile strength is related to a balance between the synthesis and lysis of collagen, the development of collagen cross-links and the orientation of collagen fibres in the existing weave (Kesson and Atkins, 1998).

In this way, DTF can produce therapeutic movement by breaking down the strong cross-links or adhesions that have formed on the "injured" structure, tendon in this case (Chamberlain, 1982; Walker, 1984; Galloway et al., 1992; Goats, 1994). DTF achieves this effect by softening scar tissue and mobilizing the cross-links between the mutual collagen fibres and the adhesions that link still-healing connective tissue and the surrounding tissues (Chamberlain, 1982; Walker, 1984; Galloway et al., 1992; Goats, 1994).

Similar to the previously reported aim of DTF, the purpose of Mill's manipulation when it is performed correctly by experienced therapists with this technique is to elongate the scar tissue by rupturing adhesions within the tenooseous junction, thus making the area mobile and pain free (Cyriax, 1982, Kushner and Reid, 1986; Kesson and Atkins, 1998). Experimental evidence to support the previously reported claim is lacking.

3.5 Supervised exercise programmes

Exercise programmes are used extensively for the physical management of LE (Noteboom et al., 1994; Selvier and Wilson, 1999; Kraushaar and Nirschl, 1999; Selvier and Wilson, 2000; Wright and Sluka, 2001). Such programmes consisting of strengthening exercises and especially of eccentric contractions (section 3.5.1.1) offer adequate rehabilitation for tendinopathies but many patients with patellar tendinopathy do not respond to this prescription alone (Cannell et al., 2001). Home exercise programmes consisting of both strengthening and stretching exercises have shown good clinical results in tendinopathies similar to LE (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001) because tendons must not only be strong but flexible as well. Despite the lack of trials to investigate the effectiveness of supervised exercise programmes on tendinopathies, the literature on this subject suggests that strengthening and stretching exercises are the main

components of supervised exercise programmes (Noteboom et al., 1994; Selvier and Wilson, 1999; Selvier and Wilson, 2000).

3.5.1 Strengthening exercises

There are essentially three forms of musculotendinous contractions that strengthen soft-tissue structures such as tendons: (i) *isometric*, in which the muscle resists an applied force and the muscle-tendon unit length is constant (no work); (ii) *concentric*, in which the muscle resists an applied force and the muscle-tendon unit shortens (positive work) and (iii) *eccentric*, in which the muscle resists an applied force and the muscle-tendon unit lengthens (negative work) (Stanish et al., 1986; Stanton and Purdam, 1989; Fyfe and Stanish, 1992; Pienimaki, 2000). Of these three forms of contractions, most therapists agree that eccentric contractions appear to have the most beneficial effects for the treatment of LE (Stanish et al., 1986; Selvier and Wilson, 1999; Kraushaar and Nirschl, 1999; Selvier and Wilson, 2000; Stanish et al., 2000; Cook et al., 2000; Khan et al., 2000a; Khan et al., 2002). Eccentric training is associated with greater strength development than both concentric and isometric contractions (Stanton and Purdam, 1989; Fyfe and Stanish, 1992; Kellis and Baltzipoulos, 1995; Hawary et al., 1997). Increasing the tendon strength the chance of eccentric overload injury decreases (Stanton and Purdam, 1989; Kellis and Baltzopoulos, 1995; Stanish et al., 2000). Eccentric exercises as components of a home exercise programme have been shown to have positive effects on tendinopathies (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001). Moreover, therapists advocate eccentric exercises only for the "injured" tendon and not for all tendons in the relevant anatomic region, because the tensile strength of the injured tendon should be increased (section 3.5.4). This procedure was followed in previously published trials on tendinopathies (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001). In the case of LE, eccentric training should be performed for the extensor tendons of the wrist, including the ECRB tendon, which LE most commonly affects (Stanish et al., 1986; Fyfe and Stanish, 1992; Khan et al., 2000a; Cook et al., 2000; Stanish et al., 2000; Khan et al., 2002), because the origin of extensor tendons of the wrist (including the ECRB) is common in the relevant anatomical area and it is impossible to be isolated and strengthened only the affected ECRB tendon.

3.5.1.1 Eccentric exercises

The three principles of eccentric exercises are: 1) the load (resistance), 2) the speed (velocity) and 3) the frequency of contractions.

3.5.1.1.1 Load (resistance)

One of the main principles of eccentric exercises is increasing the load (resistance) on the tendon progressively. Increasing the load clearly subjects the tendon to greater stress and forms the basis for the progression of the programme. Indeed, this principle of progressive overloading forms the basis of all physical-training programmes. Therapists believe that the load of eccentric exercises should be increased according to the patients' symptoms, otherwise the possibility of re-injury is high (Stanish et al., 1986; Noteboom et al., 1994; Hawary et al., 1997; Selvier and Wilson, 1999; Kraushaar and Nirschl, 1999; Selvier and Wilson, 2000; Stanish et al., 2000; Khan et al., 2000a; Wright and Sluka, 2001; Khan et al., 2002). The load of eccentric exercises was increased according to the patients' symptoms in previously published trials on tendinopathies ((Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001) because the opposite has shown poor results (Jensen and Di Fabio, 1989). The rate of increase of the load cannot be standardized among patients during the treatment period because each patient does not have the same endurance in the pain. Furthermore, anecdotal evidence in the form of discussion with therapists suggested that they did not have a protocol to account for how the injured tendon, which is loaded eccentrically, gets back to a starting position without experiencing concentric loading. Although eccentric training develops greater strength than concentric training as mentioned above in order to demonstrate the real effects of eccentric exercises, clinicians would need ways to avoid concentric loading of the tendon, otherwise the effectiveness of eccentric exercises may become controversial in the future. One approach would be to use the non-injured extremity in order to return the injured extremity to the starting position (passive return). This approach was followed in Alfredson et al (1998) trial.

3.5.1.1.2 Speed (velocity)

Another basic principle to ensure the success of eccentric exercises is the speed (velocity) of contractions. Stanish et al (1986), Fyfe and Stanish (1992) and Stanish et al (2000) state that the speed of eccentric training should be increased in every treatment

session, so that increasing the speed also increases the load on the tendon to simulate the mechanism of injury better, which usually occurs at relatively high velocities. Following this approach in a trial, patients with patellar tendinopathy continue to complain of pain at the end of the treatment (Jensen and Di Fabio, 1989). However, other therapists claim that eccentric contractions are performed at a slow velocity to avoid the possibility of re-injury (Krushaar and Nirschl, 1999; Selvier and Wilson, 1999; Selvier and Wilson, 2000; Pienimaki, 2000; Khan et al., 2000a; Wright and Sluka, 2001; Khan et al., 2002). Eccentric exercises were performed at slow speed in every treatment session in previous studies giving good clinical results (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001). In contrast to traumatic events, which produce rapid eccentric forces, low-velocity eccentric loading presumably does not exceed the elastic limit of the tendon and generates less injurious heat within the tendon assisting tissue healing and avoiding the possibility of re-injury (Kraushaar and Nirschl, 1999). Therapists and previously published trials of home exercise programmes on tendinopathies (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001) do not define the "slowness" of eccentric exercises. The most likely explanation for this lack of definition is the claim that in order to avoid pain, patients perform the eccentric exercises slowly because the development of speed should be based always on the endurance of patients in pain. Nevertheless, when a supervised exercise programme treatment protocol is developed, the "slowness" of eccentric exercises should be defined. Failure to do so will make it difficult for therapists to replicate the exercise programme and put it into practice. Based on a home exercise programme, which was given as part of a physiotherapy treatment for the management of LE, the patients performed each repetition counting to thirty (Dwars et al., 1990).

3.5.1.1.3 Frequency of contractions

The third principle of eccentric exercises is the frequency of contractions. Sets and repetitions can vary in literature, but therapists claim that three sets of ten repetitions, with the elbow in full extension, forearm in pronation and with the arm supported, can normally be performed without overloading the injured tendon, as determined by the patient's tolerance (Stanish et al., 1986; Fyfe and Stanish, 1992; Noteboom et al., 1994; Hawary et al., 1997; Selvier and Wilson, 1999; Kraushaar and Nirschl, 1999; Stanish et al., 2000; Selvier and Wilson, 2000). Although three sets of eccentric exercises have

been performed in previously published trials of home exercise programmes on tendinopathies (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001), more repetitions in each set were used in these studies. The most likely explanations for the difference in the repetitions of eccentric contractions between therapists' claims for LE and previously conducted trials on the rest tendinopathies may be the different type of exercise programmes (home versus supervised) and the different amount of strength that the tendon needs to achieve its aim (Achilles and patellar tendons versus EBRC tendon). Therapists recommend one-minute rest intervals between each set (Stanish et al., 1986; Pienimaki, 2000). Although there is lack of evidence to support the previously reported rest interval, it is claimed essential to define and accept this rest interval in order to avoid the possibility of tendon re-injury (increase of temperature, fatigue). In addition, the rest interval between the sets should be defined, so that the exercise programme can be replicated by therapists. Therefore, this period of time will be used in our trial (Chapter 6).

If the affected arm is not supported, therapists claim that patients complain of pain in other anatomical areas distant from elbow joint, areas such as the shoulder, neck and scapula (Hawary et al., 1997; Selvier and Wilson, 1999). Furthermore, therapists claim that the elbow has to be in full extension and the forearm in pronation, because, in this position, the best strengthening effect for the extensor tendons of the wrist is achieved (Selvier and Wilson, 1999; Pienimaki, 2000). However, there is no information about the treatment regimen of supervised exercise programmes, that is, the number of sessions and frequency of treatment (MacPherson et al., 2002) for the performance of these eccentric exercises. The literature offers information about treatment regimens only for home exercise programmes based on studies for other tendinopathies (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001). However, one cannot be based on treatment regimen of home exercise programmes in order to develop the treatment regimen of supervised exercise programmes on LE. The two exercise programmes differ not only in the environment that they are conducted but also in the compliance of patients.

3.5.1.2 Recommendations for the application of eccentric exercises for the treatment of LE

Based on the above evaluation, eccentric exercises for LE should be performed with elbow supported on the bed in full extension, forearm in pronation, wrist in extended position (as high as possible) and the hand hanging over the edge of the bed (Figure 3.4). In this position, patients flex their wrist slowly counting to thirty until to achieve full flexion (Figure 3.5) and then return to the starting position with the help of the other hand (Figure 3.6). Patients are instructed go ahead with the exercise even if they experience mild pain. However, they are instructed to stop the exercise if the pain becomes disabling. They perform 3 sets of 10 repetitions at each treatment session, with one-minute rest intervals between each set. When patients are able to perform the eccentric exercises without experiencing any minor pain or discomfort, the load is increased using free weights (Figures 3.7 and 3.8). However, no literature could be found to explain the treatment regimen of the eccentric exercises. This issue will be explored by conducting a survey of existing practitioners' reports of their use of a supervised exercise programme for the treatment of LE (Chapter 5).

The starting positions and final positions of eccentric exercises cannot properly be standardized for patients, nor can the increase of the load and the degree of mild or disabling pain because all these are individualized by patients' descriptions of pain experienced during the procedure.

3.5.2 Stretching exercises

Even though a variety of stretching techniques such as ballistic, static and proprioceptive neuromuscular facilitation has been proposed to increase flexibility, there is a concern as to what stretching techniques and/or procedures should be used for optimal gains in flexibility. Flexibility has been defined as the range of motion possible about a single joint or through a series of articulations (Alter, 1996; Prentice, 1999). Therapists claim that static stretching, an extremely effective and simple stretching procedure, is the most widely used stretching technique (Hubley et al., 1984; Stanish et al., 1986; Fyfe and Stanish, 1992; Noteboom et al., 1994; Stanish et al., 2000; Selvier and Wilson, 2000; Shrier and Gossal, 2000; Feland et al., 2001). This kind of stretching technique has been used as component of home exercise programmes in previously

published trials on tendinopathies (Jensen and Di Fabio, 1989; Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001).

3.5.2.1 Static stretching exercises

Static stretching is defined as passively stretching a given muscle-tendon unit by placing it in a maximal position of stretch slowly and sustaining it there for an extended period of time (Sandy et al., 1982; Taylor et al., 1990; Smith, 1994; Bandy et al., 1997; Webright et al., 1997; Selvier and Wilson, 2000). This maximal stretching position is determined by the moderate discomfort and/or pain that the patient experiences (Prentice, 1999; Shrier and Gossal, 2000; Stanish et al., 2000). Static stretching exercises are individualized by patient feedback as to the discomfort and/or pain experienced during the procedure. This approach was followed in previously published trials on tendinopathies similar to LE (Jensen and Di Fabio, 1989; Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001). Performing the static stretching slowly it is impossible for the stretch reflex that causes contraction of the muscle tendon unit instead of relaxation to be stimulated. Furthermore, the resistance of the muscle tendon unit in slow static stretching is less than in a quick static stretching because muscle tendon unit is a viscoelastic structure with result its elongation.

Therapists' advocate static stretching exercises only for the "injured" tendon and not for all tendons in the anatomic region. Similar to this, static stretching exercises were advocated for the "injured" tendon in previously published trials on Achilles tendinopathy (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001). In addition, the "injured" tendon may be tight with decreased tensile strength and the stretching technique can reverse this (section 3.5.4). On the other hand, in Jensen and Di Fabio (1989) patellar tendinopathy study static stretching exercises were described for quadriceps and hamstrings. The reason why static stretching exercises are applied in a different way between patellar and rest tendinopathies will be discussed in chapter 7. In the case of LE, static stretching should be performed for the ECRB tendon, the site most commonly affected by LE (Stanish et al., 1986; Stanish et al., 2000; Khan et al., 2002). The best stretching position result for the ECRB tendon is achieved with elbow in extension, the forearm in pronation and the wrist in flexion and an ulnar deviation according to the patients' tolerance (Selvier and

Wilson, 1999). In contrast with the strengthening exercises that it was not possible to be isolated the ECRB tendon, in stretching exercises the ECRB tendon can be isolated following the previously reported technique.

Recommendations for the optimal time for holding this stretching position vary, ranging from as little as 3 seconds to as much as 60 seconds (Herling, 1981; Sandy et al., 1982; Smith, 1994; Bandy et al., 1997; Webright et al., 1997). Therapists believe that a stretch for 30 to 45 seconds is the most effective for increasing tendon flexibility (Stanish et al., 1986; Fyfe and Stanish, 1992; Bandy et al., 1997; Selvier and Wilson, 1999; Shrier and Gossal, 2000; Selvier and Wilson, 2000; Stanish et al., 2000). Several studies have indicated that holding a stretch for 30-45 seconds is the most effective for increasing tendon flexibility (Medding et al., 1987; Lentell et al., 1992; Bandy, 1994; Bandy et al., 1997). Stretches lasting for longer than 45 seconds seem to be uncomfortable for patients without better results (Sandy et al., 1982; Madding et al., 1987; Lentell et al., 1992; Smith, 1994; Bandy, 1994; Bandy et al., 1997; Webright et al., 1997). This time period is sufficient for the Golgi tendon organs to begin responding to the increase in tension. The impulses from the Golgi tendon organs can override the impulses coming from the muscle spindles, allowing to the muscle tendon unit to reflexively relax after the initial reflex resistance to the change in length (Prentice, 1999). Lengthening the muscle tendon unit and allowing it to remain in a stretched position for an extended period of time is unlikely to produce any injury to the muscle tendon unit. This time period was followed in previously published trials on tendinopathies (Jensen and Di Fabio, 1989; Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001)

Although the first stretch repetition results in the greatest increase in muscle-tendon unit length (Taylor et al., 1990; Alter, 1996; Prentice, 1999; Selvier and Wilson, 1999; Selvier and Wilson, 2000; Shrier and Gossal, 2000), a static stretch should be repeated several times per treatment session, because Taylor et al (1990) found that more than 80% of a muscle-tendon unit length can be obtained after the fourth repetition of a static stretch. Stanish et al (1986), Fyfe and Stanish (1992) and Stanish et al (2000) claim that 6 repetitions of static stretching exercises should be performed in each treatment session, dividing those into an equal number of repetitions, three before and three after the eccentric training. This approach of static stretching has been used in the majority of

previously published trials on tendinopathies (Niesen-Vertommen et al., 1992; Mafi et al., 2001; Silberhagel et al., 2001). Clinicians suggest a 15 to 45-second rest interval between each repetition (Selvier and Wilson, 1999; Shrier and Gossal, 2000). The reasons why the above rest interval was followed in the trial stated in chapter 6 were reported previously in the eccentric exercise section (3.5.1.1.3). However, there is no information about the treatment regimen for static stretching exercises on LE in a supervised exercise programme. As was described in the eccentric exercises section, this information is available only for home exercise programmes.

Logically, it seems that increasing tissue temperature before stretching would increase the flexibility of muscle-tendon unit; however many therapists believe that stretching with or without a warm-up yields the same results (Smith, 1994; Shrier and Gossal, 2000). Therefore, in previously published studies the home exercise programmes for the management of tendinopathies were used without a warm up (Jensen and Di Fabio, 1989; Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silberhagel et al., 2001).

3.5.2.2 Recommendations for the application of static stretching exercises for the treatment of LE

Based on the previously reported evaluation, static stretching exercises for LE should be applied slowly with elbow in extension, forearm in pronation and wrist in flexion and ulnar deviation according to the patients' tolerance (Figure 3.9), in order to achieve the best stretching position result for the ECRB tendon, which is the "injured" tendon in LE. This position should be held for 30 to 45 seconds, three times before and three times after the eccentric exercises at each treatment session with a 30-second rest interval between each procedure. The treatment regimen of static stretching exercises will be resolved by surveying existing practitioners' reports on their own use of supervised exercise programmes for LE (Chapter 5). The static stretching exercises will be individualized by the patient's description of the discomfort and pain experienced during the procedure.

3.5.3 Recommendations for the application of a supervised exercise programme for the treatment of LE

A supervised exercise programme for LE should be given as 3 sets of 10 repetitions of slow progressive eccentric exercises of wrist extensors. Before and after the eccentric exercises, the patient should carry out 3 repetitions of static stretching exercises of the ECRB tendon for 30 to 45 seconds each repetition (Figure 3.10). The eccentric and static stretching exercises should be delivered as described above (sections 3.5.1.1. and 3.5.2.2). The supervised exercise programme should be individualized through the patient's description of discomfort and pain experienced during the procedure. A survey of practitioners to determine their own use of supervised exercise programmes for the treatment of LE will be conducted in chapter 5.

3.5.4 How supervised exercise programmes work

In clinical practice, the exercise programme is predominately used for the promotion of tissue healing. It has been suggested that pain relief will occur concomitantly with progression of repair, that is, the patient's pain will reduce as healing progresses. The elucidation of the mechanisms through which exercise programme can alter pain in tendinopathies remains fragmentary.

It seems that the eccentric training induced remodeling of the injured tendon. It is likely that specific eccentric training drills result in tendon strengthening by stimulating mechanoreceptors in tenocytes to produce new collagen and thus help reverse the tendinopathy cycle (Leadbetter, 1992). Collagen production is probably the key cellular phenomenon that determines recovery from tendon injuries (Khan et al., 2000; Khan et al., 2002; Ohberg et al., 2004).

The eccentric training regimen may improve collagen alignment of the tendon and stimulate collagen cross-linkage formation, both of which increase the size of fibres (hypertrophy) and the ultimate strength of tendons (tensile strength) (Hawary et al., 1997; Khan et al., 2000; Khan et al., 2002; Ohberg et al., 2004) as supported by experimental studies on animals (Vilata and de Campos Vidal, 1989). Eccentric training may induce a response that normalizes the high concentrations of glycosaminoglycans (Ohberg et al., 2004). Ohberg et al (2001) found that, during eccentric training, the blood flow is stopped in the area of damage and this leads to neovascularisation, the

formation of new blood vessels, which improves blood flow and healing in the long term.

The improvement of the fibre arrangement, the normalization of the high concentrations of glycosaminoglycans and the neovasularisation possibly result in decreased tendon thickness in the injured point where scar tissue has already formed (Ohberg et al., 2004). However, if the decrease of tendon thickness during eccentric training can be associated with the decrease of tendon pain is unknown.

It has also been proposed that the positive effects of exercise programmes for tendon injuries may also be attributable to the effect of stretching, with a "lengthening" of the muscle-tendon unit, orientation of the new collagen fibres and consequently less strain experienced during joint motion (Alfredson et al., 1998). Stretching may strengthen the tendon or make it more resistant to strain and increase the range of motion of the relevant joint (Stanish et al., 2000).

3.6 Polarised polychromatic non-coherent light (Bioptron light)

LPLL is a commonly used light-therapy modality among physiotherapists for the management of common musculoskeletal disorders such as tendinopathies (Baxter et al., 1991). The effect of LPLL on wound healing has been investigated in many studies during the last two decades with conflicting results (Medenica and Lens, 2003). Polarised polychromatic non-coherent light (Bioptron light) is another form of light therapy (Chapter 2) that is commonly used to treat wound healing in dermatology and plastic surgery (Monstrey et al., 2002a; Monstey at al., 2002b; Iordanou et al., 2002). Manufacturers claim that polarised polychromatic non-coherent light (Bioptron light) can be used in the treatment of common musculoskeletal disorders such as LE but experimental support is lacking.

Available literature is predominately in the form of manufacturers pamphlets. Polarisation seems to be the most important characteristic of polarised polychromatic non-coherent light (Bioptron light) (Table 3.1) because the polarised polychromatic non-coherent light (Bioptron light) owes its proposed mode of action in this

characteristic (section 3.6.2). LPLL and polarised, polychromatic non-coherent light (Bioptron light) differ in their characteristics of radiation (Table 3.2).

Three devices are commercially available to deliver polarised, polychromatic non-coherent light (Bioptron light): (i) the Bioptron 2, (ii) the Bioptron Pro and (iii) the Bioptron Compact III. According to the manufacturer's user guide, these three devices do not differ in output characteristics. However, according to experts in dermatology and plastic surgery (Monstrey et al., 2002a; Monstey at al., 2002b; Iordanou et al., 2002), the Bioptron 2 seems to be the most commonly used device in practice to deliver the polarised, polychromatic non-coherent light (Bioptron light).

Bioptron 2 (Figure 3.11) is a product from Harrier Inc. USA, and was developed in Switzerland. The emission of light may be administered in one-minute steps and controlled by an integrated soft-start/soft-stop electronic switch. When the treatment with Bioptron 2 is over, there is a characteristic sound (beep tone). The output characteristics of Bioptron 2, according to the manufacturers' user guide, are: light wavelength = 480-3400 nm; degree of polarization = 95%; specific power density = $40mW/cm^2$; energy density = $2.4J/cm^2$. Bioptron 2 is approved by the FDA (USA), TGA Australia, EEC and carries an ISO 9001 certificate and EN 46001 as a patented medically-approved product.

Manufacturer literature recommends that the Bioptron 2 device should be used in practice as follows: The probe of Bioptron 2 is held at a 90º angle (perpendicular) 5-10 cm above the clean bare skin of the "injured" site as this is claimed to achieve maximal penetration of light. The regimen is six minutes of stimulation for at least three times per week for four weeks. Following this protocol, the polarised polychromatic non-coherent light (Bioptron light) was found to be an effective treatment for patients with deep dermal burns (Monstrey et al., 2002a; Monstrey et al., 2002b) and ulcers (Iordanou et al., 2002). However, there is lack of evidence to support the effectiveness of this protocol in common musculoskeletal injuries such as LE.

The manufacturer claims that there are no side effects for the use of polarised, polychromatic non-coherent light (Bioptron light) because there is no ultra-violet light in the Bioptron spectrum so there is no tanning or heat effect on the skin. No reports of

adverse effects were found in conducted trials (Monstrey et al., 2002a; Monstrey et al., 2002b; Iordanou et al., 2002). Manufacturers also claim that polarised, polychromatic non-coherent light (Bioptron light) is not harmful to the eyes, or to pregnant women or to patients with pacemakers. No prophylactic measures for both, therapists and patients, were taken in conducted trials (Monstrey et al., 2002a; Monstrey et al., 2002b; Iordanou et al., 2002). In addition, pregnant women and patients with pacemakers were not excluded from the trials (Monstrey et al., 2002a; Monstrey et al., 2002b; Iordanou et al., 2002). Finally, the polarised polychromatic non-coherent light (Bioptron light) cannot cause cancer because it is known that the dangerous wavelength of light is below 250 nm and the wavelength of polarised polychromatic non-coherent light (Bioptron light) is outside of this range (480-3400nm). The lack of side effects and contraindications of the polarised polychromatic non-coherent light (Bioptron light) is supported by the conducted trials (Monstrey et al., 2002a; Monstrey et al., 2002b; Iordanou et al., 2002) and confirmed by the approval of the FDA (USA), TGA Australia, EEC, the ISO 9001 certificate and EN 46001 as a patented medically-approved product.

3.6.1 Recommendations for the application of polarised polychromatic non-coherent light (Bioptron light) for the treatment of LE

Based on the manufacturer's claims and on one unpublished report (Stasinopoulos, 1990), polarised polychromatic non-coherent light (Bioptron light) therapy should be used in a clinical setting in line with manufacturers guidelines as follows: The probe of Bioptron 2 should be held at a 90° angle 5-10 cm above the clean bare skin of the lateral condyle (i) from the upper surface (anterior) with the elbow in extension and the forearm in supination (3.12) and (ii) from the lateral surface with the elbow in 90^0 of flexion and the forearm in pronation (3.13). Next, the probe of Bioptron 2 should be held at a 90° angle 5-10 cm above the clean bare skin of the bellies of the extensors muscles of the wrist with the elbow in 90^0 of flexion and the forearm in mid-position of pronation-supination (3.14). The polarised polychromatic non-coherent light (Bioptron light) therapy should last six minutes in each position, 18 minutes totally. Treatment regimen of polarised polychromatic non-coherent light (Bioptron light) therapy should be three times per week for four weeks (Figure 3.15). The polarised polychromatic non-coherent light (Bioptron light) treatment is standardised during the treatment period.

3.6.2 How polarised polychromatic non-coherent light (Bioptron light) works

LPLL has a biostimulating effect (Mester et al., 1971). Biostimulation is the reactivation of cell functions that allows regenerative processes to take place again (Monstrey et al., 2002a). This effect is directed to those cells that have been damaged or do not function efficiently any more (Monstrey et al., 2002b). A considerable amount of research has been performed to determine which of LPLL characteristics was the most important for the biostimulation effect (Mester et al., 1971; Fenyo, 1984; Mester et al. 1985; Karu, 1987). Several different LPLL with varying monochromatic outputs were equally successful, showing that the wavelength played no role in the healing effects (Mester et al., 1971; Mester et al. 1988). Coherent (in-phase) and incoherent (out of phase) light can cause the same biostimulative effects (Karu et al., 1987). Polarisation appears to be the key factor in biostimulation (Fenyo, 1984; Kertesz et al., 1982). The polarised polychromatic non-coherent light (Bioptron light) is a truly polarised light that could induce biostimulative effects in living cells similar to LPLL. The way that polarised polychromatic non-coherent light (Bioptron light) obtains biostimulative effects is not known and is based on a variety of proposed mechanisms. Both parts, visible and infrared, of the electromagnetic spectrum of polarised polychromatic non-coherent light (Bioptron light), can explain these mechanisms. These lead to the same final photoresponse, but start the cascade of metabolic events at different cellular levels that assist tissue healing.

One proposed mechanism of action of biostimulation is the absorption of visible light energy by the mitochondria (Karu, 1989). This may cause a chain of molecular events leading to an increase in cell energy and activation of nucleic acid synthesis, which is essential for tissue repair (Medenica and Lens, 2003).

The second mechanism is obtained by the infrared portion of the light spectrum (Medenica and Lens, 2003). In a hypothetical physical model for biostimulation, the cell membrane was stated to be the site of stimulation (Kertaesz et al., 1982). In this hypothesis the polarised polychromatic non-coherent light (Bioptron light) interacts with the polar heads of the lipid double layer of the cell membrane in which the biologically active proteins are incorporated. Due to the interaction with polarised polychromatic non-coherent light (Bioptron light), structural changes may occur to give the membrane a reordered distribution of the surface changes and to modify the lipid

protein connections. This conformation change may influence the cellural processes connected with the cell membrane: receptor function, energy production, immune responses and enzyme reactions (Kertesz et al., 1982).

Different biological effects have been reported after polarised light radiation, including the stimulation of cell proliferation (especially in fibroblasts), the release of growth factors and the enhancement of collagen synthesis (Kertesz et al., 1982; Fenyo, 1984; Kubasova et al., 1988; Bolton et al., 1992). It can be suggested that the tensile strength of tendons can be improved indirectly through the previously reported observations.

Another mechanism that might be responsible for the polarised polychromatic non-coherent light (Bioptron light) therapy's therapeutic effect is the local peripheral vasodilation, which improve blood flow and the delivery of oxygen to the soft tissue area, facilitating the transport of nutrients needed for soft tissue healing (Medenica and Lens, 2003).

3.7 Conclusion

Treatment protocols for Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) for the management of the pain and functional impairment associated with LE were developed in this chapter. Cyriax physiotherapy consists of 10 minutes of DTF and one instance of Mill's manipulation, which is performed immediately after the DTF. The supervised exercise programme consists of slow progressive eccentric exercises of wrist extensors (3 sets of ten repetitions with 1-minute rest interval between each set) and of static stretching exercises of the ECRB tendon (3 repetitions before and 3 repetitions after the eccentric training for 30-45 seconds each repetition with a 30-second rest interval between each procedure). The probe emitting polarised polychromatic non-coherent light (Bioptron light) should be held at a 90^0 angle 5-10cm above the bare skin of the lateral condyle (anterior and lateral surface) and the bellies of extensors muscles of the wrist, for six minutes each position, 18 minutes totally. All treatments are administered in a clinical setting. The treatment regimen of Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) is three times per week for four weeks. The treatment regimen of supervised exercise programmes will be defined in chapter 5 by

conducting a survey of existing practitioners' reports of their use of a supervised exercise programme for the treatment of LE. Cyriax physiotherapy and supervised exercise programmes are individualised on the basis of the patient's report of pain experienced during the procedure. A physiotherapist with certificate or diploma in Orthopaedic medicine based on Cyriax principles should be applied Cyriax physiotherapy. It has been postulated that Cyriax physiotherapy can be used for both symptomatic relief of pain and promotion of tissue healing. In clinical practice, exercise programmes are predominately used for the promotion of tissue healing. It has been reported that polarised polychromatic non-coherent light (Bioptron light) has biostimulative effects assisting tissue healing at the cellular level. Two preliminary clinical trials to pilot the use of these treatment protocols on overuse injuries similar to LE that are regularly presenting to the clinic are described in the next chapter.

Figure 3.1

Deep transverse friction (DTF)
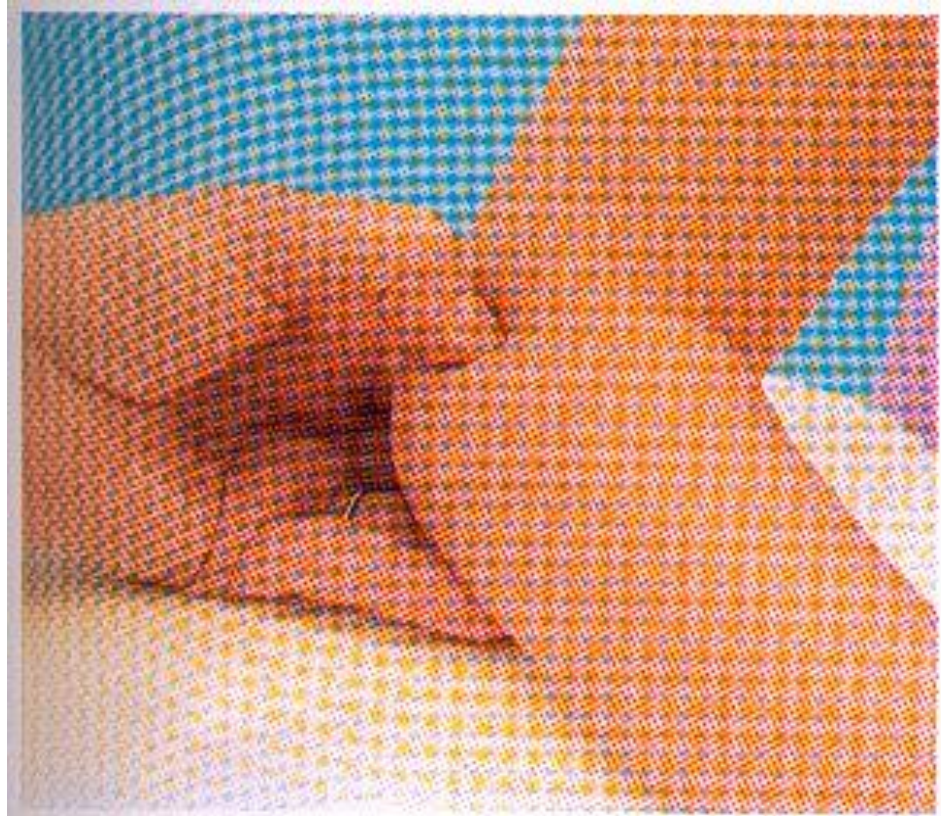
Adapted from Cyriax (1982)

Figure 3.2

Mill's manipulation
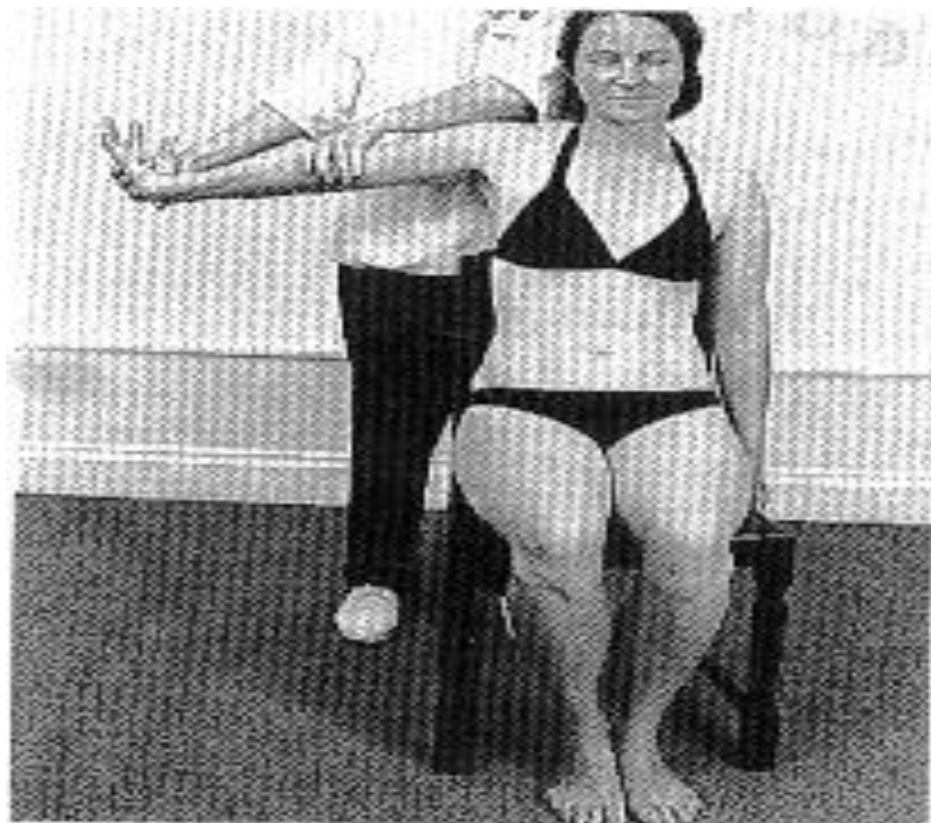
Adapted from Kesson and Atkins (1998)

Figure 3.3

Recommended treatment protocol for Cyriax physiotherapy for the treatment of LE

Cyriax physiotherapy

↓

10 minutes of DTF per session

↓

Mill's manipulation once per session

↓

Three times per week

↓

1 month
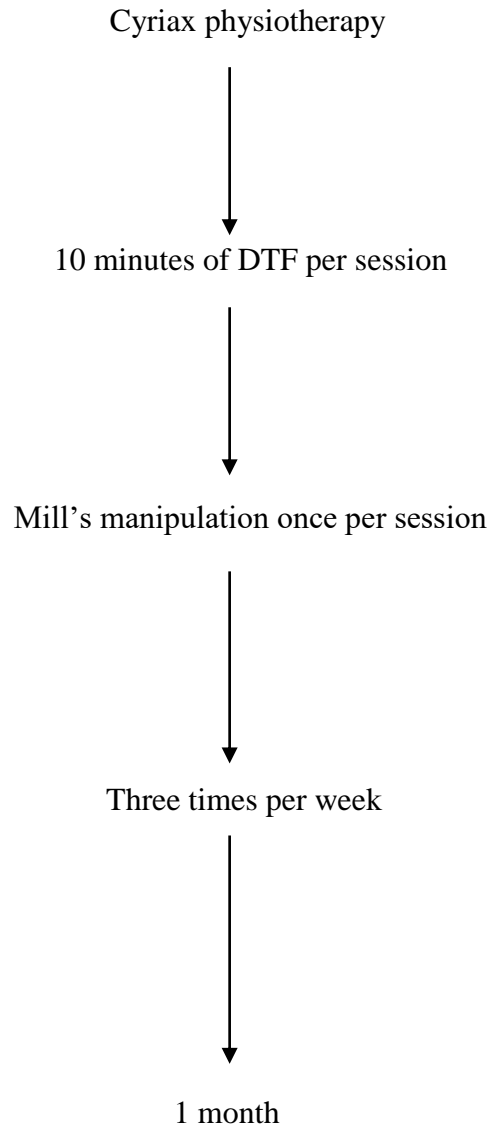
Figure 3.4

Starting position of slow eccentric strengthening exercises of wrist extensors

Figure 3.5

Final position of slow eccentric strengthening exercises of wrist extensors

Figure 3.6

Return to starting position with the help of the other hand

Figure 3.7

Starting position of slow eccentric strengthening exercises of wrist extensors using resistance

Figure 3.8

Final position of slow eccentric strengthening exercises of wrist extensors using resistance

Figure 3.9

Static stretching exercises of ECRB tendon

Figure 3.10

Recommended treatment protocol for a supervised exercise programme for the treatment of LE

Supervised exercise programme

3 repetitions of static stretching exercises of ECRB tendon for 30-45 seconds each stretching with 30 seconds rest between each stertching

Eccentric strengthening exercises of wrist extensors tendons

Load
progressive
according to
patients
allowance

Speed
Slow

Frequency of contractions
3 sets of 10 repetitions
1-minute rest
between each set

3 repetitions of static stretching exercises of ECRB tendon as described previously

Figure 3.11

Bioptron 2

Figure 3.12

**First position of polarised polychromatic non-coherent light (Bioptron light)
application**

Figure 3.13

Second position of polarised polychromatic non-coherent light (Bioptron light) application

Figure 3.14

Third position of polarised polychromatic non-coherent light (Bioptron light) application

Figure 3.15

**Recommended treatment protocol for polarised polychromatic non-coherent light
(Bioptron light) for the treatment of LE**

Polarised polychromatic non-coherent light

↓

Use Bioptron 2 device 5-10 cm above the skin

↓

To the lateral condyle from the upper surface (anterior) with the elbow in extension and
the forearm in supination for six minutes

↓

To the lateral condyle from the lateral surface with the elbow in 90^0 of flexion and the
forearm in pronation for six minutes

↓

To the bellies of the extensors muscles of the wrist with the elbow in 90^0 of flexion and
the forearm in mid position of pronation-supination for six minutes

↓

Three times per week

↓

1 month

Table 3.1

Manufacturer's explanation in the characteristic of polarized, polychromatic non-coherent light (Bioptron light).

Polarisation
Its waves move on parallel planes. In this device polarization reaches a degree of approximately 95%, which narrows and concentrates the beam.
Polychromy
Polychromatic light contains a wide range of wavelengths, including visible light and a part of infrared range. The wavelength of this device's light ranges from 480nm to 3400nm. This electromagnetic spectrum does not contain ultraviolet radiation.
Incoherency
This device's light is incoherent or out of phase light. This means the light waves are not synchronized.

Source: www.bioptron.com/characteristics/index.php

Table 3.2

Comparison of polarized, polychromatic non-coherent light (Bioptron light) with LPLL

Polarized, polychromatic non-coherent light (Bioptron light)	LPLL	Comments
polychromatic light with a wide range of wavelengths (480nm-3400nm) using visible light and a part of infrared range	monochromatic light with single wavelength (632.8nm or 904nm the most common) using visible or infrared light	It is claimed that polarised polychromatic non-coherent light (Bioptron light) with a longer wavelength has a greater penetration than LPLL
incoherent or out of phase light	coherent or sychronised light	No difference in biostimulative effects. Phase of light is not the key factor in biostimulation
truly polarized light	for practical purposes polarized light (Baxter 1996)	Polarisation is the key factor in biostimulation (Kertesz et al., 1982; Fenyo, 1984). Polarised polychromatic non-coherent light (Bioptron light) is a truly polarised light, while LPLL is polarised light for practical purposes. Thus, it is claimed that polarised polychromatic non-coherent light (Bioptron light) have better biostimulative effects than LPLL
energy density constant $(2.4 J/cm^2)$	Energy density ranges from 1 J/cm^2 to 4 J/cm^2 , but sometimes needing higher dosages up to 32 J/cm^2 (Low and Reed, 2000). Energy density is calculated according to the condition	Optimal energy density is unknown. In polarised polychromatic non-coherent light (Bioptron light) almost the mean rate of the range 0.5 J/cm^2 and 4 J/cm^2 is used, without needing calculation. However, we do not know if this is the optimal energy density
No specific user skills for handling	need specific user skills for handling and protective goggles	Polarised polychromatic non-coherent light (Bioptron light) can be used by inexperienced therapists with this modality. Its usage is easy
No contraindications	Many contraindications such as, pregnancy, cancer, peacemaker etc	It is claimed that polarised polychromatic non-coherent light (Bioptron light) can be used for all patients
Large diameter of the beam	small diameter of the beam	Polarised polychromatic non-coherent light (Bioptron light) can radiate a large surface of the body
Expensive	Expensive	Polarised polychromatic non-coherent light (Bioptron light) is less expensive than LPLL

Chapter 4: Preliminary clinical studies on the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on overuse injuries

4.1 Introduction

The recommended treatment protocols for Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) were derived from the views of advocates of these treatments, based on their personal experience with the treatment and on the putative physiological mechanisms that the treatment addresses (Chapter 3). The effectiveness of these protocols was tested on overuse injuries that were similar to LE regularly presenting to the clinic. The first study was a controlled clinical trial that evaluated the effectiveness of Cyriax physiotherapy and a supervised exercise programme in patellar tendinopathy, commonly referred to as "jumper's knee". The second study was a prospective open, uncontrolled clinical trial that assessed the effectiveness of the polarised polychromatic non-coherent light (Bioptron light) treatment protocol in idiopathic carpal tunnel syndrome.

4.2 Aim

The aim of the studies described in this chapter was to pilot the use of treatment protocols for Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light), as derived from the critical literature review in chapter 3 on overuse injuries similar to LE that are regularly presenting to the clinic.

4.3 A controlled clinical trial to compare the effects of Cyriax physiotherapy, a supervised exercise programme and ultrasound in the reduction of pain in patellar tendinopathy

4.3.1 Introduction

Patellar tendinopathy or jumper's knee causes significant morbidity in professional and recreational sports people, particularly those participating in sports involving repeated jumping and landing, rapid acceleration and deceleration, cutting moves and kicking (Nichols et al., 1991; Molnar and Fox, 1993); examples are basketball, volleyball, soccer, tennis, high jump, long jump, fencing and track (Blazina et al., 1973; Fornage and Rifkin, 1988; Raatikainen et al., 1994; Hamilton and Purdam, 2004). Patellar tendinopathy is most commonly characterized by pain at the inferior pole of the patella, although pain can also be at the tibial attachment and the attachment of the tendon to the superior pole of the patella (Blazina et al., 1973).

There is no correlation between intrinsic factors, such as malalignment of the extensor mechanism, the Q angle, or biomechanical derangements, and the incidence of jumper's knee (Ferretti, 1986; Cook et al., 2001). The principal factors that lead to its development are hard playing surfaces, increased frequency of training sessions with repetitive eccentric movement, and tight hamstring and quadriceps (Ferretti, 1986; Stanish et al., 2000; Hamilton and Purdam, 2004).

The pathology of jumper's knee shows the presence of degeneration of the tendon with collagen disorientation, disorganization and fibre separation by increased mucoid ground substance, vascularity and cellularity. Cellularity results from the presence of fibroblasts and myofibroblasts, not inflammatory cells (Khan et al., 2000a). Due to the absence of inflammatory cells, the term patellar tendonitis as diagnosis seems inappropriate. Patellar tendinosis refers to pathology of the patellar tendon and is the best diagnostic term. The term patellar tendinopathy refers to painful overuse tendon without implying pathology; it is ideal for clinical diagnosis.

Many forms of physical therapy have been proposed for the management of patients with patellar tendinopathy. Physical therapy treatment involves manual techniques such

as Cyriax physiotherapy (DTF), modalities such as LPLL, ultrasound, transcutaneous electrical nerve stimulation (TENS), etc., exercise programmes and bracing. Nevertheless, there are a limited number of studies on the conservative treatment of patellar tendinopathy. Cyriax physiotherapy, supervised exercise programmes and ultrasound are three commonly used physiotherapy treatments for patellar tendinopathy. However, the clinical value of these treatments for patellar tendinopathy is unknown. Chapter 2 found strong evidence that ultrasound is an ineffective treatment for LE, and perhaps for conditions similar to LE such as patellar tendinopathy. Ultrasound is a commonly used treatment modality in physiotherapy and the ineffectiveness identified in chapter 2 may be due to the lack of optimal treatment dosages.

4.3.2 Aim

The aim of the present study was to compare the effects of Cyriax physiotherapy, a supervised exercise programme and ultrasound in the reduction of pain in patients with patellar tendinopathy.

4.3.3 Methods

A controlled, monocenter trial was conducted to assess the effectiveness of Cyriax physiotherapy, a supervised exercise programme and ultrasound in a clinical setting over a 15-month period. A parallel group design was used in case the treatment intervention cured the condition. A cross-over design is limited in this regard because if patients are cured they do not have the opportunity to receive the other treatments following cross over (Johannsen et al., 1993). Two investigators were involved in the study: 1) The primary investigator was a qualified physiotherapist (DS) who administered the treatments and 2) the co-investigator was a specialized rheumatologist (IS) who evaluated the patients to confirm the diagnosis and also assessed all baseline and follow up measurements. The co-investigator (IS) was blind to the patients' therapy group and did not treat patients at all.

4.3.3.1 Participants and recruitment
Thirty patients, all recreational athletes who had been clinically diagnosed with patellar tendinopathy by the co-investigator (IS), took part in this study. They were selected from patients referred to our clinic (Rehabilitation and Rheumatology Centre, located in

Athens) during the season 2001- 2002. The patients were either self-referred or referred by their physician or physiotherapist. All patients were new cases to our clinic.

4.3.3.2 Inclusion criteria

The inclusion criteria for the study, which have been used in similar previously published trials (Jensen and Di Fabio, 1989; Cannell et al., 2001), were:

- Tenderness with palpation over the inferior pole of the patella
- No history of trauma to the knee
- Minimum duration of symptoms three months
- Unsuccessful conservative treatment before entering the study, but not in the preceding one month
- No other current knee or lower extremity problems including anterior knee pain, muscle strains and hip or ankle injuries
- Positive decline squat test.

4.3.3.3 Ethical consideration

The procedure was explained to patients and informed consent was obtained from all of them. The co-investigator (IS), who was the manager of the clinic, approved the study and authorized access to clinic patients.

4.3.3.4 Sequential allocation

The patients were allocated to three groups by sequential allocation. For example, the first patient with patellar tendinopathy was assigned to the Cyriax physiotherapy group, the second patient with patellar tendinopathy to the supervised exercise-programme group, the third patient with patellar tendinopathy to the ultrasound group, the fourth patient with patellar tendinopathy to the Cyriax physiotherapy group, the fifth patient with patellar tendinopathy to the supervised-exercise-programme group and so on. Patients were able to drop out from the study at any stage and without reason.

All patients were instructed to rest during the treatment period. Patients were asked to refrain from taking anti-inflammatory medication throughout the course of study. Patient compliance to this request was monitored using a treatment diary.

4.3.3.5 Treatment intervention

All treatment interventions were performed in our centre. The primary investigator (DS) administered all treatments. DS is a qualified physiotherapist with about 7 years experience in the management of common musculoskeletal disorders such as patellar tendinopathy. In addition, DS is a physiotherapist experienced in the application of Cyriax physiotherapy. He holds a Certificate in Orthopaedic Medicine on Cyriax principles (Appendix I). All patients received three treatments per week for four weeks.

4.3.3.5.1 Cyriax physiotherapy

The treatment protocol of Cyriax physiotherapy in patellar tendinopathy consists of DTF. DTF was applied to the patellar tendon as advocated by Cyriax (1982) continuously for 10 minutes. Details of DTF application are presented in chapter 3 (section 3.4.1). The Cyriax physiotherapy treatment was individualised on the basis of the patient's description of pain experienced during the procedure.

4.3.3.5.2 Supervised exercise programme

The supervised exercise programme consisted of static stretching exercises of quadriceps and hamstring, and eccentric exercises of patellar tendon. Static stretching exercises were performed as described for LE (section 3.5.2.1) before and after the eccentric exercises adapted in patellar tendinopathy. Details about the static stretching exercises in patellar tendinopathy can be found in the study by Jensen and Di Fabio (1989).

In the eccentric exercises, patients carried out three sets of 15 repetitions of unilateral squat. The squat was performed at a slow speed at every treatment session. At the beginning, the load consisted of the body weight only and patients were standing with all their body weight on the injured leg. As they moved from the standing to the squat position (about 60^0 of knee flexion), the quadriceps muscle and patellar tendon by inference were loaded eccentrically; no following concentric loading was done, as the non-injured leg was used to get back to the start position. Patients were told to go ahead with the exercise even if they experienced mild pain. However, they were told to stop the exercise if the pain was disabling. When the squat was pain-free, patients increased the load by holding weights in their hands. Between each set there was a 2-minute rest.

The supervised exercise programme treatment was individualised on the basis of the patient's description of pain experienced during the procedure.

4.3.3.5.3 Ultrasound

The ultrasound treatment was standardised during the treatment period as follows: The 10 patients in the ultrasound group received local pulsed ultrasound from 0.4 to 0.8 W/cm^2 from a RT-20 ultrasonic machine (RT-20, Pagani, Italy). The pulse ratio was 1:4, the duration of pulse 2 ms and frequency 1 MHz. The ultrasound head was applied to the patient's skin, using an ultrasonic coupling medium. The radiated area was over the inferior pole of the patella. Treatment time was 10 minutes.

4.3.3.6 Outcome measures

Patients were asked to describe the status of their pain from the following alternatives: worse, no change, somewhat better, much better, no pain. This scale was designed by the investigators in order to determine the effectiveness of each therapy. Each patient was evaluated at the end of the four-week course of treatments (week 4). Follow-up recordings were made at one month after the end of the treatment (week 8) and three months after the end of the course of treatments (week 16).

4.3.3.7 Statistical analysis

Patients in each group were placed into one of the two pain-response categories. The first category included those who reported their pain to be worse, no change, or slightly better; the second category included those reporting that they were much better or had no pain. The chi-square test (alpha= 0.05) was used to determine whether patients in the two categories were equally distributed across the three groups. This test was used because (i) there were three different (independent) subject groups; (ii) the data was nominal and (iii) the assumptions for a valid chi-square analysis were met. These assumptions were: 1. data was frequency counts; 2. observations were independent of one another; 3. expected and observed frequencies were equal one another and 4. the sample size was adequate.

4.3.4 Results

All patients completed the study, including the two follow-ups (Figure 4.1). Ten patients (5 men, 5 women), mean age 26.24±4.17 (21-33) years, were entered into the

Cyriax physiotherapy group. Ten patients (7 men, 3 women), mean age 28.12±2.03 (21-31) years, were entered into the supervised exercise programme group. Ten patients (6 men, 4 women), mean age 29.17±3.76 (22-33) years, were entered into the ultrasound therapy group. The basketball was the most common sport among the patients (Table 4.1).

Chi-square analysis showed significant differences in the distribution of pain-response categories across the groups at the end of treatment (Table 4.2), one-month follow-up (Table 4.3) and three-month follow-up (Table 4.4). It can be concluded that the supervised exercise programme was statistically significantly better than the other two treatments. There were no significant differences between Cyriax physiotherapy and ultrasound.

4.3.5 Discussion

The results obtained from this controlled clinical trial are novel, since to date there is no existing data to compare the effectiveness of Cyriax physiotherapy, supervised exercise programmes and ultrasound in the reduction of pain in patellar tendinopathy. The results of the present study showed that the supervised exercise programme was the most effective treatment in the reduction of pain in patellar tendinopathy.

Home exercise programmes have shown good clinical results in rest tendinopathies such as Achilles tendinopathy (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silbernagel et al., 2001). In all previously published trials, a home exercise programme was conducted daily, once or twice, for a period of three months. In the present study, the supervised exercise programme was conducted three times per week for four weeks. It is obvious that a supervised exercise programme can reduce pain in tendinopathies in a shorter period than a home exercise programme. This difference may be due to the supervised nature of such programmes, which are able to achieve a high degree of patient compliance. However, in order to establish strong evidence for the effectiveness of these two exercise programmes for tendon disorders, a future well-designed future clinical trial is needed to compare their effectiveness.

Recently, Purdam et al (2004) suggested that the eccentric squat for the management of patellar tendinopathy should be performed on a 25^0 decline board. This was suggested

because passive and active calf tension have the potential to reduce demand on the knee extensors in the squat by limiting forward angulation of the tibia approaching the limit of ankle dorsiflexion (Purdam et al., 2004). However, no significant differences were found between decline and flat squat for the management of patellar tendinopathy in a recently published RCT (Young et al., 2005). Flat squat was called in Young et al (2005) trial the squat that was followed in the present pilot study. Therefore, an exercise programme consisting of flat squat can be an effective treatment for patellar tendinopathy.

Although Cyriax physiotherapy is currently used extensively in rehabilitation practice and especially in conditions such as patellar tendinopathy, the results of the present study do not support its use. Moreover, previously published trials provide little support for the effectiveness of Cyriax physiotherapy on overuse injuries (Schwellnus et al., 1992; Pallechia et al., 1994; Verhaar et al., 1996). Prentice (1999) claims that if Cyriax physiotherapy does not decrease the pain in patellar tendinopathy patients after 4 or 5 treatments, this treatment approach is unlikely to resolve the problem. However, the experience of Prentice is not a reliable tool to determine the effectiveness of Cyriax physiotherapy. There is a clear need for future well-designed clinical trials to establish if there is strong evidence for the effectiveness of Cyriax physiotherapy on overuse injuries. Finally, the major drawback of Cyriax physiotherapy is that the application of this treatment placed a considerable strain on the hands of clinicians, who find it exhausting (Chapter 3).

Pulsed ultrasound at low intensities and 1 MHz frequency has been shown to have beneficial effects on collagen synthesis and on the tensile strength of tendons (Dyson and Suckling, 1978; Khan et al., 2000a). Similar parameters were used in this study. Although ultrasound is a common clinical modality, the majority of published trials have shown that it is not effective as a sole treatment for tendinopathies (Lundeberg et al., 1988; Haker and Lundeberg, 1991; Pienimaki et al., 1996). The results of the present study, supporting the results of previously published studies in tendon injuries area as well as the findings of chapter 2, showed that ultrasound produced poor results in patients with patellar tendinopathy.

The results of the present study should be interpreted cautiously because this study did not use a randomised design, the subjects' numbers were small, no power analysis was conducted and there was lack of a placebo/no treatment group. Furthermore, outcome measures of unknown validity were used, the compliance of patients was not monitored when they were away from the clinic and the "slowness" of eccentric exercises was not defined. In addition to the weaknesses discussed, structural changes in the tendon that related to treatment interventions were not demonstrated; the improvement in quadriceps strength following one of the three treatment interventions was not measured; and the long-term effects of these treatments were not investigated. All these issues will be discussed in chapter 7.

4.3.6 Conclusions

The present study was an attempt to find out if three commonly used physiotherapy treatments could reduce the pain in patients with patellar tendinopathy. The results showed that the supervised exercise programme was a better treatment than Cyriax physiotherapy and ultrasound at the end of the treatment as well as at the follow-ups. However, due to the shortcomings of the present pilot study described above, future controlled studies are needed to establish the effects of these three treatments in patellar tendinopathy.

4.4 A prospective open and uncontrolled clinical trial to evaluate the effectiveness of polarised polychromatic non-coherent light (Bioptron light) in the reduction of nocturnal pain and paraesthesia in idiopathic carpal tunnel syndrome

4.4.1 Introduction

Carpal tunnel syndrome (CTS) is a compression neuropathy of the median nerve at the level of the carpal tunnel and is by far the most common of all peripheral nerve entrapments (Szabo, 1998). The CTS patient often presents with symptoms of nocturnal pain and numbness, weakness or clumsiness in holding small objects and paraesthesia in the median nerve distribution of the hand (Donatelli and Wooden, 2000; Boscheinen-Morrin and Conolly, 2001). Despite many suggested causes of CTS, the most common presentation of CTS is idiopathic with no discernible underlying pathology (Schkind et

al., 1990; Thurston, 2000). The most likely explanation is an overuse phenomenon of the hand as in process workers or housewives (Donatelli and Wooden, 2000; Thurston, 2000; Boscheinen-Morrin and Conolly, 2001). Other cases of CTS result from trauma and from metabolic and endocrinal abnormalities (Detmars and Housin, 1986; Thurston, 2000). Phalen's test and Tinel's sign are two commonly used provocative tests to help in the clinical diagnosis of CTS, but these two tests are not absolutely diagnostic despite being positive in about two-thirds of patients with this syndrome (Gerr and Letz, 1998). Electrophysiological studies measuring median nerve function are the only objective way to show the nerve deficit (Johnson, 1993; Gerr and Letz, 1998; Szabo, 1998).

Benefit from non-surgical treatment, however, seems to be limited. Conservative treatments such as splints, injections, gliding exercises and ultrasound have been used to reduce nocturnal pain and paraesthesia associated with CTS, although these approaches have produced variable outcomes (Giele, 2001). For example, splints and carpal bone mobilization have been shown to be ineffective (Tal-Akabi and Rushton, 2000; Walker et al., 2000; Manente et al., 2001) and results with gliding exercises and ultrasound have been conflicting (Hunter et al., 1995; Ebenbichler et al., 1998; Oztas et al., 1998). Finally, there are recently clinicians' claims that neural mobilization (mobilization of the median nerve) can reduce the symptoms, nocturnal pain and paraesthesia, in patients with CTS (Kostopoulos, 2004).

The findings of a recently published RCT indicated that light therapy using LPLL could be an effective treatment for CTS (Naeser et al., 2002). Polarised polychromatic non-coherent light (Bioptron light) is the other form of light therapy. Research is required to determine if polarised polychromatic non-coherent light (Bioptron light) can also give good clinical results in CTS.

Polarised polychromatic non-coherent light (Bioptron light) has recently appeared on the market for the treatment of a wide range of medical conditions including CTS. However, descriptions of the effects of this modality are often theoretical or lacking. And even if these effects exist in laboratory models, it by no means follows that they will translate into clinically meaningful effects. Although novel modalities like polarised polychromatic non-coherent light (Bioptron light) are attractive to practitioners working in rehabilitation settings, the extent of its clinical usefulness is not

known. No studies were found on the clinical effectiveness of polarised polychromatic non-coherent light (Bioptron light) for CTS. The present trial was the first study in which polarised polychromatic non-coherent light (Bioptron light) was used to manage nocturnal pain and paraesthesia associated with idiopathic CTS.

4.4.2 Aim

The aim of this study was to assess the effectiveness of polarised polychromatic non-coherent light (Bioptron light) in the reduction of nocturnal pain and paraesthesia in idiopathic CTS.

4.4.3 Methods

An uncontrolled monocenter trial was performed to gauge the effectiveness of polarised polychromatic non-coherent light (Bioptron light) in a clinical setting over 18-month period. Two investigators were involved in the study: 1) The primary investigator who administered the treatment was a qualified physiotherapist (DS) with about seven years of experience in the management of common overuse injuries such as CTS using the polarised polychromatic non-coherent light (Bioptron light) and 2) the co-investigator was a physiotherapist (EK) who performed all baseline and follow-up assessments, was blind to the patients' therapy group, and did not treat patients at all.

4.4.3.1 Participants and recruitment

Twenty-five patients, 22 female and 3 male, with clinically-suspected CTS that had been referred to our clinic over a year (from mid-2001 to mid-2002) were invited and subsequently completed this open prospective uncontrolled clinical trial. All patients were new cases to our clinic. The mean age of patients was 47.4 years (range 34-58). CTS was diagnosed by using standard electrophysiological criteria, which were motor distal-latency and sensory-antidrotic nerve-conduction velocity. The patient population had a mean duration of CTS of 5.2 months (range 3-11).

4.4.3.2 Inclusion/exclusion criteria

Inclusion criteria for the study were unilateral idiopathic CTS, mild to moderate nocturnal pain and paraesthesia lasting more than three months (Hunter et al., 1995; Ebenbichler et al., 1998; Oztas et al., 1998; Tal-Akabi and Rushton, 2000; Walker et al., 2000; Manente et al., 2001).

Exclusion criteria were secondary entrapment neuropathies, systematic diseases with increased risk of CTS, electroneurographic or clinical signs for axonal degeneration of the median nerve, previous treatment with physical-therapy modalities for CTS, history of steroid injections into carpal tunnel, regular analgesic or anti-inflammatory drugs (Hunter et al., 1995; Ebenbichler et al., 1998; Oztas et al., 1998; Tal-Akabi and Rushton, 2000; Walker et al., 2000; Manente et al., 2001).

4.4.3.3 Ethical consideration

The procedure was explained to patients and informed consent was obtained from all of them. The manager of the centre (IS) approved the present study and authorized access to clinic patients

4.4.3.4 Drop-out rate

Patients were able to drop out from the study at any stage and without reason and would immediately receive the standard care (polytherapy such as NSAIDs, polarised polychromatic non-coherent light (Bioptron light), ultrasound, LPLL, gliding exercises, neural mobilization and nocturnal splint with the wrist in the neutral position) for CTS as provided by the clinic. If patients reported moderate or severe symptoms two to three months after the end of the treatment, an alternative form of treatment was offered for their condition.

4.4.3.5 Polarised polychromatic non-coherent light (Bioptron light) treatment intervention

Patients attended the clinic three times each week over a four-week period for each polarised polychromatic non-coherent light (Bioptron light) treatment. The primary investigator (DS) administered the polarised polychromatic non-coherent light (Bioptron light) as monotherapy, following the advice provided in the manufacturer's user guide (Chapter 3, section 3.6). The polarised polychromatic non-coherent light (Bioptron light) treatment was standardised during the treatment period.

A Bioptron 2 device[*] was used to deliver the polarised polychromatic non-coherent light (Bioptron light). Bioptron 2 is the most common polarized polychromatic non-

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[*] Harrier Inc. USA

coherent light (Bioptron light) device in practice (Chapter 3, section 3.6). The output characteristics of Bioptron 2 were reported in chapter 3 (section 3.6). Patients sat upright with the arm placed on an adjacent bed with the elbow in extension and supination. The probe of Bioptron 2 was held at a 90° (perpendicular) angle 5-10 cm above the clean bare skin of the carpal tunnel as this is claimed to achieve maximal penetration of light for exactly six minutes (Figure 4.2). A 'beep' signified the end of the 6-minute treatment.

All patients were asked to avoid activities that irritate their hand and to refrain from taking analgesic medication for any condition during the course of study. Patient compliance to this request was monitored using a treatment diary. Patients were given no additional treatment for CTS until the six-month follow-up assessment.

4.4.3.6 Outcome measures

Outcome measures were the patient's self-report of nocturnal pain and paraesthesia respectively using a verbal 5-point categorical rating scale (worse, no change, slightly better, much better, no pain or paraesthesia). Outcome measures were taken at the end of the treatment (week 4) and at the six-month follow-up after the end of treatment (week 28).

4.4.3.7 Data analysis

Due to preliminary nature of the trial and the lack of control groups data was analysed using descriptive statistics. Descriptive statistics are always appropriate, though for analyzing results from an experiment when a hypothesis has been tested, the inferential statistics is the branch of statistics that is commonly used to show some kind of difference between groups. However, some times this kind of statistics is not possible to be performed. One of these occasions is the present study, because no statistical test was found to determine the difference between three dependent samples with nominal data.

4.4.4 Results

No patients requested to withdraw from the study and all patients provided data at the 6-month follow-up.

4.4.4.1 Nocturnal pain

Twenty-three out of 25 patients (92%) reported that their pain had improved at the end of the course of polarised polychromatic non-coherent light (Bioptron light) treatments (Table 4.5). Of these 23, 5 reported that they no longer experienced nocturnal pain, and 12 reported that their nocturnal pain was 'much better'. At 6-month follow-up, all patients reported that their pain had improved, with 9 reporting no nocturnal pain and 13 reporting that their nocturnal pain was 'much better' (Table 4.5).

4.4.4.2 Paraesthesia

Twenty-one out of 25 patients (84%) reported that their paraesthesia had improved at the end of the course of polarised polychromatic non-coherent light (Bioptron light) treatments (Table 4.6). Of these 21 patients, 3 reported that they no longer experienced paraesthesia, and 13 reported that their paraesthesia was 'much better'. At 6-month follow-up, 23 out of 25 patients reported that their paraesthesia had improved, with 7 reporting no paraesthesia and 14 reporting that their paraesthesia was 'much better' (Table 4.6).

4.4.5 Discussion

The data from this preliminary prospective open and uncontrolled clinical trial in patients with idiopathic CTS suggests that a course of polarised polychromatic non-coherent light (Bioptron light) treatments given in 6-minute sessions three times per week for four weeks may reduce the self-report of nocturnal pain and paraesthesia when compared to baseline data. However, the absence of a placebo (sham)/no treatment group means that we cannot be certain that these findings were due to the polarised polychromatic non-coherent light (Bioptron light) treatment intervention itself rather than to natural fluctuations in symptoms, resolution of the idiopathic CTS, use of medication not reported to the investigators, and/or expectation of treatment success associated with receiving a medicinal intervention. The possibility that patients reported prolonged improvement at the 6-month follow-up in order to please the investigator cannot also be discounted, as there was no placebo (sham)/no treatment control group.

However, it must be noted that none of the patients wanted to discontinue polarised polychromatic non-coherent light (Bioptron light) in favor of conventional polytherapy. We must entertain the reasonable probability that symptom reduction was a real

phenomenon. For this reason, the finding that a high proportion of patients report long-term improvement with polarised polychromatic non-coherent light (Bioptron light) given as a monotherapy merits dissemination, as the conservative management of idiopathic CTS still remains controversial. Some patients self-manage idiopathic CTS in the initials stages by reducing activities of the hands and/or task modification for one or two months in order to reduce symptoms. However, this approach is effective in less than 10% of patients (McCabe, 2002). For most patients CTS is managed in the initial stages by conservative treatment and by surgery if conventional treatment fails (Giele, 2001; McCabe, 2002).

The findings of the present preliminary trial should encourage the design of a RCT with sufficient power and validated outcome measures to determine the effectiveness of polarised polychromatic non-coherent light (Bioptron light) against a valid placebo and LPLL. It is also needed to confirm or refute the manufacturer's recommendations for the application of polarised polychromatic non-coherent light (Bioptron light) in CTS, because the traditional use is not a reliable tool to determine the effectiveness of a treatment (Ernst, 1995). Finally, studies are needed to find out the analgesic effects of polarised polychromatic non-coherent light (Bioptron light) as well as to investigate the role of polarised polychromatic non-coherent light (Bioptron light) as physical therapy intervention for the management of common musculosceletal and / or orthopaedic conditions.

4.4.6 Conclusions

Polarised polychromatic non-coherent light (Bioptron light), applied as monotherapy in the current preliminary prospective open clinical trial, indicated a positive clinical effect in nocturnal pain relief and paraesthesia ability of idiopathic CTS. However, this study is limited by the lack of a control group and valid outcome measures. These shortcomings will be discussed in chapter 7. Future well-designed RCTs are required to investigate the absolute and relative effectiveness of polarised polychromatic non-coherent light (Bioptron light) and to objectively evaluate recommendations for its routine use in clinical practice.

4.5 Conclusion

The findings of these two preliminary clinical studies indicate that the supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) may reduce the symptoms in patellar tendinopathy and CTS, respectively. Cyriax physiotherapy consisting of DTF only did not reduce the pain in patients with patellar tendinopathy. However, future well-designed studies are required to confirm and further explore these findings, because methodological shortcomings were not absent from these two pilot studies. A questionnaire-based survey of the self-reports of chartered physiotherapists in Athens who are using the above-three treatments was conducted in order to establish their current clinical practice (Chapter 5).

Figure 4.1

Flowchart of patellar tendinopathy study

3 months symptoms
Previous conservative treatment
1-month therapy free interval

↓

Eligible patients (n=30)

Cyriax physiotherapy (n=10)	Supervised exercise programme (n=10)	Ultrasound (n=10)
↓	↓	↓
End of treatment (week 4) (n=10)	End of treatment (week 4) (n=10)	End of treatment (week 4) (n=10)
↓	↓	↓
Success	Success	Success
Yes (n=2) No (n=8)	Yes (n=8) No (n=2)	Yes (n=1) No (n=9)
↓	↓	↓
1-month follow-up (week 8) (n=10)	1-month follow-up (week 8) (n=10)	1-month follow-up (week 8) (n=10)
↓	↓	↓
Success	Success	Success
Yes (n=2) No (n=8)	Yes (n=10) No (n=0)	Yes (n=0) No (n=10)
↓	↓	↓
3-month follow-up (week 16) (n=10)	3-month follow-up (week 16) (n=10)	3-month follow-up (week 16) (n=10)
↓	↓	↓
Success	Success	Success
Yes (n=2) No (n=8)	Yes (n=10) No (n=0)	Yes (n=0) No (n=10)

Figure 4.2

Application of polarised polychromatic non-coherent light (Bioptron light) with Bioptron 2 device for the treatment of CTS

Table 4.1

Sports of patients (n)

	Cyriax physiotherapy	Supervised exercise programme	Ultrasound
Basketball	5	4	3
Soccer	1	3	2
Running	2	1	2
Volleyball	1	2	2
Tennis	1	0	1

Table 4.2

Frequency and percentage of pain response categories across groups at the end of the treatment

	Worse/no change/slightly better		Much better/no pain	
	Frequency	*%*	*Frequency*	*%*
Cyriax physiotherapy	8	80	2	20
Supervised exercise programme	2	20	8	80
Ultrasound	9	90	1	10

X^2=12.21, p<0.01

Table 4.3

Frequency and percentage of pain response categories across groups at one-month follow-up

	Worse/no change/slightly better		Much better/no pain	
	Frequency	*%*	*Frequency*	*%*
Cyriax physiotherapy	8	80	2	20
Supervised exercise programme	0	0	10	100
Ultrasound	10	100	0	0

X^2=23.2, p<0.001

Table 4.4

Frequency and percentage of pain response categories across groups at three-month follow-up

	Worse/no change/slightly better		Much better/no pain	
	Frequency	%	Frequency	%
Cyriax physiotherapy	8	80	2	20
Supervised exercise programme	0	0	10	100
Ultrasound	10	100	0	0

X^2=23.2, p<0.001

Table 4.5

Nocturnal pain in CTS (n(%))

	End of treatment	**Six-month follow-up**
Worse	0	0
No change	2 (8%)	0
Slightly better	6 (24%)	3 (12%)
Much better	12 (48%)	13 (52%)
No pain	5 (20%)	9 (36%)

Table 4.6

Paraesthesia in CTS (n(%))

	End of treatment	**Six-month follow-up**
Worse	0	0
No change	4 (16%)	2 (8%)
Slightly better	5 (20%)	2 (8%)
Much better (n)	13 (52%)	14 (56%)
No paraesthesia	3 (12%)	7 (28%)

Chapter 5: A questionnaire survey to establish current clinical practice of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the management of pain and functional impairment on lateral epicondylitis in Athens

5.1 Introduction

Chapter 2, which reports on a systematic review of RCTs that was conducted to establish the clinical effectiveness of physiotherapy for LE, provided information only on the treatment protocol of Cyriax physiotherapy for application to LE. Chapter 3 reports on a review of the published literature discussing the appropriate way to apply Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light). The purpose was to establish possible treatment protocols for a clinical trial that would determine the relative effectiveness of these treatments for LE. These recommended protocols were derived from the views of advocates for the various therapies, based on their personal experience of using the treatment and on the putative physiological mechanisms that the treatment might rely upon. Two preliminary clinical studies were conducted to pilot the use of treatment protocols derived from the critical review in chapter 3 on overuse injuries that are similar to LE and were regularly presenting to the clinic (Chapter 4). The findings of these two pilot studies should be interpreted cautiously due to methodological shortcomings as mentioned in chapter 4. In the first study (section 4.3), Cyriax physiotherapy was administered by a therapist who was the investigator of the present project (DS) and was based on Cyriax principles. Cyriax physiotherapy did not reduce the pain in patellar tendinopathy. In the same study, the supervised exercise programme was administered by the investigator of the project (DS) with a resulting reduction in the pain of patellar tendinopathy. In the second study (section 4.4), polarised polychromatic non-coherent light (Bioptron light) was administered by the investigator of the project (DS) with a resulting reduction in the nocturnal pain and paraesthesia of idiopathic CTS. As a preliminary to investigating the effectiveness of these protocols in treating LE, a questionnaire survey was conducted to establish the current clinical practice of Cyriax physiotherapy, supervised exercise programmes, and polarised

polychromatic non-coherent light (Bioptron light) for the management of LE. This questionnaire was designed to record the self-reports of chartered physiotherapists in Athens who were using these treatments in their clinical practices.

Questionnaire surveys have been used to establish current clinical practice using LPLL (Baxter et al., 1991) and cryotherapy (Johannsen and Langberg, 1997; Kerr et al., 1999). Surveys can quickly gather views of large number of people spread over large geographic areas, and they are less intrusive and cheaper than interviews or other forms of practice such as observation (Thomas and Nelson, 1996; Hicks, 1999; Domholdt, 2000; Berg and Latin, 2004). The present survey administered, a questionnaire designed by the investigator of the project (DS) to Greek chartered physiotherapists who worked in Athens.

5.2 Aim

The aim of this questionnaire survey was to establish current clinical practice of Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) for the management of pain and functional impairment associated with LE, through the self-reports of chartered physiotherapists of Athens.

5.3 Methods

5.3.1 Design of questionnaire

No validated instrument (questionnaire) existed for the purpose of assessing the self-reports of physiotherapists on their management of LE using either the Cyriax physiotherapy, the supervised exercise programme, or polarized polychromatic non-coherent light (Bioptron light). Therefore, the investigator of the present project (DS) designed a questionnaire (Appendix II) based on previously published questionnaires that established the current clinical practice of physiotherapy treatments such as LPLL and cryotherapy (Baxter et al., 1991; Johannsen and Langberg, 1997; Kerr et al., 1999). In addition, experts in this field were contacted and their comments on the draft questionnaire design sought. The final questionnaire comprised: (i) background information; (ii) the beliefs and opinions of respondents who worked with LE regarding signs, symptoms and management of LE; and (iii) the self-reports of respondents who worked with LE using Cyriax physiotherapy, a supervised exercise programme, and

polarised polychromatic non-coherent light (Bioptron light) in their own clinical management of LE.

5.3.1.1 Background information

Respondents were asked to report on how many years they had practiced, their area of specialisation, and if they worked with patients with LE. The last information was particularly important as this was used to exclude respondents who never saw LE patients in their practice.

5.3.1.2 Respondents' beliefs about signs, symptoms and management of LE

In this section the respondents who worked with LE patients were asked to report on which of the below terms (such as LE, lateral epicondylalgia, extensor tendinosis, extensor tendonitis and extensor tendinopathy) was in their opinion the most commonly used to describe the TE condition. Respondents in this section were also asked to report, according to their belief, (i) if the ECRB was the most commonly affected structure of LE, (ii) if LE patients complained of pain during digital palpation conducted by therapists, (iii) if LE patients complained of pain during gripping and (iv) if resistance of the wrist extension with the elbow in extension was the most common diagnostic test in LE patients. Respondents were also asked to report, in their opinion, (a) whether they had read an article about the conservative management of LE recently, (b) whether they had attended a course about the conservative management of LE during their careers, and (c) if they knew that more than 40 different treatments have been reported for the management of LE in the literature. For the purposes of the survey, the meaning "recently" was defined as four months or less before respondents receiving the questionnaire.

5.3.1.3 Self-reports on their own clinical management of LE by respondents who work with LE using Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light)

Respondents who reported that they used at least one of these three treatments to treat LE were then asked to report, in their opinion, (i) the aim; (ii) how many LE patients were managed in a clinical setting the last month; (iii) the treatment regimen (number of treatment sessions and frequency of treatment), the protocol (individual or standardised) and the compliance; (iv) the clinical outcome (short-term and long-term effects); (v) the

side effects and the contraindications; (vi) if the treatment was painful for patients; and (vi) the cost (expensive or not) and the risk (time consuming or not) applications. All these questions were asked related to the treatment the respondents used to treat LE.

5.3.2 Pilot procedure

A pilot study using the described above questionnaire was carried out in early November 2002. The number of subjects required for a pilot study is often dependent on circumstance and resource (Thomas and Nelson, 1996; Hicks, 1999; Domholdt, 2000; Berg and Latin, 2004). Georgoudis et al (2000) report that ten subjects is a satisfactory number. Since ten subjects has been used to run pilot studies for other questionnaire surveys, the present questionnaire was administered to ten physical therapists in Athens. The ten physiotherapists who were selected for the pilot study were drawn from the population for inclusion in the main study. The design of the questionnaire was subsequently discussed with the respondents and their comments noted. The results of the pilot study were not included in the final data analysis.

All respondents returned the questionnaire. Seven out of ten questionnaires were fully completed. Based upon the comments received during the pilot study, limited rewording of a number of questions was thought necessary to improve clarity. The meaning of word "recently" had to be defined (question 9). It was also necessary to reword the questions that asked when respondents attended a course about the conservative treatment of LE (question 10) and who reproduced the pain in patients by digital palpation (question 6). No additional negative comments or feedback about the completion of the questionnaire were received during the pilot study. Respondents noted that the questionnaire included clear and concise instructions on how to complete it, using simple language and leaving adequate space for them to make comments. Finally, respondents mentioned that the questionnaire held their interest and was completed easily.

5.3.3 Translation procedure

In translating an assessment instrument to a different language, misrepresentation may arise and a multi-step translation and validation process is essential for truly successful translation. These steps include a forward translation, blind back translation and pilot testing (Cull, 1998).

As recommended by the European Organisation for Research and Treatment of Cancer (EORTC) in their manual " EORTC quality of life study group: translation procedure" (Cull, 1998), for all translations, the translator(s) should be a native speaker of the language into which the questionnaire is being translated, with a high fluency in the other relevant language. The translation back to the original language should be undertaken independent of the forward translation, i.e. by a different translator, independent of the first (Cull, 1998).

The present questionnaire did not follow this translation procedure. For the pilot and main study, it was written in English and translated into Greek (Appendix III) by the investigator of the project for the purposes of administering it to chartered physiotherapists in Athens.

5.3.4 Survey procedure

The mail addresses of the 660 Athens members of the Greek Physiotherapy Association were obtained and a random sample of 220 Athens physiotherapists (33.3%) were sent the questionnaire, accompanied by an invitation letter (Appendix IV) in mid-November of 2002.

The questionnaire was designed to assure the confidentiality and anonymity of the responding physical therapists, since there was no coding to identify the questionnaires. Physical therapists completed the questionnaires and sent the completed questionnaires to the investigator using the self-addressed stamped envelope that was included. When the questionnaire was returned, the returned envelope was discarded maintaining the confidentiality and anonymity of the subjects' responses to the questionnaire.

Oppenheim (1992) suggests that questionnaires should be returned in a period of two weeks from the time they are distributed to participants. However, such a period of time is not long enough to provide a high response rate. Therefore, the investigator of the project chose to extend the deadline of the present study for two more weeks, giving an opportunity to the participants to return the questionnaires in four weeks (by mid-December 2002) from the time which they received them. This deadline was extended in the hope of increasing the response rate. No questionnaires were received after the deadline of the four weeks. No follow-up reminders were sent to assure anonymity.

5.3.5 Data analysis

Data was managed using descriptive statistical analysis (Hicks, 1999). One-way ANOVA was used to compare the mean professional experience of the groups.

5.4 Results

5.4.1 Response rate

Of the 220 questionnaires, 150 (68%) were received by mid-December 2002. Overall, the response rate of the present study was 68% and can be considered as approaching very good. Currier (1990) states that returns of 40% to 50% or less are common, and a response rate of 60% is good and 70% is very good.

Of the 150, 47 respondents (31.3%) reported that they did not work with patients who had LE. They were excluded from the analysis. Out of the remaining 103 respondents, 35 (34%) who worked with LE patients reported that they never used Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light) to treat LE. They were also excluded from the analysis. The remaining 68 respondents (66%) who worked with LE patients reported that they predominately used Cyriax physiotherapy (18, or 26.5%), a supervised exercise programme (43, or 63.2%) or polarized polychromatic non-coherent light (Bioptron light) (7, or 10.3%) to treat LE. Results of the analysis of these 68 completed questionnaires are presented below. Respondents' flow through the survey is summarized in a flow chart (Figure 5.1).

5.4.2 Background information

The mean professional experience of respondents who work with LE using Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light) was 15.93 (95%CI= 14.26-17.59) years (Table 5.1). There were no significant differences in mean professional experience between the groups ($p > 0.0005$, One Way ANOVA, Table 5.1). Orthopaedic and sports medicine physiotherapy were the specialised areas of respondents. Out of the 68 respondents, 37 (54.4%) were specialists in orthopaedic physiotherapy (Table 5.2)

5.4.3 Beliefs regarding signs, symptoms and management of LE

Respondents were permitted to identify which term (such as LE, extensor tendonitis, lateral epicondylalgia, extensor tendinopathy and extensor tendinosis) they used to describe the TE condition. LE was the most common answer, reported by 45 out of 68 respondents (66%) (Table 5.3)

64 out of 68 respondents (94%) reported that the ECRB tendon is the most common affected structure on LE (Table 5.4). All respondents (68, or 100%) reported that LE patients complain of pain by digital palpation conducted by therapists on the affected site and by gripping. In addition, 57 out of 68 respondents (84%) reported that the resisted wrist extension with the elbow in extension is the most common diagnostic test in practice for LE patients (Table 5.4).

Out of 68 respondents, 12 (17.5%) reported that they had read an article about the conservative management of LE recently (Table 5.5). Out of 68 respondents, 5 (7.5%) reported that they had attended a course about the conservative management of LE during their career (Table 5.5). Finally, out of 68 respondents, 18 (26.5%) stated that they knew that more than 40 different treatments methods have been reported in the literature for the management of LE (Table 5.5).

5.4.4 Self-reports on their own clinical management of LE

Most respondents, irrespective of whether they used Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light) to treat LE, reported that the reduction of pain and the improvement of function, individual or combined, were the main aims of these treatments (Table 5.6). It should be noted that respondents had the option to give more than one answer.

During the month prior to the survey, a total of 191 LE patients had been reported to be managed by the 68 respondents in a clinical setting with Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light) (Table 5.7). The supervised exercise programme was used more than the Cyriax physiotherapy and the polarised polychromatic non-coherent light (Bioptron light) in mean values (Table 5.7).

All respondents (68, or 100%) reported that they used a treatment regimen of 3 sessions of treatment per week for a four-week period to treat LE, irrespective of whether it was Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light). In addition, all respondents (68, or 100%) reported that they used a standardised treatment protocol during the treatment period to treat LE, irrespective of whether it was Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light).

All respondents (18, or 100%) who predominately used Cyriax physiotherapy to treat LE and all respondents (7, or 100%) who predominately used polarized polychromatic non-coherent light (Bioptron light) to treat LE reported that they administered these two physiotherapy treatments only in a clinical setting. However, 21 out of 43 respondents (49%) who predominately used a supervised exercise programme to treat LE reported that an exercise programme could be performed by LE patients at home.

All respondents (68, or 100%), irrespective of whether they used Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light) to treat LE, reported that these treatments were effective in the short-term (one month after the end of treatment) and in the long-term (six months after the end of treatment).

All respondents (68, or 100%) reported that they used a no-side-effects treatment to treat LE, irrespective of whether it was Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light).

Out of 18 respondents, who predominately used Cyriax physiotherapy to treat LE, 12 (66%) reported that this treatment had some contra-indications, of which the calcification of soft tissues was reported as the most common (Table 5.8). However, all respondents (43, or 100%) who predominately used the supervised exercise programme to treat LE and all respondents (7, or 100%) who predominately used polarized polychromatic non-coherent light (Bioptron light) to treat LE reported that these two treatments have no contra-indications in cases of LE.

All respondents (68, or 100%) reported that they used a pain-free treatment to treat LE, irrespective of whether it was Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light).

All respondents (18, or 100%) who predominately used Cyriax physiotherapy and all respondents (43, or 100%) who predominately used a supervised exercise programme to treat LE reported that these two treatments were not expensive treatments for either physical therapists or patients. However, all respondents (7, or 100%) who predominately used polarized polychromatic non-coherent light (Bioptron light) to treat LE reported that this treatment was an expensive treatment not only for patients, but also for physiotherapists.

All respondents (68, or 100%) reported that they did not use a time-consuming treatment to treat LE, irrespective of whether it was Cyriax physiotherapy, a supervised exercise programme or polarised polychromatic non-coherent light (Bioptron light).

5.5 Discussion

5.5.1 Principal (main) findings

The primary aim of this questionnaire survey was to establish current clinical practices for Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) for the management of pain and functional impairment associated with LE based on the self-reports of Athens chartered physiotherapists who used these treatments in their clinical practice. This is the first questionnaire survey to address this question.

Out of 103 respondents, 68 (66%) who worked with LE patients reported that they predominately used Cyriax physiotherapy, a supervised exercise programme, or polarised polychromatic non-coherent light (Bioptron light) to treat LE. Of those 68 responses, the most common was the supervised exercise programme (43, or 63.2%) and the least common was the polarized polychromatic non-coherent light (Bioptron light) (7, or 10.3%). It was reported that 191 LE patients were managed by the 68 respondents in a clinical setting with one of these treatments during the month prior to

the survey. The supervised exercise programme was used more than the Cyriax physiotherapy and the polarised polychromatic non-coherent light (Bioptron light).

The primary aim of these three treatments was reported to be the reduction of pain and improvement of function. The treatment regimen of these treatments was reported to be three sessions of treatment per week for a four-week period. The treatment protocol of these treatments was reported to be standardised during the treatment course. It was also reported that these treatments are characterized as not time-consuming, short-term (one month after the end of treatment) and long-term (six months after the end of treatment) effective treatments that do not cause side effects or increase of pain in patients during their application.

In addition, it was reported that the supervised exercise programme was the only of the three treatments that could be performed at home. Furthermore, it was reported that Cyriax physiotherapy was the only one of the three treatments that had some contraindications. Finally, polarised polychromatic non-coherent light (Bioptron light) was reported to be the only treatment that was expensive for both physical therapists and patients.

5.5.2 Strengths and weaknesses of study

A weakness of the present survey is that it is based on self-reports made retrospectively. This can be a problem when respondents are asked to look back and estimate the frequency of a particular behaviour. To avoid this problem a valid and reliable questionnaire has to be designed. A questionnaire is valid when it measures what it claims to measure and is not subject to bias (Streiner and Norman, 1989). Reliable questionnaires yield consistent results from repeated samples and different researchers over time (McKinley et al., 1997; Boynton and Greenhalgh, 2004). Just because a questionnaire has been piloted on a few of your colleagues, used in previous studies, or published in a peer-reviewed journal does not mean it is either valid or reliable.

Therefore, before administering a questionnaire, researchers have to be confident that the questionnaire is valid and reliable. However, in the present survey, the process of questionnaire development cannot ensure a high level of validity and reliability.

Unfortunately, this lack of a high level of validity and reliability is supported by the fact that the group of questions about beliefs of signs, symptoms and management of LE offers nothing to the aim of the study. These questions are therefore not discussed in this section. Nevertheless, the experience of respondents in diagnosis and management of LE was reported in the second section of the questionnaire. According to respondents' answers it can be concluded that they could diagnose LE simply, easily and quickly but their level of recently informing (updating) in the management of LE, apart from the treatment that they used, seemed to be low.

In addition, respondents who work with LE, irrespective of whether they used Cyriax physiotherapy, a supervised exercise programme, or polarised polychromatic non-coherent light (Bioptron light) to treat LE, were asked to report if the treatment that they applied was harmful for clinicians' hands (Question 19) and if any prophylactic measures were needed either for the therapists or for patients during its application (Questions 23 and 24). However, the findings of these questions are not presented in the results section because they were deemed not to be precise enough and were also not comparable. The answers to these excluded questions are included in Appendix V. Furthermore, these questions had not been asked of all respondents because the three treatments had different way of application (Chapter 3).

This problem could have been avoided if a more valid and reliable questionnaire had been developed and a two-stage questionnaire survey had been carried out. Although no important negative comments received during the pilot study of the present questionnaire, just a pilot study is not enough to confirm the validity and reliability of a questionnaire. A valid and reliable questionnaire could be developed following the techniques outlined by Oppenheim (1992) and Sapsford (1999). These techniques include: interviews of potential participants to identify issues about the topic and so to develop questionnaire items; comparison the list with the issues identified during the interviews with published and unpublished similar questionnaires; comments from all participants interviewed during the development of questionnaire on its content in order to suggest additional issues or questions; development a bank of questions to produce multi-items scales, which are more reliable than single questions (Ware et al., 1978); administration of questionnaire by interview to potential participants. Questions which are confusing, ambiguous, or gave very skewed responses will be either removed,

rewritten, or replaced; two further postal pilot studies for clarity will be conducted maximizing the issues that reported by participants as important; a proportion of participants will be asked to complete a second questionnaire later the same day with the administration of questionnaire and return it by post as a test of test-retest reliability; some practitioners who are not otherwise involved in the development of questionnaire will be review the components of questionnaire to recheck validity of questionnaire; statistical tests calculating Cronbach's α coefficient and a matrix of Pearson's correlation coefficients.

Later, in the first stage of a two stage questionnaire survey, a letter could be sent to all eligible participants to discover who predominately managed LE patients using Cyriax physiotherapy, using supervised exercise programmes or using polarised polychromatic non-coherent light (Bioptron light). For the second phase of the questionnaire survey, the questionnaire would be forwarded for completion to all those who predominately used one of the three physiotherapy treatments to manage LE. The questionnaire would be the same among the three groups with some modifications, for example, respondents who predominately used polarised polychromatic non-coherent light (Bioptron light) to treat LE would be asked in depth about prophylactics measures. Similar questions would be developed for the other groups. However, due to time and cost constraints, it was not possible to follow the above research design in the present survey.

The validity and reliability of the questionnaire might seem to be in doubt because of these reservations. In light of the nature of the study, it would have been anticipated that Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light), as used for the management of LE, would be overstated in the responses to this questionnaire, because the first two treatments are two of the most common treatments for LE and the last one is a novel modality, attractive to practitioners working in rehabilitation settings. However, this did not occur, since 68 out of 150 respondents used one of these three treatments to treat LE. If so, given the response rate, the length of experience reported by respondents and the amount of detail in their answers, it may be confidently assumed that the above results present a representative view of current clinical practice of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on LE at least as these treatments are applied in Athens. How much this

reflects usage in the rest of the Greece, Europe, or even the world, is yet to be seen by extending the research.

5.5.3 Comparison with previously published literature

Owing to a lack of comparable data, it is not possible to say whether the proportion of respondents who reported that they predominately used Cyriax physiotherapy, a supervised exercise programme, or polarized polychromatic non-coherent light (Bioptron light) to treat LE is high or low. The same conclusion about the number of LE patients who were managed during the last month in clinical settings using one of the three physiotherapy treatments must be drawn under consideration. The supervised exercise programme was the most commonly used treatment in practice. The most likely explanations for this are that the supervised exercise programme is a common physiotherapy treatment for a plethora of musculoskeletal disorders, no special training machines are needed, no specific "skills" from the physiotherapist are needed, more patients are familiar with it, and patients can understand that they are receiving a real treatment. Future surveys are needed to confirm these explanations and/or to add more.

The possible treatment protocols for Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) on LE were reported in chapter 3. Although these three treatments are administered in totally different manner, it was reported that they have the same aim, to reduce pain and improve function. This answer was expected because this is the priority aim of physiotherapy management (Cook et al., 2001).

The recommended regimen for Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) in the treatment of LE is three times per week for four weeks (Chapter 3). Such treatment regimens were used for these two treatments in the two preliminary clinical studies on overuse injuries that are similar to LE and were regularly presented to the clinic (Chapter 4). All respondents who predominately used one of these two treatments to treat LE reported in the present survey that they administered these treatments for LE three times per week for four weeks, supporting the findings of chapter 3.

On the other hand, the LE treatment regimen for a supervised exercise programme was not recommended in chapter 3 due to lack of available information. The most likely explanation for this may be that the exercise programmes were administered at home. The present survey found that half of respondents (21, or 49%) who predominately used supervised exercise programmes to treat LE reported that an exercise programme could be performed at home without the supervision of physical therapist. However, exercise programmes should be conducted under the supervision of physical therapists, because patients need a physiotherapist to monitor how the exercise programme is administered and how is progresses (Stasinopoulos and Johnson, 2004b). Supervised exercise programmes were used in the preliminary clinical trial in chapter 4 and in the subsequent controlled clinical trial in chapter 6. Nevertheless, the results of the present survey filled a knowledge gap in respect to the treatment regimen of supervised exercise programmes. All respondents who predominately used supervised exercise programmes to treat LE reported administering supervised exercise programmes three times per week for four weeks. Such a treatment regimen was used for the supervised exercise programme that was part of the preliminary patellar tendinopathy clinical study in chapter 4 (section 4.3).

Therefore, it was decided that Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) would be administered in the controlled clinical trial (Chapter 6) three times per week for four weeks. All respondents, irrespective of whether they used Cyriax physiotherapy, a supervised exercise programme, or polarised polychromatic non-coherent light (Bioptron light) to treat LE, reported that they used this treatment regimen. The previously reported regimen may be popular because of convenience with the clinical route/routine, or alignment with manufacturers' recommendations, expert advice, and/or personal experience. Future surveys might reveal why all clinicians reported the same treatment regimen for three different treatments. Such research was beyond the scope of this project.

Cyriax physiotherapy and a supervised exercise programme are individualized by patient verbal description of the pain experienced during the procedure (Chapter 3; Chapter 4). On the other hand, the respondents who predominately used one of these two treatments for LE reported in the present survey that the protocols of these two

treatments are standardised during the treatment course. This discrepancy occurred due to the design of the questionnaire. The questionnaire did not ask those respondents who predominately used one of these two treatments to treat LE whether the application of each of the components of these treatments should be standardised during the treatment period, that is, whether DTF should be administered in the same way to all patients during the treatment course or should be individualized in response to patients' symptoms. This discrepancy would be avoided in a future survey. For the time being, the findings of chapter 3 are supported: the treatment protocols of Cyriax physiotherapy and supervised exercise programmes for LE cannot be standardised during the treatment period and are individualized by the patient's description of pain experienced during the procedure. However, it is standard that these two treatments consist of two components during the treatment period.

The rest findings of the present survey that related to the effectiveness (clinical effectiveness, side-effects, cost effectiveness, time effects and contraindications) of the three treatments will be discussed in chapter 7, when a clinical trial comparing the clinical value of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on LE will be conducted in next chapter (Chapter 6). The findings of the present survey will be compared with the findings of the controlled clinical trial (Chapter 6) giving evidence to support or not the findings of the present project.

5.6 Treatment protocols for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) for the treatment of LE

The protocols for Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) for the management of LE were recommended in chapter 3. Some of these protocols were not effective in chapter 4 but this may be due to the type of condition e.g. not LE. Chapter 5 matches treatment regimens of protocols in use for Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) with the treatment regimens of protocols recommended in literature discussed in chapter 3. In addition, chapter 5 adds information about the treatment regimen of the supervised exercise programme. The investigator cannot say

with certainty whether these recommended protocols are the optimal treatment protocols, because the optimal treatment protocol can only be developed by synthesizing different sources of information: all kinds of published trials, anecdotal reports from therapists, published reviews, published surveys that establish treatment protocol, etc. Due to a lack of such sources for information on these treatments, it can be concluded, based on the existing literature, that the protocols for these treatments are the most appropriate and/or the most successful. These treatments protocols will be therefore applied in the subsequently described controlled clinical trial (Chapter 6).

5.6.1 Treatment protocol for Cyriax physiotherapy for the treatment of LE

It was decided that Cyriax physiotherapy would be consisted of DTF and Mill's manipulation administered three times per week for four weeks (Figure 3.3). Both components of Cyriax physiotherapy will be applied as described in chapter 3 (section 3.4.3) and will be individualised by responding to the patient's description of the pain experienced during the procedure.

5.6.2 Ttreatment protocol for a supervised exercise programme for the treatment of LE

It was decided that the supervised exercise programme would be consisted of slow progressive eccentric exercises of wrist extensors and static stretching exercises of ECRB administered three times per week for four weeks (Figure 3.10). Both components of the supervised exercise programme will be applied as described in chapter 3 (section 3.5.3) and will be individualised by responding to the patient's description of the pain experienced during the procedure.

5.6.3 Treatment protocol for polarised polychromatic non-coherent light (Bioptron light) for the treatment of LE

A Bioptron 2 device (Figure 3.11) will deliver standardised polarised polychromatic non-coherent light (Bioptron light) therapy as described in chapter 3 (section 3.6.1) three times per week for four weeks (figure 3.15).

5.7 Conclusion

Clinicians reported that they believed that Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) had the same aim (reduction of pain and improvement of function) and the same treatment regimen (three times per week for 4 weeks). It was also reported that these treatments are characterized as not time-consuming, short-term (1 month after the end of treatment) and long-term (6 months after the end of treatment) effective treatments that do not cause side-effects or increase of pain in patients during their application. Moreover, clinicians reported that (i) the supervised exercise programme could be performed at home; (ii) Cyriax physiotherapy had some contraindications; and (iii) polarised polychromatic non-coherent light (Bioptron light) was expensive for both physical therapists and patients.

It appears that research in this area is warranted not only to substantiate the subjective findings of individual physiotherapists, but also to explore the possible clinical relevance of the three treatments. While cellular and animal models have their part to play and can provide much useful information in this respect, the work would be best completed in human subjects by conducting well-designed clinical trials. Such a clinical trial comparing the effects of Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) on LE is described in the next chapter.

Figure 5.1

Flow chart of the survey

Questionnaires sent

n=220

Replies

n=150

Work with LE patients
n=103

Do not work with LE patients
n=47
(Excluded from analysis)

Predominately used
n=68

Do not use Cyriax physiotherapy, a supervised exercise
programme and polarised polychromatic non-
coherent light (Bioptron light)
n=35
(Excluded from analysis)

Cyriax
physiotehrapy
n=18

Supervised exercise
programme
n=43

Polarised polychromatic non-coherent
light (Bioptron light)
n =7

Table 5.1

Mean professional experience of respondents (years (95%CI))

	Cyriax physiotherapy	**Supervised exercise programme**	**Polarised polychromatic non-coherent light (Bioptron light)**
Mean professional experience	14.61 (11.54-17.88)	16.82 (14.61-19.03)	13.33 (7.91-18.75)

Table 5.2

Specialised areas of respondents (n (%))

	Orthopaedic physiotherapy	**Sports medicine physiotherapy**
Cyriax physiotherapy	10 (55.5%)	8 (44.5%)
Supervised exercise programme	22 (51%)	21 (49%)
Polarised polychromatic non-coherent light (Bioptron light)	5 (71.4%)	2 (28.6%)
Total	37 (54.4%)	31 (45.6%)

Table 5.3

Terms to describe the TE condition (n (%))

	Cyriax physiotherapy	**Supervised exercise programme**	**Polarised polychromatic non-coherent light (Bioptron light)**	**Total**
LE	12 (66.6%)	28 (65%)	5 (71.4%)	45 (66%)
Extensor tendonitis	5 (27.7%)	10 (23%)	0	15 (22%)
Lateral epicondylalgia	1 (5.7%)	3 (7%)	1 (13.4%)	5 (7.5%)
Extensor tendinopathy	0	1 (2.3%)	1 (13.4%)	2 (3%)
Extensor tendinosis	0	1 (2.3%)	0	1 (1.5%)

Table 5.4

Signs and symptoms of LE (n (%))

	Cyriax physiotherapy	Supervised exercise programme	Polarised polychromatic non-coherent light (Bioptron light)	Total
The most common affected site on LE is the ECRB tendon	17 (94.3%)	41 (95.4%)	6 (85.7%)	64 (94%)
The most common diagnostic test in practice is the resisted wrist extension with the elbow in extension	15 (83.2%)	37 (86.1%)	5 (71.4%)	57 (84%)

Table 5.5

Management of LE (n (%))

	Cyriax physiotherapy	Supervised exercise programme	Polarised polychromatic non-coherent light (Bioptron light)	Total
Reading an article	2 (11.3%)	9 (21%)	1 (14.3%)	12 (17.5%)
Attending a course	0	4 (9.3%)	1 (14.3%)	5 (7.5%)
Knowing that more than 40 treatments exists on LE	4 (22.6%)	12 (28%)	2 (28.6%)	18 (26.5%)

Table 5.6

Aims of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light for the treatment of LE (n (%))

	Cyriax physiotherapy	Supervised exercise programme	Polarised polychromatic non-coherent light (Bioptron light)	Total
Reduce pain	2 (11%)	6 (14%)	3 (43%)	11 (16.1%)
Improve function	2 (11%)	8 (19%)	1 (14%)	11 (16.1%)
Reduce pain & improve function	3 (17%)	10 (23%)	2 (29%)	15 (22%)
Repair connective tissue	4 (22%)	6 (14%)	1 (14%)	11 (16.1%)
Reduce pain & repair connective tissue	2 (11%)	3 (7%)		5 (7.35%)
Improve function & repair connective tissue	3 (17%)	3 (7%)		6 (8.82%)
Reduce pain & improve function & repair connective tissue	2 (11%)	4 (9%)		6 (8.82%)
Improve blood flow		2 (4.5%)		2 (2.9%)
Reduce pain & improve function & repair connective tissue & Improve blood flow		1 (2.5)		1 (1.45%)

Table 5.7

Number of patients who were managed in a clinical setting with Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) the month prior to the survey

Treatment approaches	N	x (SD)	Range
Cyriax physiotherapy	52	2.88 (1.24)	1-5
Supervised exercise programme	127	3 (1.4)	1-6
Polarised polychromatic non-coherent light (Bioptron light)	12	1.71 (0.75)	1-3

Table 5.8

Contraindications of Cyriax physiotherapy for the treatment of LE (n (%))

Participants	Contraindications
3 (25%)	skin problem
4 (33.3%)	Infection
5 (41.7%)	calcification of the soft tissues

Chapter 6: A controlled clinical trial to compare the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) in the reduction of pain and in the improvement of function in patients with lateral epicondylitis

6.1 Introduction

Strong evidence for the short-term effectiveness of acupuncture for LE was presented in chapter 2. There was also strong evidence that four modalities, LPLL, ultrasound, ESWT, and pulsed electromagnetic field therapy were not effective physiotherapy treatments for the management of LE. There was insufficient evidence available for other treatments used for LE, such as iontophoresis and home exercise programmes, to judge their effectiveness. It was recommended that more evidence from clinical trials is needed for Cyriax physiotherapy, supervised exercise programmes, and polarised polychromatic non-coherent light (Bioptron light). It appears that treatment protocols for Cyriax physiotherapy, supervised exercise programmes, and polarised polychromatic non-coherent light (Bioptron light) are mainly derived from the views of advocates of these techniques, based on their personal experiences (Chapter 3) although the treatment protocol for Cyriax physiotherapy did not reduce the pain in patellar tendinopathy (Chapter 4; section 4.3). On the other hand, a supervised exercise programme was found to reduce pain of patellar tendinopathy. However, as the number of patients included in the patellar tendinopathy was small, the data should be interpreted cautiously. Polarised polychromatic non-coherent light (Bioptron light) was found to reduce nocturnal pain and paraesthesia of idiopathic CTS although it was not possible to attribute changes to the light per se because the study lacked a control group (Chapter 4; section 4.4). A questionnaire survey of the self-reporting of their use of these treatments by chartered physiotherapists in Athens revealed that they used protocols in their daily practice that were similar to those found in the literature (Chapter 5).

In order to assess the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for LE a

clinical trial was necessary. Relative effectiveness of outcome between treatments gives more clinically meaningful information since it provides therapists with information that can be used when choosing treatments (Halle et al., 1986). Absolute effectiveness, on the other hand, is useful in determining specific effects associated with individual treatments' by comparing them to a placebo intervention. This does not provide information about the relative effects of a range of different treatments (Labelle et al., 1992). From a clinical perspective information on relative effectiveness is more relevant to the practicing therapist.

6.2 Aim

The aim of this study was to investigate the relative effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light), in the reduction of pain and improvement of function in patients with LE.

6.3 Methods

A controlled, monocenter trial was conducted in a clinical setting over 18-month period to assess the effectiveness of Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light). A parallel-group design was employed because cross-over designs are limited in situations where patients are cured by the intervention and do not have the opportunity to receive the other treatments following cross-over (Johannsen et al., 1993). Three investigators were involved in the study: 1) The primary investigator who administered the treatments (DS); 2) a specialised rheumatologist (IS), who had over 25 years experience and who evaluated the patients to confirm the LE diagnosis, and 3) a physiotherapist (EK), who performed all baseline and follow-up assessments, and gained informed consent. All assessments were conducted by EK who was blind to the patients' therapy group. EK had 15 years of experience in the management and assessment of musculoskeletal disorders including LE. EK interviewed each patient to ascertain baseline demographic and clinical characteristics including patient name, sex, age, duration of symptoms, previous treatment, occupation, affected arm and dominant arm (Appendix VI).

6.3.1 Sample size

Abbott et al (2001) suggest that a sample size of twenty-five subjects per group is sufficient to demonstrate statistical clinical significance for all outcome measures on LE. Clinical effects of 20% had been reported as clinically meaningful in placebo-controlled studies measuring pain relief and functional outcomes in response to physiotherapeutic interventions such as LPLL (Basford et al., 2000). In this study, baseline variance for pain and functional outcomes was set at 25%, in line with previously published data in this field (Dwars et al., 1990). Power calculations suggested that a sample size of 25 patients per group was sufficient to detect a 20% change in outcome measures assuming that variance was equivalent to 25% with 80% of power and a 5% significant level. The formula that used to estimate the appropriate sample size was:

$$N=16\sigma^2/d^2$$

where σ^2=the variability of the data

d^2= the effect size

For example in our trial σ=25 and d=20. Therefore the above formula is

$$N=16(25^2)/(20^2)=16\times625/400=25$$

6.3.2 Participants and recruitment

Patients suffering from lateral elbow pain were examined and evaluated in the Rheumatology and Rehabilitation centre located in Athens between January 2003 and January 2004. All patients lived in Athens, Greece, were native speakers of Greek, and were either self-referred or referred by their physician or physiotherapist. All patients were new cases to the clinic.

6.3.3 Inclusion criteria

Patients between 30 and 60 years old were included in the study if, at the time of presentation, they had been evaluated as having clinically diagnosed LE for at least 4 weeks (1 month). Patients were included in the trial if they reported (i) pain on the facet of lateral epicondyle when palpated (Figure 1.2), (ii) less pain during resistance supination with the elbow in 90º of flexion rather than in full extension (Kraushaar and Nirschl, 1999) (Figure 1.7), and (iii) pain in at least two of the following four tests (Haker, 1993):

1. Tomsen test (Figure 1.3)
2. Resisted middle finger test (Figure 1.4)
3. Mill's test (Figure 1.5)
4. Handgrip dynamometer test (Figure 1.6)

6.3.4 Exclusion criteria

Patients were excluded from the study if they had one or more of the following conditions: (i) dysfunction in the shoulder, neck and/or thoracic region; (ii) local or generalized arthritis; (iii) neurological deficit; (iv) radial nerve entrapment; (v) bi-lateral lateral epicondylitis; (vi) limitations in arm functions; (vii) pregnancy; (viii) an installed pacemaker; (ix) the affected elbow had been operated on and (x) had received any conservative treatment for the management of LE in the preceding four weeks before entering the study (Vasseljen, 1992; Haker, 1993; Pienimaki et al., 1996; Runeson and Haker 2002; Kochar and Dogra, 2002; Hake et al., 2002a).

6.3.5 Ethical considerations

All patients received a written explanation of the trial (Appendix VII) prior to entry into the study. All patients gave signed informed consent (Appendix VIII) to participate in the study. The study was approved by the Leeds Metropolitan University Research Ethics Committee and access to patients was authorized by the manager of Rheumatology and Rehabilition centre.

6.3.6 Sequential allocation

The patients were allocated to three groups by sequential allocation. For example, the first patient with LE was assigned to the Cyriax physiotherapy group, the second patient with LE to the supervised exercise-programme group, the third patient with LE to the polarised-polychromatic-non-coherent-light (Bioptron light) group, the fourth patient with LE to the Cyriax physiotherapy group, the fifth patient with LE to the supervised-exercise-programme group and so on.

All patients were instructed to use their arm during the course of the study but to avoid activities that irritated the elbow such as shaking hands, grasping, lifting, knitting, handwriting, driving a car and using a screwdriver. Patients were informed to refrain

from taking anti-inflammatory medication throughout the course of study. Patient compliance to this request was monitored using a treatment diary.

6.3.7 Treatment intervention

All treatments were administered at the centre by a qualified physiotherapist with a certificate in orthopaedic medicine on Cyriax principles (DS) (Appendix I). Each treatment was given three times per week for four weeks.

6.3.7.1 Cyriax physiotherapy

Cyriax physiotherapy consisted of 10 minutes of DTF immediately followed by one intervention of Mill's manipulation (Chapter 3, section 3.4.3, Figure 3.3). DTF was applied with the patient on a bed with the elbow on a pillow fully supinated and in ninety degrees of flexion with the therapist stood on the side of affected elbow. The inferior-lateral aspect of the lateral epicondyle was located and the area of tenderness identified. DTF was applied with the side of the thumb tip. The therapist applied pressure using the thumb in a posterior direction to the origin of ECRB tendon and this pressure was maintained whilst imparting DTF. The therapist held the other side of the elbow to establish counter pressure (Figure 3.1).

Mill's manipulation was applied with the patient positioned on a chair with a backrest and the therapist stood behind the patient. The patient's arm was supported under the crook of the elbow with the shoulder joint abducted to ninety degrees and medially rotated. The forearm fell automatically into pronation. The thumb of therapist's other hand was placed in the web space between the patient's thumb and index finger and the patient's wrist was fully flexed and the forearm was fully pronated. The hand supporting the crook of the elbow was moved on to the posterior surface of the elbow joint and whilst maintaining full wrist flexion and pronation, the patient's elbow was fully extended. Then, a minimal-amplitude high-velocity thrust was applied by simultaneously side-flexing the therapist body away from his arms and pushing smartly downwards with the hand over the patient's elbow (Figure 3.2).

Cyriax physiotherapy treatment was individualised one the basis of the patient's description of pain experienced during the procedure.

6.3.7.2 Supervised exercise programme

The supervised exercise programme consisted of slow progressive eccentric exercises of wrist extensors and static stretching exercises of ECRB tendon (Chapter 3, section 3.5.3, Figure 3.10). Three sets of 10 repetitions of slow progressive eccentric exercises of wrist extensors at each treatment session were performed with one-minute rest interval between each set. Static stretching exercises of ECRB tendon were repeated six times at each treatment session, three times before and three times after the eccentric exercises with a 30-second rest interval between each repetition.

Eccentric exercises of wrist extensors were performed with elbow on bed in full extension, forearm in pronation, wrist in extended position (as high as possible) and the hand hanging over the edge of the bed (Figure 3.4). From this position patients flexed their wrist slowly counting to thirty (Figure 3.5), then returned to starting position with the help of the other hand (Figure 3.6). Patients were told to continue with the exercise even if they experienced mild pain. However, they were told to stop the exercise if the pain became disabling. When patients were able to perform the eccentric exercises without experiencing any minor pain or discomfort, the load was increased using free weights (Figures 3.7 and 3.8).

Static stretching exercises of the ECRB tendon were performed with the help of the therapist. The therapist placed the elbow of patient in full extension, forearm in full pronation and the wrist in flexion and ulnar deviation according to the patient's tolerance (Figure 3.9). This position was held for 30 to 45 seconds each time and then released.

The supervised exercise programme treatment was individualised one the basis of the patient's description of pain experienced during the procedure.

6.3.7.3 Polarised polychromatic non-coherent light (Bioptron light)

Polarised polychromatic non-coherent light (Bioptron light) therapy was administered using a Bioptron 2 device (Figure 3.11) to three locations for six minutes in each location, (i.e. 18 minutes in total) (Chapter 3, section 3.6.1, Figure 3.15).

The probe of the Bioptron 2 was held at a 90º angle 5-10 cm above the clean bare skin of the lateral condyle (i) from the upper surface (anterior) with the elbow in extension and the forearm in supination (Figure 3.12) and (ii) from the lateral surface with the elbow in 90^0 of flexion and the forearm in pronation (Figure 3.13). In addition, the probe of Bioptron 2 was held at a 90º angle 5-10 cm above the clean bare skin of the bellies of the extensors muscles of the wrist with the elbow in 90^0 of flexion and the forearm in mid-position of pronation-supination (Figure 3.14).

The polarised polychromatic non-coherent light (Bioptron light) treatment was standardised during the treatment period.

6.3.8 Outcome measures
Pain, function and drop out rate were measured in the present study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 4), at one month (week 8), at 3 months (week 16) and at six months (week 28) after the end of treatment.

6.3.8.1 Pain
Pain was measured on visual analogue scale (VAS), where 0 (cm) was "least pain imaginable" and 10 (cm) was "worst pain imaginable". The pain VAS was used to measure the patient's worst level of pain over the previous 24 hours prior to each evaluation (Appendix IX) and this approach has been shown to be valid and sensitive of the VAS (Stratford et al., 1987).

6.3.8.2 Function
Function was measured using a visual analogue scale (VAS), in which 0 (cm) was taken as "no function" and 10 (cm) as "full function". Patients were instructed to report their overall level of elbow function over the previous 24 hours prior to each evaluation (Appendix IX). The validity and sensitivity of this measure has been shown by Stratford and his colleagues (1987).

In addition, function was measured by pain-free grip strength (PFGS). PFGS is defined as the amount of force each patient is able to generate with an isometric gripping action before eliciting pain (Stratford et al., 1993). Force was measured in pounds with a Jamar hand dynamometer (Figure 6.1) that had adjustable handles to accommodate different

hand sizes. The arm was placed in a standardized position of elbow extension, forearm pronation and internal rotation of the upper limb such that the palmar aspect of the hand faced posteriorly with the upper limb placed by the patient's side (Figure 6.2). Patients were then instructed to squeeze the dynamometer handles until they first experienced pain and then to release their grip (Haker, 1993; Vicenzino and Wright, 1995; Vicenzino et al., 1996; Abbott et al., 2001; Vicenzino et al., 2001; Smidt et al., 2002b; Tsui and Leng, 2002; Paungmali et al., 2003; Vicenzino et al., 2003). The attained grip force was subsequently recorded and the reading was not visible to the patient. Three measures of pain-free grip strength were recorded with a 30-second rest interval between each measurement and the mean value of these repetitions was calculated (Appendix X). This approach has been used in a plethora of previously published studies on LE (Chapter 2, Table 2.4). PFGS is a valid and sensitive measure for LE patients (Abbott et al., 2001).

Furthermore, function was measured by an eight-item pain-free function questionnaire. The eight-item pain-free function questionnaire was first described by Stratford et al. (1987) who assessed the functional ability of patients to perform common movements that might cause elbow pain (Table 6.1). Patients answer the question: "Today, do you or would you have any elbow discomfort at all with any of the following activities?" Possible responses are: YES (Y) or NO (N) (Appendix XI).

Function was also measured using global measure of improvement. The global measure of improvement required patients to choose a description of their status at the end of the treatment (week 4) and at the follow-ups (week 8, week 16, and week 28) from the following alternatives: worse, no change, somewhat better, much better and no pain in a scale of 1 to 5, where 1=worse and 5=no pain (Appendix XII) (Vasseljen, 1992; Vasseljen et al., 1992; Kochar and Dogra, 2002).

6.3.8.3 Drop out rate
A drop out rate was also used as an indicator of treatment outcome. Reasons for patients drop out were categorized as follows: (i) a withdraw without reason; (ii) not returned for follow-up; and (iii) request for an alternative treatment.

6.3.9 Data analysis

The problem with pain and function on VAS is how to classify the data. Pain and function are subjective, so should these be called an ordinal scale? However, length measurement in centimeters is an interval/ratio scale, so how the issue can be resolved? There is no right answer here and it must be left to the investigator. However, as a general rule of data collection, it is usually advisable to use the most sophisticated level of measurement you can, since more detailed analysis can be performed (Hicks,1999). Therefore, it may be preferable to treat VAS as interval/ratio.

The change from baseline was calculated for each follow-up for each outcome measure. Differences in this change pain on the VAS, change in function on the VAS and change in PFGS was calculated between the groups and was determined using a one-way analysis of variance (1-way ANOVA). Bonferroni post hoc comparisons were conducted when the results from the 1-way ANOVA were significant to determine how the three groups differed.

The 1-way ANOVA was used and no the t test because this would violate an assumption concerning the established alpha level (0.05 in this case) The .05 level means 1 in 20 probability that a difference could be due to chance if the groups compared are independent. In this case, the groups are not independent because each group is compared more than once with every other group. Thus, we have increased the chances of making a type I error. ANOVA allows making any number of groups comparisons without violating the alpha level.

For the same reasons, the t test did not use for post hoc comparisons. If t tests were used the probability of type I error would increase. Three t tests would be used in the present case rising the type I error to 15%. Several follow up tests protect the type I error. One of these is the Bonferroni that was used in the present statistical analysis.

The Kruskal-Wallis test was used to determine whether there were significant differences between the groups in their responses to the eight-item pain-free function questionnaire and the global measure of improvement. To determine how the three groups differed, a Mann-Whitney test was used whenever the results from the Kruskal-Wallis test were significant. These tests were used for the eight-item pain-free function

questionnaire and the global measure of improvement because the assumptions for the parametric tests were not met. The measurement level of the data in the eight-item pain-free function questionnaire was in nominal level. The measurement level of the data in the global measure of improvement was in ordinal level.

In the eight-item pain-free function questionnaire, the "NO" answers of participants was calculated by subtracting the results at baseline from those at follow-ups. A global measure of improvement was scored on a five-point scale, where 1 indicated "worst" and the 5 indicated "no pain". The results of the above outcome measure did not compare with the baseline (week 0), because this was first measured at week 4 (end of treatment). A 5% level of probability was adopted as the level for statistical significance. SPSS 11.5 statistical software was used for the statistical analysis.

6.4 Results

One hundred twenty one patients eligible for inclusion visited the clinic within the trial period. Twenty-five were unwilling to participate in the study and 21 did not meet the inclusion criteria described above (section 6.3.3). The other 75 patients were allocated by sequential allocation into one of the three possible groups: (1) Cyriax physiotherapy (n=25; 16 male, 9 female; mean age=40.44 years ±SD=5.61 years), (2) a supervised exercise programme (n=25; 15 male, 10 female; mean age=40.44 years ±SD=5.66 years) and (3) polarized polychromatic non coherent light (Bioptron light) (n=25; 15 male, 10 female; mean age=40.16 years ±SD=6.29 years) (Appendix XIII). Patient flow through the trial is summarized in a CONSORT flow chart (Figure 6.3).

At baseline there were more males in the groups (17 in total). The mean age of patients was approximately 40 years and the duration of LE was approximately 5 months. LE was in the dominant arm in 90% of patients. There were no significant differences in mean age (p>0.0005, 1-way ANOVA) or the mean duration of complaints (p>0.0005, 1-way ANOVA) between the groups. Patients had received a wide range of previous treatments (Table 6.2) (Appendix XIV). Drug therapy had been tried by 30-45%. Some 4%-8% of patients were athletes (Table 6.3) (Appendix XV).

6.4.1 Pain

Baseline pain on VAS was 6.96 (95%CI= 6.77-7.15) for the whole sample (n=75) (Table 6.4). There were no significant differences between the groups for baseline pain (p>0.05-1 way ANOVA, Table 6.4). The data passed the test for normality and subsequent data was analysed using parametric statistical tests (Appendix XVI).

At week 4 there was a decline in VAS of approximately 4 units in all groups when compared to the pre-treatment baseline (p<0.0005, paired t-test, Table 6.5, Figure 6.4). There was a significant difference in the magnitude of reduction between the groups (p<0.0005-1-way ANOVA, Table 6.5), so post hoc tests were performed. The magnitude of reduction was significantly larger for the supervised exercise programme than for Cyriax physiotherapy (+0.60 VAS units) and polarised polychromatic non-coherent light (Bioptron light) (+1.04 VAS units, p<0.05, Bonferroni, Table 6.5, Figure 6.4). There was no significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (+0.44 VAS units, p>0.05, Bonferroni, Table 6.5, Figure 6.4).

Similarly, at week 8, 16 and 28 there were comparable magnitudes of reduction with larger reduction for the supervised exercise programme than for Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (p<0.05, Bonferroni, Table 6.5, Figure 6.4). There was a significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) at week 28 (p<0.05, Bonferroni, Table 6.5, Figure 6.4).

6.4.2 Function
<u>*6.4.2.1 Function on VAS*</u>

Baseline function on VAS was 3.93 (95%CI= 3.74 - 4.13) for the whole sample (n=75) (Table 6.6). There were no significant differences between the groups for baseline function (p>0.05, 1 way ANOVA, Table 6.6). The data passed the test for normality and subsequent data was analysed using parametric statistical tests (Appendix XVII).

At week 4 there was a rise in VAS of approximately 3 units in all groups when compared to the pre-treatment baseline (p<0.0005, paired t-test, Table 6.7, Figure 6.5). There was a significant difference in the magnitude of improvement between the groups

(p<0.0005, 1-way ANOVA, Table 6.7), so post hoc tests were performed. The magnitude of improvement was significantly larger for the supervised exercise programme when compared to Cyriax physiotherapy (+0.68 VAS units) and polarised polychromatic non-coherent light (Bioptron light) (+1.08 VAS units, p<0.05, Bonferroni, Table 6.7, Figure 6.5). There was no significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (+0.40 VAS units, p>0.05, Bonferroni, Table 6.7, Figure 6.5).

Similarly, at week 8, 16 and 28 there were comparable magnitudes of improvement with larger improvements for the supervised exercise programme than for Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (p<0.05, Bonferroni, Table 6.7, Figure 6.5). There was no significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) at any of the follow-up time points (p>0.05, Bonferroni, Table 6.7, Figure 6.5).

6.4.2.2 Pain Free Grip Strength (PFGS)

Baseline PFGS was 25.93 (95%CI= 25.00 – 26.87) for the whole sample (n=75) (Table 6.8). There were no significant differences between the groups for baseline PFGS (p>0.05, 1- way ANOVA, Table 6.8). The data passed the test for normality and subsequent data was analysed using parametric statistical tests (Appendix XVIII).

At week 4 there was a rise in PFGS of approximately 40 units in all groups when compared to the pre-treatment baseline (p<0.0005, paired t-test, Table 6.9, Figure 6.6). There was a significant difference in the magnitude of improvement between the groups (p<0.0005, 1-way ANOVA, Table 6.9), so post hoc tests were performed. The magnitude of improvement was significantly larger for the supervised exercise programme when compared to Cyriax physiotherapy (+7.12 PFGS units) and polarised polychromatic non-coherent light (Bioptron light) (+10.76 PFGS units, p<0.05, Bonferroni, Table 6.9, Figure 6.6). There was no significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (+3.64 PFGS units, p>0.05, Bonferroni, Table 6.9, Figure 6.6).

Similarly, at week 8, 16 and 28 there were comparable magnitudes of improvement, with larger improvements for the supervised exercise programme than for Cyriax

physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (p<0.05, Bonferroni, Table 6.9, Figure 6.6). There was no significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) at any of the follow-up time points (p>0.05, Bonferroni, Table 6.9, Figure 6.6).

6.4.2.3 Eight-item pain-free function questionnaire

The baseline of the eight-item pain-free function questionnaire was 0 for the whole sample (n=75, Table 6.10). There were no significant differences between the groups for baseline pain free function questionnaire (p>0.05, Kruskal-Wallis test ranks, Table 6.10). The data was analysed using non-parametric statistical tests (Appendix XIX).

At week 4 there was a rise in "no" responses to the pain-free function questionnaire for 6 items in the Cyriax physiotherapy group and the supervised exercise programme group, and 5 items in the polarised-polychromatic-non-coherent-light (Bioptron light) group when compared to the pre-treatment baseline (Table 6.11, Figure 6.7). There was a significant difference in the magnitude of improvement between the groups (p<0.0005, Kruskal-Wallis test ranks, Table 6.11), so post hoc tests were performed. The magnitude of improvement was significantly larger for the supervised exercise programme when compared to Cyriax physiotherapy (0 pain free items) and polarised polychromatic non-coherent light (Bioptron light) (+1 pain free items p<0.05, Mann-Whitney, Table 6.11, Figure 6.7). There was significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (+1 pain-free items VAS units, p<0.05, Mann-Whitney, Table 6.11, Figure 6.7).

Similarly, at week 8, 16 and 28 there were comparable magnitudes of improvement, with larger improvements for the supervised exercise programme than for Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) (p<0.05, Mann-Whitney, Table 6.11, Figure 6.7). There was no significant difference between Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) at any of the follow-up time points (p>0.05, Mann-Whitney, Table 6.11, Figure 6.7).

<u>*6.4.2.4 Global measure of improvement*</u>

At week 4, 8, 16 and 28, the global measure of improvement was 4 (much better) on a 5-point scale of improvement in all groups, where 1 meant worse and 5 meant no pain. The data was analysed using non-parametric statistical tests (Appendix XX).

There were no comparable magnitudes of improvement between the groups at week 4 and at any of the follow-up time points ($p > 0.05$, Kruskal-Wallis test ranks).

6.4.3 Drop out rate

There were no drop out and all patients successfully completed the study.

6.5 Discussion

6.5.1 Principal findings

The results obtained from this controlled clinical trial are novel, as to date there has been no data comparing the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) for pain and function in LE.

When compared to the pre-treatment baseline, Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) reduced pain and improved function at the end of the treatment and at any of the follow-up time points. The supervised exercise programme produced the largest effect in the short, intermediate and long term. When compared to polarised polychromatic non-coherent light (Bioptron light), Cyriax physiotherapy was also found to produce superior improvement on the pain-free function questionnaire immediately after treatment intervention (week 4) and superior pain relief at the six-month follow-up (week 28). There were no significant differences between the groups for the global measure of improvement. This lack of difference may indicate that a 5-point scale is not sensitive enough to detect minor changes. There were no drop-outs reported at the end of treatment or at any points of follow-ups.

6.5.2 Do the findings match previous knowledge?

Although no previously published RCTs have examined the effectiveness of supervised exercise programmes for LE (Chapter 2), a home exercise programme has been used in some previously published clinical trials on LE (Pienimaki et al., 1996; Drechsler et al., 1997; Svelnlov and Adolfsson, 2001; Kochar and Dogra, 2002; Smidt et al., 2002b; Struijs et al., 2003; Struijs et al., 2004). Nevertheless, a home exercise programme was the sole treatment in only one previously published RCT (Pienimaki et al., 1996; Chapter 2). A home exercise programme was only part of the treatment approach in other studies (Drechsler et al., 1997; Svelnlov and Adolfsson, 2001; Kochar and Dogra, 2002; Smidt et al., 2002b; Struijs et al., 2003; Struijs et al., 2004), and therefore it was not possible to establish with certainty the degree to which the home exercise programme contributed to the overall results.

In the only previously published RCT (Pienimaki et al., 1996) the home exercise programme was administered in a totally different manner than the supervised exercise programme employed in the present controlled clinical trial. The differences were not only in the environment in which the exercise programmes administered, at home in Pienimaki et al (1996) study and in a clinical setting in the present study, but also in the development of treatment protocol (type of exercises, intensity, frequency, duration of treatment). In all likelihood, Pienimaki and his colleagues did not evaluate the literature to establish recommended protocols based on therapists' anecdotal reports, as was done in the present project (Chapter 3, section 3.5). Nevertheless, although the protocol of the home exercise programme treatment administered by Pienimaki et al (1996) does not follow this author's views (Chapter 3, section 3.5), research has to be continued to investigate the long-term effects of this treatment. In addition, there is clearly a need for a future clinical trial that would compare the effects of the present study supervised exercise programme treatment protocol with the home exercise programme treatment protocol used by Pienimaki et al (1996).

Previously published trials (randomized and non-ransomised) found that a home exercise programme consisting of slow progressive eccentric and static stretching exercises reduced the pain in patellar (Chapter 4, section 4.3; Purdam et al., 2004) and Achilles tendinopathy (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silbernagel et al., 2001; Ohberg et al., 2004; Roos et al., 2004) respectively.

However, the home exercise programme was performed daily, once or twice per day, for about three months in all previously published studies. In contrast, the present controlled clinical trial and the preliminary clinical trial in chapter 4 (section 4.3) administered a supervised exercise programme three times per week for four weeks. Thus, it seems that the supervised exercise programme may give good long-term clinical results in a shorter period of time than the home exercise programme. The most likely explanation for this difference may be that a supervised exercise programme achieves a higher degree of patient compliance. Future studies to compare the effects of these two exercise programmes are required to confirm the findings of the present controlled clinical trial and of the preliminary clinical study in chapter 4 (section 4.3).

There have been previously published trials of DTF (Stratford et al., 1989; Dwars et al., 1990; Vasseljen, 1992; Drechsler et al., 1997; Smidt et al., 2002b; Struijs et al., 2003; Struijs et al., 2004) and Mill's manipulation (Burton, 1988) administered separately for LE. However, in all previously published studies DTF and Mill's manipulation were given as a part of a combined treatment approach and it was not possible to determine how much either component contributed to the results. The authors of all previously published studies did not report that Cyriax physiotherapy was administered, but components of Cyriax physiotherapy were administered as advocated by Cyriax (Chapter 3, section 3.4). Cyriax (1982) stated that, if clinicians intend to use Cyriax physiotherapy in treating patients with LE, it can only be considered Cyriax physiotherapy if DTF and Mill's manipulation are used together (not separately) and the Mill's performed immediately after the DTF (Chapter 3; section 3.4). Whether the two components of Cyriax physiotherapy are effective "sole" treatments must be confirmed by other researchers.

The only previously published RCT that studied the effectiveness of Cyriax physiotherapy on LE administered in a manner identical to the present controlled clinical trial was conducted by Verhaar et al (1996). They found that Cyriax physiotherapy was a less effective treatment than steroid injection in short-term follow-up (6 weeks after the end of treatment), but found no significant differences for the effectiveness of the treatments in the long-term follow-up (one year after the end of treatment). However, Verhaar and his colleagues (1996) did not conclude whether both treatments were effective or ineffective in the long-term follow-up, leaving the reader

with questions about their effectiveness. In contrast, Cyriax physiotherapy reduced pain and improved function, in the present controlled clinical trial, but it was less effective than the supervised exercise programme in the short, intermediate and long term. We cannot say with certainty that Cyriax physiotherapy is an effective treatment for LE because we did not use a placebo/sham (no treatment) group and the reduction of symptoms could have occurred just because of the natural fluctuations in healing.

Research on the effectiveness of Cyriax physiotherapy on overuse injuries is sparse. Two studies showed poor outcomes for the effectiveness of Cyriax physiotherapy in patellar tendinopathy (Pallechia et al., 1994; Chapter 4, section 4.3) and one study showed similar results in iliotibial band friction syndrome (Schwellnus, 1992). However, these previously published studies had methodological shortcomings such as small sample size, lack of blinding (therapists, patients), lack of power analysis, invalid outcome measures, lack of follow-ups and lack of randomisation. Thus, definite conclusions about the effectiveness of Cyriax physiotherapy cannot be drawn. In addition, in all previously published studies, Cyriax physiotherapy consisted of 10 minutes of DTF only, though, Cyriax physiotherapy for LE consists of DTF and Mill's manipulation (Chapter 3, section 3.4). The possible explanations why Cyriax physiotherapy is applied in a different way between LE and rest tendinopathies will be discussed in chapter 7.

Although novel modalities like polarised polychromatic non-coherent light (Bioptron light) are attractive to practitioners working in rehabilitation settings, the present controlled clinical trial was the first study to examine the effectiveness of light therapy using polarised polychromatic non-coherent light (Bioptron light) on LE. The preliminary clinical trial was also the only previously conducted clinical trial that assessed the effectiveness of this treatment in CTS, an overuse injury similar to LE that is regularly presented to the clinic (Chapter 4, section 4.4). The most likely explanation for this lack of trials is that polarised polychromatic non-coherent light (Bioptron light) has only become recently available in the physiotherapy area, though it is used routinely in our clinical practice the last 7-8 years. Both studies found that a course of polarised polychromatic non-coherent light (Bioptron light) treatments based on manufactures' claims may improve patients' symptoms on LE (pain and function) and CTS (nocturnal pain and paraesthesia) respectively. The findings of these two trials encourage the

design of future well-designed RCTs that might produce strong evidence for the effectiveness of polarised polychromatic non-coherent light (Bioptron light) on overuse injuries.

In contrast, there are several trials to assess the effectiveness of LPLL, the light therapy most commonly used in practice for the treatment of LE (Chapter 2, Table 2.4) and of other conditions similar to LE that are presented to the clinic. Chapter 2 found strong evidence that LPLL is an ineffective treatment on LE, but this modality cannot be ruled out as a target for research because this is a dose-response modality and the optimal treatment dosage (if any) for the management of LE and other conditions similar to LE has not yet have been determined. Even though LPLL and polarised polychromatic non-coherent light (Bioptron light) are two forms of light therapy with biostimulative effects assisting tissue healing at cellular level, these two forms differ in their radiation characteristics (Chapter 3, Table 3.2). Therefore, the effects of LPLL on LE cannot be translated into those for polarised polychromatic non-coherent (Bioptron light). The effects of polarised polychromatic non-coherent light (Bioptron light) are yet to be confirmed by other researchers.

6.5.3 Shortcomings of this controlled clinical trial

The present study did not use a randomised design, a placebo (sham)/no treatment group was not included, what activities/other treatments patients might be getting when not in the clinic was not monitored and finally there was the lack of standardisation of treatment protocols for Cyriax physiotherapy and the supervised exercise programme. The shortcomings of the present trial will be discussed and answered in chapter 7 and will be compared with the shortcomings of the two preliminary clinical studies of chapter 4.

6.6 Conclusion

Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) reduced pain and improved function at the end of the treatment and at any of the follow-up time points. It is possible that these improvements were due to natural fluctuations in the symptoms and/or a placebo response. However, the supervised exercise programme produced the largest effect in the short, intermediate

and long term. This means that, choosing among these treatments, the supervised exercise programme should be the first treatment option for therapists when they manage LE patients. If it is not possible to administer the supervised exercise programme, Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) may be suitable to reduce symptoms but further well designed RCTs are needed to confirm the effectiveness of the treatments in patients with LE.

Figure 6.1

Jamar hand dynamometer

Figure 6.2

Position of pain free grip strength measure

Figure 6.3

Flow chart of the controlled clinical trial

All LE patients presenting the clinic (n=121)

Unwillingness (n=25)

Potential participants (n=96)

Inclusion criteria

Not meeting inclusion criteria (n=21)

Eligible patients (n= 75)

Sequential allocation (n=75)

Cyriax physiotherapy (n=25)   Supervised exercise programme (n=25)   Bioptron light (n=25)

Completed trial (n=25)   Completed trial (n=25)   Completed trial (n=25)
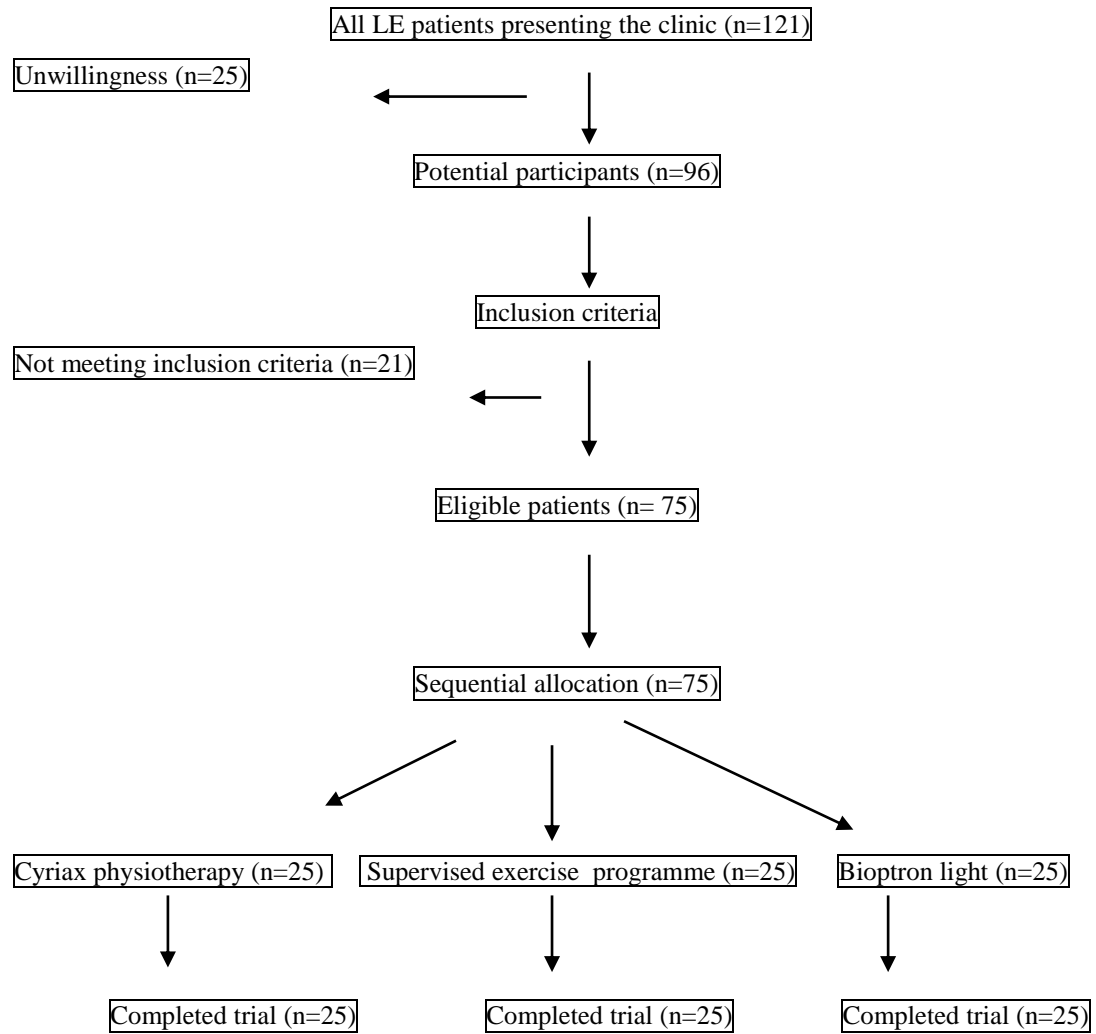
Figure 6.4

Pain over the previous 24 hours prior to each evaluation (Mean (95%CI) VAS
where 0= least pain imaginable and 10 = worst pain imaginable**)**
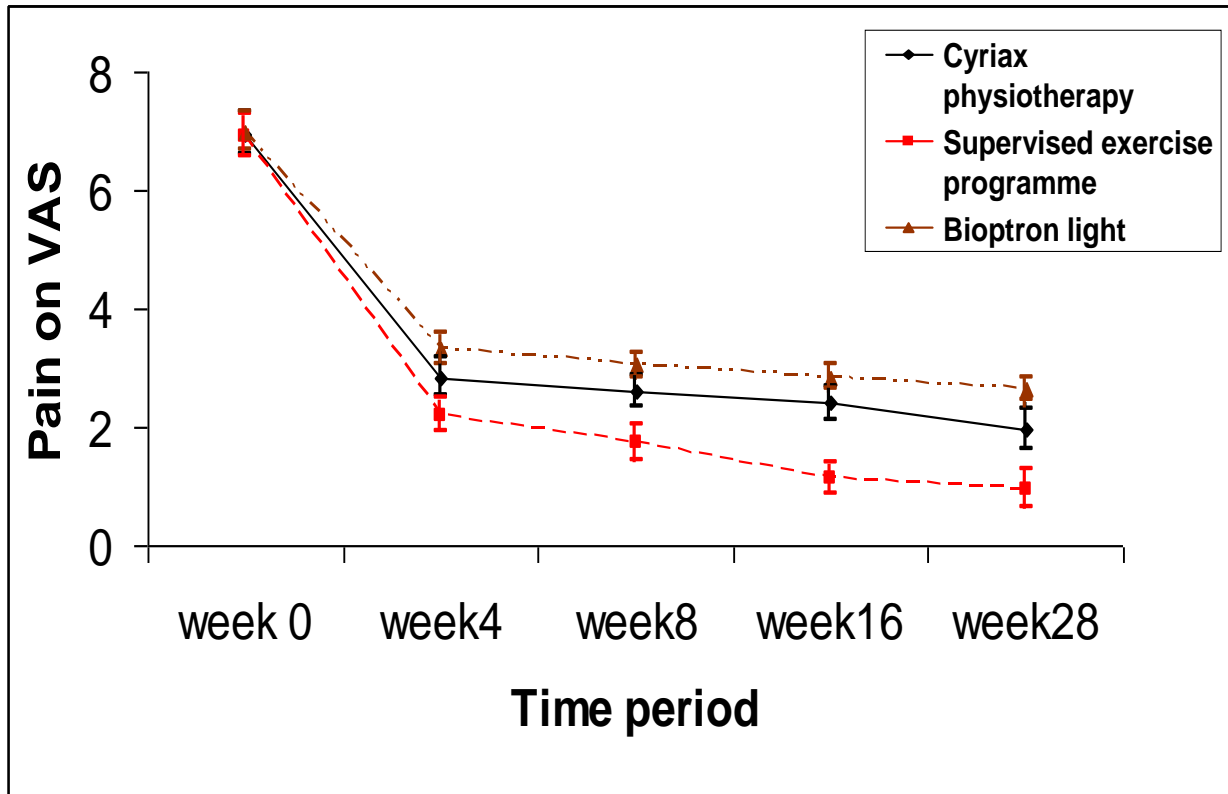
Figure 6.5

**Elbow function over the previous 24 hours prior to each evaluation (Mean
(95%)** VAS where 0= no function and 10 = full function)
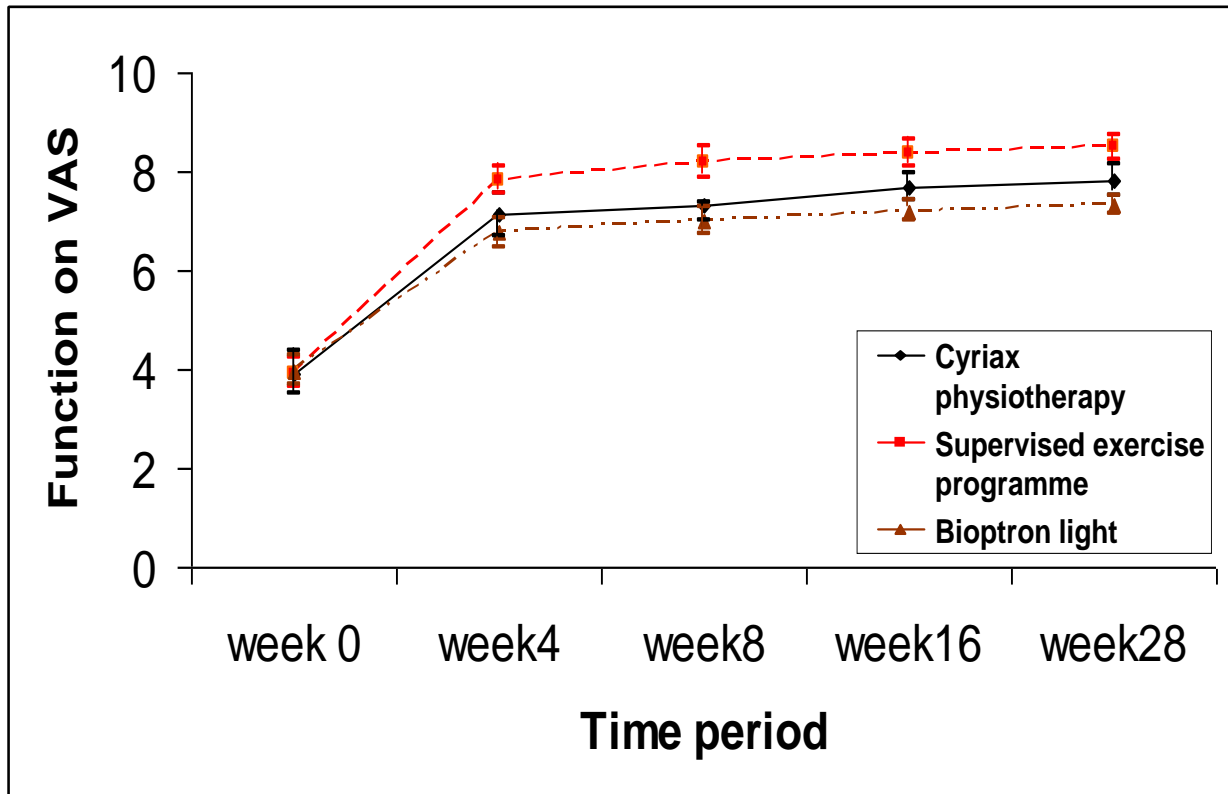
Figure 6.6

PFGS (Mean (95%CI) pounds)
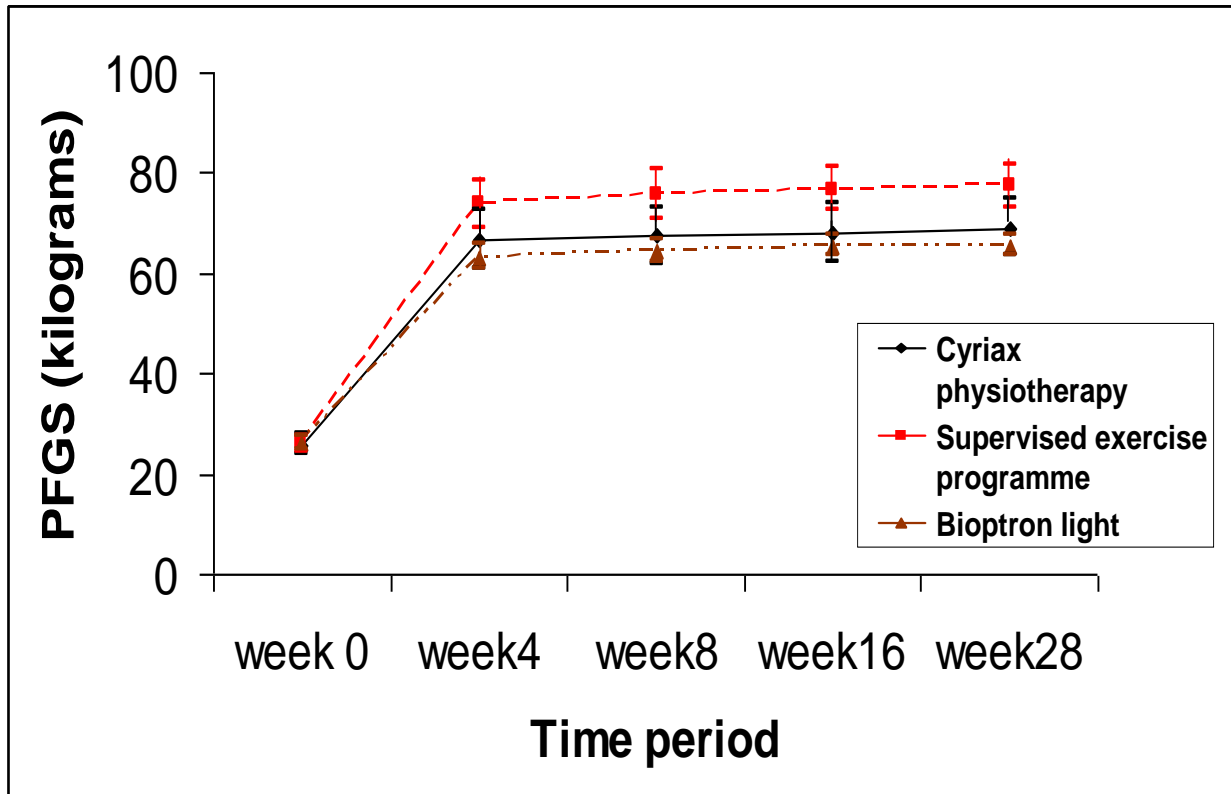
Figure 6.7

Eight-item pain free function questionnaire (Median "no" responses where 0=no
pain free function items and 8=only pain free function items**)**
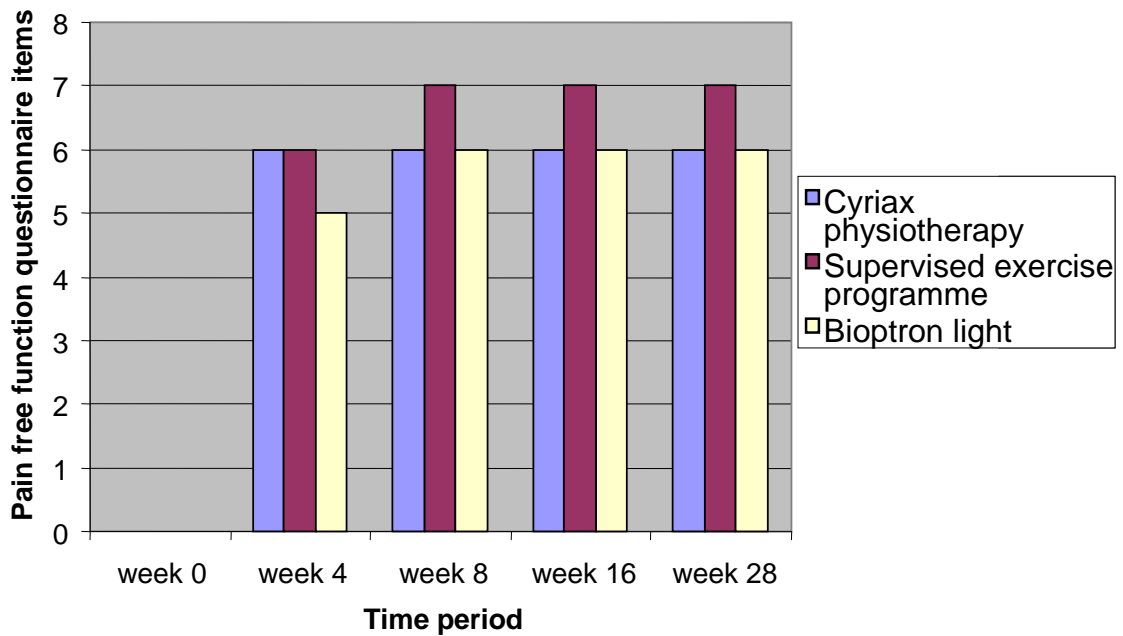
Table 6.1

Eight item pain free function questionnaire

Activity	YES	NO
Dressing yourself or pulling up your slacks		
Opening a jar or feeding yourself		
Washing yourself or wringing out a face cloth		
Household tasks (cleaning, lifting a chair, gardening)		
Opening doors		
Carrying objects with your involved hand		
Everyday activities		
Recreation or sporting activities		

Table 6.2

Previous treatments of participants (n (%))

	Cyriax physiotherapy	Supervised exercise programme	Bioptron light
LPLL	4 (16%)	4 (16%)	4 (16%)
Drugs	10 (40%)	11 (44%)	9 (36%)
Ultrasound	5 (20%)	3 (12%)	5 (20%)
Iontophoresis	3 (12%)	2 (8%)	2 (8%)
Heat	0 (0%)	2 (8%)	2 (8%)
Injection	3 (12%)	3 (12%)	3 (12%)

Table 6.3

Occupations of participants (n (%))

	Cyriax physiotherapy	**Supervised exercise programme**	**Bioptron light**
Housework	9 (36%)	7 (28%)	7 (28%)
Manual work	7 (28%)	7 (28%)	8 (32%)
Secreterial	8 (32%)	9 (36%)	8 (32%)
Sport	1 (4%)	2 (8%)	2 (8%)

Table 6.4

Pain over the previous 24 hours prior to each evaluation (Mean (95%CI) VAS
where 0= least pain imaginable and 10 = worst pain imaginable)

	week 0	week 4	week 8	week 16	week 28
Cyriax physiotherapy	6.96(6.61-7.31)	2.84(2.51-3.17)	2.60(2.33-2.87)	2.40(2.11-2.69)	1.96(1.61-2.31)
Supervised exercise programme	6.92(6.56-7.28)	2.20(1.91-2.49)	1.72(1.42-2.02)	1.12(0.85-1.39)	0.96(0.63-1.29)
Bioptron light	7(6.68-7.32)	3.32(3.04-3.60)	3.04(2.82-3.26)	2.84(2.64-3.04)	2.64(2.44-2.84)

Table 6.5

Change in pain over the previous 24 hours prior to each evaluation from baseline
(**Mean** VAS where 0= least pain imaginable and 10 = worst pain imaginable)

	Cyriax physiotherapy	Supervised exercise programme	Bioptron light	1-way ANOVA on change in VAS from baseline	Cyriax physiotherapy Vs Supervised exercise programme	Cyriax physiotherapy Vs Bioptron light	Supervised exercise programme Vs Bioptron light
Week 4	-4.12	-4.72	-3.68	p<0.0005	+0.60 (*)	-0.44	-1.04 (*)
Week 8	-4.36	-5.20	-3.96	p<0.0005	+0.84 (*)	-0.40	-1.24 (*)
Week 16	-4.56	-5.80	-4.16	p<0.0005	+1.24 (*)	-0.40	-1.64 (*)
Week 28	-5.00	-5.96	-4.36	p<0.0005	+0.96 (*)	-0.64 (*)	-1.60 (*)

* The mean difference is significant at the .05 level

Table 6.6

Elbow function over the previous 24 hours prior to each evaluation (Mean (95%CI) VAS where 0= no function and 10 = full function**)**

	week 0	week 4	week 8	week 16	week 28
Cyriax physiotherapy	3.92(3.48-4.36)	7.12(6.69-7.55)	7.32(6.99-7.35)	7.68(7.40-7.96)	7.8(7.48-8.12)
Supervised exercise programme	3.92(3.63-4.21)	7.80(7.53-8.07)	8.20(7.88-8.52)	8.36(8.10-8.62)	8.48(8.24-8.72)
Bioptron light	3.96(3.66-4.26)	6.76(6.46-7.06)	7(6.73-7.27)	7.20(6.99-7.41)	7.32(7.12-7.52)

Table 6.7

Change in elbow function over the previous 24 hours prior to each evaluation from baseline (Mean VAS where 0= no function and 10 = full function**)**

	Cyriax physiotherapy	Supervised exercise programme	Bioptron light	1-way ANOVA on change in VAS from baseline	Cyriax physiotherapy Vs Supervised exercise programme	Cyriax physiotherapy Vs Bioptron light	Supervised exercise programme Vs Bioptron light
Week 4	+3.20	+3.88	+2.80	p<0.0005	-0.68 (*)	+0.40	+1.08 (*)
Week 8	+3.40	+4.28	+3.04	p<0.0005	-0.88 (*)	+0.36	+1.24 (*)
Week 16	+3.76	+4.44	+3.24	p<0.0005	-0.68 (*)	+0.52	+1.20 (*)
Week 28	+3.88	+4.56	+3.36	p<0.0005	-0.68 (*)	+0.52	+1.20 (*)

* The mean difference is significant at the .05 level

Table 6.8

	week 0	week 4	week 8	week 16	week 28
	PFGS (Mean (95%CI) pounds)				
Cyriax physiotherapy	25.8(23.77-27.83)	66.52(60.67-72.37)	67.48(61.93-73.03)	68.04(62.28-73.80)	69.04(63.32-74.76)
Supervised exercise programme	25.92(24.14-27.7)	73.76(68.93-78.59)	75.6(70.77-80.43	76.68(72.36-81)	77.44(73.19-81.69)
Bioptron light	26.08(24.88-27.28)	63.16(60.69-65.63)	64.36(61.99-66.73)	65.46(63.4-67.56)	65.4(63.44-67.36)

Table 6.9

Change in PFGS from baseline (Mean pounds)

	Cyriax physiotherapy	Supervised exercise programme	Bioptron light	1-way ANOVA on change in kilograms from baseline	Cyriax physiotherapy Vs Supervised exercise programme	Cyriax physiotherapy Vs Bioptron light	Supervised exercise programme Vs Bioptron light
Week 4	+40.72	+47.84	+37.08	p<0.0005	-7.12 (*)	+3.64	+10.76 (*)
Week 8	+41.68	+49.68	+38.28	p<0.0005	-8.00 (*)	+3.40	+11.40 (*)
Week 16	+42.24	+50.76	+39.38	p<0.0005	-8.52 (*)	+2.84	+11.36 (*)
Week 28	+43.24	+51.52	+39.32	p<0.0005	-8.28 (*)	+3.92	+12.20 (*)

* The mean difference is significant at the .05 level

Table 6.10

Eight-item pain free function questionnaire (Median "no" responses where 0=no
pain free function items and 8=only pain free function items**)**

	week 0	week 4	week 8	week 16	week 28
Cyriax physiotherapy	0	6	6	6	6
Supervised exercise programme	0	6	7	7	7
Bioptron light	0	5	6	6	6

Table 6.11

Change in eight-item pain free function questionnaire from baseline (Median
"no" responses where 0=no pain free function items and 8=only pain free function
items**)**

	Cyriax physiotherapy	Supervised exercise programme	Bioptron light	Kruskal-Walis test rank on change in "no" responses from baseline	Cyriax physiotherapy Vs Supervised exercise programme	Cyriax physiotherapy Vs Bioptron light	Supervised exercise programme Vs Bioptron light
Week 4	+6	+6	+5	p<0.0005	0 (*)	+1(*)	+1 (*)
Week 8	+6	+7	+6	p<0.0005	-1 (*)	0	+1 (*)
Week 16	+6	+7	+6	p<0.0005	-1 (*)	0	+1 (*)
Week 28	+6	+7	+6	p<0.0005	-1 (*)	0	+1 (*)

* The mean difference is significant at the .05 level

Chapter 7: Discussion

7.1 Findings of the project

LE is one of the most common lesions of the arm. LE is usually defined as a syndrome of pain in the area of the lateral epicondyle, the main complaints being pain and decreased function, both of which may affect activities of daily living and result in considerable morbidity and financial cost (Chapter 1). Many clinicians advocate a conservative approach as the treatment of choice for LE (Chapter 1). Physiotherapy is a conservative treatment that is usually recommended for LE patients (Chapter 1). A wide array of physiotherapy treatments have been recommended for the management of LE (Chapter 1). These treatments have different theoretical mechanisms of action, but all have the same aim, to reduce pain and improve function. Such a variety of treatment options suggests that the optimal treatment strategy is not known, and more research is needed to discover the most effective treatment in patients with LE. This lack of evidence may be related to the difficulty of establishing nomenclature, pathophysiology, etiology, epidemiology, diagnosis and conservative treatment of LE. Reviewing the literature, answers tried to present in the previously reported issues (Chapter 1).

The term LE was used in the present thesis because this is the most common used term to describe this condition in medicinal literature. LE is a degenerative or failed healing tendon response characterised by the increased presence of fibroblasts, by increased amounts of proteoglycans and glycosaminoglycans, by vascular hyperplasia, and by disorganised collagen in the origin of ECRB, the most commonly affected structure. LE is generally a work related or sport related mechanical pain disorder usually caused by excessive quick, monotonous, repetitive activities, including eccentric contractions and gripping, of the wrist. Therefore, LE characterized as an overuse syndrome. The dominant arm is commonly affected, with a prevalence of 1–3% in the general population. Although LE occurs at all ages, the peak prevalence of LE is between 30 and 60 years of age. The proportion of those afflicted by LE is not influenced by the sex of the patient, but the disorder appears to be of longer duration and severity in females. Even though the diagnosis of LE is simple, many conditions mimic LE pain, can be easily misdiagnosed as LE, and complicate the prospect for optimal treatment for LE. The diagnosis of LE can be confirmed by a plethora of diagnostic tests that reproduce

the pain. However, such a plethora of diagnostic tests suggests that the most variable and valid test for LE is not known and the most commonly diagnostic tests were used in our controlled clinical trial to identify LE patients (Chapter 6). The history of patients and clinical examination are adequate in order to be diagnosed LE. Radiological investigation (MRI, ultrasound) can add information in diagnosis, but it is not routinely obtained probably due to high cost. Finally, conservative treatments including medicinal (injections and NSAIDs) and physiotherapy whose only role is to reduce inflammation may not prove helpful to treat patients with LE. Conservative physiotherapy treatments that reverse the pathophysiology of LE may be effective for the management of this condition.

Labelle et al (1992) was the only published systematic review that examined the clinical effectiveness of physiotherapy in the management of LE until 2002. Several new RCTs have been published since, however, and an updated systematic review is required to evaluate the clinical effectiveness of available physiotherapy treatments. A systematic review was conducted in chapter 2 to establish the clinical effectiveness of treatments available to physiotherapists to manage the pain and functional impairment associated with LE. This information will provide future treatment strategies for LE in the present project. RCTs identified by a search strategy in six databases (until October 2002) were used in combination with reference checking. RCTs that included physiotherapy as sole treatment, patients with LE, and at least one of the clinically relevant outcome measure (pain and/or function) were selected. A qualitative analysis of the selected studies was conducted using the Chalmers' scale. Chalmers' scale was validated and tested for reliability by Berard et al (2000). A vote count trial was used to present the results using a rating system for level of evidence developed by Linton and Tulder (2001). This rating system consisted of four levels of scientific evidence: (i) Level A—Strong evidence (consistent findings from multiple RCTs); (ii) Level B--Moderate evidence (one RCT or consistent findings from multiple NRCTs); (iii) Level C—Limited evidence (only one NRCT); (iv) Level D—No evidence (no RCTs or NRCTs). As NRCTs were not included in this review, level C became irrelevant and therefore only three levels remained: strong, moderate and no evidence. Twenty-seven RCTs fulfilled the criteria and were included in the review. This review showed that there was strong evidence for the short-term effectiveness of acupuncture for LE. It also found that there was strong evidence that four physiotherapy modalities, LPLL, ultrasound, ESWT and

pulsed electromagnetic field therapy were not effective treatments on LE. Other treatments used for LE such as iontophoresis and home exercise programmes had insufficient evidence available to judge the results of their effectiveness. However, all the previously reported physiotherapy treatments for LE cannot be refuted or recommended as ideal treatment for LE, because the optimal treatment protocols are unknown. Additional well-designed RCTs are needed to provide definite conclusions for the effectiveness of these LE-treatment modalities. Finally, this review found no evidence for the effectiveness of Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) for LE. Therefore, it was concluded to investigate the clinical use and effectiveness of Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) as treatments for LE in the present project. It was the first time that such an effort was conducted in research.

However, it was necessary to establish optimal protocols for Cyriax physiotherapy, supervised exercise programmes, and polarised polychromatic non-coherent light (Bioptron light) for the management of LE before a suitable clinical trial could be designed. Conducting a critical review of literature in chapter 3 the recommended treatment protocols for Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) were derived from the views of advocates of these treatments, based on their personal experience with the treatment and on the putative physiological mechanisms that the treatment addresses. Cyriax physiotherapy consists of 10 minutes of DTF and one instance of Mill's manipulation, which is performed immediately after the DTF. The supervised exercise programme consists of slow progressive eccentric exercises of wrist extensors (3 sets of ten repetitions with 1-minute rest interval between each set) and of static stretching exercises of the ECRB tendon (3 repetitions before and 3 repetitions after the eccentric training for 30-45 each repetition with a 30-second rest interval between each procedure). The probe emitting polarised polychromatic non-coherent light (Bioptron light) should be held at a 90^0 angle (perpendicular) 5-10cm above the bare skin of the lateral condyle (anterior and lateral surface) and the bellies of extensors muscles of the wrist, for six minutes each position, 18 minutes totally. All treatments are administered in a clinical setting. The treatment regimen of Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) is three times per week for four

weeks. The treatment regimen of supervised exercise programmes will be defined in chapter 5 by conducting a survey of existing practitioners' reports of their use of a supervised exercise programme for the treatment of LE. Cyriax physiotherapy and supervised exercise programmes are individualised on the basis of the patient's report of pain experienced during the procedure. A physiotherapist with certificate or diploma in Orthopaedic medicine based on Cyriax principles should be applied Cyriax physiotherapy. It has been postulated that Cyriax physiotherapy can be used for both symptomatic relief of pain and promotion of tissue healing. In clinical practice, exercise programmes are predominately used for the promotion of tissue healing. It has been reported that polarised polychromatic non-coherent light (Bioptron light) has biostimulative effects assisting tissue healing at the cellular level (Chapter 3).

Two preliminary clinical trials to pilot the use of these treatment protocols on overuse injuries similar to LE that are regularly presenting to the clinic were performed in chapter 4. The first study was a controlled clinical trial that evaluated the effectiveness of Cyriax physiotherapy and a supervised exercise programme in patellar tendinopathy, commonly referred to as "jumper's knee". The second study was a prospective open, uncontrolled clinical trial that assessed the effectiveness of the polarised polychromatic non-coherent light (Bioptron light) treatment protocol in idiopathic CTS. The findings of these two preliminary clinical studies indicate that the supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) may reduce the symptoms in patellar tendinopathy and idiopathic CTS, respectively. Cyriax physiotherapy did not reduce the pain in patients with patellar tendinopathy. However, data of the previously reported trials should be interpreted cautiously, because the number of patients included in the patellar tendinopathy study was small and CTS trial lacked of a control group. Therefore, future well-designed studies are required to confirm and further explore these findings.

As a preliminary to investigating the effectiveness of Cyriax physiotherapy, supervised exercise programmes, and polarised polychromatic non-coherent light (Bioptron light) in treating LE, a questionnaire survey was conducted to establish the current clinical practice of these protocols for the management of LE in chapter 5. This questionnaire was designed by the investigator of the present project to record the self-reports of chartered physiotherapists in Athens who were using these treatments in their clinical

practices, because there is lack of a validated existed questionnaire to fulfill the aim of the present survey. Of the 220 questionnaires, 150 were received. Results of the analysis of 68 completed questionnaires are presented. Of those 68 responses, the most common was the supervised exercise programme (43, or 63.2%) and the least common was the polarized polychromatic non-coherent light (Bioptron light) (7, or 10.3%). Clinicians reported that they believed that Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) had the same aim (reduction of pain and improvement of function) and the same treatment regimen (three times per week for 4 weeks). It was also reported that these treatments are characterized as not time-consuming, short-term (1 month after the end of treatment) and long-term (6 months after the end of treatment) effective treatments that do not cause side-effects or increase of pain in patients during their application. Moreover, clinicians reported that (i) the supervised exercise programme could be performed at home; (ii) Cyriax physiotherapy had some contraindications; and (iii) polarised polychromatic non-coherent light (Bioptron light) was expensive for both physical therapists and patients. It may be confidently assumed that the above results present a representative view of current clinical practice of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on LE at least as these treatments are applied in Athens. How much this reflects usage in the rest of the Greece, Europe, or even the world, is yet to be seen by extending the research.

In order to assess the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for LE a clinical trial was necessary. Such a controlled clinical trial was conducted in chapter 6. Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) reduced pain and improved function at the end of the treatment and at any of the follow-up time points. Whether this is due to placebo effects is not known. The supervised exercise programme produced the largest effect in the short, intermediate and long term. This means that, choosing among these treatments, the supervised exercise programme should be the first treatment option for therapists when they manage LE patients. If it is not possible to administer the supervised exercise programme, Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) may be suitable. Further well designed RCTs are needed to confirm the effectiveness of these treatments in patients with LE.

7.2 Differences in the application of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) between the two preliminary clinical studies on overuse injuries similar to LE (Chapter 4) and the main clinical trial on LE (Chapter 6)

LE (Chapter 6) and patellar tendinopathy (Chapter 4) are similar conditions in the clinical behaviour and in histopathology (Khan et al., 2000a; Cook et al., 2000; Cook et al., 2001). However, Cyriax physiotherapy for these two conditions is applied in a different way. As already mentioned, Cyriax physiotherapy for LE consists of DTF and Mill's manipulation, which is conducted immediately after the DTF (Chapter 3, section 3.4.3). Cyriax physiotherapy in patellar tendinopathy and for other conditions similar to LE consists of DTF only. DTF in all previously reported conditions is applied with the same way, already described in chapter 3 (section 3.4.1). Mill's manipulation is not conducted in patellar tendinopathy and for other conditions similar to LE.

Someone might question why, for other conditions similar to LE, Cyriax physiotherapy should consist of DTF only and not of DTF plus Mill's manipulation. The most likely explanation is that Mill's manipulation is a technique that can be applied only for LE; it cannot be applied to other conditions that are similar to LE. Again, someone might question why a similar manipulative manoeuvre is not recommended for the management of these other overuse injuries similar to LE when trials showed poor outcomes for the effectiveness of Cyriax physiotherapy consisting of ten minutes of DTF only in patellar tendinopathy (Pallechia et al. 1994; Chapter 4, section 4.3) and in iliotibial band friction syndrome (Schwellnus et al. 1992).

DTF and Mill's manipulation showed positive effects on LE in the controlled clinical trial of present project (Chapter 6) and it is concluded that the effectiveness of Cyriax physiotherapy is based mostly on Mill's manipulation. Therefore, the presence of Mill's manipulation alone or in combination with DTF is important for the effectiveness of Cyriax physiotherapy. If a manipulation technique similar to Mill's manipulation could be developed for other overuse injuries, the ineffective Cyriax physiotherapy treatment may become effective. Therefore, research is needed to find the optimal protocol of Cyriax physiotherapy in overuse injuries which is based on Cyriax's views to date,

since no literature exists to contradict these views (Chapter 3) and future well designed RCTs may provide strong evidence for the effectiveness (absolute and relative) of this treatment. However, for the time being the treatment protocol of Cyriax physiotherapy for the management of LE consists of DTF and Mill's manipulation and the treatment protocol of Cyriax physiotherapy for the management of patellar tendinopathy and rest overuse injuries consists of DTF only.

The supervised exercise programme employed in the patellar tendinopathy study (Chapter 4) consisted of static stretching and eccentric exercises. The static-stretching exercises in the patellar tendinopathy study were administered as recommended for LE in chapter 3 (section 3.5.2.1) and followed in the controlled clinical trial (Chapter 6). The major difference in the application of static-stretching exercises between the two conditions was that, for LE, it was recommended stretching only the injured tendon (ECRB), whereas in patellar tendinopathy not only the injured tendon (quadriceps muscle is inserted into patellar tendon, which is the "injured" tendon in patellar tendinopathy) but also the tendons of the hamstrings were stretched. This occurred because, as already mentioned in the introduction section to the patellar-tendinopathy study (4.3.1), hamstrings and quadriceps are tight in patellar tendinopathy and this is one of the causes for the development of the condition. Therefore, by stretching the above two tendons, one of the causes of patellar tendinopathy was addressed, while helping in the management of patellar tendinopathy, reducing pain and improving function. However, future clinical studies could evaluate the effectiveness of exercise programmes consisting only of static stretching exercises of the quadriceps and by inference the patellar tendon in patients with patellar tendinopathy.

The eccentric exercises in the patellar tendinopathy study (Chapter 4) were performed as recommended for LE in chapter 3 (section 3.5.1.1) and followed in chapter 6. However, there were two main differences between the administration of eccentric exercises administered for patellar tendinopathy and those eccentric exercises recommended for application in LE. Patients in the patellar-tendinopathy study performed three sets of 15 repetitions of eccentric exercises with two-minute rest between each set, whereas in our application to LE, three sets of 10 repetitions of eccentric exercises were recommended, with a one-minute rest between each set.

In the patellar-tendinopathy study, patients performed 15 repetitions of eccentric exercises in each set, because this value was the mean value of clinicians' practices (10 repetitions in each set) and conducted clinical trials (Cannell et al., 2001) (20 repetitions in each set). In two recently published clinical trials on patellar tendinopathy, patients performed 15 repetitions in each set (Purdam et al., 2004; Young et al., 2005), the number of repetitions employed in the preliminary clinical study of chapter 4 (section 4.3). However, due to a lack of clinical trials of supervised exercise programmes for LE (Chapter 2), it was recommended (Chapter 3) and followed in the controlled clinical trial (Chapter 6) 10 repetitions of eccentric exercises in each set for LE. 15 repetitions were chosen in patellar tendinopathy study because the patellar tendon is different from ECRB in anatomic morphology (length and width) and in function (tolerate greater forces).

It was not considered a 1-minute rest between each set enough time for patients when they had performed 15 repetitions per set. Therefore it was recommended 2-minute rest between sets for the reasons, which were mentioned in chapter 3. However, there is lack of evidence to support the 2-minute rest between each set and we are relying on the investigator's experience. The experience of therapists is an unreliable tool to determine either the effectiveness or the safety of a treatment (Ernst, 1995). Thus, well-designed future RCTs in patellar tendinopathy will be needed to support the 2-minute rest between each set.

A Bioptron 2 device was used to deliver the polarised polychromatic non-coherent light (Bioptron light) in the idiopathic CTS clinical trial, as recommended in chapter 3 (section 3.6) and followed in the controlled clinical trial (Chapter 6). Idiopathic CTS was chosen because this is the type of CTS that responds better in the treatment since it is not the cause of metabolic and endocrinal abnormalities. Although the CTS gives symptoms in the distribution of the median nerve, the median nerve becomes compressed when pathophysiological changes in the tendons of carpal tunnel occurred reducing the space within carpal tunnel. However, for LE, Bioptron 2 delivers polarised polychromatic non-coherent light (Bioptron light) in three positions and not in one, over the affected (injured) site, as for the other musculoskeletal conditions such as CTS (Chapter 3, section 3.6.1; Chapter 6). Although there is no evidence to explain why this should be, the most likely explanation relates to LPLL.

Polarised polychromatic non-coherent light (Bioptron light) is a form of light therapy and the other form of light therapy is the LPLL. The LPLL has been used in a total of nine trials on LE (Chapter 2). In some of these trials, the probe of LPLL was applied not only to the affected site, but also to acupuncture points around the lateral epicondylitis. The manufacturers may, based on these studies, claim that, for LE, Bioptron 2 will deliver polarised polychromatic non-coherent light (Bioptron light) in three positions, thus radiating the acupuncture points. However, further research is needed to discover if the recommended protocols, based on the manufacturers' claims for the management of LE and CTS with Bioptron 2, are effective.

7.3 Strengths and weaknesses of the clinical trials of the present project

Methodological shortcomings such as lack of (i) adequate allocation concealment; (ii) blinding of participants and therapists increasing the possibility that expectations of patients and therapists might influence the outcome of the trials; (iii) standardised outcome measures; (iv) power analysis; (v) recruitment strategies; (vi) long term follow-up; (vii) reasons for drop-outs; and (viii) clear descriptions of interventions, were present in the studies covered in the systematic review of the present project (Chapter 2). In the above methodological shortcomings the absence of placebo (sham)/no treatment group can be added, as well as other activities/ treatments patients might be getting when not in the clinic and also ethical issues such as payment Vs non-payment. It is presented below, how all these methodological shortcomings were addressed on the present project.

As the conducted trials of the present project (Chapter 4; Chapter 6) were not RCTs, it is possible that some changes during the allocation procedure (such as some patients holding back and waiting until they were allocated to the supervised exercise programme) biased it towards the supervised exercise programme treatment, the most effective treatment in the present project. However, although no genuine randomisation procedure was followed in the trials, the use of sequential allocation to allocate patients to treatment groups allowed for a true cause-and-effect relationship to be demonstrated. During the use of sequential allocation the therapist who performed the treatments did not participate in the diagnosis of the condition and the patients did not have the right to

choose the treatment. Patients who wanted to follow a particular treatment approach did not participate in the studies. The randomisation would have done our studies more reliable, however the way that the sequential allocation was performed in our studies contributes to the reliability of our studies.

No placebo (sham)/no treatment group was included in the trials of the present project (Chapter 4; Chapter 6). Without a placebo group it would be difficult to know what effect was attributed to the treatment and what amount the placebo was responsible for. Actually, there may be a placebo effect for any type of research treatment. Adding a placebo (sham)/no treatment group may have increased the quality of the trials of the present project. However, the reasons why a placebo (sham)/no treatment group was not used in this project are mentioned below. As these trials were conducted in an environment of private medicine where the patients might justifiably expect some therapeutic action, the withholding of treatment was considered unethical (Burton, 1988). The placebo (sham)/no treatment group is important when the absolute effectiveness of a treatment is to be determined. Absolute effectiveness determines whether the clinical effectiveness of a treatment takes account of normal fluctuations in the patients' symptoms. However, absolute effectiveness of such a technique based-interventions is difficult to investigate, because a good and trustworthy placebo (sham)/no treatment control for Cyriax physiotherapy and exercise programmes appears to be difficult or impossible to develop due in part to difficulties in defining the active element of these treatments. In addition, there is strong evidence that LE and overuse injuries similar to LE are not self-limiting conditions and patients' symptoms cannot be reduced without appropriate "active" treatment if these are persistent for more than two-three weeks (Binder and Hazleman, 1983; Vasseljen, 1992; Haker et al, 1993; Verhaar et al., 1996; Solveborn, 1997; Sverlnov and Adolfsson, 2001). Finally, absolute effectiveness does not provide the therapists with information as to which is the most appropriate treatment for the management of a condition, in this case LE and similar conditions to LE.

What activities/other treatments patients might be getting when not in the clinic was not monitored in the trials of the present project (Chapter 4; Chapter 6). Patients' diaries suggested that patients were compliant to studies instructions' although patients may have given incorrect details to please the investigators. For example, it was possible that

patients followed the treatment, but they took NSAIDs at the same time because physicians usually recommend this kind of common used treatment as the normal treatment for the management of musculoskeletal conditions, and the improvement of symptoms may be due to those medications. Therefore, ways should be found to measure how other treatments such as NSAIDs contribute to the improvement of symptoms. A possible solution for the previously reported issue is to include a control group of patients in a future trial that they will receive NSAIDs as the only treatment, even though the effectiveness of NSAIDs for the management of LE is controversial (Chapter 1). NSAIDs had been used as treatment by many patients before participating in the trials without positive results.

It is generally accepted that blinding in studies of technique-based interventions is problematic (Thorsteinsson et al., 1990; Deyo et al., 1990). Double blinding is considered the "gold standard" in clinical trials for isolating this effect. Reports on physical therapy interventions that claim to have achieved double blinding rarely do provide details on how blinding was maintained or monitored throughout the trial (Chapter 2). In drug trials, the investigator can administer the treatment and record outcome measurements while remaining blinded. It is believed that a triple-blind method should be considered the "gold-standard" in physiotherapy trials (Johnson and Tabasam, 2003). Subject membership in a treatment group is concealed from the subject, the investigator recording outcomes, and the investigator administering the treatment. However, many of the interventions used in physical therapy including Cyriax physiotherapy and exercises programmes are technique-based interventions but the criteria for the gold standard cannot be achieved. If the criteria for the gold standard cannot be achieved then a gold standard perhaps does not exist at all. In the trials of the present project (Chapter 4; Chapter 6) blinding the investigator who was administering the treatment was problematic, if not impossible, because the investigator needed to be aware of the treatments in order to administer treatments appropriately. In a future trial the treatment approaches can be applied by therapists who will be irrelevant to the conducted study, because the presence of the main investigator of the present project (DS) in the treatments could influence the patients' outcomes. The investigator who administered treatments was likely to have prior knowledge and expectations about treatment outcome, and this might influence the way in which treatment was given and thus biased the outcome. One approach could be to train an investigator who was naive

to the therapeutic strategy and outcome to administer treatment (Johnson and Tabasam, 2003). However, due to the nature of Cyriax physiotherapy and supervised exercise programme this approach could not be achieved because the participating therapist needed to be familiar with the treatments being applied in order to maximize the treatment effectiveness. In studies on the effectiveness of massage therapy, for example, the researchers have attempted to use personnel with little or no training in massage therapy, but such studies have provided conflicting results (Menard, 2002). Blinding of patients was hampered in the trials of the present project (Chapter 4; Chapter 6) by the fact that, from the content of technique-based interventions included in the present project, the patients in most cases knew which treatment they received. Receiving such a treatment, patients might show an improvement in accordance with their expectations. Measures should have been taken in order to reduce the patients' expectations. An approach with a placebo (sham)/no treatment group should have been useful to the present project, in case the above negative factors could have been overcome. However, blinding of patients by including a placebo group was not possible because a good and trustworthy placebo (sham) may be impossible to design due in part to difficulties in defining the active element of Cyriax physiotherapy and supervised exercise programmes. Therefore other measures might need to have been taken in order to reduce bias arising from the subject's expectations, since knowledge on the part of the patients might influence the outcome of the present trials. One measure that was used in the present project was that during the process of selecting patients, the specialised rheumatologist asked the potential participants about their treatment preferences, and it was decided only to include patients with no strong preferences for or against the treatments included in the studies of the present project (Koes, 2004). In the same way, patients with extensive previous experiences with one of the investigated treatments were also excluded of the trials of the present project (Vicenzino et al., 2001; Koes, 2004). In addition, communication and interaction (verbal and non-verbal) between the therapist and patient was kept to a minimum and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided in the trials of the present project (Vicenzino et al., 1996). For example, patients were given no indication of the potentially beneficial effects of the treatments or any feedback on their performance in the pre- and post-application measurements. The only available method to include blinded outcome measurement is to use a blinded independent observer. This observer should assess the patient without knowledge of the assigned

therapy. In randomized clinical trials published in the last few years, this method seems to have become more common, since evaluator-blinding is the only one of the triple-blind methods that is feasible. This approach was followed in the trials of the present project (Chapter 4; Chapter 6).

Few studies have explicitly defined the exact identity of the treatment and this lack of specificity in definition is troubling. Many studies do not define or describe the specific technique used in the treatment protocol in sufficient detail and as a result, it is difficult for the reader to determine exactly what was done. Descriptions of treatment interventions should be more explicit, including clear descriptions of the techniques, dosage and progression, as well as training and experience requirements. Good descriptions make it easy for therapists to replicate study interventions. Such good descriptions of treatment protocols were presented in the trials of the present project (Chapter 4; Chapter 6).

The question of standardisation is related to the issue of definitions. The lack of standardisation of treatment protocols for Cyriax physiotherapy and supervised exercise programmes might be a possible shortcoming of the clinical trials of the present project (Chapter 4; Chapter 6). However, in order that study findings could be generalized, it is essential that the type, intensity, frequency and duration of the treatment be sufficiently described in order to make it possible to replicate the therapy elsewhere (Koes, 2004; Trudel et al., 2004). It is not always necessary and/or feasible to develop a strict treatment protocol. In such cases, it is certainly permissable to work with some kind of treatment algorithm in which the steps in the treatment path depend on the outcome of a previous step (Koes, 2004). In any case, in the absence of a clear treatment protocol or algorithm, a clear description of the actual treatment applied in the study should be recorded and presented. Moreover, there may be ethical reasons for the lack of standardised protocols for Cyriax physiotherapy and supervised exercise programmes. Individualised Cyriax physiotherapy treatment protocol respect the patient's physical and emotional boundaries, which may encourage higher rates of participation and greater adherence to compliance with the study protocol (Menard, 2002). An essential feature of the exercise programme is that the progression of static stretching and eccentric exercises should be based on the patients' symptoms and not the time elapsed since the treatment started (Jensen and Di Fabio, 1989).

All previously published trials in Achilles and patellar tendinopathy (Niesen-Vertommen et al., 1992; Alfredson et al., 1998; Mafi et al., 2001; Silbernagel et al., 2001; Ohberg et al., 2004; Purdam et al., 2004; Roos et al., 2004), including the preliminary clinical trial in Chapter 4 (section 4.3), failed to define the "slowness" of eccentric exercises of the "injured" tendon. This failure may be due to the therapists' belief that pain will not allow patients to perform the eccentric exercises quickly. In contrast, the "slowness" of eccentric exercises of wrist extensors tendons was defined in the clinical trial for the management of LE (Chapter 6). This definition helped the development of a successful treatment protocol for the supervised exercise programme, making it easy for therapists to replicate it and put it into practice.

How confident are therapists that the treatment protocol they administer is the optimal treatment protocol for the management of a condition? Constructing the optimal treatment approach based on current evidence is difficult. There is confusion regarding protocols of treatments in the physiotherapy literature. Selection of physiotherapy treatments protocols in clinical trials seems to be circumstantial, and is either made at random based on manufacturers' recommendations and the researchers' empirical observations as demonstrated in chapter 3. There is a missing link between the increasing number of successful results from physiotherapy treatments in the laboratory and the mediocre results of clinical trials. If this gap can be filled, an optimal treatment protocol for physiotherapy interventions will be able to be found. Following this procedure, Bjordal and his colleagues (2001) found a dose-response pattern broadly resembling that of the LPLL laboratory trials. Having established the optimal protocol for a treatment, the challenge is to draw definite conclusions about the effectiveness of the treatment by using adequate methodology in research, thus assisting therapists to use the most successful treatment in their practices.

An important issue in research design is determined by an adequate sample size. Although the sample size addresses more the precision of the estimation of effect rather than the validity of the study, it remains an important aspect of a trial (Koes, 2004). The patellar tendinopathy trial (Chapter 4; section, 4.3) was a preliminary pilot study with small sample size. The problem with small sample sizes is that the comparability of the study groups may be in danger. Only with increasing numbers of patients do we have some assurance that known, but also unknown, prognostic factors will be evenly

distributed over the study groups (Koes, 2004). However, in the main study of the present project on LE (Chapter 6) an adequate sample size was used (75 subjects totally, 25 per group). To do this, the investigator of the present project performed a power analysis, which requires an estimate of the magnitude of effect the proposed intervention may have on the measured dependent variable. The lack of power analysis as occurred in the preliminary studies in chapter 4 becomes an important issue that fail to report any difference between interventions because of the risk of type II error (Wright and Vicenzino, 1997), i.e. it becomes difficult to determine whether the results are due to the fact that no treatment effect exists or to the fact that the study lacked sufficient statistical power to detect any small but clinically important therapeutic effect (Stratford et al., 1993). Abbott et al (2001) suggest that a sample size of twenty-five subjects per group as used in the controlled clinical study of the present project on LE (Chapter 6) is sufficient to demonstrate statistical clinical significance for outcome measures on LE. Related to the issue of sample size it is the question of prognostic homogeneous study populations. Homogenous study populations were used in the trials of the present project (Chapter 4; Chapter 6) using the criteria (inclusion/exclusion) that have been reported in previously published trials because heterogeneous study groups may hamper finding a treatment effect if, for instance, an intervention is effective only for one subset of the population. In this case the positive effect in this subgroup will be diluted due to the absence of effect in the complementary subgroups.

The outcome assessment often includes a subjective rating of pain and functioning (Cook et al., 2001). The pain was only measured in the preliminary clinical studies (Chapter 4). Pain and function were measured in the main clinical study of this project on LE (Chapter 6), avoiding the previously reported shortcoming of the preliminary clinical studies (Chapter 4). Outcome measures of unknown validity were used in the preliminary clinical studies, since there are no studies to demonstrate which measures are variable and valid in patients with patellar tendinopathy (Chapter 4; section 4.3) and idiopathic CTS (Chapter 4, section 4.4), respectively. No electrophysiological examination was conducted in the long-term follow-up of the idiopathic CTS study (Chapter 4; section 4.4) due to high cost and the avoidance of patients to pass this painful lab examination for a second time. The outcome measures that were used in the main clinical trial on LE (Chapter 6) are valid and reliable. If more objective outcome measures such as MRI and/or ultrasound examinations had been used, the results of the

main trial of the present project (Chapter 6) would have been more valid and reliable. However, the lack of use of standardised outcome measurement has been an area of particular deficiency on LE as revealed in chapter 2. Self-report scales designed specifically for patients with LE are available and are likely to be most responsive to changes in LE symptoms (Stratford et al., 1987; Stratford et al., 1993; Overend et al., 1999). The Patient-Rated Forearm Scale has pain and function (specific and usual activity) subscales, which are weighted equal to provide a global score. The eight-item Pain-free Function Questionnaire is a pain scale that focuses on pain with activity (Stratford et al., 1987). Both were developed with items specific to LE. Other self-report measures with sound psychometric properties such as the Disability of the Arm, Shoulder, and Hand Measure (DASH), VAS, and the McGill Pain Questionnaire might also contribute to a more comprehensive comparison of treatment interventions but are less specific to the present condition. In terms of measuring physical impairments, strength measures have been studied. PFGS has been shown to be reliable, valid, and responsive in this LE population (Stratford et al., 1987; Abbott et al., 2001). Pain threshold can be measured by algometry (Klaiman et al., 1998; Vicenzino et al., 2001; Vicenzino et al., 2003) although there is lack of validity and sensitivity of this outcome measure in LE patients. Structural changes in the tendon related to treatment intervention(s) can be shown by ultrasound examinations (Alfredson *et al*., 1998; Ohberg et al., 2004; Shalabi et al., 2004), but a specialist in ultrasound examinations is needed to help the investigator(s) identify structural changes. MRI of elbow joint confirms the effectiveness of physiotherapy treatments showing the structural changes in the tendon, but it is difficult to be performed because the cost is high and the help of a specialist in MRI examinations is also needed. Adoption of a core set of outcome measures would facilitate future trials and allow for meta-analyses of smaller studies. Although a consensus process is advisable for this, a reasonable strategy at this time is that all studies should include outcome measures that do not need self-report responses; examples are PFGS, the pressure algometer, ultrasound and MRI examinations. If it is not possible to use these outcome measures in trials due to lack of available devices to measure PFGS and algometer pressure or due to a lack of qualified personnel to help investigator(s) with ultrasound and MRI examinations, self-reported scales should be used. The disadvantage of these self-reported scales is that patients may remember how they had experienced the condition during a previous evaluation and regress to the mean with their answers.

Recruitment strategies often not described in studies, made the results difficult to generalise (White and Park, 1999). Recruitment strategies were well described in the trials of the present project. However, the results of the trials of the present project should be interpreted cautiously, because some changes in the patient recruitment may have had an impact on the outcome of the study. The results might have been different whether (i) the trials were conducted in a hospital instead of in a private clinic; (ii) different inclusion/exclusion criteria had been used; (iii) the patients had paid for the treatment approach increasing their expectation for the outcome and (iv) the patients with psychological problems such as depression had included in the trials.

Trials should always include long-term follow-ups at six months and over as followed in the main clinical study of this project on LE (Chapter 6) and in the preliminary clinical study in idiopathic CTS (Chapter 4; section 4.3), although patients are often interested in little more than a rapid recovery. If the initial advantage of a treatment maintains at long-term follow-up, definite conclusions for treatment effectiveness can be drawn. However, effects over the long term might be harder to detect due to, for example, recurrence of complaints. Loss to follow-up may also be substantial in trials of physiotherapy. Loss to follow-up relates to the number of patients participating in the outcome assessment (Koes, 2004). No loss of follow-up was reported in the main clinical study of the present project on LE (Chapter 6) and in the preliminary clinical studies on overuse injuries similar to LE (Chapter 4). It is obvious that, if there are large numbers lost to follow-up (>20%), the outcome of the study can be much influenced. Again, this is even more problematic if the loss to follow-up is selective (Koes, 2004). It is possible, however, to deal with selective follow-up in the analysis phase of a study. Additional analysis, for example a 'worst case analysis', could be carried out (Koes, 2004).

The normal process in our clinic when patients receive a treatment approach to improve their condition is to pay fees at the end of each treatment session. Patients who visited our clinic and participated in the trials of the present project (Chapter 4; Chapter 6) no fee was to be charged. This would have increased the possibility that patients with no true LE, patellar tendinopathy and idiopathic CTS had been included in the trials of the present project. However, the fact that all the previous reported conditions were diagnosed by a specialised rheumatologist with extensive experience in the area of

musculoskeletal conditions by means of the most commonly used diagnostic tests in practice, eliminated this possibility. In a future project, the diagnosis of these conditions can be confirmed using MRI and/or ultrasound examinations. MRI and/or ultrasound examinations were not used in the present project for the reasons mentioned previously. Furthermore, receiving a treatment (pay or not for it) patients have expectations to improve their condition. Measures to reduce patients' expectations mentioned previously. The possibility that patients reported improvement at the end of treatment and at follow-ups in conducted studies in order to please the investigator cannot be discounted. However, none of the patients wanted to discontinue treatments included in the trials of the present project (Chapter 4; Chapter 6) in favor of conventional polytherapy as provided by the clinic and patients with patellar tendinopathy (Chapter 4; section 4.3) who received Cyriax physiotherapy and pulsed ultrasound respectively continued to complain of pain at the end of the treatment and at any follow-up point, it may be assumed that the symptom reduction was an actual phenomenon in the trials of the present project and patients told the truth to investigator since their priority receiving a treatment was to reduce their symptoms and no to please the investigator. Finally, using the PFGS as an outcome measure in the main study of this project (Chapter 6), which is a valid, reliable and no self-reported outcome measure, supported the assumption that the symptom reduction was a real phenomenon.

The patients who participated in all trials in the present project were examined and evaluated in the Rheumatology and rehabilitation centre, an environment of private medicine in Athens. The manager of this centre is the father of the investigator, a specialised rheumatologist. The investigator of the present project knew that he would have easy access to patients in his fathers' clinic. It was decided to collect data in Greece. The university was informed about this decision from the beginning of the project (October 2001). Someone might believe that the manager of the clinic coerced patients to participate in the trials. It can be assumed that the previously reported issue was avoided since the standards of good practice such as those that are laid down in the Declaration of Helsinki were followed. Again, as the trials of the present project were conducted in a private clinic and no in a university lab or in a hospital someone might question about the way that the collected data would be stored. The data was stored securely at the investigator's office, a place in the clinic with restricted access, protecting with this way the integrity of the data.

The quality score of the controlled clinical trial on LE (Chapter 6) is 52% on Chalmers scale. This score matches the scores of previously conducted trials on LE described in chapter 2. Lack of randomisation and blinding of patients and therapist are the main responsible methodological shortcomings for this quality score in the main clinical trial of the present project. Blinding of patients and therapist were not possible in this trial, as mentioned previously in this section. However, if blinding had been followed, the study would have been considered as high quality (more than 70%). Following this kind of allocation (sequential allocation) in the trial of Chapter 6, it was thought that the trial was a randomized one, because this allocation had been used in other trials as randomisation incorrectly (Burton, 1988; Dwars et al., 1990). When it was realized that a no randomized design was followed, it was late, since the trial had progressed a lot. If a randomized designed had been used in this trial the quality score of the study would have been more than 70% and the study would have been considered as high quality. Therefore, using randomisation instead of sequential allocation a future clinical trial should be conducted comparing the relative effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the management of LE. However, the use of sequential allocation allowed for a true cause-and-effect relationship to be demonstrated in the present trial as mentioned previously. In addition, the quality score of patellar tendinopathy pilot trial (Chapter 4; section 4.3) and of preliminary prospective open idiopathic CTS clinical trial (Chapter 4; section 4.3) is 38% and 30% respectively on Chalmers scale. These two pilot studies had more methodological shortcomings than the main clinical trial of chapter 6, as mentioned previously and such scores were expected. Future well-designed trials are needed to assess the effectiveness of the investigated treatments on the previously two reported conditions.

7.4 Clinical implications

A supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) reduced the symptoms in patellar tendinopathy and CTS respectively (Chapter 4), two overuse injuries that are similar to LE and are regularly presented to the clinic. The positive effects of these studies should be under consideration due to methodological shortcomings (see previous section). Cyriax physiotherapy was not an effective treatment in patellar tendinopathy (Chapter 4). The different way of Cyriax

physiotherapy application between LE and patellar tendinopathy may be responsible for the ineffectiveness of Cyriax physiotherapy in patellar tendinopathy as mentioned previously. Clinicians reported that they believed that Cyriax physiotherapy, a supervised exercise programme, and polarised polychromatic non-coherent light (Bioptron light) were effective treatments for LE in both the short term (one month after the end of treatment) and in the long term (6 months after the end of treatment) (Chapter 5). The finding that the supervised exercise programme treatment is the most effective of the three treatments for LE means that, of the three treatments, it should be the first treatment option (Chapter 6). Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) may also be suitable treatments for the management of LE, because it was found that these two treatments may reduce pain and improve function in patients with LE (Chapter 6). Whether this is due to placebo effects or the patients' expectations receiving a treatment is not known. To maximize the effectiveness of Cyriax physiotherapy treatment, physiotherapists should be experienced with Cyriax physiotherapy treatment and hold a certificate or diploma in orthopaedic medicine based on Cyriax principles.

In addition, the choice of treatment should be based not only on clinical effectiveness, but also on clinical considerations such as which treatment is the most time efficient, which is the least expensive and which is the least invasive (Halle et al., 1986). Clinicians reported that they believed that the three treatments were not time-consuming procedures for them to apply (Chapter 5), probably due to the nature of clinical rote/routines. The application times investigated in the controlled clinical trial on LE (Chapter 6) produced the best results for the supervised exercise programme, but it is possible that Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) may be more effective with longer application times. New treatments protocols will be developed modifying the application times that will be in contrast with the recommended protocols (Chapter 3). However, following this approach the optimal treatment protocol may be developed.

Clinicians reported that they felt that the only expensive treatment was the polarised polychromatic non-coherent light (Bioptron light) (Chapter 5). This treatment is expensive because devices that deliver polarised polychromatic non-coherent light (Bioptron light) are costly. However, a benefit of polarised polychromatic non-coherent

light (Bioptron light) therapy is that physiotherapists place the device over the affected (injured) site and can then treat other patients simultaneously. In contrast, clinicians reported that Cyriax physiotherapy and a supervised exercise programme are not expensive treatments since no special equipment is required (Chapter 5). However, Cyriax physiotherapy and a supervised exercise programme must be administered under the supervision of a physiotherapist and the physiotherapist cannot treat other patients at the same time. But again, Cyriax physiotherapy must be administered by a physiotherapist who is experienced with this treatment and has a certificate or diploma in orthopaedic medicine based on Cyriax principles. Finally, the administration of Cyriax physiotherapy places considerable strain on physiotherapists' hands and physiotherapists usually find this treatment exhausting. Any future trial should incorporate a cost-effectiveness analysis into the analysis of the compared treatments, since reduced costs are important issues for the recommendation of a treatment (White and Park, 1999).

Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) advocates reported that the application of these treatments for the treatment of LE caused no side effects (Chapter 3). In preliminary clinical trials (Chapter 4) and in the controlled clinical trial (Chapter 6), there were no adverse effects reported at the end of treatment or at any point during follow-up. The implication is that the treatments are both safe and effective in producing pain relief and function improvement. Clinicians also reported that these treatments cause no side effects in patients during their application (Chapter 5). However, in order to establish the safety of these treatments, it would be necessary to perform a RCT and survey to record only the side effects of these treatments, as it had been done for ESWT (Haake et al., 2002b) and acupuncture (MacPherson et al., 2001; White et al., 2001) respectively. A systematic review of a wide spectrum of published literature could also be carried out to evaluate the side effects of these treatments as it has also been done for acupuncture (Ernst and White, 2000).

The application of Cyriax physiotherapy was the only one of the three treatments that had some contra-indications on LE (Chapter 3). In the conducted survey, respondents who predominately used Cyriax physiotherapy to treat LE reported that this treatment has some contra-indications on LE (Chapter 5). The way that these contraindications are

overcome has already been mentioned in chapter 3. However, studies similar to those were reported previously for side effects are needed to confirm the contra-indications of Cyriax physiotherapy on LE. There is a lack of such studies for the other physiotherapy treatments in the literature.

Using the rating system for levels of evidence described in chapter 2, there is moderate evidence for the effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) on LE. In addition to the reported treatments for LE in chapter 2 there is also Mulligan physiotherapy-mobilization with movement (Vicenzino and Wright, 1995; Vicenzino et al., 2001; Abbott et al., 2001; Paungmali et al., 2003), cervical mobilization (Vicenzino et al., 1996; Rompe et al., 2001; Cleland et al., 2004), wrist manipulation (Struijs et al., 2003), neural tension technique (Drechsler et al., 1997), Rebox (Johannsen et al., 1993) and elbow taping (Vicenzino et al., 2003). These have been used in some trials, but the effectiveness of these treatments was not evaluated in the systematic review in chapter 2 because these trials did not meet the inclusion criteria. None of these treatments can be recommended as first line treatment for LE because of insufficient evidence. Well-designed RCTs are needed to draw definite conclusions about their effectiveness on LE. It is recommended that practitioners use the treatments techniques that have the strongest evidence supporting their outcomes. Given the lack of evidence on the relative benefits of these treatments options, therapists must construct a treatment plan and progression from these options based on clinical practicalities and experience. To obtain the best results, it is imperative that patients match to the characteristics and injury presentations of participants in specific treatment studies.

7.5 Underlying mechanisms of investigated treatments

One of the difficulties in establishing an optimal treatment for LE has been that the pathophysiology of this condition was unknown until recently (Chapter 1). It is now known that LE is a degenerative or failed-healing tendon response that is characterized by the increased presence of fibroblasts, by increased amounts of proteoglycans and glycosaminoglycans, by vascular hyperplasia and by disorganized collagen in the origin of the ECRB, the injured tendon (Chapter 1). Physiotherapy treatments that reverse the pathophysiology of LE may be effective for the management of this condition (Chapter

1). In contrast, chapter 2 found strong evidence only for the short-term effectiveness of acupuncture on LE, a symptomatic pain relief treatment. Although further research is needed to establish the effectiveness of acupuncture on LE, it is believed that this kind of treatment cannot offer long-term effectiveness because this treatment address the symptoms (pain) of LE rather than the cause of symptoms (pathophysiology changes of tendon).

The mechanisms behind the positive effects of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) as treatments for LE are not fully explained based on a number of hypotheses that are acceptable in the medicinal literature today (Chapter 3). The proposed mode of these treatments (Chapter 3) may cause changes in the pathophysiology of LE, giving one more explanation for the effectiveness of the three treatments.

It has been postulated that Cyriax physiotherapy can be used for both sympromatic relief of pain and promotion of tissue healing (Chapter 3). The symptomatic relief of pain can be achieved through (i) the gate control theory and (ii) the production of hyperemia (Chapter 3). The promotion of tissue healing can be achieved by (i) reorienting the collagen in a longitudinal fashion with the result of enhancing tensile strength because the more fibers stretch in accordance with the applied force the greater strains the tissue will tolerate and (ii) breaking down (rupturing) the strong cross-links or adhesions that have formed on the "injured" structure, tendon in this case (Chapter 3).

It is reported that supervised exercise programmes used for the promotion of tissue healing by (i) stimulating mechanoreceptors in tenocytes to produce collagen because the more fibers exist in the tendon the greater strains the tendon will tolerate; (ii) improving collagen alignment of the tendon and stimulate collagen cross-linkage formation, both of which increase the tensile strength (see previous paragraph); (iii) normalizing the high concentrations of glycosaminoglycans and (iv) leading to neovascularisation, the formation of new blood vessels, which improves blood flow in the area of injured (Chapter 3).

It is claimed that polarised polychromatic non-coherent light (Bioptron light) has biostimulative effects assisting tissue healing (Chapter 3). The biostimulative effects of this intervention accelerate the cellular mechanisms and improve the tensile strength indirectly through the cell proliferation (especially fibroblasts), growth factor release and collagen synthesis enhancement (Chapter 3). It is also claimed that the radiation of polarised polychromatic non-coherent light (Bioptron light) may improve the blood supply (Chapter 3).

Based on the previously reported evaluations, it is obvious that the proposed mechanism of action of the supervised exercise programme is the only of the three mechanisms that reverse the pathophysiology of LE in full, and therefore it may be explained why the supervised exercise programme was the most effective treatment in the present project. The recommended mode of action of the other two treatments, Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light), reverse the pathophysiology of LE partially and it was expected these two treatment to be less effective than the supervised exercise programme. Such as observations are expected for conditions similar to LE.

7.6 Implications for future research

Although completing this project constitutes an important step towards strengthening the evidence base, it is hoped that the findings obtained in the course of this project will inspire future studies ensuring that clinical practice is built on firm foundations of research evidence.

All treatments, that are used to treat LE including Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light), have to be shown to be effective if they are to be continued in future practice. The effectiveness of a treatment should be investigated when the optimal protocol of this treatment has been established. The optimal protocol for a treatment should be established by combining a wide spectrum of published literature (anecdotal reports from therapists, manufacturers' claims, a variety of trials and reviews of literature, patient information sheets, etc) with self-report by therapists using this treatment in their clinical practice. Using the optimal treatment protocols, well designed RCTs that can

resolve the issues discussed should be conducted to determine the absolute effectiveness (e.g., against a placebo (sham)/ no treatment control) and relative effectiveness (e.g., against other treatments) of treatments in order to inform clinical decisions. RCTs appear to be a powerful research tool for answering questions on the effectiveness of interventions. Despite some problems with the conduct of RCTs, problems largely related to the blinding of patients and therapists, it is undoubtedly possible to carry out high-quality studies in this area. Of course, other types of research aimed at increasing the body of knowledge about treatments should also be carried out. Basic sciences, including animal studies and biomechanical work, are needed to develop new therapies and improve old therapies. However, only by the results of high-quality RCTs will be able to determine whether specific therapies are effective or not. When a wide range of differing treatment options are presented, as is the case for LE, comparisons of effects produced by different treatments can provide information about relative effectiveness and can inform decisions about treatment selection.

Investigations using physiological variables should be carried to demonstrate how the treatments work. A cost-effectiveness analysis should be incorporated into future trials, because reduced costs are important issues for the recommendation of a treatment. The safety of treatments should be confirmed by RCTs and surveys that record only the side effects of treatments, with the side effects summarised by systematic reviews.

In addition, research should be conducted that will help clinicians to understand the underlying nature of LE. A genuine understanding of the true nature of LE will make it easier to establish the most effective treatment to be used in clinical practice and produce a better prognosis for the condition. The pathophysiology of LE, which has been an obstacle to establishing effective treatments for the condition, is now more known. Further research is required to determine if this knowledge of the pathophysiology may be translated into clinical effectiveness and vice versa. Moreover, reviews of literature and surveys are recommended i) to develop a precise definition of LE; ii) to resolve the inconsistency of nomenclature; iii) to establish the etiology of LE and iv) to establish the epidemiology of LE. In addition, literature reviews, surveys and test-retest studies are needed to assess the validity and sensitivity of diagnostic tests for LE.

In conclusion, despite the need for further research to understand the nature of LE and the lack of optimal protocols to investigate the effectiveness of treatments, practitioners should be encouraged to use the treatments that have the strongest evidence supporting their outcomes. Cook et al (2001) suggest that physiotherapy treatments should be considered to be effective if they reduce the pain and improve function. Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) reduced pain and improved function at the end of the treatment and at any of the follow-up time points. It can be concluded that these three treatments are promising interventions for the management of patients with LE. However, the supervised exercise programme was clearly superior and should be used as a first treatment option when physiotherapists manage LE patients. The superiority of the supervised exercise programme is also confirmed from the proposed mode of action, that reverses the pathophysiology of LE (cause of symptoms) in full. If it is not possible the supervised exercise programme to be carry out, Cyriax physiotherapy and polarised polychromatic non-coherent light (Bioptron light) may be suitable with less positive effects since reduce the pathophysiology of LE partially. Further research is warranted to investigate and confirm the effectiveness of Cyriax physiotherapy, supervised exercise programmes and polarised polychromatic non-coherent light (Bioptron light) in the treatment of impairment and disability resulting from LE.

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APPENDIX I

Certificate in Orthopaedic Medicine

APPENDIX II

English Questionnaire

Questionnaire about management of Tennis Elbow

1. How many years do you work as physiotherapist?

2. In which area are you specialized?

3. Do you work patients with Tennis elbow? (Circle your answer)

     YES   NO

If you answered NO in question 3, I would like to thank you for your participation, as you do not need to complete the rest questionnaire. If you answered YES in question 3, go on in question 4.

Circle your answer to the following questions 4-12

4. Which of the below terms is most commonly used instead of Tennis elbow? (Circle only one answer)

        Lateral Epicondylitis

        Lateral Epicondylalgia

        Extensor Tendinosis

        Extensor Tendinitis

        Extensor Tendinopathy

5. Do you believe that Extensor Carpi Radialis Brevis (ECRB) is the most common affected structure of Tennis elbow?

     YES   NO

6. Do you believe that patients with Tennis elbow complain of pain by digital palpation conducted by therapist?

     YES   NO

7. Do you believe that patients with Tennis elbow complain of pain in gripping?

     YES   NO

8. Do you believe that the resisted wrist extension with the elbow in extension is the most common diagnostic test in patients with Tennis elbow?

     YES   NO

9. Have you read an article about the conservative management of Tennis elbow recently (the last four months)?

       YES   NO

10. Have you attended a course about the conservative management of Tennis elbow during your career?

       YES   NO

11. Do you know that more than 40 different treatment methods have been reported in order to treat patients with Tennis elbow?

       YES   NO

12. Which of the below treatments do you use the most in order to treat patients with Tennis elbow in clinic? (Circle only one answer)

       Cyriax Physiotherapy

       Supervised exercise programme

       Polarised polychromatic non-coherent light (Bioptron light)

       None of the above treatments

If you answered none of the above treatments, I would like to thank you for your participation.

Circle your answer to the following questions, apart from questions 15, 16, 28, 29, where you will answer in your own words

13. Does this treatment have short-term effect?

       YES   NO

14. Does this treatment have long-term effect?

       YES   NO

15. How many times per week do patients follow this treatment?

16. How long do patients follow this treatment? (Your answer in months)

17. Do you use the same protocol for all patients?

       YES   NO

17a. If you answered NO, refer when you vary the protocol

18. Is painful this treatment for patients?

      YES   NO

19. Is time-consuming this treatment?

      YES   NO

20. Is harmful this treatment for clinician's hands?

      YES   NO

21. Is an expensive treatment for patients?

      YES   NO

22. Is an expensive treatment for clinicians?

      YES   NO

23. Do patients use any prophylactic measures?

      YES   NO

23a. If you answered YES, refer

24. Do clinicians use any prophylactic measures?

      YES   NO

24a. If you answered YES, refer

25. Does this treatment have any side effects in patients?

      YES   NO

25a. If you answered YES, refer

26. Does this treatment have any contraindications?

YES   NO

26a. If you answered YES, refer

27. Can patients follow this treatment at their home?

YES   NO

28. Which is the aim of the treatment you use?

29. How many patients did you manage with this treatment last month?

Thank you for your participation

APPENDIX III

Greek Questionnaire

Ερωτηματολόγιο για την αντιμετώπιση του αγκώνα των τενιστών

1. Πόσα χρόνια δουλεύετε σα φυσικοθεραπευτής;

2. Σε ποιο τομέα είστε εξειδικευμένος;

3. Δουλεύετε ασθενείς με αγκώνα των τενιστών (Tennis Elbow); (Κυκλώστε την απαντησή σας)

<div align="center">ΝΑΙ   ΟΧΙ</div>

Αν απαντήσατε ΟΧΙ στην ερώτηση 3, θα ήθελα να σας ευχαριστήσω για τη συμμετοχή σας, καθώς δε χρειάζεται να συμπληρώσετε το υπόλοιπο ερωτηματολόγιο. Αν απαντήσατε ΝΑΙ στην ερώτηση 3, συνεχίστε στην ερώτηση 4.

Κυκλώστε την απάντηση σας στις παρακάτω ερωτήσεις

4. Ποιον από τους παρακάτω όρους χρησιμοποιείτε κυρίως αντί για τον όρο αγκώνα των τενιστών (Tennis Elbow); (Κυκλώστε μόνο μια απάντηση)

<div align="center">Επικονδυλίτιδα (Lateral Epicondylitis)</div>
<div align="center">Lateral epicondylalgia</div>
<div align="center">Τενόντωση</div>
<div align="center">Τενοντίτιδα</div>
<div align="center">Τενοντικό πρόβλημα (Tendinopathy)</div>

5. Πιστεύετε ότι ο βραχύς κερκιδικός εκτείνοντας του καρπού είναι η πιο συχνά τραυματιζόμενη περιοχή στους ασθενείς με αγκώνα των τενιστών (Tennis Elbow);

<div align="center">ΝΑΙ   ΟΧΙ</div>

6. Πιστεύετε ότι οι ασθενείς με αγκώνα των τενιστών (Tennis Elbow) παραπονιούνται για πόνο κατά τη ψηλάφιση από το φυσικοθεραπευτή;

NAI   OXI

7. Πιστεύετε ότι οι ασθενείς με αγκώνα των τενιστών (Tennis Elbow) παραπονιούνται για πόνο στις δραστηριότητες που απαιτούν σφίξιμο;

NAI   OXI

8. Πιστευέτε ότι η έκταση του καρπού με αντίσταση με τον αγκώνα σε έκταση είναι το πιο κοινό διαγνωστικό τεστ σε ασθενείς με αγκώνα των τενιστών (Tennis Elbow);

NAI   OXI

9. Έχετε διαβάσει κάποιο άρθρο για τη συντηρητική αντιμετώπιση του αγκώνα των τενιστών (Tennis Elbow) πρόσφατα (τους τελευταίους 4 μήνες);

NAI   OXI

10. Έχετε παρακολουθήσει κάποιο σεμινάριο για τη συντηρητική θεραπεία του αγκώνα των τενιστών (Tennis Elbow) κατά τη διάρκεια της καριέρας σας;

NAI   OXI

11. Γνωρίζετε ότι υπάρχουν παραπάνω από 40 θεραπείες για την αντιμετώπιση του αγκώνα των τενιστών (Tennis Elbow);

NAI   OXI

12. Ποια από τις παρακάτω θεραπείες χρησιμοποιείτε κυρίως για την αντιμετώπιση των ασθενών με αγκώνα των τενιστών (Tennis Elbow) στην κλινική; (Κυκλώστε μόνο μια απάντηση)

Cyriax φυσικοθεραπεία

Επιβλεπόμενο πρόγραμμα ασκήσεων

Πολωμένο φως

Καμια από τις παραπάνω

Αν απαντήσατε καμια από τις παραπάνω, θα ήθελα να σας ευχαριστήσω για τη συμμετοχή σας.

Κυκλώστε την απαντησή σας στις παρακάτω απαντήσεις, εκτός από τις ερωτήσεις 15, 16, 28, 29 που θα απαντήσετε με δικά σας λόγια

13. Η θεραπεία που χρησιμοποιείτε έχει βραχυπρόθεσμα αποτελέσματα;

NAI   OXI

14. Η θεραπεία που χρησιμοποιείτε έχει βραχυπρόθεσμα αποτελέσματα;

NAI   OXI

15. Πόσες φορές την εβδομάδα ακολουθούν οι ασθενείς τη θεραπεία;

16. Πόσο καιρό οι ασθενείς ακολουθούν αυτή τη θεραπεία; (Η απάντηση σας σε μήνες)

17. Χρησιμοποιείτε το ίδιο πρωτόκολλο για όλους τους ασθενείς;

NAI   OXI

17ᵃ. Αν απαντήσατε OXI, αναφέρετε πότε τροποποιείτε το πρωτόκολλο

18. Είναι οδυνηρή αυτή η θεραπεία για τους ασθενείς;

NAI   OXI

19. Είναι χρονοβόρα αυτή η θεραπεία;

NAI   OXI

20. Είναι επιζήμια αυτή η θεραπεία για τα χέρια των φυσικοθεραπευτών;

NAI   OXI

21. Ἔίναι ακριβή η θεραπεία για τους ασθενείς;

NAI   OXI

22. Ἔίναι ακριβή η θεραπεία για τουςφυσικοθεραπευτές;

NAI   OXI

23. Χρησιμοποιούν οι ασθενείς προφυλακτικά μέτρα κατά την εφαρμογή της θεραπείας;

NAI   OXI

23ᵃ. Αν απαντήσατε ΝΑΙ, αναφέρετε τα μέτρα

24. Χρησιμοποιούν οι φυσικοθεραπευτές προφυλακτικά μέτρα κατά την εφαρμογή της θεραπείας;

ΝΑΙ   ΟΧΙ

24ᵃ. Αν απαντήσατε ΝΑΙ, αναφέρετε τα μέτρα

25. Έχει παρενέργειες η θεραπεία στους ασθενείς;

ΝΑΙ   ΟΧΙ

25ᵃ. Αν απαντήσατε ΝΑΙ, αναφέρετε τις παρενέργειες

26. Έχει αντενδείξεις η θεραπεία;

ΝΑΙ   ΟΧΙ

26ᵃ. Αν απαντήσατε ΝΑΙ, αναφέρετε τις αντενδείξεις

27. Μπορούν οι ασθενείς να ακολουθήσουν αυτή τη θεραπεία σπίτι τους;

<div align="center">ΝΑΙ   ΟΧΙ</div>

28. Ποιος είναι ο σκοπός της θεραπείας που χρησιμοποιείτε;

29. Πόσους ασθενείς με αγκώνα των τενιστών (Tennis Elbow) αντιμετωπίσατε με αυτή τη θεραπεία τον τελευταίο μήνα;

<div align="center">**Ευχαριστώ πολύ για τη συμμετοχή σας**</div>

APPENDIX IV

Invitation letter of questionnaire

RHEUMATOLOGY AND REHABILITATION CENTRE
16 ORFANIDOU STREET, PATISSIA, ATHENS 11141,GREECE
LEEDS METROPOLITAN UNIVERSITY
Faculty: Health and Environment, School: Health Sciences
City campus, Leeds LS1 3HE,U.K

_____

November 14, 2002

Dear Sir/Madam

I am requesting your participation in a survey of physical therapy programmes in Greece to establish the clinical practice of three treatments, Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non coherent light (Bioptron Light), for the treatment of patients with lateral epicondylitis (tennis elbow). I believe that a compilation of information about the clinical use of these three interventions will be helpful to physical therapists as the currently clinical use of the three modalities will be established.

The enclosed questionnaire takes an average of less than 15 minutes to complete. I would greatly appreciate your time in completing the questionnaire and returning it in the enclosed envelope by mid-December, 2002. If you would like a copy of the results, please complete the enclosed postcard and return it separately from the questionnaire.

Thank you in advance for your consideration. If you have any questions or concerns about the study, please feel free to contact me at the address or telephone numbers listed.

Sincerely,

DIMITRIOS STASINOPOULOS
PHYSIOTHERAPIST, M.Sc, P.hD STUDENT, PGCRM, Cert Clin. Ed., Cert Orth. Med. (Cyriax)
210 2015655
210 2022500
6944713312

APPENDIX V

Questionnaire data

Q1	Q2	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
10	1	1	1	1	1	1	2	2	2
12	1	1	1	1	1	1	2	2	1
20	1	1	1	1	1	1	2	2	2
26	2	2	1	1	1	1	2	2	2
23	2	5	1	1	1	2	2	2	2
13	2	1	1	1	1	1	2	2	1
6	2	2	1	1	1	1	1	2	2
11	1	1	1	1	1	1	2	2	2
15	2	3	1	1	1	2	2	2	2
20	1	1	1	1	1	1	2	2	2
8	1	1	2	1	1	1	2	2	2
12	2	2	1	1	1	1	2	2	1
27	2	1	1	1	1	1	2	2	2
9	1	3	1	1	1	1	2	2	2
10	1	1	1	1	1	2	2	2	2
11	2	1	1	1	1	1	2	2	2
15	1	1	1	1	1	1	1	2	2
15	1	1	1	1	1	1	2	2	1
10	1	2	1	1	1	1	2	2	2
6	1	1	1	1	1	1	2	2	2
15	2	1	1	1	1	1	2	2	2
23	2	1	1	1	1	1	2	2	1
31	1	2	1	1	1	1	2	2	2
8	1	1	1	1	1	1	2	2	2
15	2	1	1	1	1	2	1	2	2
16	1	4	1	1	1	1	2	2	2
19	1	1	1	1	1	1	2	2	1
22	2	1	1	1	1	1	2	2	2
26	1	1	2	1	1	1	2	2	2
28	1	2	1	1	1	1	1	2	2
5	1	1	1	1	1	1	2	2	2
9	2	1	1	1	1	1	2	2	1
11	2	2	1	1	1	1	1	1	2
13	1	1	1	1	1	1	2	2	2
15	1	1	1	1	1	1	2	2	2
22	1	1	1	1	1	1	1	2	2
21	1	2	1	1	1	1	2	2	2
20	2	1	1	1	1	1	2	2	1
32	2	3	1	1	1	2	1	2	2
6	1	1	1	1	1	2	2	1	2
5	2	2	1	1	1	1	2	2	2
11	1	1	1	1	1	1	2	2	1
17	2	1	1	1	1	1	1	2	2
21	1	1	1	1	1	1	2	2	2
20	1	3	1	1	1	1	2	2	1
10	2	1	1	1	1	1	1	1	2

15	2	1	1	1	1	1	2	2	1
25	2	1	2	1	1	2	2	2	1
25	2	1	1	1	1	1	1	2	2
25	1	2	1	1	1	1	2	2	2
27	1	1	1	1	1	1	2	2	1
12	2	1	1	1	1	2	2	2	2
15	2	1	1	1	1	1	2	2	2
8	1	1	1	1	1	1	2	2	1
5	2	1	1	1	1	1	1	2	2
19	2	2	1	1	1	1	2	2	1
20	1	2	1	1	1	1	2	1	2
25	2	1	1	1	1	2	2	2	2
15	2	3	1	1	1	1	2	2	1
16	2	2	1	1	1	1	2	2	2
16	1	4	1	1	1	1	2	2	2
15	1	1	1	1	1	2	2	2	2
21	1	2	2	1	1	1	2	2	2
8	1	1	1	1	1	1	1	1	1
9	1	1	1	1	1	1	2	2	2
17	2	1	1	1	1	2	2	2	2
15	1	2	1	1	1	1	2	2	1
10	2	1	1	1	1	1	2	2	2

In all these questions the first 18 answers related to Cyriax physiotherapy, the rest 43 answers related to the supervised exercise programme and the final 7 answers related to polarised polychromatic non-coherent light (Bioptron light).

In Q1 are presented the experience years of respondents.

In Q2, 1= Orthopaedic area and 2=Sports medicine area.

In Q4 1=Lateral epicondylitis 2=Extensor tendonitis 3=Lateral epicondylalgia 4=Extensor tendinopathy and 5=Extensor tendinosis

In Q5, Q6, Q7, Q8, Q9,Q10, Q11 1=YES and 2= NO

Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
1	1	1	3	1	1	2	2	1	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2

2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
2	1	1	3	1	1	2	2	2	2	2
3	1	1	3	1	1	2	2	2	1	1
3	1	1	3	1	1	2	2	2	1	1
3	1	1	3	1	1	2	2	2	1	1
3	1	1	3	1	1	2	2	2	1	1
3	1	1	3	1	1	2	2	2	1	1
3	1	1	3	1	1	2	2	2	1	1
3	1	1	3	1	1	2	2	2	1	1

In Q12 1=Cyriax physiotherapy, 2= supervised exercise programme and 3=polarised polychromatic non-coherent light (Bioptron light).

According to the previously reported division were answered the Q13, Q14, Q17-Q22 where 1= YES and 2=NO and the same division was followed in the rest questions in the next pages.

In Q15 the number 3 means 3 times per week and the answer was the same for the three groups. In Q16 the number 1 means 1 month and the answer was the same for the three groups.

Q23	Q24	Q25
2	2	2
2	2	2
2	2	2
2	2	2
2	2	2
2	2	2
2	2	2
2	2	2
2	2	2
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2	2	2
2	2	2
2	2	2
2	2	2

In Q23, Q24 and Q25, 2 means NO

Q26   Q26a

2
1
1

skin prob
infection
infection
skin prob
cal sof tis
cal sof tis
skin prob
cal sof tis
cal sof tis
infection
infection
cal sof tis

1
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1
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2

In Q26, 1means YES and 2 means NO. In Q26a the YES answers of respondents who predominately used Cyriax physiotherapy to treat LE are presented.

skin prob=skin problem

cal sof tis= calcification of soft tissues

Q27		Q29
2	.	3
2	.	2
2	.	1
2	.	2
2	.	3
2	.	2
2	.	5
2	.	3
2	.	3
2	.	5
2	.	5
2	.	3
2	.	4
2	.	3
2	.	2
2	.	3
2	.	2
2	.	1
2	.	6
1	.	5
2	.	3
2	.	3
1	.	3
2	.	2
1	.	4
2	.	3
1	.	3
2	.	2
1	.	5
2	.	5
1	.	2
2	.	6
2	.	1
1	.	1
1	.	2
2	.	4
2	.	3
2	.	5
1	.	4
1	.	4
1	.	3
2	.	3
1	.	2
1	.	2
2	.	2
1	.	3
2	.	1

1	.	4
2	.	5
1	.	5
2	.	2
1	.	3
1	.	2
2	.	2
1	.	2
2	.	2
1	.	1
2	.	2
2	.	1
1	.	2
2	.	1
2	.	2
2	.	1
2	.	2
2	.	3
2	.	2
2	.	1
2	.	1

In Q 27, 1means YES and 2 means NO

In Q29 are presented the patients that managed in a clinical setting the last month

Q28 is in the next page

pain	function	function
function	pain	pain
pain/fun	p/function	p/function
rep con	rep con	rep co
	function	pain
pain	pain	pain
pain/fun	pain	p/function
rep con	function	
pain/rep c	p/function	
fun/rep co	hyperem	
function	pain/rep c	
rep con	fun/rep co	
fun/rep co	function	
pain/fun	fuction	
rep con	pain	
fun/rep co	p/function	
pain/rep c	p/function	
p/f/rep c	hyperem	
p/f/rep c	pain	
	fun/rep co	
	p/function	
	p/function	
	pain	
	function	
	pain/rep c	
	rep con	
	rep con	
	p/f/rep co	
	p/f/rep co	
	function	
	function	
	p/function	
	rep con	
	pain/rep c	
	fun/rep co	
	p/function	
	p/f/rep co	
	p/function	
	p/function	
	rep con	
	p/f/rep co	
	rep con	
	p/f/hyp/co	

Q28 Answers of respondents. The first column presents the answers of respondents who predominately used Cyriax participants to treat LE, the second column presents the answers of respondents who predominately used a supervised exercise programme to treat LE and the third column presents the answers of respondents who predominately used polarised polychromatic non-coherent light (Bioptron light) to treat LE.
p=pain, hyper=hyperemia, f=Function, rep con=repair connective tissue

Descriptives

	VAR00001			Statistic	Std. Error
Q1	1,00	Mean		14,61	1,453
		95% Confidence Interval for Mean	Lower Bound	11,54	
			Upper Bound	17,68	
		5% Trimmed Mean		14,40	
		Median		12,50	
		Variance		38,016	
		Std. Deviation		6,166	
		Minimum		6	
		Maximum		27	
		Range		21	
		Interquartile Range		10,00	
		Skewness		,804	,536
		Kurtosis		-,320	1,038
	2,00	Mean		16,82	1,096
		95% Confidence Interval for Mean	Lower Bound	14,61	
			Upper Bound	19,03	
		5% Trimmed Mean		16,68	
		Median		16,00	
		Variance		52,850	
		Std. Deviation		7,270	
		Minimum		5	
		Maximum		32	
		Range		27	
		Interquartile Range		11,00	
		Skewness		,125	,357
		Kurtosis		-,751	,702
	3,00	Mean		13,33	2,108
		95% Confidence Interval for Mean	Lower Bound	7,91	
			Upper Bound	18,75	
		5% Trimmed Mean		13,20	
		Median		12,50	
		Variance		26,667	
		Std. Deviation		5,164	
		Minimum		8	
		Maximum		21	
		Range		13	
		Interquartile Range		9,25	
		Skewness		,511	,845
		Kurtosis		-1,399	1,741

Descriptive statistics for years of experience of respondents.
1,00= Cyriax physiotherapy
2,00= Supervised exercise programme
3,00= Polarised polychromatic non-coherent light (Bioptron light)

Descriptives

		Statistic	Std. Error
Mean		15,93	,833
95% Confidence Interval for Mean	Lower Bound	14,26	
	Upper Bound	17,59	
5% Trimmed Mean		15,75	
Median		15,00	
Variance		47,144	
Std. Deviation		6,866	
Minimum		5	
Maximum		32	
Range		27	
Interquartile Range		11,00	
Skewness		,353	,291
Kurtosis		-,696	,574

Descriptive statistics for years of experience for the whole sample

One-way Anova

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	106,476	2	53,238	1,134	,328
Within Groups	3052,157	65	46,956		
Total	3158,632	67			

283

APPENDIX VI

Baseline assessment sheet

Date:

Name:

Sex:

Age:

Duration of symptoms:

Previous treatment:

Occupation:

Affected arm:

Dominant arm:

APPENDIX VII

Patient information sheet

DIMITRIOS I STASINOPOULOS

Physiotherapist, M.Sc, PGCRM,

RHEUMATOLOGY AND REHABILITATION CENTRE

16 ORFANIDOU STREET, PATISSIA, ATHENS GREECE

P.hD STUDENT LEEDS METROPOLITAN UNIVERSITY

Faculty: Health and Environment, School: Health Sciences

PATIENT INFORMATION SHEET

TITLE OF PROJECT: An investigation into the clinical use and clinical effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) for the treatment of lateral epicondylitis.

You are invited to participate in a **research study, which forms part of my PhD training.** The research study investigates the clinical effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarised polychromatic non-coherent light (Bioptron light) for the treatment of lateral epicondylitis, commonly referred to as tennis elbow (lateral elbow pain). Before entering this study you should be between 30 and 60 years old, have been complained of pain for at least a month, have been treated unsuccessfully for tennis elbow and have been either self-referred to our clinic or referred by your physician or physiotherapist to our clinic. Please inform the investigator if this is not the case. Participation in this study requires attendance in clinic at three 30-minute sessions per week for four weeks (a month). You would also be required to attend our clinic for a 10-minute assessment of your condition at one month after the end of treatment, three months after the end of treatment and six months after the end of treatment. You can withdraw from the study at any stage and without giving the reasons.

If you agree to participate and are accepted in to the study you will be randomly allocated to receive ONE of three possible treatment interventions (i) Cyriax physiotherapy, (ii) a supervised exercise programme or (iii) polarised polychromatic non-coherent light (Bioptron light).

Cyriax physiotherapy will consist of a 10-minute massage treatment applied by a qualified Cyriax therapist to the area around the elbow. The therapist will then straighten your arm using a short and quick movement. Occasionally the Cyriax physiotherapy can increase the pain during the treatment and if this happens you should immediately tell the therapist.

Treatment using the supervised exercise programme aims to increase the strength and flexibility of wrist extensors (muscles on the side of the elbow) muscles around the elbow. You will be shown how to perform the exercises and the therapist will provide guidance when you carry out the exercises. You will start with three sets of stretching exercises for 30-45 seconds at each session with 30-second rest interval between each procedure. This will be followed by 3 sets of 10 eccentric exercises, which last a few seconds each, with one-minute rest interval between each set. You will finish performing again three sets of stretching exercises. Performing these exercises minimal pain can be expected, but this type of pain is usually easily tolerated. Eccentric/stretching exercises will be conducted slowly in each session to reduce the risk of pain resulting from this treatment. If pain becomes too high during the exercises you should immediately tell the therapist who will make you stop the exercises and will appraise the situation with a view of stopping the experiment.

Polarised polychromatic non-coherent light (Bioptron light) delivers light energy at intensities much lower than that achieved using therapeutic lasers. It will be applied over three sites around the painful area for six minutes at each site (a total of 18 minutes in each treatment). The polarised polychromatic non-coherent light (Bioptron light) probe will be positioned 5-10 cm above your skin and you are unlikely to feel any sensations from the probe or therapy. As a relatively new treatment there have been no reports in the literature of any adverse events arising from polarised polychromatic non-coherent light (Bioptron light) given in this way. No any hypothetical effects can be found.

Because it is not known whether these treatments are useful in tennis elbow it is possible that participation in this study will result in you receiving a treatment that does not directly help your condition. If there are no clear beneficial effects of treatment allocated to you at the first follow up measurement (one month after the end of treatment, week 8) then you will be offered an alternative form of treatment consisting of the standard care (polytherapy) for tennis elbow as provided by the clinic. Alternative treatment will be offered to every patient who will find the treatment interventions ineffective, but it is not compulsory to take up the alternative treatment, you can stay on the original treatment.

You are reminded that you can withdraw from the study at any point without consequence for further treatment, which will be free of charge for a month.

During the study period we would like you to try to avoid activities that irritate the elbow such as gripping activities, and to try to refrain from taking pain reliving medication such as anti-inflammatory drugs like aspirin and ibuprofen or paracetamol. If you need for any reason to take medication we would like you to inform the investigator during your next visit to the clinic.

During the study we will take measures of pain and function using a series of questionnaires. Grip strength will also be measured using a hand-held dynamometer which requires to grip and squeeze two handles until you feel the very first sensation of pain in the arm - at which point you will be asked to stop squeezing. This procedure is used routinely in physiotherapy and should not cause a new episode of pain.

The treatment and measurements will be performed in our medical centre. The researcher, who is a qualified physiotherapist, will give treatments. Measurements will be performed by a physiotherapist during the course of study from baseline (week 0) to six-month follow-up (week 28), who will be blind to the patients' therapy group and who will not treat you at all.

Data resulting from this study will be used in my PhD thesis and in publications articles about this study. However, data will be coded and your identity will remain concealed at all times. You will not be identified in the reporting of any findings resulting from this study. All documentation will be held in a secure place where only the researcher has access and will be disposed carefully at the end of the study.

Your participation in this study will help to inform physiotherapy practice so that patients with tennis elbow will receive effective treatment in the future. However, it is unlikely that the results of this study will be of direct benefit to yourself.

If you have questions about this research or you feel your participation have been placed at risk, you can contact the investigator Dimitrios Stasinopoulos at 2015655. Your participation in this research is voluntary. If you elect to participate in the study, you

have the right to withdraw from the study at any time without giving a reason and without affecting your future care. You are not waiving any legal claims, rights, or remedies. You will receive a copy of this form.

APPENDIX VIII

Informed Consent

CONSENT FORM

Title of Project

An investigation into the clinical use and clinical effectiveness of Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) for the treatment of lateral epicondylitis.

Please delete as applicable

1. I have read the Patient Information Sheet.   YES/NO

2. I have had the opportunity to ask questions and discuss the
   research study.   YES/NO

3. I am satisfied with the answer to my questions.   YES/NO

4. I have received enough information about this study   YES/NO

5. I have spoken to Mr. Stasinopoulos Dimitrios.   YES/NO

6. I am understand that I am free to withdraw from the study at
   any time without giving a reason and without affecting my
   future care.   YES/NO

7. I agree to take part in this research study.   YES/NO

8. I am aware that I can withdraw at anytime without this having
   any impact on my future treatment.   YES/NO

Signature

Name (block capitals)   Date

Signature of witness

Name (block capitals)   Date

APPENDIX IX

Pain and function on Visual Analogue Scale (VAS) (cm)

How do you describe your level of pain and your function on an 11- point numerical rating scale, in which 0 (cm) means ´least pain imaginable` and ´no function` respectively and 10 (cm) means ´worst pain imaginable` and ´full function` respectively, in the last twenty-four hours?

PAIN & FUNCTION ON VAS

	0 week	4 week	8 week	16 week	28 week
PAIN					
FUNCTION					

APPENDIX X

Pain Free Grip Strength (PFGS) (pounds)

Place your arm in a standardized position of elbow extension, forearm pronation and internal rotation of the upper limb such that the palmar aspect of the hand faced posteriorly with the upper limb placed by the subject's side. Squeeze the dynamometer handles until they first experience pain and then to release their grip. Repeat this three times with a 30-second rest interval between each measurement

PAIN FREE GRIP STRENGTH (PFGS) (pounds)

PFGS	0 week	4 week	8 week	16 week	28 week
1 trial					
2 trial					
3 trial					
average					

APPENDIX XI

Eight-item pain free function questionnaire ("no" answers)

Today, do you or would you have any elbow discomfort at all with any of the following activities?

Eight item pain free function questionnaire ('no answers')

	0 week	4 week	8 week	16 week	28 week
Activity					
Dressing yourself or pulling up your slacks					
Opening a jar or feeding yourself					
Washing yourself or wringing out a face cloth					
Household tasks (cleaning, lifting a chair, gardening)					
Opening doors					
Carrying objects with your involved hand					
Everyday activities					
Recreation or sporting activities					

Y=YES   N=NO

APPENDIX XII

Global measure of improvement (5-point scale)

How do you feel today?

Global measure of improvement (5-point scale)

	4 week	**8 week**	**16 week**	**28 week**
WORSE-1				
NO CHANGE-2				
SLIGHTLY BETTER-3				
MUCH BETTER-4				
NO PAIN-5				

APPENDIX XIII

Participants' characteristics

Cyriax physiotherapy

SEX	AGE	Dur sym	Aff Arm	Dom arm
male	32	2	1	1
MALE	35	4	1	1
MALE	46	5	1	1
MALE	45	5	1	1
female	31	1	1	1
MALE	39	5	1	1
female	40	2	1	1
MALE	50	2	1	1
female	47	10	1	1
MALE	45	5	2	2
female	37	4	1	1
MALE	33	11	1	1
MALE	38	16	1	1
MALE	42	1	1	1
MALE	42	9	1	1
female	38	5	1	1
MALE	39	5	2	2
MALE	30	7	1	1
female	45	4	1	1
MALE	47	2	1	1
female	48	5	1	1
MALE	44	3	1	1
female	43	7	2	2
MALE	36	6	1	1
female	39	3	1	1

Age in years
Dur sym= Duration of symptoms in months
Aff Arm= Affected arm where 1=right arm and 2=left arm
Dom Arm= Dominant arm where 1=right arm and 2=left arm

Supervised exercise programme

SEX	AGE	Dur sym	Aff Arm	Dom Arm
male	35	6	1	1
male	45	5	1	1
male	43	5	1	1
male	44	4	1	1
male	43	4	1	1
male	49	7	2	2
female	32	1	2	2
female	36	3	1	1
female	37	8	1	1
male	38	10	1	1
male	48	9	1	1
female	41	8	2	1
female	40	6	1	1
male	48	4	1	1
male	49	3	1	1
male	36	6	1	1
female	35	1	1	2
female	48	2	2	1
male	33	10	1	1
male	32	7	1	1
female	38	1	1	1
female	36	5	1	1
male	38	7	1	1
male	39	5	1	1
female	48	2	1	1

Age in years
Dur sym= Duration of symptoms in months
Aff Arm= Affected arm where 1=right arm and 2=left arm
Dom Arm= Dominant arm where 1=right arm and 2=left arm

Polarised polychromatic non-coherent light (Bioptron light)

SEX	AGE	Dur sym	Aff Arm	Dom Arm
male	40	3	2	2
male	45	8	1	1
male	48	9	1	1
female	48	4	1	1
female	49	6	1	1
female	32	6	1	1
female	31	5	1	1
male	30	3	1	1
male	36	7	1	1
male	45	7	1	1
male	42	2	2	2
male	40	7	1	1
male	38	5	1	1
female	39	8	1	1
female	36	4	1	1
female	43	2	1	2
male	43	3	2	1
male	48	10	2	1
male	31	8	1	2
female	35	4	1	1
male	39	2	1	1
female	30	1	1	1
male	49	7	1	1
female	46	1	2	2
male	41	6	1	1

Age in years
Dur sym= Duration of symptoms in months
Aff Arm= Affected arm where 1=right arm and 2=left arm
Dom Arm= Dominant arm where 1=right arm and 2=left arm

Patients' characteristics

	Cyriax physiotherapy	**Supervised Exercise programme**	**Polarised polychromatic non-coherent light (Bioptron light)**
Patients (n)	25	25	25
Male/female (n)	16/9	15/10	15/10
Mean age in years (SD)	40.44 (5.61)	40.44 (5.66)	40.16 (6.29)
Mean duration of complaints in months (95%CI)	5.16 (3.74-6.58)	5.16 (4.04-6.28)	5.12 (4.05-6.19)
Dominant elbow affected (n) (%)	25 (100%)	22 (88%)	21 (84%)

One Way ANOVA

AGE

	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	1,307	2	,653	,019	,981
Within Groups	2477,680	72	34,412		
Total	2478,987	74			

One Way ANOVA

DURATION of Symptoms

	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	,027	2	,013	,002	,998
Within Groups	621,360	72	8,630		
Total	621,387	74			

APPENDIX XIV

Previous treatments of participants

drugs	laser	ultrasound
drugs	drugs	ultrasound
drugs	drugs	drugs
ultrasound	drugs	drugs
iontophoresis	ultrasound	drugs
drugs	iontophoresis	injection
laser	heat	iontophoresis
drugs	drugs	laser
laser	drugs	iontophoresis
injection	injection	drugs
iontophoresis	laser	heat
ultrasound	laser	drugs
ultrasound	injection	laser
drugs	drugs	ultrasound
injection	laser	drugs
laser	iontophoresis	injection
ultrasound	ultrasound	drugs
drugs	ultrasound	laser
drugs	drugs	injection
drugs	drugs	drugs
laser	heat	ultrasound
injection	drugs	ultrasound
iontophoresis	drugs	heat
ultrasound	injection	drugs
drugs	drugs	laser

The first column presents the Cyriax physiotherapy participants' answers, the second one highlights the supervised exercise programme participants' answers and the last one presents the polarised polychromatic non-coherent light (Bioptron light) participants' answers.

APPENDIX XV

Occupations of participants

housework	housework	secreterial
housework	housework	secreterial
manual work	housework	manual
housework	manual	manual
secretarial	manual	housework
secretarial	secreterial	secreterial
housework	housework	secreterial
housework	housework	housework
secretarial	manual	housework
manual work	manual	manual
sport	secreterial	sport
manual work	secreterial	sport
manual work	secreterial	secreterial
housework	sport	secreterial
housework	secreterial	manual
secretarial	secreterial	housework
secretarial	secreterial	manual
manual work	housework	housework
secretarial	manual	secreterial
housework	housework	secreterial
manual work	manual	housework
secretarial	secreterial	housework
housework	secreterial	manual
secretarial	sport	manual
manual work	manual	manual

The first column presents the Cyriax physiotherapy participants' answers, the second one highlights the supervised exercise programme participants' answers and the last one presents the polarised polychromatic non-coherent light (Bioptron light) participants' answers.

APPENDIX XVI

Raw data and statistical tests pain on VAS (cm)

Gr	0w	4w	8w	16w	28w
1	7	3	3	3	2
1	7	3	3	3	2
1	8	4	3	3	3
1	7	2	2	3	2
1	6	3	3	3	3
1	7	2	2	2	2
1	7	2	2	2	2
1	7	3	2	2	2
1	7	2	2	3	3
1	6	3	2	2	2
1	6	3	2	2	1
1	8	2	2	1	1
1	8	5	4	4	3
1	7	4	4	3	3
1	7	3	3	2	2
1	7	4	3	3	3
1	6	2	2	3	3
1	5	3	3	2	2
1	9	3	3	2	2
1	7	3	3	1	0
1	7	2	2	2	1
1	8	3	3	3	2
1	7	2	2	2	1
1	7	2	2	2	1
1	6	3	3	2	1
2	8	2	2	2	2
2	8	3	2	2	2
2	7	2	2	1	1
2	6	1	0	0	0
2	6	2	2	1	0
2	7	2	1	1	0

2	6	2	2	1	0
2	5	1	0	0	0
2	7	2	2	1	1
2	8	3	2	1	1
2	7	3	2	1	1
2	8	3	3	2	1
2	7	2	2	2	1
2	8	2	2	1	0
2	7	1	1	1	1
2	7	3	3	1	1
2	6	1	1	1	0
2	7	2	2	2	2
2	8	3	2	2	2
2	8	3	2	1	2
2	7	2	1	1	2
2	6	2	1	0	1
2	6	3	2	0	0
2	6	2	2	1	1
2	7	3	2	2	2
3	7	4	3	3	3
3	7	3	3	3	3
3	8	4	3	3	3
3	8	5	4	3	3
3	7	4	4	3	3
3	7	3	3	3	3
3	6	3	3	2	2
3	6	3	2	2	2
3	6	3	3	3	2
3	5	3	3	3	2
3	8	4	4	3	3
3	8	3	3	3	3
3	7	3	3	3	2

3	7	4	3	3	3
3	8	4	4	4	3
3	7	3	3	3	3
3	7	3	3	3	3
3	7	4	3	3	2
3	6	2	2	2	2
3	8	4	3	3	3
3	7	3	3	3	3
3	7	3	3	2	2
3	7	3	3	3	3
3	7	2	2	2	2
3	7	3	3	3	3

Gr= group

0w= 0week

4w=4week

8w=8week

16w=16week

28w=28week

In Group column the 1=Cyriax physiotherapy group, the 2= Supervised exercise programme group and the 3=Polarised polychromatic non-coherent (Bioptron light) group

Descriptives

	GROUP			Statistic	Std. Error
PAIN0W	1	Mean		6,96	,168
		95% Confidence Interval for Mean	Lower Bound	6,61	
			Upper Bound	7,31	
		5% Trimmed Mean		6,96	
		Median		7,00	
		Variance		,707	
		Std. Deviation		,841	
		Minimum		5	
		Maximum		9	
		Range		4	
		Interquartile Range		,50	
		Skewness		,079	,464
		Kurtosis		,980	,902
	2	Mean		6,92	,172
		95% Confidence Interval for Mean	Lower Bound	6,56	
			Upper Bound	7,28	
		5% Trimmed Mean		6,96	
		Median		7,00	
		Variance		,743	
		Std. Deviation		,862	
		Minimum		5	
		Maximum		8	
		Range		3	
		Interquartile Range		2,00	
		Skewness		-,262	,464
		Kurtosis		-,690	,902
	3	Mean		7,00	,153
		95% Confidence Interval for Mean	Lower Bound	6,68	
			Upper Bound	7,32	
		5% Trimmed Mean		7,04	
		Median		7,00	
		Variance		,583	
		Std. Deviation		,764	
		Minimum		5	
		Maximum		8	
		Range		3	
		Interquartile Range		,50	
		Skewness		-,610	,464
		Kurtosis		,675	,902
PAIN4W	1	Mean		2,84	,160
		95% Confidence Interval for Mean	Lower Bound	2,51	
			Upper Bound	3,17	

315

		5% Trimmed Mean	2,78	
		Median	3,00	
		Variance	,640	
		Std. Deviation	,800	
		Minimum	2	
		Maximum	5	
		Range	3	
		Interquartile Range	1,00	
		Skewness	,838	,464
		Kurtosis	,726	,902
	2	Mean	2,20	,141
		95% Confidence Interval for Mean	Lower Bound	1,91	
			Upper Bound	2,49	
		5% Trimmed Mean	2,22	
		Median	2,00	
		Variance	,500	
		Std. Deviation	,707	
		Minimum	1	
		Maximum	3	
		Range	2	
		Interquartile Range	1,00	
		Skewness	-,307	,464
		Kurtosis	-,846	,902
	3	Mean	3,32	,138
		95% Confidence Interval for Mean	Lower Bound	3,04	
			Upper Bound	3,60	
		5% Trimmed Mean	3,31	
		Median	3,00	
		Variance	,477	
		Std. Deviation	,690	
		Minimum	2	
		Maximum	5	
		Range	3	
		Interquartile Range	1,00	
		Skewness	,303	,464
		Kurtosis	,329	,902
PAIN8W	1	Mean	2,60	,129
		95% Confidence Interval for Mean	Lower Bound	2,33	
			Upper Bound	2,87	
		5% Trimmed Mean	2,56	
		Median	3,00	
		Variance	,417	
		Std. Deviation	,645	
		Minimum	2	
		Maximum	4	
		Range	2	

		Interquartile Range		1,00	
		Skewness		,606	,464
		Kurtosis		-,480	,902
	2	Mean		1,72	,147
		95% Confidence Interval for Mean	Lower Bound	1,42	
			Upper Bound	2,02	
		5% Trimmed Mean		1,74	
		Median		2,00	
		Variance		,543	
		Std. Deviation		,737	
		Minimum		0	
		Maximum		3	
		Range		3	
		Interquartile Range		1,00	
		Skewness		-,848	,464
		Kurtosis		,994	,902
	3	Mean		3,04	,108
		95% Confidence Interval for Mean	Lower Bound	2,82	
			Upper Bound	3,26	
		5% Trimmed Mean		3,04	
		Median		3,00	
		Variance		,290	
		Std. Deviation		,539	
		Minimum		2	
		Maximum		4	
		Range		2	
		Interquartile Range		,00	
		Skewness		,047	,464
		Kurtosis		,981	,902
PAIN16W	1	Mean		2,40	,141
		95% Confidence Interval for Mean	Lower Bound	2,11	
			Upper Bound	2,69	
		5% Trimmed Mean		2,40	
		Median		2,00	
		Variance		,500	
		Std. Deviation		,707	
		Minimum		1	
		Maximum		4	
		Range		3	
		Interquartile Range		1,00	
		Skewness		,000	,464
		Kurtosis		-,024	,902
	2	Mean		1,12	,133
		95% Confidence Interval for Mean	Lower Bound	,85	
			Upper Bound	1,39	

317

		5% Trimmed Mean	1,13	
		Median	1,00	
		Variance	,443	
		Std. Deviation	,666	
		Minimum	0	
		Maximum	2	
		Range	2	
		Interquartile Range	1,00	
		Skewness	-,134	,464
		Kurtosis	-,557	,902
	3	Mean	2,84	,095
		95% Confidence Interval for Mean — Lower Bound	2,64	
		95% Confidence Interval for Mean — Upper Bound	3,04	
		5% Trimmed Mean	2,83	
		Median	3,00	
		Variance	,223	
		Std. Deviation	,473	
		Minimum	2	
		Maximum	4	
		Range	2	
		Interquartile Range	,00	
		Skewness	-,568	,464
		Kurtosis	1,213	,902
PAIN28W	1	Mean	1,96	,168
		95% Confidence Interval for Mean — Lower Bound	1,61	
		95% Confidence Interval for Mean — Upper Bound	2,31	
		5% Trimmed Mean	2,00	
		Median	2,00	
		Variance	,707	
		Std. Deviation	,841	
		Minimum	0	
		Maximum	3	
		Range	3	
		Interquartile Range	2,00	
		Skewness	-,378	,464
		Kurtosis	-,409	,902
	2	Mean	,96	,158
		95% Confidence Interval for Mean — Lower Bound	,63	
		95% Confidence Interval for Mean — Upper Bound	1,29	
		5% Trimmed Mean	,96	
		Median	1,00	
		Variance	,623	
		Std. Deviation	,790	
		Minimum	0	
		Maximum	2	
		Range	2	

		Interquartile Range	2,00	
		Skewness	,073	,464
		Kurtosis	-1,351	,902
3		Mean	2,64	,098
	95% Confidence Interval for Mean	Lower Bound	2,44	
		Upper Bound	2,84	
		5% Trimmed Mean	2,66	
		Median	3,00	
		Variance	,240	
		Std. Deviation	,490	
		Minimum	2	
		Maximum	3	
		Range	1	
		Interquartile Range	1,00	
		Skewness	-,621	,464
		Kurtosis	-1,762	,902

1= Cyriax physiotherapy group

2= Supervised exercise programme group

3= Polarised polychromatic non-coherent light (Bioptron light) group

0W=0 week

4W= 4 week

8W= 8week

16W= 16week

28W= 28 week

Pain on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 0

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	,080	2	,040	,059	,943
Within Groups	48,800	72	,678		
Total	48,880	74			

Descriptives for pain on VAS for the whole sample at week 0

			Statistic	Std. Error
PAIN0W	Mean		6,96	,094
	95% Confidence Interval for Mean	Lower Bound	6,77	
		Upper Bound	7,15	
	5% Trimmed Mean		6,99	
	Median		7,00	
	Variance		,661	
	Std. Deviation		,813	
	Minimum		5	
	Maximum		9	
	Range		4	
	Interquartile Range		1,00	
	Skewness		-,236	,277
	Kurtosis		,068	,548

Normal distribution of pain on VAS data

Std. Dev = ,81
Mean = 7,0
N = 75,00

PAIN0W
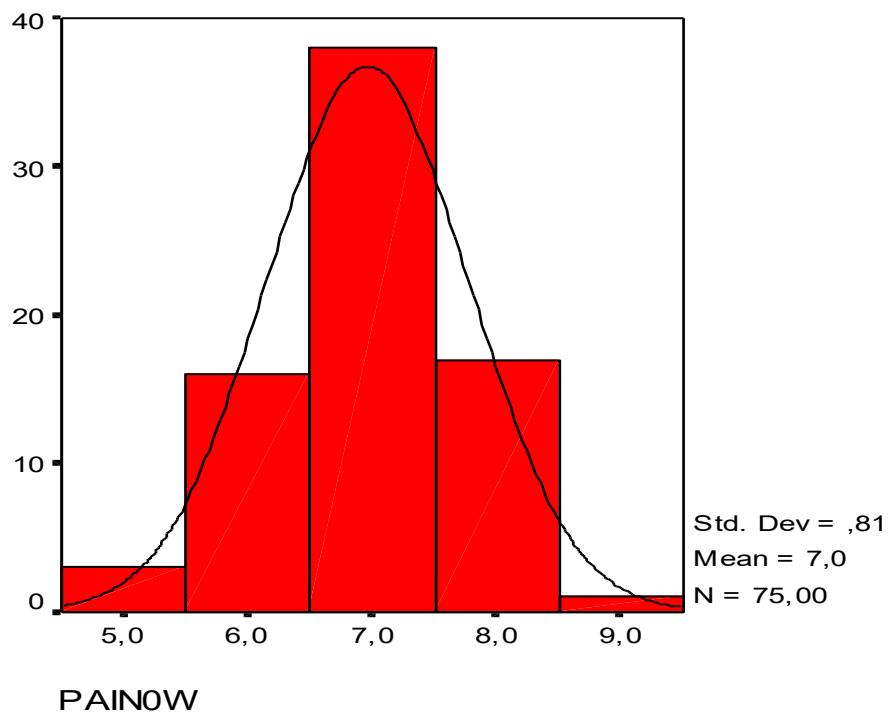
Paired t-test for pain on VAS from week 0 to week 4

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	GROUP & PAIN40	75	,193	,097

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	GROUP	2,00	75	,822	,095
	PAIN40	-4,17	75	,935	,108

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	GROUP - PAIN40	6,17	1,120	,129	5,92	6,43	47,755	74	,000

Pain on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 4

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	13,627	2	6,813	9,596	,000
Within Groups	51,120	72	,710		
Total	64,747	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	-,60(*)	,238	,042
	3	-1,04(*)	,238	,000
3	1	,44	,238	,207

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Pain on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 8

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	20,027	2	10,013	15,432	,000
Within Groups	46,720	72	,649		
Total	66,747	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	-,84(*)	,228	,001
	3	-1,24(*)	,228	,000
3	1	,40	,228	,250

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Pain on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 16

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	36,560	2	18,280	27,697	,000
Within Groups	47,520	72	,660		
Total	84,080	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	-1,24(*)	,230	,000
	3	-1,64(*)	,230	,000
3	1	,40	,230	,258

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Pain on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 28

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	32,427	2	16,213	22,143	,000
Within Groups	52,720	72	,732		
Total	85,147	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	-,96(*)	,242	,001
	3	-1,60(*)	,242	,000
3	1	,64(*)	,242	,030

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

APPENDIX XVII

Raw data and statistical tests of function on VAS (cm)

Gr	0w	4w	8w	16w	28w
1	3	7	7	8	8
1	3	8	8	8	8
1	4	8	8	9	9
1	3	7	7	8	8
1	5	8	8	8	8
1	5	7	7	8	8
1	4	7	7	7	6
1	3	6	7	7	7
1	5	8	8	8	8
1	5	9	9	9	9
1	3	7	7	7	8
1	3	6	7	8	7
1	3	5	7	8	7
1	4	7	7	7	8
1	4	8	8	7	7
1	5	8	8	8	8
1	6	8	8	8	8
1	3	6	7	8	9
1	4	6	6	7	7
1	3	6	6	7	8
1	4	7	7	7	8
1	5	8	7	7	7
1	6	9	9	9	9
1	3	6	6	7	8
1	2	6	7	7	7
2	4	8	8	9	9
2	4	8	9	9	9
2	3	8	8	8	8
2	5	9	9	9	9
2	5	8	9	9	9
2	5	9	9	8	9

2	4	8	8	8	8
2	4	7	9	9	9
2	3	8	8	8	8
2	4	8	8	8	8
2	4	7	8	7	8
2	4	8	8	8	7
2	5	9	10	10	9
2	3	7	8	8	8
2	3	7	8	8	8
2	3	7	7	8	8
2	4	8	8	8	9
2	4	8	9	9	9
2	4	7	7	8	9
2	3	8	8	9	9
2	5	8	9	9	9
2	4	8	8	8	9
2	3	7	7	8	8
2	4	8	8	8	8
2	4	7	7	8	8
3	5	8	8	8	8
3	4	7	7	7	7
3	4	7	7	7	7
3	4	6	7	7	7
3	3	6	6	7	8
3	4	6	6	6	7
3	4	7	7	7	7
3	3	6	7	7	7
3	3	6	6	7	7
3	5	7	7	7	8
3	3	6	6	7	7
3	2	5	6	7	7
3	4	7	7	7	8

3	4	7	7	7	7
3	4	7	8	8	8
3	4	6	7	7	7
3	4	7	7	7	7
3	4	7	7	7	7
3	5	8	8	8	8
3	4	7	7	7	7
3	5	7	8	8	8
3	4	7	7	7	7
3	4	7	7	7	7
3	5	8	8	8	7
3	4	7	7	8	8

Gr= group

0w= 0week

4w=4week

8w=8week

16w=16week

28w=28week

In Group column the 1=Cyriax physiotherapy group, the 2= Supervised exercise programme group and the 3=Polarised polychromatic non-coherent (Bioptron light) group

Descriptives

	GROUP			Statistic	Std. Error
FUN0W	1	Mean		3,92	,215
		95% Confidence Interval for Mean	Lower Bound	3,48	
			Upper Bound	4,36	
		5% Trimmed Mean		3,90	
		Median		4,00	
		Variance		1,160	
		Std. Deviation		1,077	
		Minimum		2	
		Maximum		6	
		Range		4	
		Interquartile Range		2,00	
		Skewness		,388	,464
		Kurtosis		-,776	,902
	2	Mean		3,92	,140
		95% Confidence Interval for Mean	Lower Bound	3,63	
			Upper Bound	4,21	
		5% Trimmed Mean		3,91	
		Median		4,00	
		Variance		,493	
		Std. Deviation		,702	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		1,00	
		Skewness		,112	,464
		Kurtosis		-,816	,902
	3	Mean		3,96	,147
		95% Confidence Interval for Mean	Lower Bound	3,66	
			Upper Bound	4,26	
		5% Trimmed Mean		4,00	
		Median		4,00	
		Variance		,540	
		Std. Deviation		,735	
		Minimum		2	
		Maximum		5	
		Range		3	
		Interquartile Range		,00	
		Skewness		-,621	,464
		Kurtosis		,991	,902
FUN4W	1	Mean		7,12	,211
		95% Confidence Interval for Mean	Lower Bound	6,69	
			Upper Bound	7,55	

		5% Trimmed Mean	7,12	
		Median	7,00	
		Variance	1,110	
		Std. Deviation	1,054	
		Minimum	5	
		Maximum	9	
		Range	4	
		Interquartile Range	2,00	
		Skewness	-,025	,464
		Kurtosis	-,765	,902
	2	Mean	7,80	,129
		95% Confidence Interval for Mean — Lower Bound	7,53	
		95% Confidence Interval for Mean — Upper Bound	8,07	
		5% Trimmed Mean	7,78	
		Median	8,00	
		Variance	,417	
		Std. Deviation	,645	
		Minimum	7	
		Maximum	9	
		Range	2	
		Interquartile Range	1,00	
		Skewness	,202	,464
		Kurtosis	-,480	,902
	3	Mean	6,76	,145
		95% Confidence Interval for Mean — Lower Bound	6,46	
		95% Confidence Interval for Mean — Upper Bound	7,06	
		5% Trimmed Mean	6,78	
		Median	7,00	
		Variance	,523	
		Std. Deviation	,723	
		Minimum	5	
		Maximum	8	
		Range	3	
		Interquartile Range	1,00	
		Skewness	-,312	,464
		Kurtosis	,312	,902
FUN8W	1	Mean	7,32	,160
		95% Confidence Interval for Mean — Lower Bound	6,99	
		95% Confidence Interval for Mean — Upper Bound	7,65	
		5% Trimmed Mean	7,30	
		Median	7,00	
		Variance	,643	
		Std. Deviation	,802	
		Minimum	6	
		Maximum	9	
		Range	3	

		Interquartile Range		1,00	
		Skewness		,383	,464
		Kurtosis		,034	,902
	2	Mean		8,20	,153
		95% Confidence Interval for Mean	Lower Bound	7,88	
			Upper Bound	8,52	
		5% Trimmed Mean		8,18	
		Median		8,00	
		Variance		,583	
		Std. Deviation		,764	
		Minimum		7	
		Maximum		10	
		Range		3	
		Interquartile Range		1,00	
		Skewness		,244	,464
		Kurtosis		-,005	,902
	3	Mean		7,00	,129
		95% Confidence Interval for Mean	Lower Bound	6,73	
			Upper Bound	7,27	
		5% Trimmed Mean		7,00	
		Median		7,00	
		Variance		,417	
		Std. Deviation		,645	
		Minimum		6	
		Maximum		8	
		Range		2	
		Interquartile Range		,00	
		Skewness		,000	,464
		Kurtosis		-,332	,902
FUN16W	1	Mean		7,68	,138
		95% Confidence Interval for Mean	Lower Bound	7,40	
			Upper Bound	7,96	
		5% Trimmed Mean		7,64	
		Median		8,00	
		Variance		,477	
		Std. Deviation		,690	
		Minimum		7	
		Maximum		9	
		Range		2	
		Interquartile Range		1,00	
		Skewness		,523	,464
		Kurtosis		-,688	,902
	2	Mean		8,36	,128
		95% Confidence Interval for Mean	Lower Bound	8,10	
			Upper Bound	8,62	

		5% Trimmed Mean		8,34	
		Median		8,00	
		Variance		,407	
		Std. Deviation		,638	
		Minimum		7	
		Maximum		10	
		Range		3	
		Interquartile Range		1,00	
		Skewness		,575	,464
		Kurtosis		,549	,902
	3	Mean		7,20	,100
		95% Confidence Interval for Mean	Lower Bound	6,99	
			Upper Bound	7,41	
		5% Trimmed Mean		7,21	
		Median		7,00	
		Variance		,250	
		Std. Deviation		,500	
		Minimum		6	
		Maximum		8	
		Range		2	
		Interquartile Range		,50	
		Skewness		,435	,464
		Kurtosis		,490	,902
FUN28W	1	Mean		7,80	,153
		95% Confidence Interval for Mean	Lower Bound	7,48	
			Upper Bound	8,12	
		5% Trimmed Mean		7,82	
		Median		8,00	
		Variance		,583	
		Std. Deviation		,764	
		Minimum		6	
		Maximum		9	
		Range		3	
		Interquartile Range		1,00	
		Skewness		-,244	,464
		Kurtosis		-,005	,902
	2	Mean		8,48	,117
		95% Confidence Interval for Mean	Lower Bound	8,24	
			Upper Bound	8,72	
		5% Trimmed Mean		8,52	
		Median		9,00	
		Variance		,343	
		Std. Deviation		,586	
		Minimum		7	
		Maximum		9	
		Range		2	

		Interquartile Range	1,00	
		Skewness	-,592	,464
		Kurtosis	-,540	,902
3		Mean	7,32	,095
	95% Confidence Interval for Mean	Lower Bound	7,12	
		Upper Bound	7,52	
		5% Trimmed Mean	7,30	
		Median	7,00	
		Variance	,227	
		Std. Deviation	,476	
		Minimum	7	
		Maximum	8	
		Range	1	
		Interquartile Range	1,00	
		Skewness	,822	,464
		Kurtosis	-1,447	,902

1= Cyriax physiotherapy group

2= Supervised exercise programme group

3= Polarised polychromatic non-coherent light (Bioptron light) group

0W=0 week

4W= 4 week

8W= 8week

16W= 16week

28W= 28 week

Function on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 0

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	,027	2	,013	,018	,982
Within Groups	52,640	72	,731		
Total	52,667	74			

Descriptives for f function on VAS for the whole sample at week 0

			Statistic	Std. Error
FUN0W	Mean		3,93	,097
	95% Confidence Interval for Mean	Lower Bound	3,74	
		Upper Bound	4,13	
	5% Trimmed Mean		3,93	
	Median		4,00	
	Variance		,712	
	Std. Deviation		,844	
	Minimum		2	
	Maximum		6	
	Range		4	
	Interquartile Range		1,00	
	Skewness		,128	,277
	Kurtosis		-,201	,548

Normal distribution of function on VAS data

Std. Dev = ,84
Mean = 3,9
N = 75,00

FUN0W
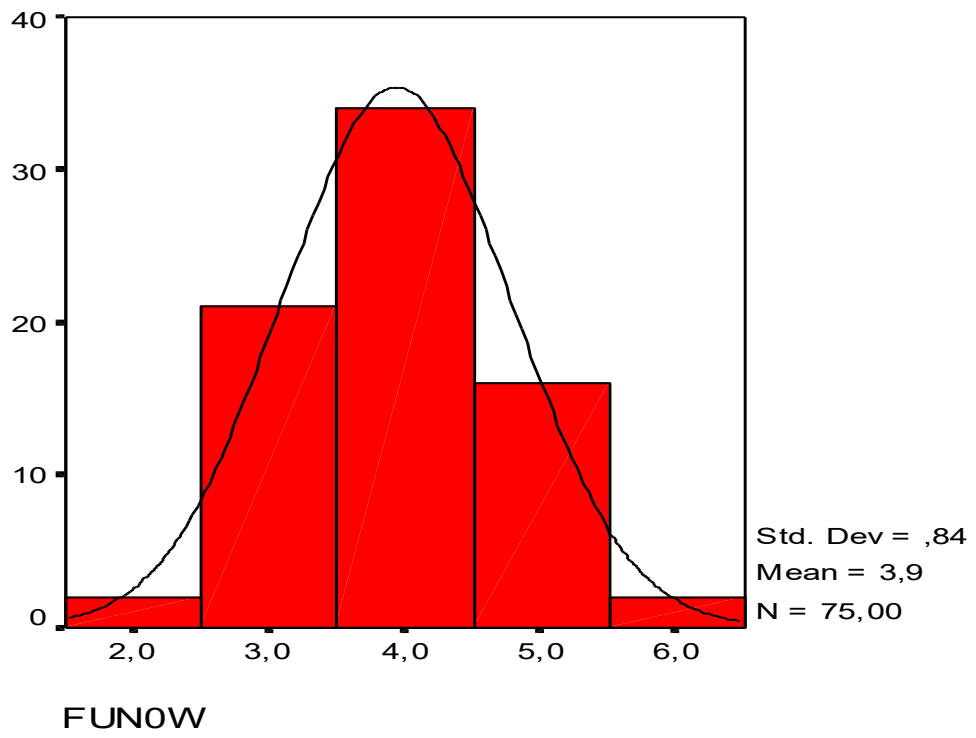
Paired t-test for function on VAS from week 0 to week 4

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	GROUP	2,00	75	,822	,095
	FUN40	3,29	75	,749	,087

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	GROUP & FUN40	75	-,219	,059

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	GROUP - FUN40	-1,29	1,228	,142	-1,58	-1,01	-9,123	74	,000

Function on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 4

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	14,907	2	7,453	20,144	,000
Within Groups	26,640	72	,370		
Total	41,547	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	,68(*)	,172	,001
	3	1,08(*)	,172	,000
3	1	-,40	,172	,069

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Function on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 8

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	20,347	2	10,173	22,890	,000
Within Groups	32,000	72	,444		
Total	52,347	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	,88(*)	,189	,000
	3	1,24(*)	,189	,000
3	1	-,36	,189	,181

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Function on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 16

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	18,107	2	9,053	13,787	,000
Within Groups	47,280	72	,657		
Total	65,387	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	,68(*)	,229	,012
	3	1,20(*)	,229	,000
3	1	-,52	,229	,079

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Function on VAS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 28

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	18,107	2	9,053	12,402	,000
Within Groups	52,560	72	,730		
Total	70,667	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	,68(*)	,242	,019
	3	1,20(*)	,242	,000
3	1	-,52	,242	,104

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

APPENDIX XVIII

Raw data and statistical tests of PFGS (pounds)

Gr	0w	4w	8w	16w	28w
1	22	45	49	50	50
1	20	43	45	45	43
1	25	57	56	55	55
1	24	70	73	75	75
1	23	78	80	80	82
1	26	55	57	58	56
1	25	70	75	76	75
1	30	90	91	94	93
1	22	60	60	63	63
1	33	68	67	70	70
1	25	78	75	75	75
1	27	49	54	55	57
1	28	45	47	52	54
1	25	59	57	63	65
1	29	70	72	75	77
1	36	90	91	94	95
1	40	90	88	86	86
1	24	73	75	77	77
1	25	75	75	77	78
1	22	65	65	66	69
1	21	49	52	50	54
1	20	60	62	60	65
1	20	67	65	51	53
1	26	80	81	81	84
1	27	77	75	73	75
2	23	70	72	71	72
2	24	73	74	75	75
2	27	77	75	75	75
2	21	55	59	62	65
2	25	67	70	70	71
2	22	68	72	75	77

2	25	59	63	65	63
2	31	79	84	85	85
2	25	63	66	65	65
2	22	67	65	69	66
2	24	79	86	84	85
2	28	80	84	83	85
2	27	78	80	85	85
2	31	94	95	95	93
2	34	97	95	94	95
2	40	103	107	104	105
2	22	70	73	75	75
2	25	69	70	74	75
2	21	56	58	64	69
2	25	67	65	66	67
2	26	79	77	78	78
2	27	82	83	83	85
2	24	69	71	74	75
2	25	73	77	76	77
2	24	70	69	70	73
3	26	60	62	61	61
3	25	62	63	65	65
3	30	70	71	70	70
3	22	47	50	54	55
3	24	67	69	68	67
3	25	65	66	66	67
3	25	66	68	69	70
3	36	73	75	75	75
3	26	59	62	64	65
3	21	53	55	58	60
3	26	60	61	64	65
3	25	62	65	63	65
3	28	68	70	74	74

3	27	67	67	70	71
3	28	66	68	70	73
3	25	70	72	74	63
3	24	57	59	63	65
3	23	55	56	58	60
3	25	68	68	65	65
3	27	64	65	65	64
3	26	66	66	63	63
3	28	70	68	65	62
3	25	62	60	64	66
3	26	61	60	64	61
3	29	61	63	65	63

Gr= group

0w= 0week

4w=4week

8w=8week

16w=16week

28w=28week

In Group column the 1=Cyriax physiotherapy group, the 2=Supervised exercise programme group and the 3=Polarised polychromatic non-coherent (Bioptron light) group

Descriptives

	GROUP			Statistic	Std. Error
PFGS0W	1	Mean		25,80	,981
		95% Confidence Interval for Mean	Lower Bound	23,77	
			Upper Bound	27,83	
		5% Trimmed Mean		25,38	
		Median		25,00	
		Variance		24,083	
		Std. Deviation		4,907	
		Minimum		20	
		Maximum		40	
		Range		20	
		Interquartile Range		5,50	
		Skewness		1,350	,464
		Kurtosis		2,053	,902
	2	Mean		25,92	,862
		95% Confidence Interval for Mean	Lower Bound	24,14	
			Upper Bound	27,70	
		5% Trimmed Mean		25,48	
		Median		25,00	
		Variance		18,577	
		Std. Deviation		4,310	
		Minimum		21	
		Maximum		40	
		Range		19	
		Interquartile Range		3,50	
		Skewness		1,763	,464
		Kurtosis		3,864	,902
	3	Mean		26,08	,583
		95% Confidence Interval for Mean	Lower Bound	24,88	
			Upper Bound	27,28	
		5% Trimmed Mean		25,87	
		Median		26,00	
		Variance		8,493	
		Std. Deviation		2,914	
		Minimum		21	
		Maximum		36	
		Range		15	
		Interquartile Range		2,50	
		Skewness		1,517	,464
		Kurtosis		4,832	,902
PFGS4W	1	Mean		66,52	2,835
		95% Confidence Interval for Mean	Lower Bound	60,67	
			Upper Bound	72,37	

349

		5% Trimmed Mean	66,50	
		Median	68,00	
		Variance	200,927	
		Std. Deviation	14,175	
		Minimum	43	
		Maximum	90	
		Range	47	
		Interquartile Range	21,50	
		Skewness	-,010	,464
		Kurtosis	-,823	,902
	2	Mean	73,76	2,339
		95% Confidence Interval for Mean	Lower Bound	68,93	
			Upper Bound	78,59	
		5% Trimmed Mean	73,23	
		Median	70,00	
		Variance	136,773	
		Std. Deviation	11,695	
		Minimum	55	
		Maximum	103	
		Range	48	
		Interquartile Range	12,00	
		Skewness	,822	,464
		Kurtosis	,855	,902
	3	Mean	63,16	1,198
		95% Confidence Interval for Mean	Lower Bound	60,69	
			Upper Bound	65,63	
		5% Trimmed Mean	63,48	
		Median	64,00	
		Variance	35,890	
		Std. Deviation	5,991	
		Minimum	47	
		Maximum	73	
		Range	26	
		Interquartile Range	7,50	
		Skewness	-,817	,464
		Kurtosis	,863	,902
PFGS8W	1	Mean	67,48	2,689
		95% Confidence Interval for Mean	Lower Bound	61,93	
			Upper Bound	73,03	
		5% Trimmed Mean	67,40	
		Median	67,00	
		Variance	180,760	
		Std. Deviation	13,445	
		Minimum	45	
		Maximum	91	
		Range	46	

350

		Interquartile Range		18,50	
		Skewness		,086	,464
		Kurtosis		-,878	,902
	2	Mean		75,60	2,342
		95% Confidence Interval for Mean	Lower Bound	70,77	
			Upper Bound	80,43	
		5% Trimmed Mean		74,96	
		Median		73,00	
		Variance		137,083	
		Std. Deviation		11,708	
		Minimum		58	
		Maximum		107	
		Range		49	
		Interquartile Range		16,00	
		Skewness		,909	,464
		Kurtosis		,903	,902
	3	Mean		64,36	1,149
		95% Confidence Interval for Mean	Lower Bound	61,99	
			Upper Bound	66,73	
		5% Trimmed Mean		64,54	
		Median		65,00	
		Variance		32,990	
		Std. Deviation		5,744	
		Minimum		50	
		Maximum		75	
		Range		25	
		Interquartile Range		7,50	
		Skewness		-,552	,464
		Kurtosis		,383	,902
PFGS16W	1	Mean		68,04	2,790
		95% Confidence Interval for Mean	Lower Bound	62,28	
			Upper Bound	73,80	
		5% Trimmed Mean		67,82	
		Median		70,00	
		Variance		194,540	
		Std. Deviation		13,948	
		Minimum		45	
		Maximum		94	
		Range		49	
		Interquartile Range		22,00	
		Skewness		,141	,464
		Kurtosis		-,865	,902
	2	Mean		76,68	2,092
		95% Confidence Interval for Mean	Lower Bound	72,36	
			Upper Bound	81,00	

351

		5% Trimmed Mean	76,06	
		Median	75,00	
		Variance	109,393	
		Std. Deviation	10,459	
		Minimum	62	
		Maximum	104	
		Range	42	
		Interquartile Range	14,00	
		Skewness	,906	,464
		Kurtosis	,640	,902
	3	Mean	65,48	1,007
		95% Confidence Interval for Mean	Lower Bound	63,40	
			Upper Bound	67,56	
		5% Trimmed Mean	65,56	
		Median	65,00	
		Variance	25,343	
		Std. Deviation	5,034	
		Minimum	54	
		Maximum	75	
		Range	21	
		Interquartile Range	6,50	
		Skewness	-,022	,464
		Kurtosis	,282	,902
PFGS28W	1	Mean	69,04	2,772
		95% Confidence Interval for Mean	Lower Bound	63,32	
			Upper Bound	74,76	
		5% Trimmed Mean	68,99	
		Median	70,00	
		Variance	192,040	
		Std. Deviation	13,858	
		Minimum	43	
		Maximum	95	
		Range	52	
		Interquartile Range	22,00	
		Skewness	,028	,464
		Kurtosis	-,781	,902
	2	Mean	77,44	2,060
		95% Confidence Interval for Mean	Lower Bound	73,19	
			Upper Bound	81,69	
		5% Trimmed Mean	76,80	
		Median	75,00	
		Variance	106,090	
		Std. Deviation	10,300	
		Minimum	63	
		Maximum	105	
		Range	42	

		Interquartile Range	15,00	
		Skewness	,895	,464
		Kurtosis	,749	,902
3		Mean	65,40	,949
	95% Confidence Interval for Mean	Lower Bound	63,44	
		Upper Bound	67,36	
		5% Trimmed Mean	65,40	
		Median	65,00	
		Variance	22,500	
		Std. Deviation	4,743	
		Minimum	55	
		Maximum	75	
		Range	20	
		Interquartile Range	6,00	
		Skewness	,273	,464
		Kurtosis	,135	,902

1= Cyriax physiotherapy group

2= Supervised exercise programme group

3= Polarised polychromatic non-coherent light (Bioptron light) group

0W=0 week

4W= 4 week

8W= 8week

16W= 16week

28W= 28 week

PFGS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 0

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	,987	2	,493	,029	,971
Within Groups	1227,680	72	17,051		
Total	1228,667	74			

Descriptives for PFGS for the whole sample at week 0

			Statistic	Std. Error
PFGS0W	Mean		25,93	,471
	95% Confidence Interval for Mean	Lower Bound	25,00	
		Upper Bound	26,87	
	5% Trimmed Mean		25,57	
	Median		25,00	
	Variance		16,604	
	Std. Deviation		4,075	
	Minimum		20	
	Maximum		40	
	Range		20	
	Interquartile Range		3,00	
	Skewness		1,500	,277
	Kurtosis		3,032	,548

Normal distribution of PFGS data

Std. Dev = 4,07
Mean = 25,9
N = 75,00

PFGS0W
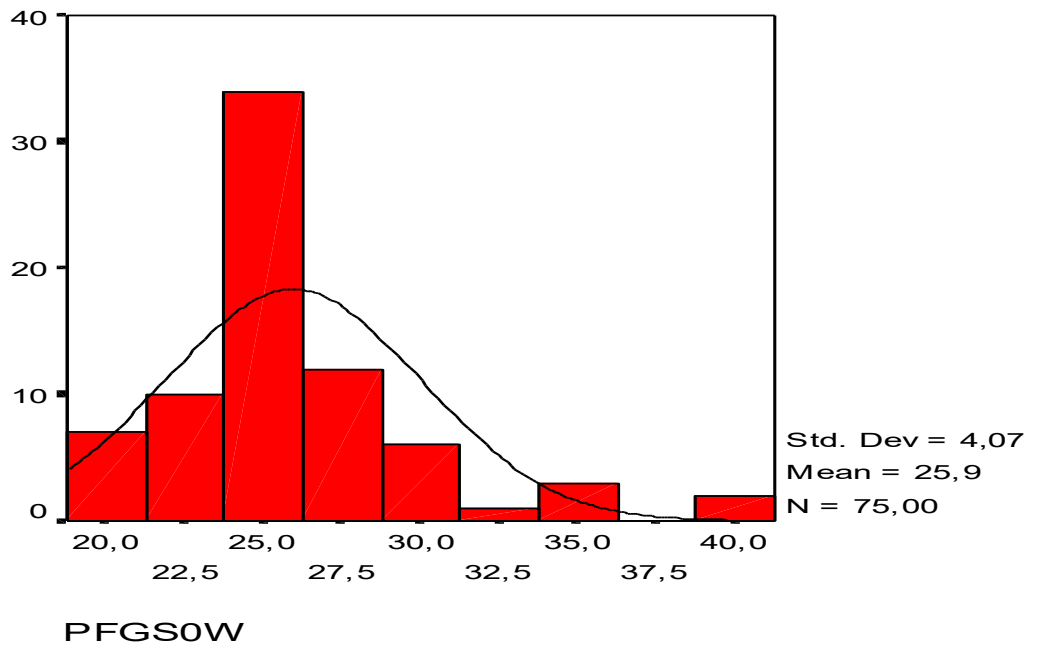
Paired t-test for PFGS from week 0 to week 4

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	GROUP	2,00	75	,822	,095
	PFGS40	41,88	75	9,792	1,131

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	GROUP & PFGS40	75	-,153	,191

Paired Samples Test

		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	GROUP - PFGS40	-39,88	9,951	1,149	-42,17	-37,59	-34,707	74	,000

PFGS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 4

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1497,680	2	748,840	9,631	,000
Within Groups	5598,240	72	77,753		
Total	7095,920	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	7,12(*)	2,494	,017
	3	10,76(*)	2,494	,000
3	1	-3,64	2,494	,446

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

PFGS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 8

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1712,667	2	856,333	11,862	,000
Within Groups	5197,920	72	72,193		
Total	6910,587	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	8,00(*)	2,403	,004
	3	11,40(*)	2,403	,000
3	1	-3,40	2,403	,484

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

PFGS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 16

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1747,547	2	873,773	13,208	,000
Within Groups	4763,120	72	66,154		
Total	6510,667	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	8,52(*)	2,301	,001
	3	11,36(*)	2,301	,000
3	1	-2,84	2,301	,663

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

PFGS for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 28

One Way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1939,707	2	969,853	14,688	,000
Within Groups	4754,240	72	66,031		
Total	6693,947	74			

Bonferroni post-hoc test

(I) GROUP	(J) GROUP	Mean Difference (I-J)	Std. Error	Sig.
2	1	8,28(*)	2,298	,002
	3	12,20(*)	2,298	,000
3	1	-3,92	2,298	,277

* The mean difference is significant at the .05 level

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

APPENDIX XIX

Raw data and statistical tests of eight-item pain free function questionnaire ("no" answers)

Gr	0w	4w	8w	16w	28w
1	0	6	6	6	6
1	0	5	6	7	7
1	0	6	6	6	6
1	0	4	5	5	5
1	0	5	5	5	5
1	0	7	7	7	7
1	0	8	8	8	8
1	0	6	6	6	6
1	0	8	8	8	8
1	0	6	6	6	6
1	0	5	6	6	6
1	0	4	4	6	6
1	0	6	6	6	6
1	0	4	5	5	5
1	0	5	5	5	5
1	0	7	7	7	7
1	0	8	8	8	8
1	0	8	8	8	8
1	0	6	6	6	6
1	0	4	4	5	5
1	0	5	6	6	6
1	0	4	4	5	5
1	0	5	6	6	6
1	0	6	6	6	6
1	0	6	7	7	7
2	0	6	6	7	7
2	0	6	6	6	6
2	0	6	7	7	7
2	0	6	6	6	7
2	0	6	6	7	7
2	0	7	8	8	8

2	0	8	8	8	8
2	0	8	8	8	8
2	0	8	8	8	8
2	0	6	6	6	8
2	0	7	7	7	7
2	0	6	6	6	6
2	0	6	7	7	7
2	0	6	6	8	8
2	0	7	7	7	7
2	0	8	8	8	8
2	0	8	8	8	8
2	0	8	8	8	8
2	0	7	7	7	7
2	0	5	7	7	7
2	0	6	6	6	8
2	0	4	6	7	7
2	0	5	6	6	7
2	0	7	7	7	7
2	0	8	8	8	8
3	0	5	5	6	6
3	0	5	5	6	6
3	0	4	6	6	7
3	0	4	6	6	6
3	0	5	5	6	6
3	0	6	6	6	7
3	0	6	7	7	7
3	0	6	6	6	6
3	0	7	7	7	7
3	0	5	6	6	6
3	0	5	6	6	6
3	0	3	4	5	6
3	0	6	6	6	6

3	0	4	6	6	6
3	0	5	5	5	5
3	0	5	6	6	6
3	0	6	6	6	6
3	0	6	6	6	6
3	0	6	6	6	6
3	0	4	4	5	6
3	0	4	5	5	5
3	0	4	6	6	6
3	0	5	5	6	6
3	0	5	6	6	6
3	0	4	6	7	7

Gr= group

0w= 0week

4w=4week

8w=8week

16w=16week

28w=28week

In Group column the 1=Cyriax physiotherapy group, the 2=Supervised exercise programme group and the 3=Polarised polychromatic non-coherent (Bioptron light) group

Descriptives(a,b,c)

	GROUP			Statistic	Std. Error
EIPFQ4	1	Mean		5,76	,266
		95% Confidence Interval for Mean	Lower Bound	5,21	
			Upper Bound	6,31	
		5% Trimmed Mean		5,73	
		Median		6,00	
		Variance		1,773	
		Std. Deviation		1,332	
		Minimum		4	
		Maximum		8	
		Range		4	
		Interquartile Range		1,50	
		Skewness		,364	,464
		Kurtosis		-,769	,902
	2	Mean		6,60	,224
		95% Confidence Interval for Mean	Lower Bound	6,14	
			Upper Bound	7,06	
		5% Trimmed Mean		6,66	
		Median		6,00	
		Variance		1,250	
		Std. Deviation		1,118	
		Minimum		4	
		Maximum		8	
		Range		4	
		Interquartile Range		2,00	
		Skewness		-,272	,464
		Kurtosis		-,431	,902
	3	Mean		5,00	,191
		95% Confidence Interval for Mean	Lower Bound	4,60	
			Upper Bound	5,40	
		5% Trimmed Mean		5,00	
		Median		5,00	
		Variance		,917	
		Std. Deviation		,957	
		Minimum		3	
		Maximum		7	
		Range		4	
		Interquartile Range		2,00	
		Skewness		,000	,464
		Kurtosis		-,485	,902
EIPFQ8	1	Mean		6,04	,241
		95% Confidence Interval for Mean	Lower Bound	5,54	
			Upper Bound	6,54	
		5% Trimmed Mean		6,04	
		Median		6,00	
		Variance		1,457	
		Std. Deviation		1,207	
		Minimum		4	
		Maximum		8	
		Range		4	
		Interquartile Range		2,00	

		Skewness		,072	,464
		Kurtosis		-,433	,902
	2	Mean		6,92	,172
		95% Confidence Interval for Mean	Lower Bound	6,56	
			Upper Bound	7,28	
		5% Trimmed Mean		6,91	
		Median		7,00	
		Variance		,743	
		Std. Deviation		,862	
		Minimum		6	
		Maximum		8	
		Range		2	
		Interquartile Range		2,00	
		Skewness		,162	,464
		Kurtosis		-1,667	,902
	3	Mean		5,68	,150
		95% Confidence Interval for Mean	Lower Bound	5,37	
			Upper Bound	5,99	
		5% Trimmed Mean		5,70	
		Median		6,00	
		Variance		,560	
		Std. Deviation		,748	
		Minimum		4	
		Maximum		7	
		Range		3	
		Interquartile Range		1,00	
		Skewness		-,679	,464
		Kurtosis		,586	,902
EIPFQ16	1	Mean		6,24	,202
		95% Confidence Interval for Mean	Lower Bound	5,82	
			Upper Bound	6,66	
		5% Trimmed Mean		6,21	
		Median		6,00	
		Variance		1,023	
		Std. Deviation		1,012	
		Minimum		5	
		Maximum		8	
		Range		3	
		Interquartile Range		1,50	
		Skewness		,524	,464
		Kurtosis		-,658	,902
	2	Mean		7,12	,156
		95% Confidence Interval for Mean	Lower Bound	6,80	
			Upper Bound	7,44	
		5% Trimmed Mean		7,13	

		Median	7,00	
		Variance	,610	
		Std. Deviation	,781	
		Minimum	6	
		Maximum	8	
		Range	2	
		Interquartile Range	1,50	
		Skewness	-,220	,464
		Kurtosis	-1,280	,902
	3	Mean	5,96	,108
		95% Confidence Interval for Mean — Lower Bound	5,74	
		95% Confidence Interval for Mean — Upper Bound	6,18	
		5% Trimmed Mean	5,96	
		Median	6,00	
		Variance	,290	
		Std. Deviation	,539	
		Minimum	5	
		Maximum	7	
		Range	2	
		Interquartile Range	,00	
		Skewness	-,047	,464
		Kurtosis	,981	,902
EIPFQ28	1	Mean	6,24	,202
		95% Confidence Interval for Mean — Lower Bound	5,82	
		95% Confidence Interval for Mean — Upper Bound	6,66	
		5% Trimmed Mean	6,21	
		Median	6,00	
		Variance	1,023	
		Std. Deviation	1,012	
		Minimum	5	
		Maximum	8	
		Range	3	
		Interquartile Range	1,50	
		Skewness	,524	,464
		Kurtosis	-,658	,902
	2	Mean	7,36	,128
		95% Confidence Interval for Mean — Lower Bound	7,10	
		95% Confidence Interval for Mean — Upper Bound	7,62	
		5% Trimmed Mean	7,40	
		Median	7,00	
		Variance	,407	
		Std. Deviation	,638	
		Minimum	6	
		Maximum	8	
		Range	2	
		Interquartile Range	1,00	

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		Skewness		-,473	,464
		Kurtosis		-,538	,902
	3	Mean		6,12	,105
		95% Confidence Interval for Mean	Lower Bound	5,90	
			Upper Bound	6,34	
		5% Trimmed Mean		6,13	
		Median		6,00	
		Variance		,277	
		Std. Deviation		,526	
		Minimum		5	
		Maximum		7	
		Range		2	
		Interquartile Range		,00	
		Skewness		,176	,464
		Kurtosis		,885	,902

a EIPFQ0W is constant when GROUP = 1. It has been omitted.

b EIPFQ0W is constant when GROUP = 2. It has been omitted.

c EIPFQ0W is constant when GROUP = 3. It has been omitted.

1= Cyriax physiotherapy group

2= Supervised exercise programme group

3= Polarised polychromatic non-coherent light (Bioptron light) group

0W=0 week

4W= 4 week

8W= 8week

16W= 16week

28W= 28 week

"No" answers of eight-item pain free function questionnaire for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 0

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	38,00
2	25	38,00
3	25	38,00
Total	75	

Test statistics[a,b]

Chi-Square	,000
df	2
Asymp. Sig.	1,000

a Kruskal Wallis Test

b Grouping Variable: GROUP

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

"No" answers of eight-item pain free function questionnaire for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 4

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	37,52
2	25	51,40
3	25	25,08
Total	75	

Test statistics[a,b]

Chi-Square	18,286
df	2
Asymp. Sig.	,000

a Kruskal Wallis Test

b Grouping Variable: GROUP

Mann-Whitney test

	1 Vs 2	1 Vs 3	2 Vs 3
Mann-Whitney U	195,500	214,500	93,000
Wilcoxon W	520,500	539,500	418,000
Z	-2,348	-1,970	-4,388
Asymp. Sig. (2-tailed)	,049	,109	,000

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

"No" answers of eight-item pain free function questionnaire for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 8

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	35,96
2	25	52,64
3	25	25,40
Total	75	

Test statistics[a,b]

Chi-Square	18,899
df	2
Asymp. Sig.	,000

a Kruskal Wallis Test

b Grouping Variable: GROUP

Mann-Whitney test

	1 Vs 2	1 Vs 3	2 Vs 3
Mann-Whitney U	179,500	259,500	102,000
Wilcoxon W	504,500	584,500	427,000
Z	-2,715	-1,116	-4,395
Asymp. Sig. (2-tailed)	,007	,264	,000

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

"No" answers of eight-item pain free function questionnaire for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 16

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	34,90
2	25	54,16
3	25	24,94
Total	75	

Test statistics[a,b]

Chi-Square	23,276
df	2
Asymp. Sig.	,000

a Kruskal Wallis Test

b Grouping Variable: GROUP

Mann-Whitney test

	1 Vs 2	1 Vs 3	2 Vs 3
Mann-Whitney U	159,000	276,000	87,000
Wilcoxon W	484,000	601,000	412,000
Z	-3,105	-,795	-4,702
Asymp. Sig. (2-tailed)	,002	,427	,000

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

"No" answers of eight-item pain free function questionnaire for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups from week 0 to week 28

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	35,88
2	25	54,06
3	25	24,06
Total	75	

Test statistics[a,b]

Chi-Square	24,078
df	2
Asymp. Sig.	,000

a Kruskal Wallis Test

b Grouping Variable: GROUP

Mann-Whitney test

	1 Vs 2	1 Vs 3	2 Vs 3
Mann-Whitney U	121,000	308,000	58,000
Wilcoxon W	446,000	633,000	383,500
Z	-3,871	-,098	-5,245
Asymp. Sig. (2-tailed)	,000	,922	,000

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

APPENDIX XX

Raw data and statistical test of global measure of improvement (5-point scale)

Gr	4w	8w	16w	28w
1	3	3	3	3
1	3	4	4	4
1	4	4	4	4
1	4	4	4	4
1	5	5	5	5
1	3	4	5	5
1	5	5	5	5
1	4	4	4	4
1	4	5	5	5
1	4	4	4	4
1	3	3	3	3
1	3	3	3	3
1	5	5	5	5
1	3	3	4	4
1	5	5	5	5
1	4	4	4	4
1	4	5	5	5
1	4	4	4	4
1	5	5	5	5
1	3	3	3	3
1	3	4	4	4
1	4	4	4	4
1	5	5	5	5
1	3	3	3	3
1	4	4	4	4
2	4	4	4	4
2	4	4	5	5
2	5	5	5	5
2	3	4	4	4
2	5	5	5	5
2	4	4	4	4

2	4	4	4	4
2	5	5	5	5
2	3	3	4	4
2	4	4	4	4
2	4	4	4	4
2	5	5	5	5
2	3	3	4	4
2	4	4	4	4
2	4	4	4	4
2	5	5	5	5
2	3	4	4	5
2	4	5	5	5
2	4	4	4	4
2	5	5	5	5
2	5	5	5	5
2	4	4	4	4
2	4	4	4	4
2	3	4	4	4
2	5	5	5	5
3	3	3	3	3
3	3	4	4	4
3	4	4	4	4
3	4	4	4	4
3	3	3	3	3
3	5	5	5	5
3	3	3	4	4
3	4	4	4	4
3	3	3	3	3
3	4	4	5	5
3	3	3	3	3
3	5	5	5	5
3	4	4	4	4

3	4	4	5	5
3	4	4	4	4
3	3	4	5	5
3	3	3	3	3
3	5	5	5	5
3	3	3	3	5
3	3	3	4	4
3	4	4	4	4
3	4	4	4	4
3	3	3	3	3
3	4	4	5	5
3	4	4	4	4

Gr= group

4w=4week

8w=8week

16w=16week

28w=28week

3=somewhat better

4=much better

5=no pain

In Group column the 1=Cyriax physiotherapy group, the 2=Supervised exercise programme group and the 3=Polarised polychromatic non-coherent (Bioptron light) group

Descriptives

	GROUP			Statistic	Std. Error
RELIEF4W	1	Mean		3,88	,156
		95% Confidence Interval for Mean	Lower Bound	3,56	
			Upper Bound	4,20	
		5% Trimmed Mean		3,87	
		Median		4,00	
		Variance		,610	
		Std. Deviation		,781	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		1,50	
		Skewness		,220	,464
		Kurtosis		-1,280	,902
	2	Mean		4,12	,145
		95% Confidence Interval for Mean	Lower Bound	3,82	
			Upper Bound	4,42	
		5% Trimmed Mean		4,13	
		Median		4,00	
		Variance		,527	
		Std. Deviation		,726	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		1,00	
		Skewness		-,189	,464
		Kurtosis		-,971	,902
	3	Mean		3,68	,138
		95% Confidence Interval for Mean	Lower Bound	3,40	
			Upper Bound	3,96	
		5% Trimmed Mean		3,64	
		Median		4,00	
		Variance		,477	
		Std. Deviation		,690	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		1,00	
		Skewness		,523	,464
		Kurtosis		-,688	,902
RELIEF8W	1	Mean		4,08	,152
		95% Confidence Interval for Mean	Lower Bound	3,77	
			Upper Bound	4,39	

379

		5% Trimmed Mean	4,09	
		Median	4,00	
		Variance	,577	
		Std. Deviation	,759	
		Minimum	3	
		Maximum	5	
		Range	2	
		Interquartile Range	1,50	
		Skewness	-,138	,464
		Kurtosis	-1,179	,902
	2	Mean	4,28	,123
		95% Confidence Interval for Mean	Lower Bound	4,03	
			Upper Bound	4,53	
		5% Trimmed Mean	4,31	
		Median	4,00	
		Variance	,377	
		Std. Deviation	,614	
		Minimum	3	
		Maximum	5	
		Range	2	
		Interquartile Range	1,00	
		Skewness	-,224	,464
		Kurtosis	-,445	,902
	3	Mean	3,76	,133
		95% Confidence Interval for Mean	Lower Bound	3,49	
			Upper Bound	4,03	
		5% Trimmed Mean	3,73	
		Median	4,00	
		Variance	,440	
		Std. Deviation	,663	
		Minimum	3	
		Maximum	5	
		Range	2	
		Interquartile Range	1,00	
		Skewness	,302	,464
		Kurtosis	-,612	,902
RELIEF16	1	Mean	4,16	,149
		95% Confidence Interval for Mean	Lower Bound	3,85	
			Upper Bound	4,47	
		5% Trimmed Mean	4,18	
		Median	4,00	
		Variance	,557	
		Std. Deviation	,746	
		Minimum	3	
		Maximum	5	
		Range	2	

		Interquartile Range		1,00	
		Skewness		-,274	,464
		Kurtosis		-1,076	,902
	2	Mean		4,40	,100
		95% Confidence Interval for Mean	Lower Bound	4,19	
			Upper Bound	4,61	
		5% Trimmed Mean		4,39	
		Median		4,00	
		Variance		,250	
		Std. Deviation		,500	
		Minimum		4	
		Maximum		5	
		Range		1	
		Interquartile Range		1,00	
		Skewness		,435	,464
		Kurtosis		-1,976	,902
	3	Mean		4,00	,153
		95% Confidence Interval for Mean	Lower Bound	3,68	
			Upper Bound	4,32	
		5% Trimmed Mean		4,00	
		Median		4,00	
		Variance		,583	
		Std. Deviation		,764	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		2,00	
		Skewness		,000	,464
		Kurtosis		-1,213	,902
RELIEF28	1	Mean		4,16	,149
		95% Confidence Interval for Mean	Lower Bound	3,85	
			Upper Bound	4,47	
		5% Trimmed Mean		4,18	
		Median		4,00	
		Variance		,557	
		Std. Deviation		,746	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		1,00	
		Skewness		-,274	,464
		Kurtosis		-1,076	,902
	2	Mean		4,44	,101
		95% Confidence Interval for Mean	Lower Bound	4,23	
			Upper Bound	4,65	

381

		5% Trimmed Mean		4,43	
		Median		4,00	
		Variance		,257	
		Std. Deviation		,507	
		Minimum		4	
		Maximum		5	
		Range		1	
		Interquartile Range		1,00	
		Skewness		,257	,464
		Kurtosis		-2,110	,902
	3	Mean		4,08	,152
		95% Confidence Interval for Mean	Lower Bound	3,77	
			Upper Bound	4,39	
		5% Trimmed Mean		4,09	
		Median		4,00	
		Variance		,577	
		Std. Deviation		,759	
		Minimum		3	
		Maximum		5	
		Range		2	
		Interquartile Range		1,50	
		Skewness		-,138	,464
		Kurtosis		-1,179	,902

Relief=Global measure of improvement

1= Cyriax physiotherapy group

2= Supervised exercise programme group

3= Polarised polychromatic non-coherent light (Bioptron light) group

4W= 4 week

8W= 8week

16W= 16week

28W= 28 week

1=worse

2=no change

3=somewhat better

4=much better

5=no pain

Global measure of improvement for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 4

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	37,56
2	25	44,20
3	25	32,24
Total	75	

Test statistics[a,b]

Chi-Square	4,363
df	2
Asymp. Sig.	,113

a. Kruskal-Wallis test
b. Grouping variable: group

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Global measure of improvement for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 8

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	39,18
2	25	44,74
3	25	30,08
Total	75	

Test statistics[a,b]

Chi-Square	4,168
df	2
Asymp. Sig.	,122

a. Kruskal-Wallis test
b. Grouping variable: group

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Global measure of improvement for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 16

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	37,44
2	25	43,60
3	25	32,96
Total	75	

Test statistics[a,b]

Chi-Square	3,600
df	2
Asymp. Sig.	,165

a. Kruskal-Wallis test
b. Grouping variable: group

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)

Global measure of improvement for Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Bioptron light) groups at week 28

Kruskal-Wallis test ranks

GROUP	N	Mean Rank
1	25	36,32
2	25	43,58
3	25	34,10
Total	75	

Test statistics[a,b]

Chi-Square	3,102
df	2
Asymp. Sig.	,212

a. Kruskal-Wallis test
b. Grouping variable: group

Group 1=Cyriax physiotherapy
Group 2=Exercise programme
Group 3=Polarised polychromatic non-coherent light (Bioptron light)